



joule™

Operator Manual

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ProLipo^{PLUS}™ BBL[®] BroadBand Light ClearScan[®] ALX™ ClearScan[®] YAG ClearSense™

CelluSmooth™ Temp^{ASSURE}™ Pro-V™ halo[®] BYOTEMP P MONITORING LASER diVa[®] LASER VAGINAL THERAPY

Contour TRL™ MicroLaserPeel™ ProFractional™ ProFractional[®] XC™



SkinTyte II



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1.0 Safety and Regulatory Compliance

1.1 Introduction

To protect health care providers, operation and maintenance of the Joule system should only be performed by personnel familiar with the safety information provided in this and other sections of this manual.

The laser systems are classified as Class IV lasers by the National Center for Devices and Radiological Health. Class IV represents the highest power lasers; for this reason, the user must take precautions to prevent exposure of laser energy to the eye and/or skin from either direct or diffused reflected laser beams, except as a therapeutic application. In addition, precautions must be observed in the surgical environment to prevent fire and electrical hazards.

Although the following precautions are extensive, they may not be complete. Laser users are advised to supplement these precautions with information regarding technological advances in surgical products and techniques as they become available to the medical laser user community through medical literature. See also the American National Standard publications ANSI Z136.3 "American National Standard for the Safe Use of Lasers in Health Care Facilities" and ANSI Z136.1 "American National Standard for Safe Use of Lasers."

The treatment room door should be kept closed during operation of the Joule system. A warning sign should be placed on the outside of the treatment room door when the system is in use to alert personnel before they enter the controlled area. Protective eyewear should be placed outside the treatment room door for personnel to put on before entering the room. The use of door interlocks is available to automatically disable the laser when the treatment door is opened. All personnel inside the treatment room must wear protective eyewear when the system is turned on. The following table specifies the correct eyewear:

Energy Source	Eyewear Required - when power is turned on
2940 nm Er:YAG	Optical density of 4.0 or higher at wavelength of 2940 nm – side shields required.
1470 nm Diode	Optical density of 2.0 or higher at wavelength of 1470 nm – side shields required.
1319 nm Nd:YAG	Optical density of 5 or higher at wavelength of 1319 nm – side shields required.
1064 nm Nd:YAG	Optical density of 5 or higher at wavelength of 1064 nm – side shields required.
755 nm Alexandrite	Optical density of 5 or higher at wavelength of 755 nm – side shields required.
BBL (300 – 1400 nm)	Patient: Optical Density of 5 or higher, or opaque eye protection – side shields required. Operator and all attending personnel: Optical density 1 or higher – side shields required.
Aiming Beam (Class II, low power visible red diode laser beam)	For Class II laser, the safe exposure duration limit at the maximum power level of 5 milliwatts is 0.24 seconds.

A warning message is shown on the control panel display screen at turn on to confirm which wavelength has been selected. The operator must acknowledge this screen before any further operation can take place.



To avoid risk of electrical shock, this equipment must be connected to supply mains with protective earth. Never look directly into the treatment or aiming laser light source or scattered laser light from reflective surfaces. Never look directly into the laser aperture or optical fiber tip when power is applied to the system, even when wearing safety eye wear; severe and/or permanent eye damage could occur.

Do not use the system in the presence of flammables or explosives, such as volatile anesthetics, alcohol, certain surgical preparation solutions and other such substances. Do not use the system before ensuring that treatment drapes and gowns are made of flame retardant material.

Do not use the laser system with the attached delivery system if you cannot see the red aiming beam, as the delivery system may be damaged. Such use may result in accidental laser exposure to health care providers or patient, and/or fire in the treatment room.

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

Attention is drawn to the danger of ignition of endogenous gases. The flammability of methane gas must be considered when treating in the perianal area.

In poorly ventilated treatment rooms, the use of a smoke evacuator should be considered. NIOSH and OSHA recommend the use of a smoke evacuator during procedures that create smoke or plume. Therefore, it is highly recommended that a smoke evacuator be used during all 2940nm Er:YAG procedures.



To avoid risk of electrical shock, this equipment must be connected to supply mains with protective earth. Never open the system console protective covers. Opening the covers will expose the user to high voltage components, and possible harmful radiation. Only Sciton-Certified Service Technicians shall work inside the console.

This device meets the requirements of IEC 60601-1-2 for electromagnetic emissions (Class A) and immunity. However, in order to avoid any potential electromagnetic or other interference with other sensitive electronic equipment in your environment, do not operate these devices simultaneously.

The area around the system and footswitch should be kept dry. Do not place fluid-filled containers on top of the system console. Do not operate the system if any of the power cords are faulty or frayed. The system should undergo routine inspection and maintenance per standards. Sciton recommends an annual inspection and preventive maintenance.

1.2 Protecting Non-Target Tissues

To prevent accidental laser or pulsed light discharge, always place the system in the Standby mode before removing the delivery device or moving the system.

Never place hands or other objects in the path of the laser beam or pulsed light. Severe burns could occur.

Only the person directing the aim of the laser beam or pulsed light should have access to the footswitch. Use caution depressing the footswitch when it is in proximity to footswitches for other equipment. Ensure the footswitch depressed is the correct one to avoid accidental laser exposure.

1.3 Regulatory Compliance Safety Features

The Joule system complies with 21 CFR Subchapter J as administered by the Center for Devices and Radiological Health of the Food and Drug Administration (FDA) along with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-4 and IEC 60601-2-22. It includes the following special features:

Emergency Turn-off Button

The system has a red emergency-off button that latches when depressed. This button de-energizes the system in emergency situations. Once latched, the button must be depressed and rotated clockwise to re-enable system operation.



Emergency Turn-off Button

Key Lock Switch

The system can only be turned on with the proper key. The key can only be removed in the Off position. When the key switch is turned to the Start position and released, power is available to the system. The system will operate only with the key in place. When treatments are complete, always remove and secure the key in a separate location to prevent unauthorized use of the system. A power failure will turn off the system. The user will need the key to turn the system back on.



USB Port Plug

USB Port Plug

The USB port plug is used to cover the USB port. Please note that the operator of this system does not use the USB port. The USB port plug should always cover this port. This port is only used by a Sciton-Certified Technician.

Emission Indicator

The control panel display screen acts as an emission indicator. When the system is turned on, the display illuminates as internal system tests are performed. When the self-test is complete, the screen displays available applications. The user will select the desired application. Upon entering the desired application, laser emission is set by selecting treatment parameters. In the Ready mode, the emission settings displayed on the touch screen will be delivered upon activation of the footswitch.

Remote Interlock

A Remote interlock outlet is installed to allow the capability to disable the system if the treatment room doors are opened. When utilized, opening the treatment room door activates the interlock and the system is automatically disabled, the "Attach Interlock" advisory message appears on the control panel display screen, and the system reverts to the Standby mode. To resume treatment, the message condition must be rectified (e.g., the treatment door must be closed) and the operator must select the Ready mode. An interlock plug is supplied with the system. If the interlock plug is removed, the system will be inoperative. Refer to ANSI Z136.3 for recommendations on procedures to be used with Class IV lasers in controlled areas.



Remote Interlock Plug

Reference section below on how to set up a Remote Interlock.

Protective Housing

The system has a protective housing, which prevents unintended human access to the laser radiation above Class I limits. This housing is to be opened only by a Sciton-Certified Technician.

Safety Interlocks

No section of the protective housing can be easily opened without special tools. The optical assembly is to be accessed only by a Sciton-Certified Technician.

Locations of Controls

For safe access during operation, the controls are located on a swivel pedestal on top of the console.



Safety Shutter

The laser system includes a safety shutter which prevents the treatment beam from exiting the console. The safety shutter is opened only when the operator places the system in the treatment mode and depresses the footswitch. Pulsed light is only generated when the footswitch is activated.

Manual Reset

If system emission is externally interrupted during treatment (e.g., remote interlock activation) the system will automatically go into "Standby" and the safety shutter will revert to a closed position. To resume treatment, the system must be manually reset by pressing the screen and then selecting "Ready."

Electronic Fault Detection Circuitry

If any of the electronic system monitors detect a fault condition, laser or pulsed light exposure cannot occur. The high voltage power supply is turned off, the high voltage capacitors are discharged, the safety shutter is closed, and the footswitch is disabled.

If the Footswitch, Low Energy, Pulse Rate, Remote interlock, Overheating, or Calibration advisory message appears on the control panel display screen, the operator can correct the fault. After taking corrective action, as described in the Maintenance section of this manual, the advisory message will disappear and the system will enter "Standby" mode.

If a fault message, such as Simmer Fault, appears on the control panel display screen, press the Ready softkey to clear the screen. If the condition persists, turn the system Off momentarily and then back On. If the condition continues, record the error code, turn Off the system and contact Sciton Service.

Location of Regulatory and Other Labels

As required by the FDA, appropriate warning labels have been mounted in specified locations on the system to indicate conditions under which the user could be subjected to harmful laser/light radiation. Examples of these labels are shown in "Joule System Labels" section of this manual.

2.0 Operation



The Joule system generates a highly concentrated beam of light that may cause injury if improperly used. This entire manual should be carefully read and understood before operation. The Joule system is intended for use by clinicians trained in the operation of lasers. Use of controls, adjustments or performance of procedures, other than those specified herein, may result in hazardous laser radiation exposure.

2.1 System Characteristics

The Joule system provides the clinician with a choice of wavelengths for a variety of applications. Joule systems are available with either or all of these laser wavelengths: 1064 nm, 1319 nm, 2940 nm as well as broadband pulsed light with 300-1400 nm wavelengths. The fluence and the duration of each pulse or pulse sequence can be varied to suit the application.

2.2 Moving the Joule System



Use extreme caution when moving system over threshold or on uneven surfaces to prevent it from tilting over. Lock casters when equipment is not being moved.

- 2.2.1** Retract Articulated Delivery Arm and clamp. Tighten the Articulated Arm Locking Screw.



Articulated Arm Locking Screw

Articulated Arm Clamp



- 2.2.2** Turn OFF the main power circuit breaker located at the bottom of the back panel.



Main Power Circuit Breaker

- 2.2.3** Remove the plug from the wall receptacle. Wrap the power cable around the cable wrap.



- 2.2.4** Remove the Footswitch plug from the footswitch receptacle. Stow the Footswitch on the Footswitch Storage Mounts by turning the upper mount as shown below.



Upper Storage Mount

- 2.2.5** Place Footswitch cable in the Footswitch housing or wind the cable around the cable wrap.



- 2.2.6** If using the remote interlock system, disconnect the cord and store it on the cable wrap.



Do not drag or pull the Footswitch by the cord when moving the laser system. Never use the Articulated Arm or Display Screen to move the laser. The assistance of a second person is required when moving the system up or down an incline.

- 2.2.7** Using the laser system handles, move the system to the desired site. Position Joule system a minimum of 46 centimeters (18 inches) away from walls, furniture and other equipment. Adequate space around the laser console will ensure sufficient air circulation for proper cooling.



Handle

2.3 Connecting the Footswitch to the Laser Console

- 2.3.1** Remove the Footswitch from the storage mounts.

- 2.3.2** Insert the Footswitch plug into the laser console Footswitch receptacle at the rear of the console. The connector is NOT a screw in type. It is a locking push-in type requiring proper alignment of the slot and key before insertion. Inappropriate forced rotation can damage the connector or loosen the receptacle. There is a Magnetic Breakaway Connector located on the footswitch cable near the laser console which will disconnect should excessive tension be applied to the cable. If the Footswitch is not properly connected, upon startup the "Connect Footswitch" advisory message will appear on the control panel display screen. The message will continue to appear and the laser will remain inoperable until the Footswitch is properly connected.



Magnetic Breakaway Connector

2.4 Remote Interlock

- 2.4.1** The Remote Interlock receptacle, located on the back of the console, is provided to disable the laser system if the treatment room doors are opened. A Remote Interlock plug is supplied with the laser system. If the Remote Interlock plug is removed, the laser will not operate without the proper Remote Interlock connections. Consult your local Sciton representative for help.
- 2.4.2** When installed, the Interlock is activated by opening the treatment room door. This automatically disables the laser placing it into Standby and displaying the "Attach Interlock; Press Button to Continue" advisory message on the control panel display screen.
- 2.4.3** To resume treatment, the treatment room door must be closed and the "Continue" softkey on the control panel display screen must be selected. If the Remote Interlock is not installed on the treatment room doors, removal of the Remote Interlock plug will result in the display of the above

advisory message. To correct the situation, replace the interlock plug.

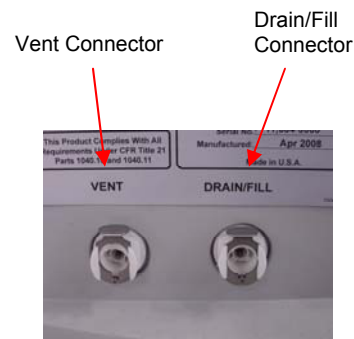
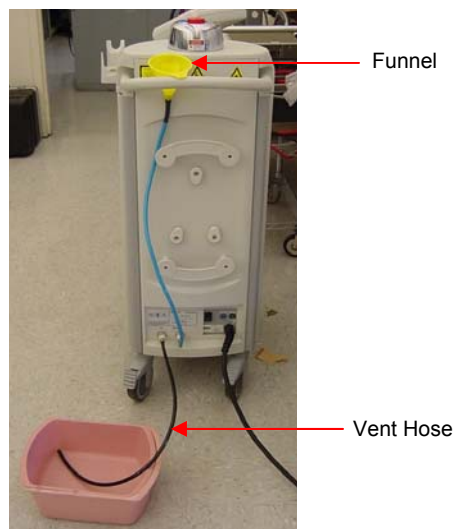
2.5 Filling Water Reservoir



Permanent damage to internal components will occur if improper coolant is used. Under no circumstance should ethylene glycol, tap water or any liquid other than distilled or de-ionized (DI) water be used.

Water circulates within the system to keep it cool. Should the water level fall below normal, a system warning message will display on the control panel display screen. The message "Low Water Level Fault 1001" will occur upon start up and the message "Coolant Level Low Fault 51" will occur during use, indicating the need to add water to the system.

- 2.5.1** Turn off the system and allow it to cool down.
- 2.5.2** In the back of the laser there are two white quick disconnect connectors labeled VENT and DRAIN/FILL. They are underneath the serial number and to the left of the power cable. See picture below. With your laser you received a "Fill Funnel Kit" that consists of two hoses with white connectors on one end. One is blue and it has a funnel at the other end, and the other one is black.
- 2.5.3** First connect the blue hose with the funnel to the quick disconnect connector on the laser labeled DRAIN/FILL. In order to prevent water from draining out of the hose when connected to the laser, it is recommended that the hose be kept higher than the connector. To support the funnel at the proper level, thread the hose between the handle and the console as shown.
- 2.5.4** Fill funnel with distilled or deionized water. Always keep water in the funnel to prevent air bubbles from entering the hose.
- 2.5.5** Next, put the open end of the black hose into a bucket or trash can and connect the other end into the quick disconnect connector on the laser labeled VENT.
- 2.5.6** Continue to add distilled water to the funnel and observe the black hose. Water will flow out at first and then there will be a brief period where there is just air escaping from the hose.
- 2.5.7** Keep filling the funnel until a steady stream of water comes out of the hose with no air bubbles present. The stream of water coming out of the black hose should be as fast as the water being poured into the funnel.
- 2.5.8** Once the flow of water is correct, stop filling the funnel and disconnect both hoses from the laser.



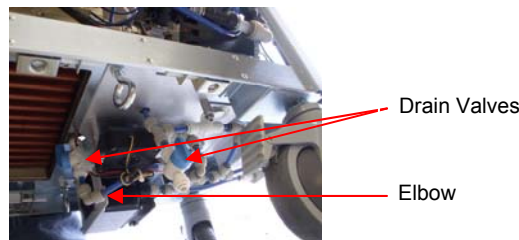
2.5.9 It is now safe to turn the system back on.

2.6 Draining Water Reservoir

If there is a possibility that the water in the system may freeze due to storage or transportation, it is necessary that water within the system be drained. This will prevent costly damage that can occur to internal components of the system due to water expanding as it freezes.

2.6.1 To drain the laser, reconnect the hoses but this time lower the Drain/Fill Hose to the ground and let the water drain out.

2.6.2 On systems equipped with water piping located underneath the system (systems with ProFractional), open the two drain valves located underneath the console by rotating the valves 90 degrees to the in-line position as shown below. Also disconnect the elbow connected to the centrally located valve. Be sure to reconnect the elbow and close the valves before refilling.



2.7 Preparing the Joule System for Use

2.7.1 Verify that the power cable and plug are properly connected.

2.7.2 Verify that the electrical service is turned ON.

2.7.3 Verify that the "Danger" warning sign has been posted outside of the treatment room door.

2.7.4 Ensure that the patient and all attending personnel in the treatment room are wearing appropriate laser safety eyewear.

2.8 Turning on the Joule System

2.8.1 Switch the main power circuit breaker to the ON position.

2.8.2 Ensure that the Emergency-Off button is released. If not, twist the button counterclockwise until it springs up into the ready position.

2.8.3 Insert the key into the Key switch and turn clockwise to the "II" (START) position, hold it for one full second, and release. Upon release, the spring-loaded Key switch rotates to the "⊙" (ON) position.



- 2.8.4** The Joule system application screen on the control panel display screen will allow the operator to select an application for use.

2.9 Turning off the Joule System



- 2.9.1** Turn the key switch to the "O" position to turn-off the system. Remove the key to prevent unauthorized use of the system.
- 2.9.2** If desired, move the main power circuit breaker to the OFF position and disconnect the main power cord from the electrical source. If the power cord is still connected to the electrical source, some internal circuits will remain energized.

2.10 Joule System Application

The Joule console allows up to 4 laser modules and a pulsed light module to be operated. Any combination of available wavelengths can be configured into the Joule console. In some models, multiple wavelengths can be enabled simultaneously. Energy can be delivered through an articulated arm, fiber or BBL handpiece. When the system starts up, the available delivery options will appear in the system main menu. A selection screen on the control panel display screen will allow the operator to select an option of a delivery system.



When a delivery system option application softkey is touched, the system will initialize the selected delivery system and enter into that application menu.

2.10.1 Arm Applications



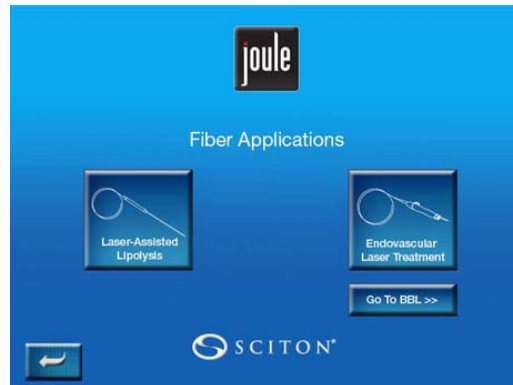
Contour TRL 2940 nm Module: The Contour module can be configured as a 1-head or 2-head system. The wavelength is 2940 nm and has associated handpieces.

Hybrid 1470 / 2940 nm Module: The Hybrid module consists of 1470 nm diode and 2940 nm laser.

ClearScan YAG 1064 nm Module: The ClearScan YAG module can be configured as a 1-head or 2-head system. The wavelength is 1064 nm and has associated handpieces and contact cooler.

ThermaScan 1319 nm Module: The ThermaScan module can be configured as a 1-head system. The wavelength is 1319 nm and has associated handpieces and contact cooler.

2.10.2 Fiber Applications



Laser-Assisted Lipolysis Module: The Laser-Assisted Lipolysis module can be configured as a 1-head or 2-head system. The wavelength is 1064 and/or 1319 nm and has an associated fiber delivery system.

Endovascular Laser Treatment Module: The Endovascular Laser Treatment Module can be configured as a 1-head system. The wavelength is 1319 nm and has an associated fiber delivery system.

2.10.3 BBL Handpiece Applications



Broadband Light Module (BBL): The BBL module is a pulsed broadband light source. The handpiece has the capability of using variable filters for a wide range of applications.

3.0 Delivery System

The Joule system uses an articulated arm or optical fiber to deliver laser energy and/or a BBL handpiece assembly to deliver pulsed light energy.



Sciton handpieces are supplied non-sterile and require disinfection or sterilization prior to use. Refer to section below on how to disinfect or sterilize handpiece.

3.1 Laser Energy Delivery

3.1.1 Articulated Arm Delivery (all laser wavelengths)

- 3.1.1.1** Attach the articulated arm by rotating the arm base in the clockwise direction. Continue until the arm base will not rotate and is well seated into the system.



Articulated Arm

Arm Base

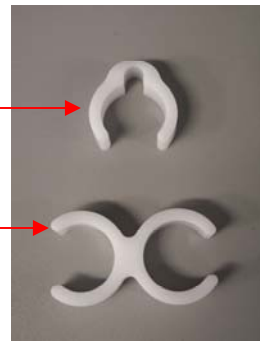
- 3.1.1.2** Route the handpiece cable along the arm and attach using the cable clips.



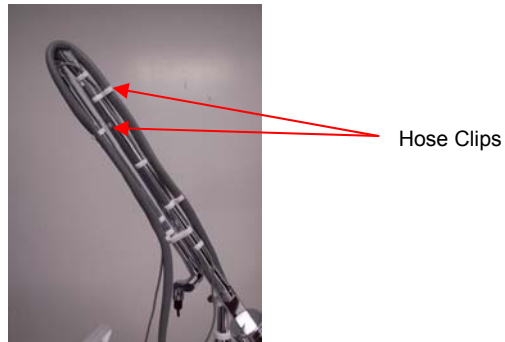
Cable Clip

Hose Clip

Handpiece Cable



For systems with 755 nm, 1064 nm and 1319 nm wavelengths, the contact cooling hose should be routed along the arm as well and attached using the hose clips.



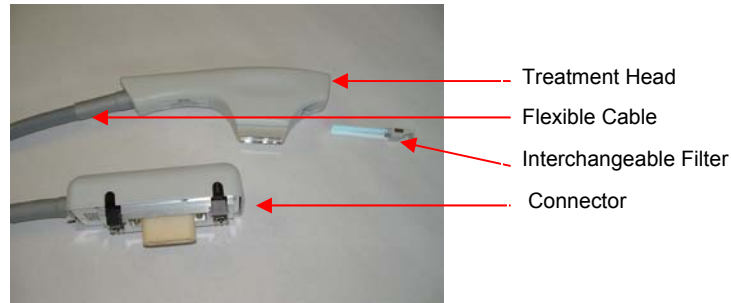
- 3.1.1.3** If a handpiece or a scanner is not attached to the end of the articulated arm, the black dust cap (as shown below) should be attached to prevent contamination of optics within the articulated arm.



3.2 BBL Pulsed Light Delivery

Joule BBL pulsed light delivery system consists of a flexible cable attached to a treatment head at one end and a connector at the other end. The treatment head houses a flashlamp that generates the desired emissions incident upon tissue. The connector plugs into the side of the Joule console. Interchangeable filters, which control the spectral output incident upon tissue, are inserted into the treatment head to obtain the desired wavelength. Each filter is coated to generate the desired spectral transmission.

Note: Keeping the filter clean and damage-free is essential for optimum treatment. Do not insert a dirty filter into the handpiece. Use a clean, lint-free cloth moistened with alcohol to carefully clean the optical surfaces.

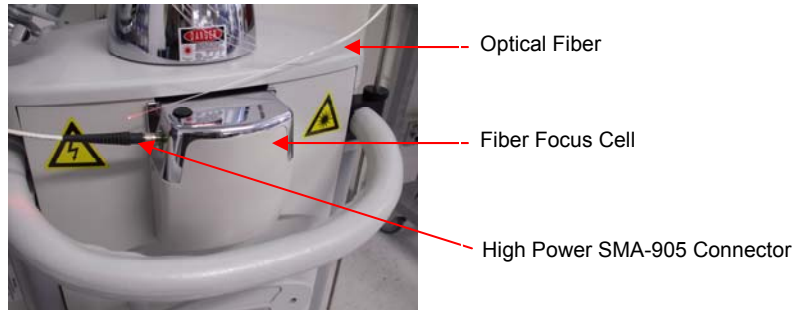


The following accessories are available with the Joule BBL system:

Item	Qty	Part No.
Footswitch Assembly	1	1500-031-00
CDRH Plug	1	1500-012-00
Patient Eye Shields	1	7005-007-00
<u>BBL Handpiece & Accessory Kit</u>		
Filter, BBL, 420 nm	1	1500-201-01
Filter, BBL, 515 nm	1	1500-201-02
Filter, BBL, 560 nm	1	1500-201-03
Filter, BBL, 590 nm	1	1500-201-04
Filter, BBL, 640 nm	1	1500-201-05
Filter, BBL, 695 nm	1	1500-201-06
Filter, BBL, ST	1-optional	1500-201-08
BBL Aperture 15 mm Square	1	1500-202-18
BBL Aperture 7 mm Round	1	1500-202-24
BBL Aperture 11 mm Round	1	1500-202-25
BBL Multispot Handpiece	1	1500-202-20
Handpiece Bleeder Kit	1	1500-202-08
BBL Safety Glasses	3	7005-015-00

3.3 Fiber Delivery: Endovenous and ProLipo *PLUS*

The Endovenous/ProLipo *PLUS* fiber delivery system consists of an open source optical fiber which delivers laser energy at wavelengths of 1319 and 1064 nm. The fiber is approximately 3.5 meters long and is terminated with high power SMA-905 connector for easy connection to the Endovenous/ProLipo *PLUS* Fiber Focus Cell on the Joule console.



*For Endovenous and ProLipo *PLUS* applications, the optical fiber assembly is packaged sterile for single use and should not be re-sterilized or reused. Optical fibers are inherently fragile and so care should be taken to avoid breakage due to excessive bending.*

A blast shield is provided to minimize damage to optical components in the event of fiber failure. Should this fiber failure occur remove the Blast Shield by pulling it out of the Fiber Focus Cell and examine the glass surfaces. Presence of contamination indicates fiber failure and both the blast shield and the fiber should be replaced. The laser will not operate without the blast shield in place.



4.6 Emergency Stop Label

This label is mounted on the Red Emergency Button on top of the laser console.



4.7 Footswitch Guard

This is the model label for the footswitch and is mounted on the side of the footswitch guard.



4.8 Footswitch Connector

This label is mounted at the bottom of the rear panel and is used to indicate the footswitch connector.



4.9 Remote Interlock Connector

This label identifies the Remote Interlock Connector and is mounted at the bottom of the rear panel.



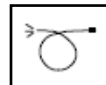
4.10 Laser Aperture

This label is mounted at the end of the articulated arm.



4.11 Optical Fiber Applicator

This label is affixed near the SMA connector where the optical fiber is connected.



4.12 Representative in the EC



4.13 Danger Warning Label

 **DANGER**



VISIBLE AND/OR INVISIBLE RADIATION AND/OR INTENSE PULSED LIGHT. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION AND/OR INTENSE PULSED LIGHT.

Contains one or more of the following lasers and/or intense pulsed light:

Laser	Alexandrite, Nd:YAG, Er:YAG, Diode
Wavelength	0.75, 1.06, 1.32, 1.47, 2.94 μm
Pulse Duration	Up to 200 ms
Pulse Energy	Upto 75 J
Max. Average Power	Upto 100 W
May also contain intense pulsed light, 300-1400 nm, 300 J	

CLASS IV LASER PRODUCT

 SCITON®
Palo Alto, CA 94303
(650) 493-9155

2500-034-00 Rev G

5.0 Joule System Specifications

General Specifications

Cooling Air Requirements	Minimum 18 inches (46 centimeters) distance from walls Cooling internal water-to-air heat exchanger.
System Dimensions	
Width:	15 inches (38 cm)
Length:	32 inches (82 cm)
Height:	43 inches (110 cm)
System Weight	Depends upon configuration, approx. 200 pounds (91 kilograms)
Rated Voltage	200-240 V~
Rated Frequency	50/60 Hz
Rated Current	25 A
Classification	Class I, Type BF
Laser Output	Class IV, 0.7-3 μ m, 100W, 75J, 200 ms
Light Output	300-1400 nm, 0-300J
Pulse Duration of individual pulse	0.5 to 1.5 ms
Pulse Interval	0.2 to 200 ms
Number of Pulses in a Pulse Train	2 to 10 individual pulses
Mains Connection	IEC 306 connection or permanently installed
Power Cord Length	15 feet (4.6 meters)
Footswitch Cable Length	15 feet (4.6 meters)
Certification	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-4, IEC 601-2-22

Environmental Requirements

Maximum Operating Altitude	10,000 feet (3,048 m)
Ambient Operating Temperature	50 °F (10 °C) to 95 °F (35 °C), must be above dew point
Maximum Humidity	90%, non-condensing

Shipping and Storage (Non-Operational) Requirements

Maximum Operating Altitude	45,000 feet (13,716 m)
Ambient Temperature	5 °F (-15 °C) to 113 °F (45 °C), must be above dew point
Maximum Humidity	90%, non-condensing

Maximum Permissible Exposure & Nominal Ocular Hazard Distance

	Units	Articulated Arm Delivery				Optical Fiber Delivery		Diode
Wavelength	nm	755	1064	1319	2940	1064	1319	1470
Maximum Permissible Exposure (MPE)	J/m ²	0.65	0.84	884.24	4.98	1.04	1149.51	10000.00
Nominal Ocular Hazard Distance (NOHD)	meter	288.39	179.89	3.83	1.72	31.76	0.83	0.15

6.0 Warranty

LIMITED WARRANTY – LIMITATION OF REMEDIES

Except as otherwise specified herein, Seller warrants the Products commencing after full payment has been received by the Seller:

- (a)
 - i) To be free from defects in material and workmanship for a period of time specified in the purchasing terms and conditions and under such conditions as specified in Seller's warranty for the individual Product, or until twelve (12) months from shipment if a warranty for an individual Product is not specified, and
 - ii) To perform in the manner and under the conditions as specified in Seller's warranty for the individual Product or until twelve (12) months from shipment if a warranty for an individual product is not specified.
- (b) No representative or person is authorized to bind Seller for any obligations or liabilities beyond this warranty in connection with the sale of Seller's goods. This warranty is made to the original purchaser only at the original location and is non-transferable, and may only be modified or amended by a written instrument signed by a duly authorized officer of Seller.
 - i) Goods or parts that are replaced or repaired under this warranty are warranted only for the remaining unexpired portion of the original warranty period applicable to the specified product.
 - ii) Goods or parts that are replaced or repaired under this warranty because of normal wear or use, such as contact plates, wear surfaces, and flashlamps are warranted on a monthly prorated basis only for the remaining portion of the warranty as credit toward new replacement goods or parts.
 - iii) Optical coatings, filters, lenses, and mirrors will be repaired or replaced under this warranty if kept clean according to manufacturer's instructions. Dirt or debris on the surface of such an item during usage may cause thermal damage and void the warranty for such item.
 - iv) Third party items are warranted by their manufacturer and are not covered by the Sciton system warranty.
- (c) These remedies are available only if Buyer notifies Seller in writing promptly upon discovery of the defect, and in any event within the warranty period for the individual Product. Seller's examination of such goods discloses to Seller's satisfaction that such defects actually exist and the goods have not been (i) repaired, worked on, or altered by persons not authorized by Seller so as, in Seller's sole judgment, to injure the stability, reliability, or proper operation of such goods; (ii) subject to misuse, negligence or accident; or (iii) connected, installed used or adjusted otherwise than in accordance with the instructions furnished by Seller.
- (d) All Products not requiring fixed installation which Buyer considers defective shall be returned to Seller's office as designated on the face hereof transportation costs prepaid and borne by Buyer (unless otherwise provided on the face hereof). The risk of loss of the goods shipped or delivered to Seller's plant for repair or replacement will be borne by Buyer
- (e) If it is found that any Product has been returned without cause and is still serviceable, Buyer will be notified and the Product returned at Buyer's expense, in addition, a charge for testing and examination may, in Seller's sole discretion, be made on Products so returned.
- (f) NOTWITHSTANDING THE FOREGOING, IN NO EVENT WILL SELLER BE LIABLE FOR ANY CONSEQUENTIAL DAMAGES (INCLUDING BUT NOT LIMITED TO LOSS OF USE OR LOSS OF PROFITS) OR FOR ANY DAMAGES SUFFERED BY ANY THIRD PARTY.
- (g) THE FOREGOING WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES (EXCEPT FOR SPECIFIC WRITTEN PRODUCT PERFORMANCE GUARANTEES) WHETHER WRITTEN, ORAL OR IMPLIED, INCLUDING ANY WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND SHALL BE THE BUYER'S SOLE REMEDY AND SELLER'S SOLE LIABILITY ON CONTRACT OR WARRANTY OR OTHERWISE FOR THE PRODUCT.

7.0 Maintenance

The Joule system is simple to use, yet at the same time is very complex piece of equipment. The following maintenance procedures should be performed on a regular basis to keep the system operating at its optimum performance. Please contact Sciton Service at 650-493-9155 to learn more about a maintenance contract that will best suit your needs.



Maladjustment or damage to the beam delivery system can lead to considerable deviations of the laser power incident on the patient from the laser power actually generated. It is therefore imperative that the laser output actually emitted to tissue is checked by means of a calibrated laser power or laser energy meter during regular inspections of the laser equipment. No modification of this equipment is allowed. Do not modify this equipment without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

7.1 Annual Maintenance

Preventative maintenance should be performed annually by a Sciton field service engineer (FSE) to ensure proper laser and/or pulsed-light performance. During this visit, the FSE will perform the following checks:

- a. Full optical alignment
- b. Complete power/energy check and calibration
- c. Cooling system inspection and replacement of all filters and cartridges
- d. High and low voltage testing
- e. Optical inspection and cleaning
- f. Full user mode operational check of the laser system
- g. Mechanical integrity check
- h. Inspection of all accessories, filters and handpieces

7.2 Routine Maintenance

7.2.1 Cleaning External Surfaces of the System

The external surfaces of the laser console should also be cleaned and disinfected by wiping down on a regular basis using a soft dampened cloth with a non-caustic cleaning solution such as water, isopropyl alcohol or a hospital grade disinfectant. The Articulated Arm, hand piece and scanner can also be wiped clean with a soft damp cloth. Avoid excessively wet cloth to prevent moisture from getting into the system.



Do not spray or pour cleaning solution directly on the control panel display screen, fiber delivery port or the system console. Do not attempt to gain access to any internal components of the console. Electrical shock and/or unintended laser exposure may result.

It may be necessary during the procedure to clean tissue debris from the scanner lens. To clean the lens, gently wipe with a soft cotton swab or cloth that has been moistened with isopropyl alcohol or sterile water.

7.2.2 Cleaning & Disinfection Requirements of Handpieces & Scanners Prior to Reuse

These instructions are provided for safely disinfecting Sciton handpieces and scanners prior to reuse so that they will continue to meet their performance specifications. The sapphire and/or stainless steel surfaces of a handpiece sometimes come into contact with a patient during treatment. These surfaces require cleaning and disinfecting prior to reuse.

It is the responsibility of the medical practice to ensure that disinfection is performed using the appropriate method and materials, and that personnel have been adequately trained in order to achieve the desired result. Any deviation from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.



Never spray anything directly on the handpiece or scanner. Never soak a handpiece or scanner and place it under running liquid.

Point of Use Preparation

Remove any fluid and/or contaminants with a disposable, non-shedding wipe or a soft, non-scratching brush. The handpieces should be cleaned within 30 minutes of use to minimize the potential for any substance to dry onto the sapphire and/or stainless steel surface, therefore making it more difficult to clean.

Preparation of Cleaning Agents

Neutral pH enzymatic and cleaning agents with low foaming surfactants are recommended by Sciton. All cleaning agents should be prepared with dilution and temperature recommended by the manufacturer of cleaning agent. Dry powdered cleaning agents should be completely dissolved prior to use to avoid staining, scratching or corrosion of instruments. Common hospital grade disinfectants (such as Cydexplus, Biocide or methanol) can also be used. If the handpiece is currently connected to the articulated arm, ensure that the power to the system is turned off prior to proceeding with the disinfection process.

Cleaning/Disinfection and Drying

Use a non-shedding wipe dampened with cleaning agent to remove all visible contamination. Particular attention must be given to crevices, mated surfaces and other hard-to-clean areas. Remove excess moisture from the handpiece with clean, absorbent and non-shedding wipe. External scanner windows should be optically clean to prevent damage by the laser beam.

Inspection, Maintenance and Testing

Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process. Visually inspect for completeness of cleaning, damage and/or excessive wear. If damage or wear is noted that may compromise the function of the handpiece, contact Sciton Service.

Packaging and Storage

If the handpiece is not being used, place the disinfected handpiece in the designated slot in the Sciton carrying case prior to storage. Do not leave handpieces out in the open where dust or particulate matter could contaminate the optics located in each handpiece. Optics contamination will result in reduced efficiency and premature failure of the system.

7.2.3 Cleaning & Sterilization Requirements Prior to Reuse of Devices

These instructions are provided for cleaning and sterilizing ProLipo cannulas and handpieces prior to use and/or reuse so that they will continue to meet their performance specifications.



Please note that the TempASSURE™ cannula (supplied with thermocouple) is a single use device; do not reuse this device.

It is the responsibility of the medical practice to ensure that cleaning and sterilization is performed using the appropriate method and materials, and that personnel have been adequately trained in order to achieve the desired result. Any deviation from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

Cleaning Procedure:

Prepare Cidex®, Enzol®, or equivalent detergent, according to manufacturers' instructions using tap water. Fully immerse the devices in the detergent and allow to soak for a period noted in manufacturers' instructions. After the soak, scrub devices using a soft bristled brush paying particular attention to hard-to-reach areas. A pipe cleaner and syringe may be used to brush and flush the hard-to-reach areas of the devices.

Remove the devices from the detergent and rinse with tap water for a minimum of one minute to remove any residual detergent. A syringe may be used to aid in rinsing.

Allow to clean in ultrasonic tank filled with reverse osmosis (RO) or deionized (DI) water for a minimum of 10 minutes.

Remove devices from the ultrasonic tank and rinse with RO/DI water. A syringe may be used to aid in the rinsing.

Visually inspect each device for visible soil, while paying close attention to hard to reach areas, ensuring that all soil has been removed.

Dry devices using a clean, lint-free cloth. Pressurized air (<20 psi) may be used to assist in the drying.

Sterilization Procedure:

Insert parts in steam sterilization pouch. Place pouch in sterilizer.

The following steam sterilization parameters, or those cleared at your medical practice for autoclaving stainless steel and glass parts, should be used for sterilization.

Sterilizer Type:	Gravity
Minimum Temperature:	132°C
Cycle Time:	15 minutes
Minimum Dry Time:	30 minutes

7.3 System Repair

Repair on the Joule system should be performed by a Sciton-Certified field service engineer. Contact Sciton Service at 650-493-9155 if a repair is required.

Calibration of the Joule as described in the next section is to be performed only by Sciton-Certified field service engineer. Calibration or other adjustment of this device by persons other than Sciton-Certified field service engineer will result in the warranty of the unit being voided.



All equipment must be properly decontaminated before return to Sciton. Failure to perform proper decontamination will result in delays and additional charges.

7.4 Disposal and Recycling

Contact your local recycling operator for separate collection or Sciton for appropriate disposal information.



Do not dispose laser console as unsorted municipal waste. End of life electronic equipment must be collected separately to prevent harm to the environment or human health.

Used single use consumable items such as laser fibers should be disposed of according to your institution's protocol for disposal of medical waste.

8.0 Joule System Calibration

The Food and Drug Administration (FDA) requires laser manufacturers of Class II and IV medical laser systems to supply customers with power calibration procedures.

8.1 Laser Calibration

The energy meter on the control panel display screen is calibrated to indicate the laser energy delivered to the distal end of the handpiece. Under normal operating conditions, the laser should be checked for calibration once a year or whenever an optical component has been cleaned, replaced or adjusted, the energy monitor circuit adjusted or the CPU board replaced. Sciton Service representatives check the calibration during each service call.



Calibration is a SERVICE procedure to be performed ONLY by trained SCITON Service Engineers or customers who have taken and passed a Sciton Service Training Course. Calibration by anyone other than a trained Sciton Service Engineer or a certified customer will void any existing warranty on the laser system. Unauthorized access to the laser service mode can expose anyone in the immediate area to dangerous conditions. Furthermore, damage to the system can occur if proper procedures are not followed. In order to prevent accidental exposure of the laser beam, all persons in the room should wear protective eyewear whenever the laser is fired.

The calibration procedure for the Joule, a multi-wavelength system, is performed in multiple parts. The first is written for the Joule Er:YAG calibration while the second portion is the Joule Nd:YAG calibration and the third is for Joule Alexandrite.

8.2 Calibration Procedure for Joule (2940nm Er:YAG)

The Erbium calibration procedure must be performed only after the lasers are properly aligned and all the optics are clean. The arm must be installed along with the Contour Scanner/handpiece. When the calibration has been completed, the system must be reset or restarted before operating in the user mode.

8.2.1 Calibration of Joule 2940nm Er:YAG

Tools Needed: A calibrated 45W or higher power meter and an Oscilloscope.

- 8.2.1.1** Start the system and wait until it comes up into the Joule Delivery Selection screen. Enter Service Mode by pressing and holding the service switch button on the CPU board. Release the service switch when the keypad is displayed. Enter the service passcode with the keypad to enter service mode.
- 8.2.1.2** Select "Lasers" from the main service screen, then select "Just Fire'em". In the "Just Fire'em" screen, select the Er laser by pressing "2940". Once the "2940" is highlighted select the red "X" in the "selected" column. You should now have a green check mark. Now select the "Charger On/Off" to enable the high voltage power supply followed by selecting "trigger simmer". The "simmer" column will now have a check mark. The laser is now simmering and the "X" in the "Gate" column needs to be selected to enable the Laser Gate. This will now show a green checkmark.
- 8.2.1.3** Set up the power meter approximately 4 feet from the scanner and aim the scanner to the center of the power meter head.
- 8.2.1.4** Er Laser Calibration Parameters:
Set the 2940nm pulse width (PW) to 0.250ms, "800V" (Cap Volt OUT), and "25Hz"(Frequency) by selecting the parameters on the screen and using the Up/Down arrow keys to set desired values.
- 8.2.1.5** Press "Return" to return to the Laser service menu.
- 8.2.1.6** Select "Calibration" to go to the calibration screen.
- 8.2.1.7** Select the Er Laser again by pressing "2940".
- 8.2.1.8** Open the shutter by selecting "Toggle Shutter".
- 8.2.1.9** Turn on idle lensing by selecting "Idle Lensing".

- 8.2.1.10 Using an Oscilloscope, attach Oscilloscope probes to the main CPU board on TP1 (P1) and TP2 (P2).
- 8.2.1.11 Depress footswitch and measure the amplitude of the signals. The signals should measure 5-6Volts. If the signals are high/low, select the "E2 Gain" box and adjust up/down accordingly with the up/down arrows to achieve the correct amplitude.
- 8.2.1.12 Once the correct gain is achieved, select "Save" to save the new gain value.
- 8.2.1.13 Depress the footswitch and observe the "E1" and "E2" values. These values should be approximately 2000 counts each. If the counts are high/low, select the "Attenuation" box and increase/decrease the value with the up/down arrow. Verify the counts again by depressing the footswitch. Repeat until the counts are approximately 2000 each.
- 8.2.1.14 Depress the footswitch once again and observe the value measured on the power meter. After the power meter stabilizes, note its value and release the footswitch.
- 8.2.1.15 Select the box in the calibration screen labeled "Enter Output Power" and use the up/down arrows to adjust the value to the power measured in the previous step. Now push "calculate". The Ablation Calibration Constant should have been updated.
- 8.2.1.16 Press "Save" to store the new calibration constant.

8.3 Calibration Procedure for Joule (1064nm Nd:YAG)

Tools Needed: A calibrated 100W or higher power meter with a 50 mm aperture for laser light at 1064nm and an Oscilloscope.

This calibration procedure must be performed only after the lasers are properly aligned and all of the optics is clean. The arm must be installed along with the HF, 6mm, or Duo Scanner. When the calibration has been completed, the system must be reset or restarted before operating in the user mode.

8.3.1 Calibration of Joule 1064nm Nd:YAG

- 8.3.1.1 Start the system and wait until it comes up into the Joule Delivery Selection screen. Enter Service Mode by pressing and holding the service switch button on the CPU board. Release the service switch when the keypad is displayed. Enter the service passcode with the keypad to enter service mode.
- 8.3.1.2 Select "Lasers" from the main service screen, then select "Just Fire'em". In the "Just Fire'em" screen, select the 1064nm laser by pressing "1064". Once the "1064" is highlighted select the red "X" in the "selected" column. You should now have a green check mark. Now select the "Charger On/Off" to enable the high voltage power supply followed by selecting "trigger simmer". The "simmer" column will now have a check mark. The laser is now simmering and the "X" in the "Gate" column needs to be selected to enable the Laser Gate. This will now show a green checkmark.
- 8.3.1.3 Set up the power meter approximately 1 foot from the scanner and aim the scanner to the center of the power meter head.
- 8.3.1.4 1064nm Laser Calibration Parameters:
Set the 1064nm pulse width (PW) to 0.800ms, "800V" (Cap Volt OUT), and "2Hz"(Frequency) by selecting the parameters on the screen and using the Up/Down arrow keys to set desired values.
- 8.3.1.5 Press "Return" to return to the Laser service menu.
- 8.3.1.6 Select "Calibration" to go to the calibration screen.
- 8.3.1.7 Select the 1064nm Laser again by pressing "1064".
- 8.3.1.8 Open the shutter by selecting "Toggle Shutter".
- 8.3.1.9 Turn on idle lensing by selecting "Idle Lensing".
- 8.3.1.10 Using an Oscilloscope, attach Oscilloscope probes to the main CPU board on TP1 (P1) and TP2 (P2).
- 8.3.1.11 Depress footswitch and measure the amplitude of the signals. The signals should measure 5-6Volts. If the signals are high/low, select the "E2 Gain" box and adjust up/down accordingly with the up/down arrows to achieve the correct amplitude.
- 8.3.1.12 Once the correct gain is achieved, select "Save" to save the new gain value.
- 8.3.1.13 Depress the footswitch and observe the "E1" and "E2" values. These values should be approximately 2000 counts each. If the counts are high/low, select the "Attenuation" box and increase/decrease the value with the up/down arrow. Verify the counts again by depressing the footswitch. Repeat until the counts are approximately 2000 each.
- 8.3.1.14  When using 1064nm Nd:YAG, only fire the laser with Idle Lensing On if the shutter is open. Damage to the Beam Combiner and Beam Pickoff Mirrors can occur.

- 8.3.1.15** Depress the footswitch once again and observe the value measured on the power meter. After the power meter stabilizes, note its value and release the footswitch.
- 8.3.1.16** Select the box in the calibration screen labeled "Enter Output Power" and use the up/down arrows to adjust the value to the power measured in the previous step. Now push "calculate". The Ablation Calibration Constant should have been updated.
- 8.3.1.17** Press "Save" to store the new calibration constant.

8.4 Calibration Procedure for Joule (1319nm Nd:YAG)

Tools Needed: A calibrated 100W or higher power meter with a 50mm aperture for laser light at 1319nm and an Oscilloscope.

The following steps are for 1319 Nd:YAG. This calibration procedure must be performed only after the lasers are properly aligned and all of the optics is clean. The arm must be installed along with the HF/6mm Scanner. When the calibration has been completed, the system must be reset or restarted before operating in the user mode.

8.4.1 Calibration of Joule 1319nm Nd:YAG

- 8.4.1.1** Start the system and wait until it comes up into the Joule Delivery Selection screen. Enter Service Mode by pressing and holding the service switch button on the CPU board. Release the service switch when the keypad is displayed. Enter the service passcode with the keypad to enter service mode.
- 8.4.1.2** Select "Lasers" from the main service screen, then select "Just Fire'em". In the "Just Fire'em" screen, select the 1319nm laser by pressing "1319". Once the "1319" is highlighted select the red "X" in the "selected" column. You should now have a green check mark. Now select the "Charger On/Off" to enable the high voltage power supply followed by selecting "trigger simmer". The "simmer" column will now have a check mark. The laser is now simmering and the "X" in the "Gate" column needs to be selected to enable the Laser Gate. This will now show a green checkmark.
- 8.4.1.3** Set up the power meter approximately 1 foot from the scanner and aim the scanner to the center of the power meter head.
- 8.4.1.4** 1319nm Laser Calibration Parameters:
Set the 1319nm pulse width (PW) to 0.400ms, "800V"(Cap Volt OUT), and "10Hz"(Frequency) by selecting the parameters on the screen and using the Up/Down arrow keys to set desired values.
- 8.4.1.5** Press "Return" to return to the Laser service menu.
- 8.4.1.6** Select "Calibration" to go to the calibration screen.
- 8.4.1.7** Select the 1319nm Laser again by pressing "1319".
- 8.4.1.8** Open the shutter by selecting "Toggle Shutter".
- 8.4.1.9** Turn on idle lensing by selecting "Idle Lensing".
- 8.4.1.10** Using an Oscilloscope, attach Oscilloscope probes to the main CPU board on TP1 (P1) and TP2 (P2).
- 8.4.1.11** Depress footswitch and measure the amplitude of the signals. The signals should measure 5-6Volts. If the signals are high/low, select the "E2 Gain" box and adjust up/down accordingly with the up/down arrows to achieve the correct amplitude.
- 8.4.1.12** Once the correct gain is achieved, select "Save" to save the new gain value.
- 8.4.1.13** Depress the footswitch and observe the "E1" and "E2" values. These values should be approximately 2000 counts each. If the counts are high/low, select the "Attenuation" box and increase/decrease the value with the up/down arrow. Verify the counts again by depressing the footswitch. Repeat until the counts are approximately 2000 each.
- 8.4.1.14**  *When using 1319nm Nd:YAG, only fire the laser with Idle Lensing On if the shutter is open. Damage to the Beam Combiner and Beam Pickoff Mirrors can occur.*
- 8.4.1.15** Depress the footswitch once again and observe the value measured on the power meter. After the power meter stabilizes, note its value and release the footswitch.
- 8.4.1.16** Select the box in the calibration screen labeled "Enter Output Power" and use the up/down arrows to adjust the value to the power measured in the previous step. Now push "calculate". The Ablation Calibration Constant should have been updated.
- 8.4.1.17** Press "Save" to store the new calibration constant.

8.5 Calibration Procedure for Joule (1470nm)

The 1470 calibration procedure must be performed only after the lasers are properly aligned and all the optics are clean. The arm must be installed along with the Halo Scanner/handpiece. When the calibration has been completed, the system must be reset or restarted before operating in the user mode.

8.5.1 Calibration of Joule 1470nm

Tools Needed: A calibrated 45W or higher power meter.

- 8.5.1.1** Start the system and wait until it comes up into the Joule Delivery Selection screen. Enter Service Mode by pressing and holding the service switch button on the CPU board. Release the service switch when the keypad is displayed. Enter the service passcode with the keypad to enter service mode.
- 8.5.1.2** Select "Lasers" from the main service screen, then select "Just Fire'em". In the "Just Fire'em" screen, select the 1470 laser by pressing "1470". Once the "1470" is highlighted select the red "X" in the "selected" column. You should now have a green check mark. Now select "trigger simmer". The "simmer" column will now have a check mark. The laser is now enabled and the "X" in the "Gate" column needs to be selected to enable the Laser Gate. This will now show a green checkmark.
- 8.5.1.3** Set up the power meter approximately 1 inch from the scanner and aim the scanner to the center of the power meter head.
- 8.5.1.4** 1470 Laser Calibration Parameters:
Select the "CW" mode button to enable continuous pulse.
- 8.5.1.5** Open the shutter by selecting "Toggle Shutter".
- 8.5.1.6** Depress the footswitch and observe the value measured on the power meter. After the power meter stabilizes, note its value and release the footswitch.
- 8.5.1.7** Select the box labeled "Diode Power" and use the up/down arrows to adjust the value to the power measured in the previous step. Now push "Return" to exit to the previous screen.
- 8.5.1.8** Select the "Head Config" button and next select "1470 MaxPwr" and verify the power matches the value in the previous step.
- 8.5.1.9** Press "Save" to store the new calibration power.

8.6 Calibration Procedure for Joule (755nm Alexandrite)

Tools Needed: A calibrated 100W or higher power meter with a 50mm aperture for laser light at 755nm and an Oscilloscope.

This calibration procedure must be performed only after the lasers are properly aligned and all of the optics is clean. The arm must be installed along with the Duo Scanner/handpiece. When the calibration has been completed, the system must be reset or restarted before operating in the user mode.

8.6.1 Calibration of Joule 755nm Alexandrite

- 8.6.1.1** Start the system and wait until it comes up into the Joule Delivery Selection screen. Enter Service Mode by pressing and holding the service switch button on the CPU board. Release the service switch when the keypad is displayed. Enter the service passcode with the keypad to enter service mode.
- 8.6.1.2** Select "Lasers" from the main service screen, then select "Just Fire'em". In the "Just Fire'em" screen, select the 755nm laser by pressing "755". Once the "755" is highlighted select the red "X" in the "selected" column. You should now have a green check mark. Now select the "Charger On/Off" to enable the high voltage power supply followed by selecting "trigger simmer". The "simmer" column will now have a check mark. The laser is now simmering and the "X" in the "Gate" column needs to be selected to enable the Laser Gate. This will now show a green checkmark.
- 8.6.1.3** Set up the power meter approximately 1 foot from the scanner and aim the scanner to the center of the power meter head.
- 8.6.1.4** 755nm Laser Calibration Parameters:
Set the 755nm pulse width (PW) to "0.500ms", "700V" (Cap Volt OUT), and "10Hz"(Frequency) by selecting the parameters on the screen and using the Up/Down arrow keys to set desired values.
- 8.6.1.5** Press "Return" to return to the Laser service menu.
- 8.6.1.6** Select "Calibration" to go to the calibration screen.

- 8.6.1.7 Select the 755nm Laser again by pressing "755".
- 8.6.1.8 Open the shutter by selecting "Toggle Shutter".
- 8.6.1.9 Turn on idle lensing by selecting "Idle Lensing".
- 8.6.1.10 Using an Oscilloscope, attach Oscilloscope probes to the main CPU board on TP1 (P1) and TP2 (P2).
- 8.6.1.11 Depress footswitch and measure the amplitude of the signals. The signals should measure 5-6Volts. If the signals are high/low, select the "E2 Gain" box and adjust up/down accordingly with the up/down arrows to achieve the correct amplitude.
- 8.6.1.12 Once the correct gain is achieved, select "Save" to save the new gain value.
- 8.6.1.13 Depress the footswitch and observe the "E1" and "E2" values. These values should be approximately 2000 counts each. If the counts are high/low, select the "Attenuation" box and increase/decrease the value with the up/down arrow. Verify the counts again by depressing the footswitch. Repeat until the counts are approximately 2000 each.
- 8.6.1.14  *When using 755nm Alexandrite, firing the laser with can only occur with Idle Lensing. Damage to the 755nm Laser, Beam Combiner and Beam Pickoff Mirrors can occur without Lensing.*
- 8.6.1.15 Depress the footswitch once again and observe the value measured on the power meter. After the power meter stabilizes, note its value and release the footswitch.
- 8.6.1.16 Select the box in the calibration screen labeled "Enter Output Power" and use the up/down arrows to adjust the value to the power measured in the previous step. Now push "calculate". The Ablation Calibration Constant should have been updated.

Press "Save" to store the new calibration constant.

8.7 Calibration Procedure for Joule BBL

BBL module is responsible for measuring instantaneous current and voltage applied to the flashlamp for the indicated time interval. The product of these values is the energy delivered to the lamp. Input lamp energy is directly related to output lamp energy with a calibration constant that is measured and set during final test. The energy is monitored continuously (shorter than the failure tolerance time) during the pulse while in operation.

During the startup test, both lamp current and lamp voltage are checked to verify proper operation of the voltage and current sensors. These sensors are validated at startup and if inoperable will not allow the system to continue to ready mode. In operation these sensors control the voltage and current being applied to the lamp.

The short wavelength boundary is defined by the absorption of the cerium doping of the flashlamp and flowtube materials used in the system. Doping with cerium causes the materials to blocks all wavelengths below 385 nm. An additional filter is inserted in the light path to further guarantee the lower wavelength limit.

Pulse timing and pulse duration is checked during maintenance at regular intervals.

Tools Needed: A calibrated 100 J or higher energy meter for broadband light at 300-1400 nm and a small screwdriver.

The energy meter on the control panel display screen is calibrated to indicate the energy delivered to the distal end of the handpiece. Under normal operating conditions, the system should be checked for calibration once a year or whenever an optical component has been cleaned, replaced or adjusted, the energy monitor circuit adjusted or the CPU board replaced. Sciton Service representatives check the calibration during each service call.



Calibration is a SERVICE procedure to be performed ONLY by trained SCITON Service Engineers or customers who have taken and passed a Sciton Service Training Course. Calibration by anyone other than a trained Sciton Service Engineer or a certified customer will void any existing warranty on the system. Unauthorized access to the BBL service mode can expose anyone in the immediate area to dangerous conditions. Furthermore, damage to the system can occur if proper procedures are not followed. In order to prevent accidental exposure to the BBL light, all persons in the room should wear protective eyewear whenever the BBL flashlamp is fired.

8.7.1 Calibration for Joule BBL

The calibration procedure must be performed only after the system is properly aligned and all optical components are clean. Whenever the calibration has been completed, the system must be reset or restarted before operating in the user mode.

- 8.7.1.1** Set up the power meter according to the manufacturer's recommendations and position the sapphire waveguide so that the power meter head captures all the energy.
- 8.7.1.2** Start the system and wait until it comes up into the Joule Delivery Selection screen. Enter Service Mode by pressing and holding the service switch button on the CPU board. Release the service switch when the keypad is displayed. Enter the service passcode with the keypad to enter service mode.
- 8.7.1.3** Select "BBL" from the main service screen.
- 8.7.1.4** Select "Just Fire" and increase voltage to start voltage.
- 8.7.1.5** Select "BBL Interface". Enable "PWR", "HV SWITCH" and strike lamp.
- 8.7.1.6** Return to "Just Fire" menu and select "ON" for Slot number 1.
- 8.7.1.7** Increase "NUM" to 5 with 1.5 ms pulse spacing and verify pulse width equals 1 ms
- 8.7.1.8** Install the 590 nm filter into the handpiece and depress footswitch to fire one pulse into the energy meter. The total output energy should be at approximately 100 Joules for accurate calibration. Increase or decrease the pulse width to adjust the energy.
- 8.7.1.9** Depress the footswitch again to fire the flashlamp into the energy meter. Adjust R4 on BBL Integrator PCB so that integrated energy is equal to measured energy.
- 8.7.1.10** Select "Calibrate Pyro's" from the menu selection. Verify Auto Enter =On
- 8.7.1.11** Remove filter from handpiece to calibrate for system efficiency.
- 8.7.1.12** Depress the footswitch to fire the flashlamp. Enter the energy displayed on energy meter using the keypad provided on the touch screen, then push "Enter." The efficiency and calibration constant will now be updated to the correct value.
- 8.7.1.13** Install the 515 nm filter and repeat 6.5.1.10.
- 8.7.1.14** Repeat 6.5.1.10 for each of the filters installed verifying filter selected is displayed on touch screen.
- 8.7.1.15** Reinitialize the system by turning the key switch OFF and then return it to the ON position.
- 8.7.1.16** The system is ready to use.

9.0 Clinical Applications



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

Sciton handpieces are supplied non-sterile and require disinfection or sterilization prior to use. Reference "Maintenance" section on how to disinfect or sterilize a handpiece.

Laser fume and/or plume may contain tissue particulates.

9.1 Operator Training

Clinicians handling laser and light based devices should complete a training program. Sciton offers a comprehensive training class in the safe operation of the Joule system.

Practitioners may also consider the following additional training:

- "Hands-on" training under the preceptorship of a medically qualified user.
- An accredited training course within the practitioner's specialty.

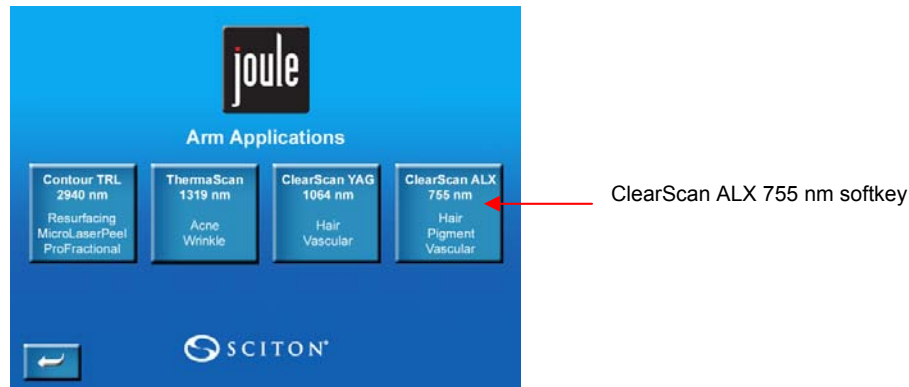
ClearScan ALX™

9.2 ClearScan ALX 755 nm Alexandrite

ClearScan ALX emits a near infrared beam at 755 nm, which coincides with a high absorption peak for melanin and hemoglobin while sparing epidermal melanin. Its principal uses are permanent hair reduction, vascular and pigmented lesion treatments.

Arm Application Menu Screen

The Arm Application menu screen allows the user to enter the ClearScan ALX 755 nm user application screen.



Pressing the ClearScan ALX 755 nm softkey will allow the user to enter into the ClearScan ALX 755 nm Applications screen.



1. Application Header
Application Header displays the selected ClearScan ALX 755 nm application.
2. Scanner application softkey.
Attach Duo Scanner with Contact Cooler connected and press the Scanner softkey to enter the 755 nm hair reduction user screen.
3. Single Spot application softkey
Starting settings for single spot hair reduction must be obtained in the Scanner applications screen and then applied to the Single Spot screen. Attach the 6 mm single spot handpiece with

either the single spot chill plate or paddle chill plate. Connect the external Contact Cooler to chill plate selected.

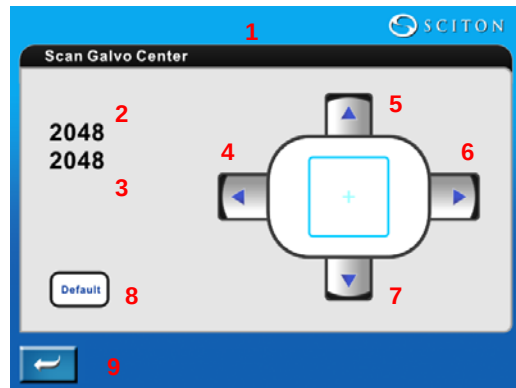
Press the Single Spot softkey to enter the Single Spot user screen.

4. Handpiece Alignment softkey.

The 6 mm Scanner has the ability to adjust the scan pattern output center. Press HandPiece Alignment softkey to access the centering screen. The X-axis and Y-axis can be adjusted and stored into memory. This adjustment should be made each time a new scanner is attached to the system and any time the scan pattern output is not centered in the center of the chill plate window (edge of aiming beam is cut-off or is hitting the metal surrounding the chill plate window).

5. Return to Arm Applications screen softkey.

Return to Arm Applications softkey will return the system to the previous screen.



1. Scanner Handpiece indicator
2. Current center settings indicator for x-axis
3. Current center settings indicator for y-axis
4. Adjust pattern left softkey
5. Adjust pattern up softkey
6. Adjust pattern right softkey
7. Adjust pattern down softkey
8. Center scanner to default position softkey
9. Return to ClearScan ALX 755 nm Applications screen softkey

9.2.1 Indications for Use

The ClearScan ALX 755nm Alexandrite laser system with its accessories is indicated for stable long-term, or permanent hair reduction for all skin types (Fitzpatrick I - VI) including tanned skin. It is also indicated for the treatment of vascular lesions, benign pigmented lesions and wrinkles.

9.2.2 Contraindications

The ClearScan ALX 755 nm Alexandrite laser system is contraindicated for:

- Patients who take medication which is known to increase sensitivity to sunlight
- Patients with infectious disease
- Patients with connective tissue disease
- Patients who are immunocompromised
- Patients who are pregnant
- Patients who have used isotretinoin (Accutane) within the past 6 - 12 months
- Patients with a medical condition that may affect wound healing
- Patients with bleeding abnormalities

9.2.3 Complications

Complications, though rare, occasionally occur and should be discussed and understood. The patient must understand the importance of the post care instructions and that failure to comply may increase the probability of complications.

- Scarring, though rare can occur following any laser procedure.
- Blistering during treatment may be an indication of recent sun exposure or too high a fluence for the skin type. Blistering can occur during the first three days following the laser procedure. Blistered areas should be treated with care and kept moist with an ointment until area has healed.
- Histamine/Hives: some patients develop raised papules similar to hives. This irritation usually subsides within a few hours after the treatment.
- Pigmentary changes: hyperpigmentation or hypopigmentation can occur when treating with a 755 nm wavelength.

9.2.4 Warnings

- In pretreatment work-ups, screen lesions that are located in close proximity to known arteries or veins in order to locate these circulatory structures.
- Water condensation on the upper surface of the contact cooling plate of the Duo Scanner may result in laser beam scattering and an incorrect setting for fluence. Treating the top of the plate with a surfactant, such as Sea Drops, will reduce scattering due to condensation.
- A dirty chill plate may lead to an incorrect setting for fluence. Clean the chill plate with a soft cotton gauze moistened with alcohol prior to each treatment and throughout extended, lengthy treatments.
- Check the chill plate temperature prior to each treatment. The risk of epidermal injury, such as blistering, increases if the temperature of the chill plate is too warm.
- Tattooed areas, and the area of skin 4-5 mm outside of the tattoo in all directions, should not be treated. Tattoo ink may absorb laser energy resulting in a color change of the tattoo ink or a risk of epidermal damage.
- Darkened moles should not be treated. Moles may absorb laser energy causing a color change of the mole resulting in the inability to monitor the mole under ABCD guidelines for melanoma detection. Excess energy may also be absorbed into the mole resulting in the risk of epidermal damage.
- Do not stack pulses or overlap consecutive scans. Repeated pulses in the same location, improper chill plate placement, repeated scans, improper cooling temperatures, or excessive fluence may lead to a buildup of subsurface heat and a subsequent blister or burn.
- There is a risk of “paradoxical effect” resulting from the activation of dormant hair follicles in untreated areas close to hirsute-treated areas in subjects with facial hirsutism, which is diagnosed with polycystic ovarian syndrome and presenting ovarian hyperandrogenism. Basically, treatment with ClearScan ALX 755 nm can stimulate hair growth.
- Do not allow combustibles or flammables, including drapes and paper panties, in the laser treatment area. Fire prevention/control methods should be in place.

9.2.5 Selective Photothermolysis

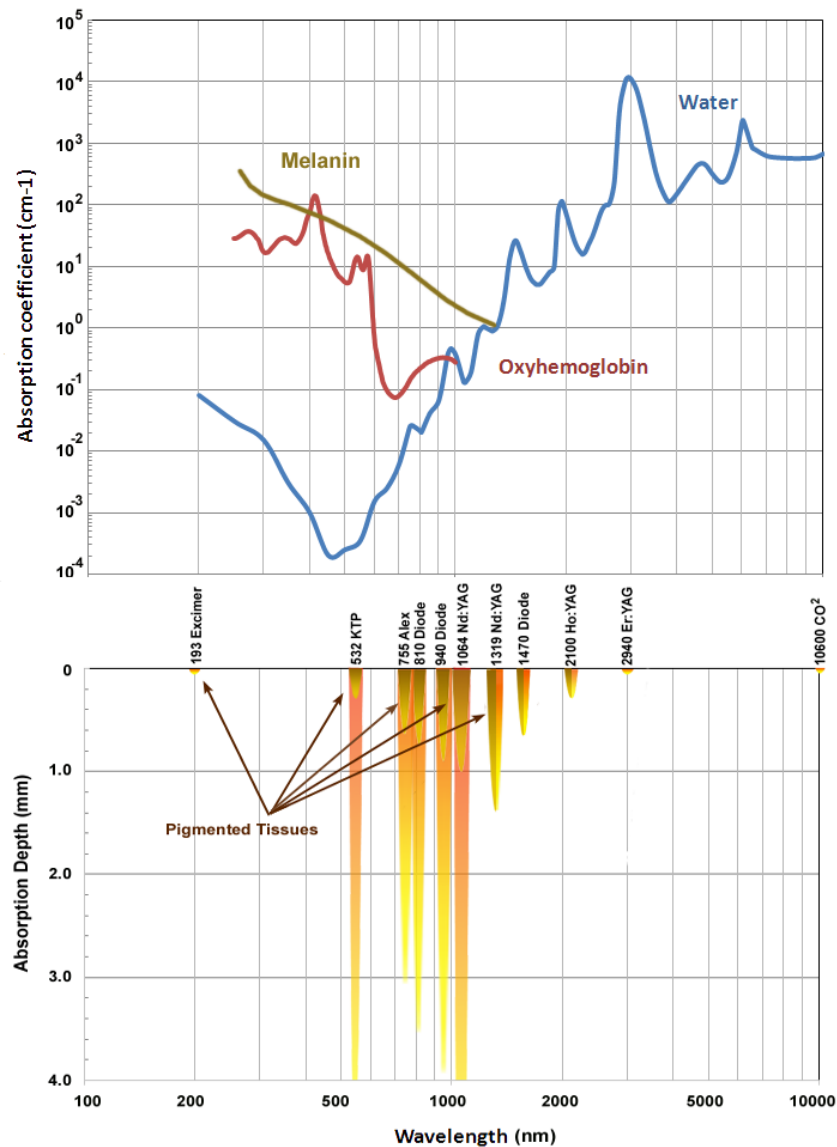
This technique relies on selective absorption of a laser light pulse to generate and confine heat within certain pigmented targets. The goal of Selective Photothermolysis is to have sufficient energy penetrate to and be absorbed by the desired target while minimizing the effect on the surrounding tissue.

Absorption Curve

Absorption curve shows the relationship of the variation in absorbed laser light as a function of wavelength. The graphic shows absorption spectra of major intracellular absorbers. The molecular absorption coefficients of oxygenated hemoglobin, melanin and water are shown.

Depth of Penetration

Depth of penetration of laser energy for different types of lasers is also illustrated.



The goal when treating with ClearScan ALX 755 nm is to heat the target to a temperature that is sufficient to destroy it, but not to the point that the heat damages skin and surrounding tissue. This is termed Selective Photothermolysis and relies on 3 critical parameters:

- Pulse width
- Fluence
- Wavelength

Pulse width is the amount of time that the target is exposed to the heat and is typically measured in milliseconds (ms). Pulse width must be less than the Thermal Relaxation Time (TRT) of the target. In other words, the pulse width must be long enough to allow heating of the target but also short enough that the target can cool so that there is no heat buildup in surrounding skin and tissue. The cooling time of a target is relative to its size, structure and density. Larger targets take longer to cool than smaller ones. Likewise, a very densely pigmented target will cool down slower than a target with less concentrated pigment. Refer to ClearScan ALX 755 nm Treatment Starting Parameters for safe start pulse width parameters.

Fluence is the amount of heat or energy delivered into the target. Fluence is measured in units of Joules/cm². Refer to ClearScan ALX 755 nm Treatment Starting Parameters for safe start fluence parameters.

The higher the fluence selected, the higher the temperature of the target, the surrounding tissue and the epidermis. Treating with excess energy can result in adverse effects such as abnormal pigmentation, blistering and scarring.

Patient response can vary, so the fluence setting should begin low and be increased gradually after assessing the individual patient response and observation of endpoints desired.

Wavelength is the spatial period of a wave from the peak of one wave to the peak of the next. Photons of 755 nm are preferentially absorbed by the target chromophores of melanin and hemoglobin.

Surface Cooling

ClearScan ALX 755 nm integrates a powerful 250 Watt external cooling system that connects to the 7 mm Scanner, paddle or single spot chill plates in order to keep the treatment area cool. Skin surface temperature changes of 1 °C can cause immediately observable differences in the clinical response.



External Cooling Systems: A black or white version of the external chiller may have been supplied with your system. Refer to Appendix I for operating instructions, including instructions for attaching the chiller hose.



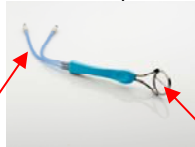
Chill Plates connected to the system

All chill plates are all made of 100% sapphire. Each chill plate consists of two sapphire plates that are sandwiched together. When connected to the external Contact Cooler, Chiller Mixture flows from the cooler, through the chiller hose, down the chill plate tubing and between the two sapphire plates. The Chiller Mixture continues up the opposite tube on the chill plate and then recycled back through the contact cooler.

Single spot chill plate



Paddle chill plate



Integrated Scanner with chill plate



Chill plate tubing

Sapphire plates

The chill plate should be in complete contact with skin throughout the entire scan or pulse to ensure that skin is protected before, during and after a pulse or scan pattern is delivered.

Although absorption of the ClearScan ALX 755 nm energy into a certain chromophore is desirable, some epidermal cooling is necessary to protect the skin. Refer to ClearScan ALX 755 nm Starting Parameters for temperature setting of the external cooling system.

Continuous observation of skin during a ClearScan ALX 755 nm treatment is critical and will ensure appropriate fluence, pulse width and temperature settings have been selected and that skin integrity has not been compromised.

9.2.6 Getting Started

9.2.6.1 Consultation/Education

A consultation is essential in order to establish realistic expectations and to gain a full understanding of the patient and his/her treatment goals. The patient must understand the procedure, pre and post care instructions, expectations, contraindications and possible complications prior to beginning any treatment.

9.2.6.2 Medical History

A detailed medical history should be obtained prior to treatment outlining any former or active medical condition or medication that is contraindicated or that could possibly affect the outcome of the treatment.

It is recommended that a brief medical history be taken before beginning any subsequent treatment with questions such as, but not limited to, any new medications, skin care, sun exposure, pregnancy etc.

9.2.6.3 Skin Typing

Accurate skin typing is critical to treatment success and the avoidance of complications. It is important to know that in most situations an individual's previous response and genetic tendency to sun exposure will be the biggest indicators in establishing skin type. Some patients, such as Asians and Hispanics, may appear to be a skin type II or III and never tan but react to laser energy like a IV or V skin type. Hence, it is very important not to base skin type on appearance.

The skin type of a patient does not change. Do not confuse skin type with a tan. A person's skin type is something they are born with and it does not change, but the degree of tan can change.

Type	Hair Color	Skin Color & Ethnic Background	Eye Color	Sun Reaction
I	Red, White Blonde	Very fair <i>Scandinavian, Nordic, and North European</i>	Blue	Always burns, never tans
II	Red, Blonde, light brown	Fair <i>North European, Celtic (Scottish, Irish)</i>	Blue, green	Always burns, tans with difficulty and tends to be freckled
III	Sandy Blonde, Brown	Medium <i>Southern Europe</i>	Hazel, green, blue,	Burns initially, tans fairly well and evenly
IV	Brown, Black	Moderate brown, Olive <i>Mediterranean, Latin (Italian, Hispanic)</i>	Hazel, brown	Burns are rarely evident, tans easily
V	Black	Dark Brown <i>(Asian, Middle Eastern, American Indian)</i>	Dark brown, black	Burns are never evident, tans always <i>*some Asian skin always burns and never tans</i>
VI	Black	Black <i>(African-American, Indonesian)</i>	Dark brown, black	Burns are never evident, tans always



Skin type V is the most under-typed skin. Often Asian skin will look very light and have no history of sun exposure. Occasionally they have "bleached" their skin with hydroquinone. Treating them as a III or IV (based on look and reaction to sun) could result in higher risk of complications. Initially, all Asian skin should be treated as a Skin Type V until reaction to laser light has been determined. Similarly, not all black skins are of the same degree of darkness and there may be the temptation to type these patients as a lower type.

9.2.6.4 Informed Consent

The process of accepting and confirming treatment must be reviewed, understood and signed by the patient prior to treatment. This document must review the topics discussed during the consultation. It acknowledges that the patient understands the procedure, possible risks and complications and that all questions have been answered. *Reference sample Informed Consent in Appendix of this manual.*

9.2.6.5 Photographs

Pictures should be taken prior to each treatment to document the progress of the treatment. Photographs are useful in demonstrating efficacy of treatment to the patient.

Camera settings, distance, backdrop, and body/face angle, position and expression should be the same for each photography session to maintain similar quality.

The patient should sign a photo release form if before and after pictures are to be used for educational or marketing purposes.

9.2.6.6 Topical Anesthesia

The use of topical anesthetic is not typically recommended for ClearScan ALX 755 nm treatments. Patient feedback is needed to evaluate appropriate endpoints. If a patient is "numb" they may not be able to accurately assess if a treatment is too warm which could lead to a blister or a burn. However, if topical preparation is used to alleviate discomfort for highly sensitive patients or sensitive areas prior to treatment, the manufacturer's guidelines for the application and duration of the anesthetic should be read prior to topical application. Remove before treatment with mild soap and water or a gauze moistened with alcohol, then plain water. Dry the area thoroughly before treatment.

Reminder: Each patient should be assessed and questioned regarding allergies or sensitivities to ingredients in topical anesthetics prior to application.



Be extremely cautious when applying topical anesthetics to large areas of the body. Lidocaine toxicity has been linked to several deaths.

9.2.6.7 Eye Protection

Eye protection should always be worn by everyone present in the treatment room during any laser or light based treatment. When treating on the patient's face, they should always wear external, matte-finish metal goggles.



It is not recommended that any ClearScan ALX 755 nm treatment be performed within the orbital rim of the eye due to the high risk of retinal damage.

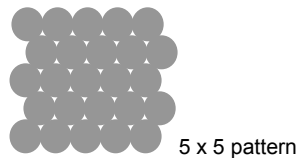
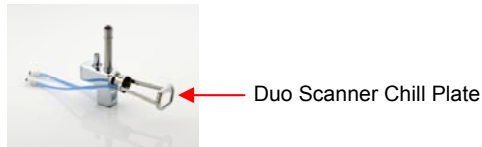
9.2.7 Safe Start Protocol for ClearScan ALX 755 nm Hair Reduction

The theory of Selective Photothermolysis explains how wavelength, energy and pulse width in relation to Thermal Relaxation Time (TRT) all play a role in the destruction of a target and the preservation of surrounding tissue.

Using the theory of selective photothermolysis, unwanted hair can be treated with the ClearScan ALX 755 nm and appropriate settings that will cause selective absorption of laser light in the melanin of hair. The light travels down the hair shaft and into the bulb of the follicle where the blood supply to the follicle is located. The absorption converts light into heat energy, which raises the temperature of the bulb causing the blood vessels that supply blood and other necessary nutrients to the follicle to be cauterized. As a result, hair growth is no longer possible. This process should happen selectively and without damage being done to the epidermis or surrounding tissue.

Duo Scanner

The Duo Scanner has a contact cooling chill plate assembly attached to it. The assembly is comprised of two sapphire plates that are separated by continuously flowing Chiller Mixture. The spot placement is achieved by using two galvanometer motors for x-axis and y-axis displacement.

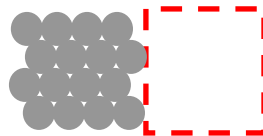


5 x 5 pattern

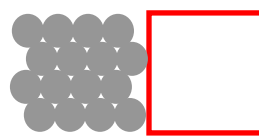
The Duo Scanner precisely places each pulse in a non-sequential pattern to eliminate improper placement of individual pulses. It also maximizes the time interval between adjacent spots and minimizes subsurface heat buildup.

The Duo Scanner allows for complete and uniform application of the laser energy by delivering 7 mm spots of energy within a designated pattern shape and size. The pattern can be adjusted from a 1 x 1 (single spot) to a 5 x 5 with any variation in between. A 5 x 5 pattern is illustrated above.

Aiming beam is represented by red box and shows the user the area to be treated. The energy will be delivered inside the red box. When the red box is "dancing" the system is in Standby. When the red box is solid the system is in Ready.



Standby



Ready

Care should be taken to apply adjoining scans without gap or excessive overlap of the previously scanned area. A visual picture of where the next scan pattern should be placed, or looking at the tracks in the gel, will assist in lining each scan pattern up to each other to avoid gap or overlap as shown above.

To achieve safe, uniform treatment as shown, the Duo Scanner should be held so that the red box within the chill plate window is in complete contact with the skin at all times.

ClearScan ALX 755 nm Scanner Application User Screen

Attach the Duo Scanner to the articulated arm. Press the Scanner softkey on the ClearScan ALX 755 nm Applications screen and the system will enter the ClearScan ALX 755 nm hair reduction application screen.



The ClearScan ALX 755 nm user screen allows the user to adjust treatment settings. The available functions are described below.

1. Wavelength indicator
Wavelength indicator shows which wavelength is being used for the treatment.
2. Handpiece indicator
Handpiece indicator shows which handpiece is being used for the treatment.
3. Fluence indicator
Fluence indicator shows the amount of fluence or energy being delivered per 7 mm spot within whatever size or shape scan pattern has been selected. Fluence is measured in joules per centimeter squared, J/cm².
4. Fluence adjustment softkeys
Fluence adjustment softkeys allow the user to increase or decrease fluence by 1 J/cm² by tapping or holding down the up ▲ or down ▼ arrow softkeys.
5. Pulse width indicator
Pulse width indicator shows the length of time the energy is being delivered per 7 mm spot within whatever size or shape scan pattern has been selected. Pulse width is measured in milliseconds (ms).
6. Pulse width adjustment softkeys
Pulse width adjustment softkeys allow the user to increase or decrease pulse width by 5 ms by tapping or holding down the up ▲ or down ▼ arrow softkeys.
7. Spot placement rate
Spot placement rate is the speed at which each 7 mm spot is being delivered within the scan pattern. The speed is measured in Hz. The maximum rate is automatically limited by the laser based on the fluence and pulse width.
8. Spot placement rate adjustment softkeys
Spot placement rate adjustment softkeys allow the user to increase or decrease the rate at which each 7 mm spot is being delivered by 0.5 Hz by tapping or holding down the up ▲ or down ▼ arrow softkeys.
9. Horizontal pattern selection softkeys
The horizontal pattern selection softkeys allow the user to increase or decrease the horizontal size of the pattern from 1 to 5 spots.
10. Vertical pattern selection softkeys
The vertical pattern selection softkeys allow the user to increase or decrease the vertical size of the pattern from 1 to 5 spots.
11. Hair reduction quick set settings section indicator
The hair reduction quick set settings section allows the user to select Skin Type I-IV (1 - 4), Hair Color (Blonde, Brn/Red or Black) and Hair Type (Fine, Medium or Coarse) of the patient in the area being treated. The laser will automatically set the laser to safe start settings of fluence, pulse width and rate.
12. Skin type selection softkeys

Skin type selection softkeys allow the user to choose skin type I, II, III, or IV by tapping or holding down the up or down arrow softkeys.

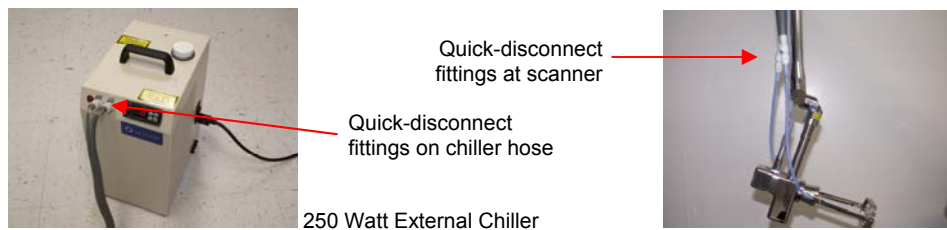
13. Hair Color to be treated softkeys
Hair Color to be treated softkeys allow the user to select blonde hair by tapping the Blonde softkey, brown or red hair by tapping the Brn/Red softkey and black hair by tapping the Black softkey.
14. Hair Type to be treated softkeys
Hair Type to be treated softkeys allow the user to select fine hair by tapping the Fine softkey, medium hair by touching the Medium softkey and coarse hair by touching the Coarse softkey.
15. Pattern center softkey
Pattern center allows the user to offset the area to be treated to the upper left corner, upper middle, upper right corner or the center of the chill plate window.



16. Pattern repeat softkey
Pattern repeat will allow the user to set an amount of time between consecutive scans of 1, 2, 3, 4, or 5 seconds by tapping the Repeat softkey. Repeat can also be turned off so that each scan pattern is delivered by lifting and depressing the footswitch.
17. Number of accumulated pulses indicator
Number of accumulated pulses indicator shows how many pulses have been delivered since the system was turned on or since the last time the reset softkey for accumulated pulses was reset.
18. Accumulated pulses reset softkey
Accumulated pulses reset softkey allows the user to reset the number of accumulated pulses to 0 by touching the reset softkey.
19. Laser Fire Symbol
Presence of this symbol indicates that the laser is being fired.
20. System status softkey
System status softkey allows the user to put the system in Standby or Ready.
21. Return to ClearScan ALX 755 nm Applications screen softkey
Return to ClearScan ALX 755 nm Applications softkey will return the system to the previous screen.

Surface Cooling

When performing ClearScan ALX 755 nm Hair Reduction, the use of a contact cooler is critical for ensuring patient safety.



Attach two quick-disconnect fittings at one end of the chiller hose to the chiller and the other two quick-disconnect fittings at the other end of the hose to the Duo Scanner. Make sure that the chiller is filled with Chiller Mixture (20% methanol in deionized water). Connect the power cable and turn on the switch at the back of the chiller.



If the contact cooler is turned on prior to the scanner being attached, the cooler will emit an alarm noise. This alarm is also emitted if there is kink or anything wrong with the hose that could prevent Chiller Mixture from flowing through the connection tubes and then recirculated back through the cooler. If this alarm is heard while treating a patient, stop the treatment and evaluate why Chiller Mixture is not flowing. If Chiller Mixture is not flowing through the contact cooler hose and through the chill plate, the patient is not getting adequate cooling. This inadequate cooling could lead to a blister or burn.

Set the temperature to the desired temperature and wait a few minutes until the desired setpoint is reached.

Hair Basics

Hair revolves through three phases of growth: anagen, catagen and telogen. It is only during the growing phase, anagen, that hair reacts to ClearScan ALX 755 nm light. Not all hair present in an area is in the anagen phase at the same time. Duration of hair growth cycles depends on the body location being treated. Multiple treatments are necessary over a time span of typically 4-8 week intervals to remove hair from most areas.

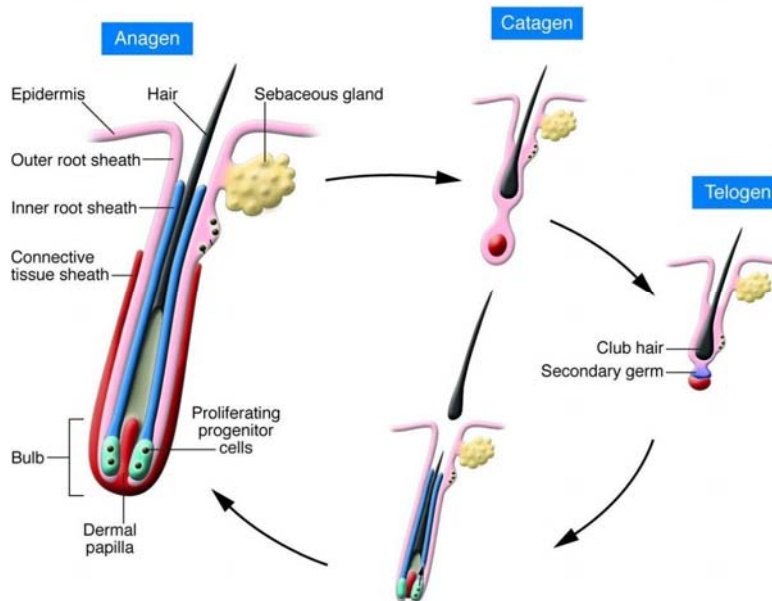
Reference Richards-Merhag Chart in the Appendix of this manual.

Hair Growth Cycle

anagen: The phase of the hair cycle during which synthesis of hair takes place. This is the active growing phase in which the hair bulb is intact.

catagen: Brief intermediate phase between anagen and telogen. During this phase, the body absorbs the lower third of the follicle.

telogen: This is the resting phase. The hair bulb is no longer present. It is now a club hair, which will fall out or be pushed out of the follicle by a new anagen growing hair.



Fluence

Refer to Treatment Starting Parameters as noted below or the Hair Reduction quick set settings section on the control panel display screen for appropriate fluence selection.

Targets that are darker absorb more energy/heat and will reach higher temperatures much quicker than targets that are lighter in color. Therefore, darker hair, and areas where there is more concentrated areas of dark hair growth, require less fluence than lighter colored hair in less concentrated areas of light colored hair growth to reach the same therapeutic level.

As treatments progress through a series, fluence settings will need to be changed. If effective treatments are being provided each treatment session, hair should be getting lighter in color, therefore fluence will need to be increased to compensate for a less melanin rich target in which the light can be absorbed.

Pulse Width

Refer to ClearScan ALX 755 nm Treatment Starting Parameters as noted below or the Hair Reduction quick set settings section on the control panel display screen for appropriate pulse width selection.

Pulse width should be shorter than the cooling time of the target to make sure that all the energy is confined to the target. Smaller objects cool faster than larger ones. Therefore, the smaller or finer the hair being treated the less time on, or the shorter the pulse width. Conversely, the larger or coarser the hair being treated the more time on with the heat, or a longer pulse width.

Areas of hair growth that are less densely populated will cool down quicker than more densely populated ones. Therefore, hair that is finer and in areas with less dense growth should be treated with shorter pulse widths and coarser more concentrated areas of hair growth should be treated with longer pulse widths.

Darker skin absorbs more light and heats to a higher temperature, therefore pulse width should be longer for darker skin.

As treatments progress through a series, pulse width settings will need to be changed. If effective treatments are being provided each treatment session, hair should be getting finer in texture. Therefore, pulse width would need to be decreased to compensate for less time needed to heat up the target melanin otherwise the excess heat will flow out of the follicle and into the surrounding skin.

Cooling

5°-10°C is recommended for maximum patient comfort. Treating with higher temperatures will require treating with lower fluence settings.

Note: *The cooling temperature is set on the external contact cooler and not on the control panel display screen.*

The area within the selected red box on the Duo Scanner chill plate should be in complete contact with skin throughout the entire scan to ensure that skin is protected before, during and after a scan pattern is delivered.



Always test the chill plate window for desired level of chilling before beginning any laser treatment. The risk of epidermal injury such as blistering increases with ineffective cooling.

9.2.7.1 ClearScan ALX 755 nm Hair Reduction Treatment

Treatment Basics

- Hair that is present in the area to be treated should be shaved prior to treatment. There should be no more than 0.5 mm hair growth, or very minimal stubble, present in treatment area. The longer the hair, the greater the risk of burning the hair to the patients skin and also "pitting" or damaging the Duo Scanner chill plate window.
- Patient should be positioned based on the area to be treated. The position should be comfortable to the patient and such that the treatment provider has good access to the area to be treated and the system control panel display screen.
- When treating a patient's upper lip, a mouth guard or a 2 x 2 piece of gauze should be placed between the teeth and upper lip.
- A mild cleanser or alcohol gauze should be used to remove any dirt, makeup, deodorant or moisture from the treatment site.
- If topical anesthetic is to be used, apply as directed prior to treatment. Before beginning treatment, ensure that topical has been completely removed from surface of skin.
- Apply 2-3 mm thickness of colorless gel to area to be treated. The gel should be used in conjunction with the 755 nm wavelength for optimal heat removal to help protect the epidermis, as well as improved optical coupling and lubrication for sliding the chill plate over skin. The gel also simulates contact with the skin and reduces the risk of "pitting" or damage to the Duo Scanner chill plate window.
- Connect the Duo Scanner to the articulated arm.
- Water condensation on the upper surface of the chill plate may result in laser beam scattering and an incorrect setting for fluence. Apply the surfactant, Sea Drops, to the upper side of the Duo Scanner chill plate window before turning on the external Contact Cooler. Reapply as needed.

- Connect external Contact Cooler to the Duo Scanner and then turn the cooler on.



If the Contact Cooler is turned on prior to the scanner being attached, the cooler will emit an alarm noise. This alarm is also emitted if there is kink or anything wrong with the hose that could prevent Chiller Mixture from flowing through the connection tubes and then recirculated back through the cooler. If this alarm is heard while treating a patient, stop the treatment and evaluate why Chiller Mixture is not flowing. If Chiller Mixture is not flowing through the contact cooler hose and through the chill plate, the patient is not getting adequate cooling. This inadequate cooling could lead to a blister or burn.

- Select appropriate temperature setting. Refer to ClearScan ALX 755 nm Hair Reduction Treatment Starting Parameters.

***Note:** Always test the chill plate window for desired level of chilling before beginning any laser treatment. The risk of epidermal injury, such as blistering, increases with decreased or ineffective cooling.*



Eye protection should always be worn by everyone present in the treatment room during any laser or light based treatment. When treating on the patient's face, they should always wear external, matte-finish metal goggles. It is not recommended that any ClearScan ALX 755 nm treatment be performed within the orbital rim due to the high risk of retinal damage.

- Select starting settings based on ClearScan ALX 755 nm Hair Reduction Treatment Starting Parameters noted below or the Hair Reduction quick set settings section on the control panel display screen.
- The Duo Scanner should be held perpendicular to the surface of the skin at all times. Move patient if necessary to accomplish this 90 degree angle. All areas of the chill plate within the red box, should be in complete contact with skin at all times throughout entire scan. For highly curved areas, select a smaller scan pattern or select Pattern Center to offset the pattern to the top edge of the chill plate to ensure that treatment area inside the red box is completely flat on skin.
- **Treating Test Area:** Treating a test area prior to beginning treatment will determine the patient's response threshold and help establish safe and effective treatment parameters.
 - Select test settings using the ClearScan ALX 755 nm Hair Reduction Treatment Starting Parameters below or the Hair Reduction quick set settings section on the control panel display screen.
 - Set the scan pattern size to 2 x 2 or 3 x 3 especially if the treatment area is small. This will allow adequate area for test spots rather than treating the entire area.
 - Depress the foot switch to deliver the entire scan pattern. Another scan pattern will not be delivered unless the footswitch is depressed again or if repeat is turned on.
 - During delivery of scan pattern, observe for endpoints; sparking, smell of burning hair, patient's report of a mild to moderate heat sensation in the area being treated and mild to moderate follicular erythema and edema.
 - If desired endpoints are observed with no adverse effects, treatment can be continued until area is completed.
 - If endpoints are not noted, increase the intensity of treatment by the following actions, in the following order (make only one change per test pulse):
 - Increase fluence by **1 - 2 J/cm²**
 - Decrease pulse width by **5 - 10 ms**
 - If reaction to test spot is too severe (intense erythema, purpura, immediate white or grey presentation of skin), the settings should be decreased in intensity by the following actions, in the following order:
 - Decrease fluence by **1-2 J/cm²** depending on intensity of reaction
 - Increase pulse width by **5 - 10 ms** depending on intensity of reaction
 - Match the trailing edge of one scan pattern to the leading edge of the next. There should be no overlap between scans. Scan patterns should "line up" right next to each other.

ClearScan ALX 755 nm Hair Reduction Treatment Starting Parameters

Area	Skin Type	Fluence (J/cm ²)	Pulse Width (ms)	Cooling (°C)
Face	I – II	21 - 25	15 - 18	5° - 10° C
	III-IV	18 - 22	17 - 20	
Body	I – II	16 - 20	20 - 23	5° - 10° C
	III-IV	12 - 18	22 - 25	
Pseudofolliculitis Barbae (PFB)	I – II	11 - 15	30 - 33	5° - 10° C
	III-IV	8 - 12	32 - 35	

Note:

In areas where skin is thinner and the bone is closer to the surface; jaw line, clavicle, shins, shoulders, knees, toes etc., fluence should be decrease by 20%.

Fluence should be decreased when treating thicker hair.

Endpoints

- Sparking – the hair shaft should flash when instantly heated by the laser pulse.
- Mild to moderate discomfort.
- Smell of success (SOS) – hair has a unique and very noticeable odor when it is heated during the laser pulse.
- Slight follicular edema and erythema within 2 - 5 minutes after treatment that resolves within 1 - 4 hours of treatment.

Post Treatment

- Observation – Erythema and follicular edema for several hours after treatment. Treated hairs can take up to 7 - 14 days to exfoliate from the follicle and may appear to be “growing” during this time, however there is a possibility that hair will extrude from the follicle during treatment.
- Intervention – Cool compresses or ice packs can provide some comfort after treatment. If blistering occurs, aggressive wound healing measures should be implemented.
- Interval - Treatments are performed 4 - 8 weeks apart. 5 - 7 treatments may be required.
- If performing hair reduction treatments in conjunction with other procedures such as MLP or ProFractional, perform hair reduction first.
- Check with manufacturer for guidelines on using injectables in conjunction with ClearScan ALX 755 nm hair reduction treatments.

9.2.7.2 ClearScan ALX 755 nm Single Hair Reduction Treatment

The ClearScan ALX 755 nm Hair Reduction Treatment protocol is utilized when treating individual hairs.

The 6 mm single spot handpiece is used for ClearScan ALX 755 nm Single Hair Reduction treatments.

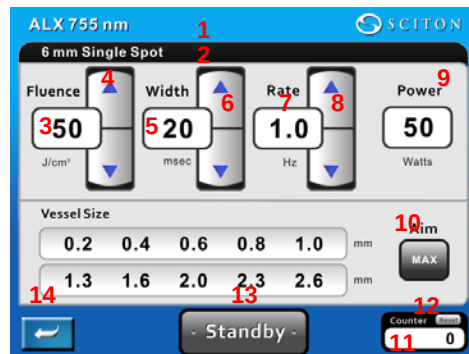


6 mm Single Spot Handpiece

When selecting settings for ClearScan ALX 755 nm Single Hair Reduction Treatments, the user can either enter the ClearScan ALX 755 nm Scanner Applications User Screen and use the Hair Reduction Quick Set Settings Section or refer to the ClearScan ALX 755 nm Hair Reduction Treatment Starting Parameters noted above.

ALX 755 nm Single Spot Application User Screen

Attach the 6 mm single spot handpiece to the articulated arm. Press the Single Spot softkey on the ClearScan ALX 755 nm Applications screen and the system will enter the ALX 755 nm application screen.



The ALX 755 nm user screen allows the user to adjust treatment settings. The available functions are described below.

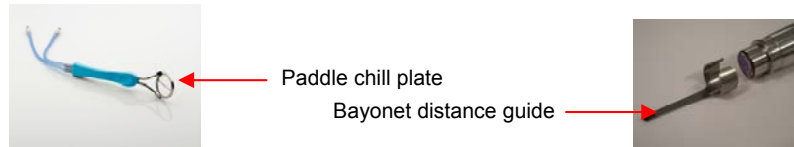
1. Wavelength indicator
Wavelength indicator shows which wavelength is being used for the treatment.
2. Handpiece spot size indicator
Handpiece spot size indicates that the 6 mm single spot handpiece is attached to the articulated arm.
3. Fluence indicator
Fluence indicator shows the amount of fluence or energy being delivered. Fluence is measured in joules per centimeter squared, J/cm^2 .
4. Fluence adjustment softkeys
Fluence adjustment softkeys allow the user to increase or decrease fluence by $1 J/cm^2$ by tapping or holding down the up ▲ or down ▼ arrow softkeys.
5. Pulse width indicator
Pulse width indicator shows the length of time the energy is being delivered per 6 mm spot. Pulse width is measured in milliseconds (ms).
6. Pulse width adjustment softkeys
Pulse width adjustment softkeys allow the user to increase or decrease pulse width by 5 ms by tapping or holding down the up ▲ or down ▼ arrow softkeys.
7. Repetition rate indicator
Repetition rate is the amount of time between each single spot delivery when the footswitch is held down continuously. The rate is measured in Hz

8. Repetition rate adjustment softkeys
Repetition rate adjustment softkeys allow the user to increase or decrease each single spot delivery rate from 0.3 Hz to 12.4 Hz by tapping or holding down the up ▲ or down ▼ arrow softkeys. It is recommended to select Shot mode when treating a single hair in an area.
9. Power
Power is displayed in Watts.
10. Aiming beam intensity softkey
Aiming beam intensity allows the user to make the aiming beam dimmer or brighter in intensity. MIN, 1, 2, 3, 4, 5 or MAX intensity can be selected by tapping the Aim softkey.
11. Number of accumulated pulses indicator
Number of accumulated pulses indicator shows how many pulses have been delivered since the system was turned on or since the last time the reset softkey for accumulated pulses was reset.
12. Accumulated pulses reset softkey
Accumulated pulses reset softkey allows the user to reset the number of accumulated pulses to 0 by touching the reset softkey.
13. System status softkey
System status softkey will allow the user to put the system in Standby or Ready.
14. Return to ClearScan ALX 755 nm Applications screen softkey
Return to ClearScan ALX 755 nm Applications softkey will return the system to the previous screen.

Surface Cooling

When performing ClearScan ALX 755 nm Single Hair Reduction treatments, the use of a contact cooler is critical for ensuring patient safety.

Either the paddle chill plate or the single spot chill plate can be used for the treatment.



The bayonet distance guide assures that proper distance from the paddle chill plate is maintained throughout the treatment for accurate spot size delivery.



Refer to ClearScan ALX 755 nm Hair Reduction Treatment protocol for Treatment Basics and ClearScan ALX 755 nm Hair Reduction Treatment Starting Parameters for safe start settings.

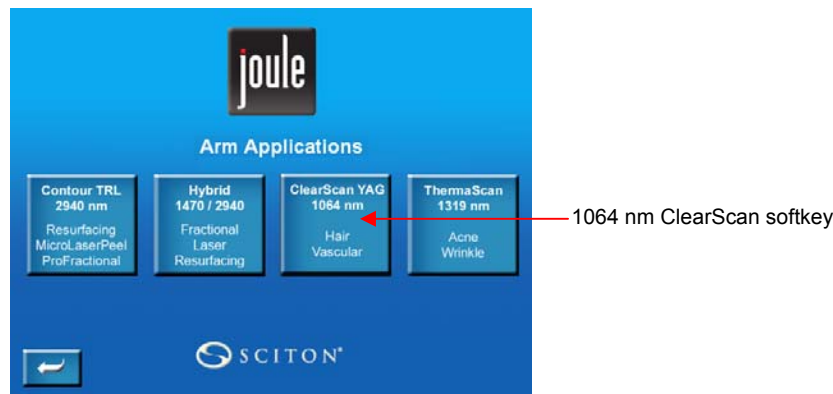
ClearScan YAG™

9.3 ClearScan YAG 1064 nm

Often referred to as the Nd:YAG or 1064 laser, it emits a mid-infrared beam at 1064 nm, which coincides with a high absorption peak for melanin and hemoglobin while sparing epidermal melanin. For this reason, ClearScan YAG 1064 nm is safe and effective for all skin types. Its principal uses are permanent hair reduction, vascular lesion treatments, wart treatments, the treatment of wrinkles, and the temporary increase of clear nail in patients with onychomycosis.

Arm Application Menu Screen

The Arm Application menu screen allows the user to enter the different 1064 nm ClearScan user application screens.



Pressing the 1064 nm ClearScan softkey will allow the user to enter into the 1064 nm Applications screen.



1. Application Header
Application Header displays the selected 1064 nm application.
2. Scanner application softkey.
Attach 5 mm HF Scanner with Contact Cooler connected and press the softkey to enter the Hair reduction user screen.
3. Single Spot application softkey
When treating vessels using the Vascular Lesion protocol, attach the 3 mm or 6 mm single spot

handpiece with either the single spot chill plate or paddle chill plate. Connect the external Contact Cooler to chill plate selected. If treating for wrinkles using the Fine Lines/Wrinkles protocol, attach the 3 mm single spot handpiece. No contact cooling necessary.

If treating for hair reduction, starting settings must be obtained in the scanner applications screen and then applied to the Single Spot screen. Attach the 6 mm single spot handpiece with either the single spot chill plate or paddle chill plate. Connect the external Contact Cooler to chill plate selected. Press the softkey to enter the Single Spot user screen.

4. PhotoRevelation softkey

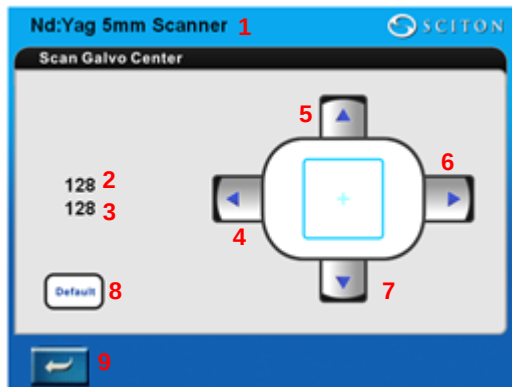
When treating redness and fine lines/wrinkles using the PhotoRevelation Safe Start Protocol, attach the 3 mm single spot handpiece. No contact cooling is necessary. Press the softkey to enter the PhotoRevelation user screen.

5. ClearSense softkey

When treating nail fungus using the ClearToe Safe Start Protocol, attach the ClearSense handpiece. Press the softkey to enter the ClearSense user screen.

6. Handpiece Alignment softkey.

The 5 mm HF Scanner has the ability to adjust the scan pattern output center. Press Handpiece Alignment softkey to access the centering screen. The X-axis and Y-axis can be adjusted and stored into memory. This adjustment should be made each time the scanner is attached to the system for the first time and any time the scan pattern output is not centered in the center of the chill plate window (edge of aiming beam is cut-off or is hitting the metal surrounding the chill plate window).



1. Scanner Handpiece indicator
2. Current center settings indicator for x-axis
3. Current center settings indicator for y-axis
4. Adjust pattern left softkey
5. Adjust pattern up softkey
6. Adjust pattern right softkey
7. Adjust pattern down softkey
8. Center scanner to default position softkey
9. Return to 1064 nm Applications screen softkey

9.3.1 Indications for Use

The ClearScan YAG1064 nm laser system is designed for use in:

- Coagulation and hemostasis of benign vascular lesions such as, but not limited to, telangiectasias and rosacea.
- Removal of unwanted hair (for stable, long term or permanent hair reduction) through selective targeting of melanin in hair follicles and for the treatment of Pseudofolliculitis Barbae (PFB).
- Treatment of facial wrinkles.
- Treatment for the temporary increase of clear nail in patients with onychomycosis.
- Treatment of periungual, subungual warts, and plantar warts.

9.3.2 Contraindications

The ClearScan YAG 1064 nm laser system is contraindicated for:

- Patients who take medication which is known to increase sensitivity to sunlight
- Patients with infectious disease
- Patients with connective tissue disease
- Patients who are immunocompromised
- Patients who are pregnant
- Patients who have used isotretinoin (Accutane) within the past 6 - 12 months
- Patients with a medical condition that may affect wound healing
- Patients with bleeding abnormalities

9.3.3 Complications

Complications, though rare, occasionally occur and should be discussed and understood. The patient must understand the importance of the post care instructions and that failure to comply may increase the probability of complications.

- Scarring, though rare can occur following any laser procedure.
- Blistering during treatment may be an indication of recent sun exposure or too high a fluence for the skin type. Blistering can occur during the first three days following the laser procedure. Blistered areas should be treated with care and kept moist with an ointment until area has healed.
- Histamine/Hives: some patients develop raised papules similar to hives. This irritation usually subsides within in a few hours after the treatment.
- Pigmentary changes: hyperpigmentation or hypopigmentation are rare when treating with a 1064 nm wavelength.

9.3.4 Warnings

- In pretreatment work-ups, screen lesions that are located in close proximity to known arteries or veins in order to locate these circulatory structures.
- Water condensation on the upper surface of the contact cooling plate may result in laser beam scattering and an incorrect setting for fluence. Treating the top of the plate with a surfactant, such as Sea Drops, will reduce scattering due to condensation.
- A dirty chill plate may lead to an incorrect setting for fluence. Clean the chill plate with a soft cotton gauze moistened with alcohol prior to each treatment and throughout extended, lengthy treatments. Allow alcohol to dry before continuing with treatment.
- Check the chill plate temperature prior to each treatment. The risk of epidermal injury, such as blistering, increases if the temperature of the chill plate is too warm or if the chill plate is too cold.
- Tattooed areas, and the area of skin 4-5 mm outside of the tattoo in all directions, should not be treated. Tattoo ink may absorb laser energy resulting in a color change of the tattoo ink or a risk of epidermal damage.
- Darkened moles should not be treated. Moles may absorb laser energy causing a color change of the mole resulting in the inability to monitor the mole under ABCD guidelines for melanoma detection. Excess energy may also be absorbed into the mole resulting in the risk of epidermal damage.
- Do not stack pulses or overlap consecutive scans. Repeated pulses in the same location, improper chill plate placement, repeated scans, improper cooling temperatures, or excessive fluence may lead to a buildup of subsurface heat and a subsequent blister or burn.
- Do not allow combustibles or flammables, including drapes and paper panties, in the laser treatment area. Fire prevention/control methods should be in place.

9.3.5 Selective Photothermolysis

This technique relies on selective absorption of a laser light pulse to generate and confine heat within certain pigmented targets. The goal of Selective Photothermolysis is to have sufficient energy penetrate to and be absorbed by the desired target while minimizing the effect on the surrounding tissue.

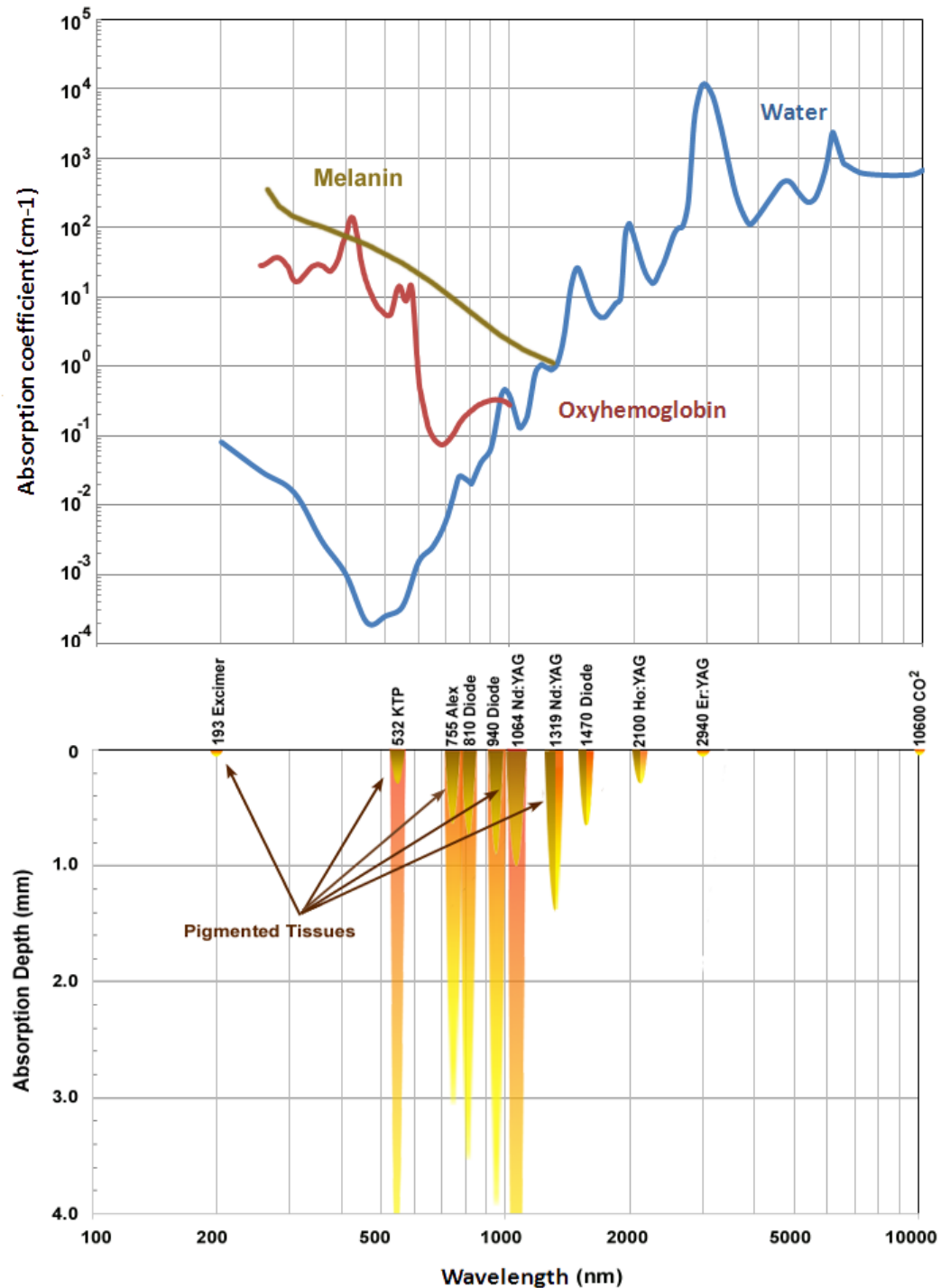


Absorption Curve

Absorption curve shows the relationship of the variation in absorbed laser light as a function of wavelength. The graphic shows absorption spectra of major intracellular absorbers. The molecular absorption coefficients of oxygenated hemoglobin, melanin and water are shown.

Depth of Penetration

Depth of penetration of laser energy for different types of lasers is also illustrated.



The goal when treating with ClearScan YAG1064 nm is to heat the target to a temperature that is sufficient to destroy it, but not to the point that the heat damages skin and surrounding tissue. This is termed Selective Photothermolysis and relies on 3 critical parameters:

- Pulse width
- Fluence
- Wavelength

Pulse width is the amount of time that the target is exposed to the heat and is typically measured in milliseconds (ms). Pulse width must be less than the Thermal Relaxation Time (TRT) of the target. In other words, the pulse width must be long enough to allow heating of the target but also short enough that the target can cool so that there is no heat buildup in surrounding skin and tissue. The cooling time of a target is relative to its size, structure and density. Larger targets take longer to cool than smaller ones. Likewise, a very densely pigmented target will cool down slower than a target with less concentrated pigment. Refer to ClearScan Treatment Starting Parameters for safe start pulse width parameters.

Fluence is the amount of heat or energy delivered into the target. Fluence is measured in units of Joules/cm². Refer to ClearScan Treatment Starting Parameters for safe start fluence parameters.

The higher the fluence selected, the higher the temperature of the target, the surrounding tissue and the epidermis. Treating with excess energy can result in adverse effects such as abnormal pigmentation, blistering and scarring.

Patient response can vary, so the fluence setting should begin low and be increased gradually after assessing the individual patient response and observation of endpoints desired.

Wavelength is the spatial period of a wave from peak of one wave to the peak of the next. Photons of 1064 nm are preferentially absorbed by the target chromophores of melanin and hemoglobin.

Surface Cooling

ClearScan YAG 1064 nm integrates a powerful 250 Watt external cooling system that connects to the 5 mm HF Scanner, paddle or single spot chill plates in order to keep the treatment area cool. Skin surface temperature changes of 1 °C can cause immediately observable differences in the clinical response.



External Cooling Systems: A black or white version of the external chiller may have been supplied with your system. Refer to Appendix I for operating instructions, including instructions for attaching the chiller hose.



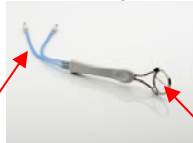
Chill Plates connected to the system

All chill plates are all made of 100% sapphire. Each chill plate consists of two sapphire plates that are sandwiched together. When connected to the external Contact Cooler, water flows from the cooler, through the chiller hose, down the chill plate tubing and between the two sapphire plates. The water continues up the opposite tube on the chill plate and then recycled back through the contact cooler.

Single spot chill plate



Paddle chill plate



5 mm HF Scanner with chill plate



Chill plate tubing

Sapphire plates

The chill plate should be in complete contact with skin throughout the entire scan or pulse to ensure that skin is protected before, during and after a pulse or scan pattern is delivered.

Although absorption of the 1064 nm Nd:YAG energy into a certain chromophore is desirable, some epidermal cooling is necessary to protect the skin. Refer to Starting Parameters for temperature setting of the external cooling system.

Continuous observation of skin during a ClearScan YAG 1064 nm ClearScan treatment is critical and will ensure appropriate fluence, pulse width and temperature settings have been selected and that skin integrity has not been compromised.

9.3.6 Getting Started

9.3.6.1 Consultation/Education

A consultation is essential in order to establish realistic expectations and to gain a full understanding of the patient and his/her treatment goals. The patient must understand the procedure, pre and post care instructions, expectations, contraindications and possible complications prior to beginning any treatment.

9.3.6.2 Medical History

A detailed medical history should be obtained prior to treatment outlining any former or active medical condition or medication that is contraindicated or that could possibly affect the outcome of the treatment.

It is recommended that a brief medical history be taken before beginning any subsequent treatment with questions such as, but not limited to, any new medications, skin care, sun exposure, pregnancy etc.

9.3.6.3 Skin Typing

Accurate skin typing is critical to treatment success and the avoidance of complications. It is important to know that in most situations an individual's previous response and genetic tendency to sun exposure will be the biggest indicators in establishing skin type. Some patients, such as Asians and Hispanics, may appear to be a skin type II or III and never tan but react to laser energy like a IV or V skin type. Hence, it is very important not to base skin type on appearance.

The skin type of a patient does not change. Do not confuse skin type with a tan. A person's skin type is something they are born with and it does not change, but the degree of tan can change.



Skin type V is the most under-typed skin. Often Asian skin will look very light and have no history of sun exposure. Occasionally they have "bleached" their skin with hydroquinone. Treating them as a III or IV (based on look and reaction to sun) could result in higher risk of complications. Initially, all Asian skin should be treated as a Skin Type V until reaction to laser light has been determined.

Similarly, not all black skins are of the same degree of darkness and there may be the temptation to type these patients as a lower type.

Type	Hair Color	Skin Color & Ethnic Background	Eye Color	Sun Reaction
I	Red, White Blonde	Very fair <i>Scandinavian, Nordic, and North European</i>	Blue	Always burns, never tans
II	Red, Blonde, light brown	Fair <i>North European, Celtic (Scottish, Irish)</i>	Blue, green	Always burns, tans with difficulty and tends to be freckled
III	Sandy Blonde, Brown	Medium <i>Southern Europe</i>	Hazel, green, blue,	Burns initially, tans fairly well and evenly
IV	Brown, Black	Moderate brown, Olive <i>Mediterranean, Latin (Italian, Hispanic)</i>	Hazel, brown	Burns are rarely evident, tans easily
V	Black	Dark Brown <i>(Asian, Middle Eastern, American Indian)</i>	Dark brown, black	Burns are never evident, tans always <i>*some Asian skin always burns and never tans</i>
VI	Black	Black <i>(African-American, Indonesian)</i>	Dark brown, black	Burns are never evident, tans always

9.3.6.4 Informed Consent

The process of accepting and confirming treatment must be reviewed, understood and signed by the patient prior to treatment. This document must review the topics discussed during the consultation. It acknowledges that the patient understands the procedure, possible risks and complications and that all questions have been answered.
Reference sample Informed Consent in Appendix of this manual.

9.3.6.5 Photographs

Pictures should be taken prior to each treatment to document the progress of the treatment. Photographs are useful in demonstrating efficacy of treatment to the patient.

Camera settings, distance, backdrop, and body/face angle, position and expression should be the same for each photography session to maintain similar quality.

The patient should sign a photo release form if before and after pictures are to be used for educational or marketing purposes.

9.3.6.6 Topical Anesthesia

The use of topical anesthetic is not typically recommended for ClearScan YAG 1064 nm treatments. Patient feedback is needed to evaluate appropriate endpoints. If a patient is "numb" they may not be able to accurately assess if a treatment is too warm which could lead to a blister or a burn. However, if topical preparation is used to alleviate discomfort for highly sensitive patients or sensitive areas prior to treatment, the manufacturer's guidelines for the application and duration of the anesthetic should be read prior to topical application. Remove before treatment with mild soap and water or an alcohol swab, then plain water. Dry the area thoroughly before treatment.

Reminder: Each patient should be assessed and questioned regarding allergies or sensitivities to ingredients in topical anesthetics prior to application.



Be extremely cautious when applying topical anesthetics to large areas of the body. Lidocaine toxicity has been linked to several deaths.

9.3.6.7 Eye Protection

Eye protection should always be worn by everyone present in the treatment room during any laser or light based treatment. When treating on the patient's face, they should always wear external, matte-finish metal goggles.



It is not recommended that any ClearScan YAG 1064 nm treatment be performed within the orbital rim of the eye due to the high risk of retinal damage.

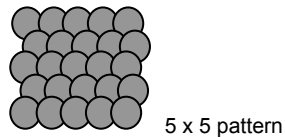
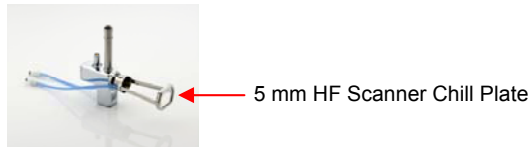
9.3.7 Safe Start Protocol for ClearScan YAG 1064 nm Hair Reduction

The theory of Selective Photothermolysis explains how wavelength, energy and pulse width in relation to Thermal Relaxation Time (TRT) all play a role in the destruction of a target and the preservation of surrounding tissue.

Using the theory of selective photothermolysis, unwanted hair can be treated with the ClearScan YAG 1064 nm and appropriate settings that will cause selective absorption of laser light in the melanin of hair. The light travels down the hair shaft and into the bulb of the follicle where the blood supply to the follicle is located. The absorption converts light into heat energy, which raises the temperature of the bulb causing the blood vessels that supply blood and other necessary nutrients to the follicle to be cauterized. As a result, hair growth is no longer possible. This process should happen selectively and without damage being done to the epidermis or surrounding tissue.

5 mm HF Scanner

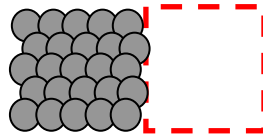
The 5 mm HF Scanner has a contact cooling chill plate assembly attached to it. The assembly is comprised of two sapphire plates that are separated by continuously flowing Chiller Mixture. The spot placement is achieved by using two galvanometer motors for x-axis and y-axis displacement.



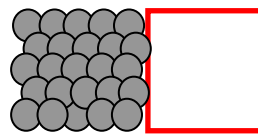
The 5 mm HF Scanner precisely places each pulse in a non-sequential pattern to eliminate improper placement of individual pulses. It also maximizes the time interval between adjacent spots and minimizes subsurface heat buildup.

The 5 mm HF Scanner allows for complete and uniform application of the laser energy by delivering 5 mm spots of energy within a designated pattern shape and size. The pattern can be adjusted from a 1 x 1 (single spot) to a 6 x 6 with any variation in between. A 5 x 5 pattern is illustrated above.

Aiming beam is represented by red box and shows the user the area to be treated. The energy will be delivered inside the red box. When the red box is "dancing" the system is in Standby. When the red box is solid the system is in Ready.



Standby



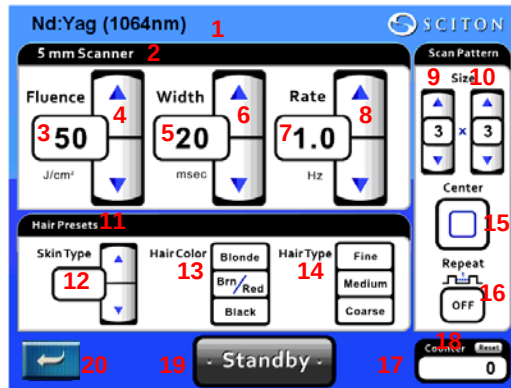
Ready

Care should be taken to apply adjoining scans without gap or excessive overlap of the previously scanned area. A mental picture of where the next scan pattern should be placed will assist in lining each scan pattern up to each other to avoid gap or overlap as shown above.

To achieve safe, uniform treatment as shown, the 5 mm HF Scanner should be held so that the red box within the chill plate window is in complete contact with the skin at all times.

ClearScan YAG 1064 nm Scanner Application User Screen

Attach the 5 mm HF Scanner to the articulated arm. Press the Scanner softkey on the 1064 nm Applications screen and the system will enter the Nd:YAG (1064 nm) application screen.



The ClearScan YAG 1064 nm user screen allows the user to adjust treatment settings. The available functions are described below.

1. Wavelength indicator
Wavelength indicator shows which wavelength is being used for the treatment.
2. Handpiece indicator
Handpiece indicator shows which handpiece is being used for the treatment.
3. Fluence indicator
Fluence indicator shows the amount of fluence or energy being delivered per 5 mm spot within whatever size or shape scan pattern has been selected. Fluence is measured in joules per centimeter squared, J/cm².
4. Fluence adjustment softkeys
Fluence adjustment softkeys allow the user to increase or decrease fluence by 1 J/cm² by tapping or holding down the up ▲ or down ▼ arrow softkeys.
5. Pulse width indicator
Pulse width indicator shows the length of time the energy is being delivered per 5 mm spot within whatever size or shape scan pattern has been selected. Pulse width is measured in milliseconds (ms).
6. Pulse width adjustment softkeys
Pulse width adjustment softkeys allow the user to increase or decrease pulse width by 5 ms by tapping or holding down the up ▲ or down ▼ arrow softkeys.
7. Spot placement rate
Spot placement rate is the speed at which each 5 mm spot is being delivered within the scan pattern. The speed is measured in Hz. The maximum rate is automatically limited by the laser based on the fluence and pulse width.
8. Spot placement rate adjustment softkeys
Spot placement rate adjustment softkeys allow the user to increase or decrease the rate at which each 5 mm spot is being delivered by 0.5 Hz by tapping or holding down the up ▲ or down ▼ arrow softkeys.
9. Horizontal pattern selection softkeys
The horizontal pattern selection softkeys allow the user to increase or decrease the horizontal size of the pattern from 1 to 6 spots.
10. Vertical pattern selection softkeys
The vertical pattern selection softkeys allow the user to increase or decrease the vertical size of the pattern from 1 to 6 spots.
11. Hair reduction quick set settings section indicator
The hair reduction quick set settings section allows the user to select Skin Type I-VI (1 - 6), Hair Color (Blonde, Brn/Red or Black) and Hair Type (Fine, Medium or Coarse) of the patient in the area being treated. The laser will automatically set the laser to safe start settings of fluence, pulse width and rate.
12. Skin type selection softkeys
Skin type selection softkeys allow the user to choose skin type I, II, III, IV, V or VI by tapping or holding down the up or down arrow softkeys.
13. Hair Color to be treated softkeys

Hair Color to be treated softkeys allow the user to select blonde hair by tapping the Blonde softkey, brown or red hair by tapping the Brn/Red softkey and black hair by tapping the Black softkey.

14. Hair Type to be treated softkeys

Hair Type to be treated softkeys allow the user to select fine hair by tapping the Fine softkey, medium hair by touching the Medium softkey and coarse hair by touching the Coarse softkey

15. Pattern center softkey

Pattern center allows the user to offset the area to be treated to the upper left corner, upper middle, upper right corner or the center of the chill plate window.



16. Pattern repeat softkey

Pattern repeat will allow the user to set an amount of time between consecutive scans of 1, 2, 3, 4, or 5 seconds by tapping the Repeat softkey. Repeat can also be turned off so that each scan pattern is delivered by lifting and depressing the footswitch.

17. Number of accumulated pulses indicator

Number of accumulated pulses indicator shows how many pulses have been delivered since the system was turned on or since the last time the reset softkey for accumulated pulses was reset.

18. Accumulated pulses reset softkey

Accumulated pulses reset softkey allows the user to reset the number of accumulated pulses to 0 by touching the reset softkey. Holding down the reset softkey until the audible beep on the laser had beeped 4 times.

19. System status softkey

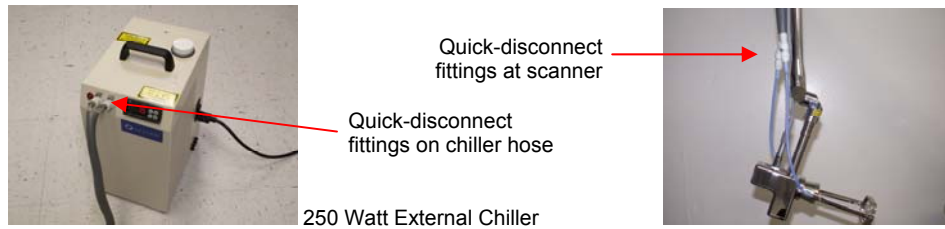
System status softkey allows the user to put the system in Standby or Ready.

20. Return to ClearScan YAG 1064 nm Applications screen softkey

Return to 1064 nm Applications softkey will return the system to the previous screen.

Surface Cooling

When performing 1064 nm Nd:YAG ClearScan Hair Reduction, the use of a contact cooler is critical for ensuring patient safety.



Attach two quick-disconnect fittings at one end of the chiller hose to the chiller and the other two quick-disconnect fittings at the other end of the hose to the 5 mm HF Scanner. Make sure that the chiller is filled with Chiller Mixture (20% methanol in water). Connect the power cable and turn on the switch at the back of the chiller.



If the contact cooler is turned on prior to the scanner being attached, the cooler will emit an alarm noise. This alarm is also emitted if there is kink or anything wrong with the hose that could prevent water from flowing through the connection tubes and then recirculated back through the cooler. If this alarm is heard while treating a patient, stop the treatment and evaluate why water is not flowing. If water is not flowing through the contact cooler hose and through the chill plate, the patient is not getting adequate cooling. This inadequate cooling could lead to a blister or burn.

Set the temperature to the desired temperature and wait a few minutes until the desired setpoint is reached.

Hair Basics

Hair revolves through three phases of growth: anagen, catagen and telogen. It is only during the growing phase, anagen, that hair reacts to ClearScan YAG 1064 nm light. Not all hair present in an area is in the anagen phase at the same time. Duration of hair growth cycles depends on the body location being treated. Multiple treatments are necessary over a time span of typically 4-8 week

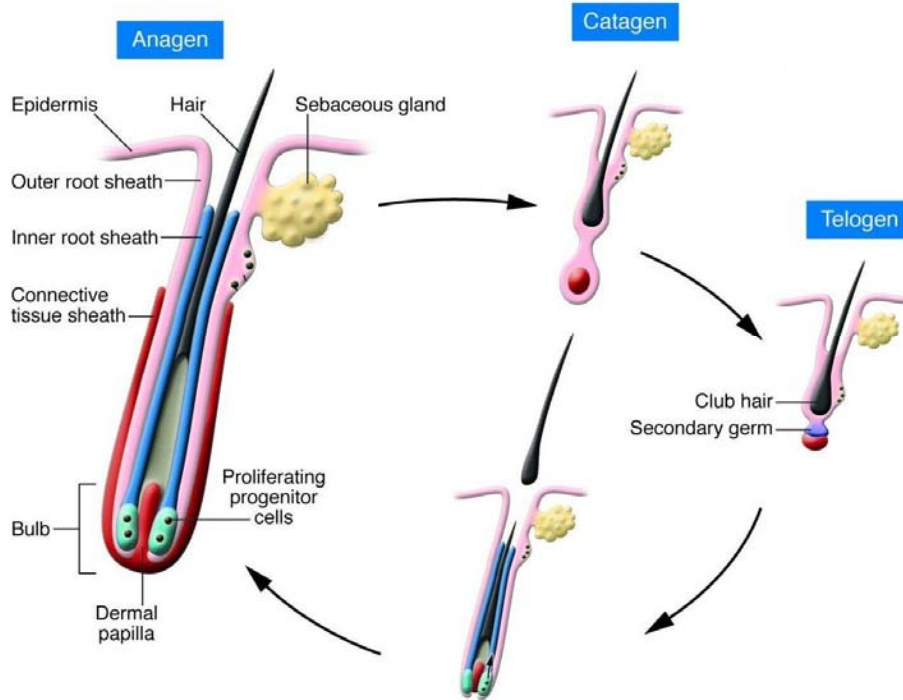
intervals to remove hair from most areas. *Reference Richards-Merhag Chart in the Appendix of this manual.*

Hair Growth Cycle

anagen: The phase of the hair cycle during which synthesis of hair takes place. This is the active growing phase in which the hair bulb is intact.

catagen: Brief intermediate phase between anagen and telogen. During this phase, the body absorbs the lower third of the follicle.

telogen: This is the resting phase. The hair bulb is no longer present. It is now a club hair, which will fall out or be pushed out of the follicle by a new anagen growing hair.



Fluence

Refer to Treatment Starting Parameters as noted below or the Hair Reduction quick set settings section on the control panel display screen for appropriate fluence selection.

Targets that are darker absorb more energy/heat and will reach higher temperatures much quicker than targets that are lighter in color. Therefore, darker hair, and areas where there is more concentrated areas of dark hair growth, require less fluence than lighter colored hair in less concentrated areas of light colored hair growth to reach the same therapeutic level.

As treatments progress through a series, fluence settings will need to be changed. If effective treatments are being provided each treatment session, hair should be getting lighter in color, therefore fluence will need to be increased to compensate for a less melanin rich target in which the light can be absorbed.

Pulse Width

Refer to Treatment Starting Parameters as noted below or the Hair Reduction quick set settings section on the control panel display screen for appropriate pulse width selection.

Pulse width should be shorter than the cooling time of the target to make sure that all the energy is confined to the target. Smaller objects cool faster than larger ones. Therefore, the smaller or finer the hair being treated the less time on, or the shorter the pulse width. Conversely, the larger or coarser the hair being treated the more time on with the heat, or a longer pulse width.

Areas of hair growth that are less densely populated will cool down quicker than more densely populated ones. Therefore, hair that is finer and in areas with less dense growth should be treated with shorter pulse widths and coarser more concentrated areas of hair growth should be treated with longer pulse widths.

Darker skin absorbs more light and heats to a higher temperature, therefore pulse width should be longer for darker skin.

As treatments progress through a series, pulse width settings will need to be changed. If effective treatments are being provided each treatment session, hair should be getting finer in texture. Therefore, pulse width would need to be decreased to compensate for less time needed to heat up the target melanin otherwise the excess heat will flow out of the follicle and into the surrounding skin.

Cooling

Refer to Safe Start Protocol as noted below for appropriate cooling selection.

Cooling temperatures are selected based on skin type and density of hair. Lighter skin is able to tolerate higher temperatures, while darker skin will require more cooling in order to be more protective of the tissue. In areas where hair is more densely populated there will be more absorption of heat and therefore require cooling temperature be lower. Conversely, in areas where the hair is less densely populated there will be less absorption of heat and therefore temperature can be higher.

Treating with higher (warmer) cooling temperatures will require treating with lower fluence settings. The inverse also applies.

Note: The cooling temperature is set on the external contact cooler and not on the control panel display screen.

The area within the selected red box on the 5 mm HF Scanner chill plate should be in complete contact with skin throughout the entire scan to ensure that skin is protected before, during and after a scan pattern is delivered.



Always test the chill plate window for desired level of chilling before beginning any laser treatment. The risk of epidermal injury such as blistering increases with ineffective cooling.

9.3.7.1 ClearScan YAG 1064 nm Hair Reduction Treatment

Treatment Basics

- Hair that is present in the area to be treated should be shaved prior to treatment. There should be no more than 0.5 mm hair growth, or very minimal stubble, present in treatment area. The longer the hair, the greater the risk of burning the hair to the patient's skin and also "pitting" or damaging the 5 mm HF Scanner chill plate window.
- Patient should be positioned based on the area to be treated. The position should be comfortable to the patient and such that the treatment provider has good access to the area to be treated and the system control panel display screen.
- When treating a patient's upper lip, a mouth guard or a 2 x 2 piece of gauze should be placed between the teeth and upper lip.
- A mild cleanser or alcohol gauze should be used to remove any dirt, makeup, deodorant or moisture from the treatment site.
- If topical anesthetic is to be used, apply as directed prior to treatment. Before beginning treatment, ensure that topical has been completely removed from surface of skin.
- Apply 2-3 mm thickness of colorless ultrasound gel to area to be treated. The gel should be used in conjunction with the 1064 nm wavelength for optimal heat removal to help protect the epidermis, as well as improved optical coupling and lubrication for sliding the chill plate over skin. The gel also simulates contact with the skin and reduces the risk of "pitting" or damage to the 5 mm HF Scanner chill plate window.
- Connect the 5 mm HF Scanner to the articulated arm.
- Water condensation on the upper surface of the chill plate may result in laser beam scattering and an incorrect setting for fluence. Apply the surfactant, Sea Drops, to the upper side of the 5 mm HF Scanner chill plate window before turning on the external Contact Cooler. Reapply as needed.
- Connect external Contact Cooler to the 5 mm HF Scanner and then turn the cooler on.



If the contact cooler is turned on prior to the scanner being attached, the cooler will emit an alarm noise. This alarm is also emitted if there is a kink or anything wrong with the hose that could prevent water from flowing through the connection tubes and then recirculated back through the cooler. If this alarm is heard while treating a patient, stop the treatment and evaluate why water is not flowing. If water is not flowing through the contact cooler hose and through the chill plate, the patient is not getting adequate cooling. This inadequate cooling could lead to a blister or burn.

- Select appropriate temperature setting. Refer to ClearScan Hair Reduction Safe Start Treatment Parameters.
Note: Always test the chill plate window for desired level of chilling before beginning any laser treatment. The risk of epidermal injury, such as blistering, increases with decreased or ineffective cooling.



Eye protection should always be worn by everyone present in the treatment room during any laser or light based treatment. When treating on the patient's face, they should always wear external, matte-finish metal goggles. It is not recommended that any ClearScan YAG 1064 nm treatment be performed within the orbital rim due to the high risk of retinal damage.

- Select starting settings based on ClearScan Hair Reduction Safe Start Treatment Parameters noted below or the Hair Reduction quick set settings section on the control panel display screen.
- The 5 mm HF Scanner should be held perpendicular to the surface of the skin at all times. Move patient if necessary to accomplish this 90 degree angle. All areas of the chill plate within the red box, should be in complete contact with skin at all times throughout entire scan. For highly curved areas, select a smaller scan pattern or select Pattern Center to offset the pattern to the top edge of the chill plate to ensure that treatment area inside the red box is completely flat on skin.
- **Treating Test Area:** Treating a test area prior to beginning treatment will determine the patient's response threshold and help establish safe and effective treatment parameters.

- Select test settings using the ClearScan Hair Reduction Safe Start Treatment Parameters below or the Hair Reduction quick set settings section on the control panel display screen.
- Set the scan pattern size to 2 x 2 or 3 x 3 especially if the treatment area is small. This will allow adequate area for test spots rather than treating the entire area.
- Depress the foot switch to deliver the entire scan pattern. Another scan pattern will not be delivered unless the footswitch is depressed again or if repeat is turned on.
- During delivery of scan pattern, observe for endpoints; sparking, smell of burning hair and patient's report of a mild to moderate heat sensation in the area being treated.
- If desired endpoints are observed with no adverse effects, treatment can be continued until area is completed.
- If endpoints are not noted, increase the intensity of treatment by the following actions, in the following order (make only one change per test pulse):
 - Increase fluence by **5 - 10 J/cm²**
 - Decrease pulse width by **5 ms**
- If reaction to test spot is too severe (intense erythema, Purpura, immediate white or grey presentation of skin), the settings should be decreased in intensity by the following actions, in the following order:
 - Decrease fluence by **5 - 10 J/cm²** depending on intensity of reaction
 - Increase pulse width by **5 - 10 ms** depending on intensity of reaction
 - Match the trailing edge of the previous scan with that of the next. There should be no overlap between scans. Scan patterns should "line up" right next to each other.

ClearScan Hair Reduction Treatment Starting Parameters

Area	Skin Type	Fluence (J/cm ²)	Pulse Width (ms)	Cooling (°C)
Face	I - II	50	10 - 35	10 - 15
	III - IV	50	10 - 35	8 - 12
	V - VI	35	25 - 50	5 - 10
Body	I - II	70	10 - 35	10 - 15
	III - IV	60	10 - 35	8 - 12
	V - VI	50	25 - 50	5 - 10
Pseudofolliculitis Barbae (PFB)	I - IV	40	10 - 35	5
	V - VI	25	25 - 50	

Note: In areas where skin is thinner and the bone is closer to the surface; jaw line, clavicle, shins, shoulders, knees, toes etc., fluence should be decrease by 20%.

Endpoints

- Sparking – the hair shaft should flash when instantly heated by the laser pulse.
- Mild to moderate discomfort.
- Smell of success (SOS) – hair has a unique and very noticeable odor when it is heated during the laser pulse.
- Slight follicular edema and erythema within 2 - 5 minutes after treatment that resolves within 1 - 4 hours of treatment.

Post Treatment

- Observation – Erythema for several hours after treatment. Treated hairs can take up to 7 - 14 days to exfoliate from the follicle and may appear to be "growing" during this time.

- Intervention – Cool compresses or ice packs can provide some comfort after treatment. If blistering occurs, aggressive wound healing measures should be implemented.
- Interval - Treatments are performed 4 - 8 weeks apart. 5 - 7 treatments may be required.
- Sun block with a minimum SPF 30 is recommended on treated areas that are exposed to the sun for at least 2 weeks after treatment to avoid excessive sunburn reaction or post inflammatory hyperpigmentation (PIH).
- ClearScan YAG 1064 nm hair reduction treatments may be given in combination with BBL for hair reduction. If a patient is undergoing both procedures, the ClearScan YAG 1064 nm treatment should be performed first and then the BBL.
- If performing hair reduction treatments in conjunction of other procedures such as MLP or ProFractional, perform hair reduction first.
- Check with manufacturer for guidelines on using injectables in conjunction with ClearScan YAG 1064 nm hair reduction treatments.

9.3.7.2 ClearScan YAG 1064 nm Single Hair Reduction Treatment

The ClearScan YAG 1064 nm Hair Reduction Treatment protocol is utilized when treating single individual hairs.

The 6 mm single spot handpiece is used for ClearScan YAG 1064 nm Single Hair Reduction treatments.

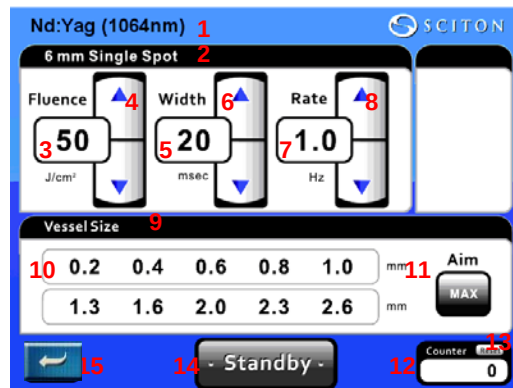


6 mm Single Spot Handpiece

When selecting settings for ClearScan YAG 1064 nm Single Spot Hair Reduction Treatments, the user can either enter the 1064 nm Scanner Applications User Screen and use the Hair Reduction Quick Set Settings Section or refer to the ClearScan Hair Reduction Treatment Starting Parameters noted above.

1064 nm Single Spot Application User Screen

Attach the 6 mm single spot handpiece to the articulated arm. Press the Single Spot softkey on the 1064 nm Applications screen and the system will enter the Nd:YAG (1064 nm) application screen.



The Nd:YAG (1064 nm) user screen allows the user to adjust treatment settings. The available functions are described below.

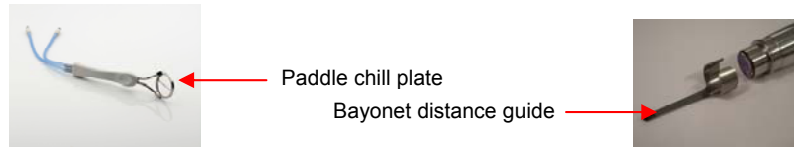
15. Wavelength indicator
Wavelength indicator shows which wavelength is being used for the treatment.
16. Handpiece spot size indicator
Handpiece spot size indicates that the 6 mm single spot handpiece is attached to the articulated arm.
17. Fluence indicator
Fluence indicator shows the amount of fluence or energy being delivered. Fluence is measured in joules per centimeter squared, J/cm^2 .
18. Fluence adjustment softkeys
Fluence adjustment softkeys allow the user to increase or decrease fluence by $1 J/cm^2$ by tapping or holding down the up $\blacktriangle$ or down $\blacktriangledown$ arrow softkeys.
19. Pulse width indicator
Pulse width indicator shows the length of time the energy is being delivered per 6 mm spot. Pulse width is measured in milliseconds (ms).
20. Pulse width adjustment softkeys
Pulse width adjustment softkeys allow the user to increase or decrease pulse width by 5 ms by tapping or holding down the up $\blacktriangle$ or down $\blacktriangledown$ arrow softkeys.
21. Repetition rate indicator
Repetition rate is the amount of time between each single spot delivery when the footswitch is held down continuously. The rate is measured in Hz

22. Repetition rate adjustment softkeys
Repetition rate adjustment softkeys allow the user to increase or decrease each single spot delivery rate from 0.3 Hz to 12.4 Hz by tapping or holding down the up ▲ or down ▼ arrow softkeys. It is recommended to select Shot mode when treating a single hair in an area.
23. Vessel size quick set settings section indicator
Vessel size quick set settings section is not utilized for single hair reduction treatments.
24. Vessel measurement softkeys
25. Aiming beam intensity softkey
Aiming beam intensity allows the user to make the aiming beam dimmer or brighter in intensity. MIN, 1, 2, 3, 4, 5 or MAX intensity can be selected by tapping the Aim softkey.
26. Number of accumulated pulses indicator
Number of accumulated pulses indicator shows how many pulses have been delivered since the system was turned on or since the last time the reset softkey for accumulated pulses was reset.
27. Accumulated pulses reset softkey
Accumulated pulses reset softkey allows the user to reset the number of accumulated pulses to 0 by touching the reset softkey.
28. System status softkey
System status softkey will allow the user to put the system in Standby or Ready.
29. Return to 1064 nm Applications screen softkey
Return to 1064 nm Applications softkey will return the system to the previous screen.

Surface Cooling

When performing ClearScan YAG 1064 nm Single Spot Hair Reduction treatments, the use of a contact cooler is critical for ensuring patient safety.

Either the paddle chill plate or the single spot chill plate can be used for the treatment.



The bayonet distance guide assures that proper distance from the paddle chill plate is maintained throughout the treatment for accurate spot size delivery.



Refer to ClearScan YAG 1064 nm Hair Reduction Treatment protocol for Treatment Basics and ClearScan Hair Reduction Treatment Starting Parameters for safe start settings.

9.3.8 Safe Start Protocol for ClearScan YAG 1064 nm for Vascular Lesion Treatment

The theory of Selective Photothermolysis explains how wavelength, energy and pulse width in relation to Thermal Relaxation Time (TRT) all play a role in the destruction of a target and the preservation of surrounding tissue.

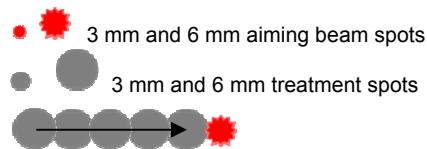
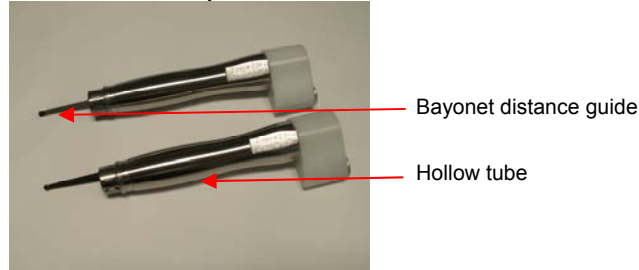
Using the theory of selective photothermolysis, benign vascular lesions can be treated with the Nd:YAG (1064 nm) and appropriate settings that will cause selective absorption of light in the blood that is flowing through the targeted vessel. The absorption converts light into heat energy, which raises the temperature of the blood. Heat is conducted to the lining of the vessel wall leading to its injury. This results in slow elimination of the vascular lesion by the macrophages of the immune system. All of this should happen selectively and without damage being done to the epidermis or surrounding tissue.

The 3 mm or 6 mm single spot handpiece is used to treat unwanted vascular lesions including but not limited to; spider veins, telangiectasias, and hemangiomas.

Single Spot Handpiece

The Single Spot handpiece consists of a hollow tube housing two lenses.

3 mm & 6 mm Handpieces

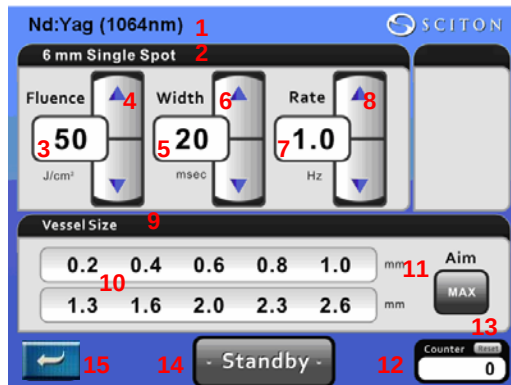


Care should be taken to apply consecutive pulses without gap or excessive overlap of the previously treated area. A mental picture of the size of the spot being delivered will assist in spot placement in order to avoid gap or overlap as shown above.

To achieve safe, uniform treatment as shown, the single spot handpiece should be held so that the red aiming beam that is reflected on the chill plate window is in complete contact with skin at all times.

1064 nm Single Spot Application User Screen

Attach either the 3 mm or 6 mm single spot handpiece to the articulated arm. Press the Single Spot softkey on the ClearScan YAG1064 nm applications screen and the system will enter the Nd:YAG (1064 nm) single spot application screen.



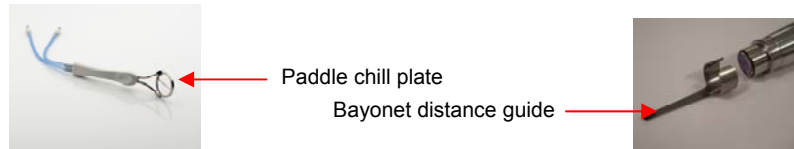
The Nd:YAG (1064 nm) user screen allows the user to adjust treatment settings. The available functions are described below.

1. Wavelength indicator
Wavelength indicator shows which wavelength is being used for the treatment.
2. Handpiece spot size indicator
Handpiece spot size indicates whether the 3 mm or 6 mm single spot handpiece is attached to the articulated arm.
3. Fluence indicator
Fluence indicator shows the amount of fluence or energy being delivered. Fluence is measured in joules per centimeter squared, J/cm².
4. Fluence adjustment softkeys
Fluence adjustment softkeys allow the user to increase or decrease fluence by 1 J/cm² by tapping or holding down the up ▲ or down ▼ arrow softkeys.
5. Pulse width indicator
Pulse width indicator shows the length of time the energy is being delivered per 3 mm or 6 mm spot. Pulse width is measured in milliseconds (ms).
6. Pulse width adjustment softkeys
Pulse width adjustment softkeys allow the user to increase or decrease pulse width by 5 ms by tapping or holding down the up ▲ or down ▼ arrow softkeys.
7. Repetition rate indicator
Repetition rate is the amount of time between each single spot delivery when the footswitch is held down continuously. The rate is measured in Hz.
8. Repetition rate adjustment softkeys
Repetition rate adjustment softkeys allow the user to increase or decrease each single spot delivery from 0.3 Hz to 11.3 Hz by tapping or holding down the up ▲ or down ▼ arrow softkeys.
9. Vessel size quick set settings section indicator
The vessel size quick set settings section allows the user to select the measured size of the vessel. Once the measured size is selected the pulse width is automatically adjusted to the appropriate pulse width. Not all vessels sizes reflected on the vein card are on the user screen. If there is a vessel size not on the user screen, pulse width can be adjusted manually in 5 ms increments by using the pulse width adjustment softkeys.
10. Vessel measurement softkeys
Vessel measurement softkeys allow the user to select a premeasured vessel size of 0.2, 0.4, 0.6, 0.8, 1.0, 1.3, 1.6, 2.0, 2.3 or 2.6 mm.
11. Aiming beam intensity softkey
Aiming beam intensity allows the user to make the aiming beam dimmer or brighter in intensity. MIN, 1, 2, 3, 4, 5 or MAX intensity can be selected by tapping the Aim softkey.
12. Number of accumulated pulses indicator
Number of accumulated pulses indicator shows how many pulses have been delivered since the system was turned on or since the last time the reset softkey for accumulated pulses was reset.
13. Accumulated pulses reset softkey
Accumulated pulses reset softkey allows the user to reset the number of accumulated pulses to 0 by touching the reset softkey.
14. System status softkey
System status softkey will allow the user to put the system in Standby or Ready.
15. Return to 1064 nm Applications screen softkey
The Return to 1064 nm Applications softkey will return the system to the previous screen.

Surface Cooling

When performing 1064 nm Nd:YAG ClearScan Vascular Lesion treatments, the use of a contact cooler is critical for ensuring patient safety.

Either the paddle chill plate or the single spot chill plate can be used for the treatment.



The bayonet distance guide assures that proper distance from the paddle chill plate is maintained throughout the treatment for accurate spot size delivery.



Causes of Vascular Lesions

Vascular lesions are typically caused by abnormal blood flow and weakening of the blood vessel wall. Any condition or activity that places pressure on the veins (weight gain, prolonged sitting or standing) can contribute to their development.

Vascular lesions increase with age and thus are quite common in the elderly. There is also a genetic basis, since spider veins do tend to run in families. In pregnancy, spider veins are quite common and have been associated with an increase in the female sex hormone, estrogen. Estrogen is known to weaken the walls of the veins and may contribute to the development of spider veins.

Acquired vascular lesions, not related to other venous abnormalities can be caused by factors such as acne rosacea, environmental damage caused by sun or cold exposure, trauma to the skin, radiation therapy, and chronic treatment with topical corticosteroids.

Superficial vascular lesions are most appropriately treated with 1064 nm Nd:YAG ClearScan. Vascular lesions that are bigger than 3 mm, bulging or deeper in tissue should not be treated with cutaneous 1064 nm Nd:YAG ClearScan. Other forms of treatment are more appropriate for these types of vessels.

Fluence

Refer to Vascular Lesion Treatment Starting Parameters noted below for appropriate fluence selection.

Targets that are darker absorb more energy/heat and will reach higher temperatures. Therefore darker, bluer vessels and areas where there is more concentrated areas of dark vessels require less fluence than lighter, red-pinkish colored vessels in less concentrated areas of light vessels to reach the same therapeutic level.

As treatments progress through a series, fluence settings will need to be changed. If effective treatments are being provided each treatment session, vessels should be getting lighter in color. Therefore, fluence will need to be increased to compensate for a less hemoglobin rich target in which the light can be absorbed.

Pulse Width

Once the vessel to be treated has been measured, refer to Vessel Size chart below or the vein card for appropriate pulse width selection.

Pulse width should be shorter than the cooling time of the target to make sure that all the energy is confined to the target. Smaller objects cool faster than larger ones. Therefore, the smaller or thinner the vessel being treated, the less time on with the heat or a shorter pulse width needed. Conversely, the larger or wider the vessel being treated, the more time on with the heat or a longer pulse width needed.

Areas where vessels are less densely populated will cool down quicker than more densely populated ones. Therefore vessels that are thinner and in areas with less dense concentration should be treated with shorter pulse widths and wider vessels in more concentrated areas should be treated with longer pulse widths.

Darker skin absorbs more light and heats to a higher temperature, therefore pulse width should be longer for darker skin.

As treatments progress through a series, pulse width settings will need to be changed. If effective treatments are being provided each treatment session, vessels should be getting thinner or smaller. Therefore, pulse width would need to be decreased to compensate for less time needed to heat up the target hemoglobin.

***Note:** The vessel should be measured prior to any treatment to assure appropriate pulse width is being used.*

Cooling

10°C is recommended for maximum patient comfort. Treating with higher (warmer) cooling temperatures will require treating with lower fluence settings. The inverse also applies.

***Note:** The cooling temperature is set on the external Contact Cooler and not on the laser control panel display screen.*

The area within the 3 mm or 6 mm aiming beam that is reflected on the chill plate window should be in complete contact with skin throughout the entire pulse to ensure that skin is protected before, during and after a pulse is delivered.



Always test the chill plate window for desired level of chilling before beginning any laser treatment. The risk of epidermal injury, such as blistering, increases with ineffective cooling.

9.3.8.1 1064 nm Nd:YAG ClearScan Vascular Lesion Treatment

Treatment Basics

- Hair that is present in the area to be treated should be shaved prior to treatment. There should be no more than 0.5 mm hair growth, or very minimal stubble, present in treatment area. The longer the hair, the greater the risk of burning the hair to the patient's skin and also "pitting" or damaging the single spot or paddle chill plate window.
- Patient should be positioned in a supine position due to hydrostatic pressure. The position should be comfortable to the patient and such that the treatment provider has good access to the area to be treated and the system control panel display screen.
- A mild cleanser or alcohol wipe should be used to remove any dirt, makeup or moisture from the treatment site.
- If topical anesthetic is to be used, apply as directed prior to treatment. Before beginning treatment, ensure that topical has been completely removed from surface of skin. Using topical anesthetic may cause blanching and constriction of the vasculature. This may interfere with assessing accurate endpoints.
- Apply 2 - 3 mm thickness of colorless gel to area to be treated. The gel should be used in conjunction with the 1064 nm wavelength for optimal heat removal to help protect the epidermis, improved optical coupling and lubrication for sliding the chill plate over skin. The gel also simulates contact with the skin and reduces the risk of "pitting" or damage to the single spot or paddle chill plate window.
- Connect the 3 mm or 6 mm single spot handpiece to the articulated arm.
Note: The 3 mm single spot handpiece is the ONLY handpiece used on the face of the patient.
- Select either the single spot or paddle chill plate based on user preference or area to be treated. However, when using the 6 mm single spot handpiece, cooling is better accomplished by using the paddle chill plate and not the single spot chill plate.
- Water condensation on the upper surface of the chill plate may result in laser beam scattering and an incorrect setting for fluence. Apply surfactant, Sea Drops, to the upper side of the single spot or paddle chill plate window before turning on the external Contact Cooler. Reapply as needed.
- Connect external Contact Cooler to the chill plate selected and then turn the cooler on. Select appropriate temperature setting. Refer to Vascular Lesion Treatment Starting parameters. ***Note: Always test the chill plate window for desired level of chilling before beginning any laser treatment. The risk of epidermal injury such as blistering increases with ineffective cooling.***
- Using the vein card provided by Sciton, measure the width of the vessel(s) to be treated. This measurement correlates to the pulse width or the length of time on with the heat or energy needed for the treatment.

Vessel Size Chart

Vessel Size	Pulse Width (ms)
<0.2 mm	10
0.2 mm	15
0.3 mm	20
0.4 mm	25
0.5 mm	30
0.6 mm	35
0.7 mm	40
0.8 mm	45
0.9 mm	50
1.0 mm	60
1.3 mm	70
1.6 mm	90
2.0 mm	100
2.3 mm	120
2.6 mm	140
3.0 mm	160



Eye protection should always be worn by everyone present in the treatment room during any laser or light based treatment. When treating on the patient's face, they should always wear external, matte-finish metal goggles.

It is not recommended that any 1064 nm Nd:YAG ClearScan treatment be performed within the orbital rim due to the high risk of retinal damage.

- Select starting settings based on Vascular Lesion Starting Parameters noted below.
- The 3 mm or 6 mm single spot handpiece should be held perpendicular to the surface of the skin at all times. Move patient if necessary to accomplish this 90 degree angle. All areas of the chill plate, where the pulse is going to occur, should be in complete contact with skin at all times throughout the entire pulse.
- **Treating Test Area:** Treating a test area prior to beginning treatment will determine the patient's response threshold and help establish safe and effective treatment parameters.
 - Select test settings using the Vascular Lesion Treatment Starting Parameters.
 - **The 3 mm single spot handpiece is the ONLY handpiece recommended for use on the face.**
 - Perform a baseline capillary refill test of the vessel to be treated.
 - Depress the foot switch to deliver 3 - 4 consecutive pulses. The consecutive pulses should be placed 3 mm apart for 3 mm handpiece and 6 mm apart for the 6 mm handpiece.



Do NOT treat repeatedly in the same area or stack pulses. Pulse stacking can lead to excessive heat buildup and may result in blisters, scarring or hyperpigmentation.

- Wipe off gel and observe test area for 1 - 2 minutes for **endpoints**. Vessels may disappear, darken, lighten, or appear unchanged but fade over time. Variations depend on the depth, diameter and oxygenation of the vessel. Assess the flow characteristics of the vessel by performing a capillary refill or blanching test. There may be blurring of the vessel margins, stasis of the vessel and edema and erythema surrounding the treated vessels. The treated vessels may have a "cat scratch" appearance post treatment.
- If desired endpoints are observed with no adverse effects, treatment can be continued until area is completed. During the process of treating the vessels, capillary refill should be tested occasionally to assess progress of stasis.

- If endpoints are not noted, increase fluence by **5 - 10 J/cm²** per test pulse until endpoints are observed. Do not treat the same vessel or area of the vessel for subsequent test spots. A test spot should occur in an area where there has been no previous treatment.
- If reaction to test spot is too severe (intense erythema, Purpura, immediate white or grey presentation of skin), decrease fluence by **5 - 10 J/cm²** depending on intensity of reaction.
- Once desired endpoints are observed, complete the area to be treated. Each vessel should be traced without overlapping pulses, approximately 2-3 mm of space between each pulse. When tracing a vessel it is recommended that 4-5 pulses be delivered and then the patient is given time to recover. Leave the chill plate over the area that has just been treated. This will give the patient increased comfort and also help to draw excess heat from the skin. Wait 2-3 seconds and continue to trace the vessel for another 4 - 5 pulses, again giving the patient a break for a couple of seconds with the chill plate over the area treated. Continue until the area has been completed.
- Each vessel can be traced up to 3 times if needed. After the first pass, an assessment is taken by checking for capillary refill. If the vessel still returns with a rapid blood flow, consider increasing the fluence.
- Do not repeatedly trace the same vessel or treat in the same area. Move the handpiece from one area to another to allow the epidermal and dermal tissues to return to a more stable temperature and to reduce patient discomfort before treating in the area or tracing the vessel again.

Vascular Lesion Treatment Starting Parameters

Area	Skin Type	Fluence (J/cm ²)	Pulse Width (ms)	Cooling (°C)	Handpiece	Chill plate
Face	I – VI	150	Refer to vein card or vessel size chart	10	3 mm	Single spot or paddle
Body <0.2 - 0.3 mm sized vessels	I – VI	150	Refer to vein card or vessel size chart	10	3 mm	Single spot or paddle
Body >0.3 mm sized vessels	I – VI	90	Refer to vein card or vessel size chart	10	6 mm	Single spot or paddle

Endpoints

- Vessels may disappear, darken, lighten, or appear unchanged but fade over time. Variations depend on the depth, diameter and oxygenation of the vessel.
- Blurring of the vessel margins.
- Stasis of the vessel.
- Edema and erythema surrounding the treated vessels. May look like a “cat scratch”.

Post Treatment

- Observation – “Cat scratch” appearance for several hours after treatment.
- Intervention – Cool compresses or ice packs can provide some comfort after treatment. If blistering occurs, aggressive wound healing measures should be implemented. Compression and avoidance of vasodilatation per physician direction.
- Interval – Treatments are performed 4 - 6 weeks apart. 2 - 3 treatments may be required.
- If performing vascular lesion treatments in conjunction of other procedures such as MLP or ProFractional, perform vein treatment first.
- Check with manufacturer for guidelines on using injectables in conjunction with 1064 nm Nd:YAG ClearScan vascular lesion treatments.

9.3.9 Safe Start Protocol for PhotoRevelation ClearScan YAG 1064 nm for Fine Lines/Wrinkles Treatment - PhotoRevelation

The theory of Selective Photothermolysis explains how wavelength, energy and pulse width in relation to Thermal Relaxation Time (TRT) all play a role in the destruction of a target and the preservation of surrounding tissue.

Using the theory of selective photothermolysis, small microvascular lesions can be treated with the PhotoRevelation ClearScan YAG 1064 nm and appropriate settings that will cause selective absorption of light in the blood that is flowing through the targeted microvessel. The absorption converts light into heat energy, which raises the temperature of the blood. Heat is conducted to the lining of the vessel wall leading to its injury. This results in slow elimination of the microvascular lesion by the macrophages of the immune system. The heating of the small vessels can also induce an inflammatory response causing the release of mediators that stimulate fibroblast activity and new collagen production resulting in a decrease in wrinkles. All of this should happen selectively and without damage being done to the epidermis or surrounding tissue.

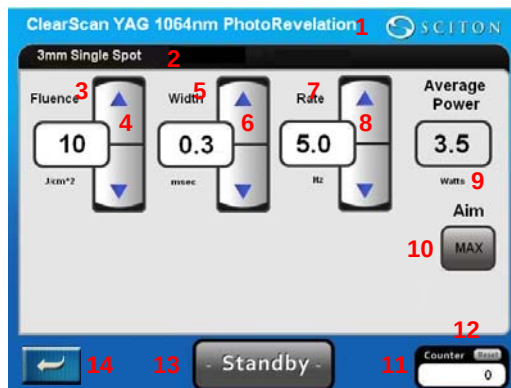
The 3 mm single spot handpiece is the handpiece that is used for the treatment of fine lines/wrinkles using the PhotoRevelation protocol.



3 mm Single Spot Handpiece

PhotoRevelation ClearScan YAG 1064 nm Application Screen

Attach the 3 mm single spot handpiece to the articulated arm. Press the PhotoRevelation softkey on the ClearScan YAG 1064 nm Application screen and the system will enter the PhotoRevelation application.



The Nd:YAG (1064 nm) user screen allows the user to adjust treatment settings. The available functions are described below.

1. Wavelength indicator
Wavelength indicator shows which wavelength is being used for the treatment.
2. Handpiece spot size indicator
Handpiece spot size indicates that the 3 mm single spot handpiece is attached to the articulated arm. The 3 mm handpiece is the only one used for the fine lines/wrinkles treatment.
3. Fluence indicator
Fluence indicator shows the amount of fluence or energy being delivered. Fluence is measured in joules per centimeter squared, J/cm².
4. Fluence adjustment softkeys
Fluence adjustment softkeys allow the user to increase or decrease fluence by 1 J/cm² by tapping or holding down the up ▲ or down ▼ arrow softkeys.
5. Pulse width indicator
Pulse width indicator shows the length of time the energy is being delivered per 3 mm spot. Pulse width is measured in milliseconds (ms).

6. Pulse width adjustment softkeys
Pulse width adjustment softkeys allow the user to increase or decrease pulse width by 5 ms by tapping or holding down the up ▲ or down ▼ arrow softkeys.
7. Repetition rate indicator
Repetition rate is the amount of time between each single spot delivery when footswitch is continuously held down. The rate is measured in Hz.
8. Repetition rate adjustment softkeys
Repetition rate adjustment softkeys allow the user to increase or decrease each single spot delivery from single shot to 20Hz (20 spots per second) by tapping or holding down the up ▲ or down ▼ arrow softkeys.
9. Average Power Display
Displays the average power in watts.
10. Aiming beam intensity softkey
Aiming beam intensity allows the user to make the aiming beam dimmer or brighter in intensity. MIN, 1, 2, 3, 4, 5 or MAX intensity can be selected by tapping the Aim softkey.
11. Number of accumulated pulses indicator
Number of accumulated pulses indicator shows how many pulses have been delivered since the system was turned on or since the last time the reset softkey for accumulated pulses was reset.
12. Accumulated pulses reset softkey
Accumulated pulses reset softkey allows the user to reset the number of accumulated pulses to 0 by holding down the reset softkey until the audible beep on the laser beeps 4 times.
13. System status softkey
System status softkey will allow the user to put the system in Standby or Ready.
14. Return to ClearScan YAG1064 nm Applications screen softkey
Return to ClearScan YAG 1064 nm Applications softkey will return the system to the previous screen.

Causes of MicroVessels and Wrinkles

Diffuse redness is a general appearance of facial redness, such as rosy cheeks. This condition is a result of dilated capillaries or microvessels, however the appearance is more general redness rather than discrete well-defined vessels. Prolonged sun exposure, aging, trauma and other factors can cause capillaries to become dilated and visible.

Aging, sun damage from ultraviolet (UV) light, smoking, stress, excessive alcohol intake and an unhealthy diet and lifestyle all destroy collagen and elastin in the dermis and cause the skin to loosen and sag.

PhotoRevelation treatment is accomplished by depositing heat into microvessels. This heat increases the temperature of the blood that is flowing through the microvessel. This in turn will heat the microvessel wall causing it to collapse and therefore be eliminated from the body. The heating of the small vessels can also induce an inflammatory response causing the release of mediators that stimulate fibroblast activity and new collagen production resulting in a decrease in fine lines and wrinkles.

Fluence

Refer to PhotoRevelation Safe Start Treatment Starting Parameters noted below for appropriate fluence selection.

Patient response can vary, so fluence setting should begin low and be increased gradually after assessing the individual patient response.

Pulse Width

Refer to Safe Start PhotoRevelation Treatment Starting Parameters noted below.

Because of the large surface area-to-volume ratio, microvessels rapidly lose absorbed energy (heat) into the surrounding tissue. The thermal relaxation time of very small vessels is less than 1 millisecond (ms), while that of larger vessels and hair can be 20 - 100 ms depending on their size. Thermal relaxation time of skin, or epidermis, is 3 - 10 ms. When laser light is applied to a vessel the pulse width of the laser must be shorter than the thermal relaxation time determined by its size, structure, and thermal diffusion properties. When targeting microvessels using the PhotoRevelation protocol, a pulse width of less than 1 ms is required.

Recommended starting pulse width is as noted in the table below. It may be necessary to increase the pulse width to achieve the desired response.

Cooling

There is no cooling integrated with the PhotoRevelation protocol. Ultrasound gel is also not used for this treatment.

9.3.9.1 PhotoRevelation ClearScan YAG 1064 nm Treatment

Treatment Basics

- Hair that is present in the area to be treated should be shaved prior to treatment. There should be no more than 0.5 mm hair growth, or very minimal stubble, present in treatment area. The longer the hair, the greater the risk of burning the hair to the patient's skin.
- The use of a topical anesthetic is contraindicated for this procedure, as the patient's reporting of heat sensation is an important clinical endpoint.
- Patient should be positioned based on the area to be treated. The position should be comfortable to the patient and such that the treatment provider has good access to area to be treated and the system control panel display screen.
- A mild cleanser or alcohol wipe should be used to remove any dirt, makeup or moisture from the treatment site.
- Connect the 3 mm single spot handpiece to the articulated arm.

Note: The 3 mm single spot handpiece is the **ONLY** handpiece that is configured for PhotoRevelation use.



Eye protection should always be worn by everyone present in the treatment room during any laser or light based treatment. When treating on patient's face, they should always wear external, matte-finish metal goggles.

It is not recommended that any PhotoRevelation ClearScan YAG 1064 nm treatment be performed within the orbital rim due to the high risk of retinal damage.

- Select starting settings based on PhotoRevelation Safe Start Treatment Parameters noted below.
- The 3 mm single spot handpiece should be held perpendicular to the surface of the skin at all times. Move patient if necessary to accomplish this 90 degree angle.
- **Treating Test Area:** Treating a test area prior to beginning treatment will determine the patient's response threshold and help establish safe and effective treatment parameters.
 - Select test settings using the PhotoRevelation Safe Start Treatment Parameters.
 - **The 3 mm single spot handpiece is the ONLY handpiece that is configured for PhotoRevelation use.**
 - Hold the handpiece so that it is 5 - 15 cm from the surface of the treatment area. The treatment area should cover a 5 x 5 cm area.
 - Depress the foot switch to deliver a series of consecutive pulses while moving the handpiece in a continuous painting or sweeping motion over the treatment area.



Do NOT treat repeatedly in the same area or stack pulses. Pulse stacking can lead to excessive heat buildup and may result in blisters, scarring or hyperpigmentation.

- Observe test area for 1 - 2 minutes for endpoints; slight erythema and patient's report of a sense of warmth in the area treated.
- If desired endpoints are observed with no adverse effects, treatment can be continued until entire area is completed.
- If endpoints are not noted, increase the intensity of treatment by the following actions, in the following order (make only one change per series test pulses):
 - Increase fluence by **1 - 2 J/cm²**

- Increase pulse width. It may be necessary to change the pulse width to 1 ms to achieve the desired response.
- If reaction to test spot is too severe (intense erythema, purpura, immediate white or grey presentation of skin), the settings should be decreased in intensity by the following actions, in the following order:
 - Decrease fluence by **1 - 2 J/cm²** depending on intensity of reaction.
 - Decrease pulse width. The minimum allowable increment is 0.3 ms.
- Do not treat the same area for subsequent test spots. Test spots should occur in an area where there has been no previous treatment.
- Once desired endpoints are observed, complete the area to be treated. Divide the treatment sites into manageable areas of about 5 cm across. Paint the area being treated by quickly moving the handpiece over the area so that it is uniformly heated. Make sure the entire area is treated with as even a distribution of the pulses as possible. The treatment should take 500 - 2500 pulses for each 5 cm x 5 cm area. The pulse counter on the laser console will update the pulse count each time the footswitch is released.
- When treating smaller or more curved areas, a lower repetition rate may be needed to evenly treat the skin without overheating.

PhotoRevelation Treatment Starting Parameters

Skin Type	Fluence (J/cm ²)	Pulse Width (ms)	Repetition Rate (Hz)	Handpiece
I – VI	13 - 20	0.3	10 - 20	3 mm

Endpoints

- Slight erythema
- Patients report of a sense of warmth in the area being treated.

Post Treatment

- Observation – Slight redness and a minimal sun burn sensation for several hours after treatment.
- Intervention – Cool compresses or ice packs can provide some comfort after treatment. If blistering occurs, aggressive wound healing measures should be implemented.
- Interval – Treatments are performed 2 - 4 weeks apart. 5 - 6 treatments may be required.
- Sunblock with a minimum SPF 30 is recommended on treated areas that are exposed to the sun for at least 2 weeks after treatments to avoid excessive sunburn reaction or post inflammatory hyperpigmentation (PIH).
- If performing PhotoRevelation treatments in conjunction of other procedures such as MLP or ProFractional, perform PhotoRevelation treatment first.
- Check with manufacturer for guidelines on using injectables in conjunction with PhotoRevelation ClearScan YAG 1064 nm treatments.

9.3.10 Safe Start Protocol for 1064 Nd:YAG nm ClearSense Treatment for Onychomycosis

The JOULE ClearSense Laser System is indicated for ablation, vaporization, incision, excision and coagulation of soft tissue, including:

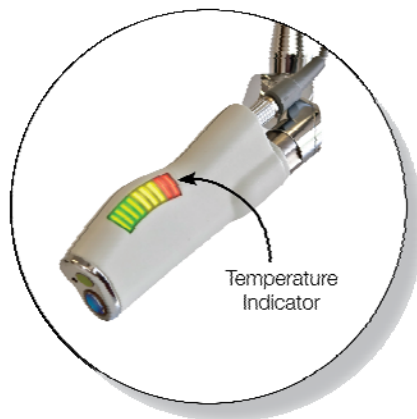
- Matrixectomy
- Periungual and subungual warts
- Plantar warts
- Radical nail excision
- Neuromas

It is also indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *T. mentagrophytes*, and/or yeasts *Candida albicans*, etc.).

The theory of Selective Photothermolysis explains how wavelength, energy and pulse width in relation to Thermal Relaxation Time (TRT) all play a role in the destruction of a target and the preservation of surrounding tissue.

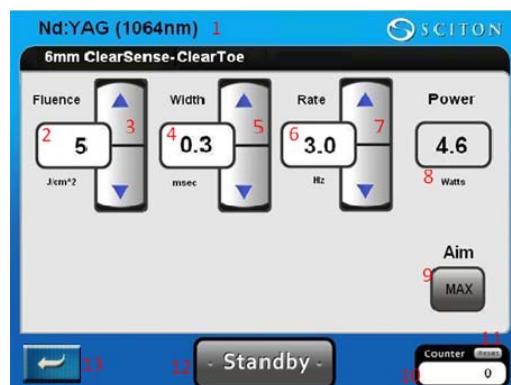
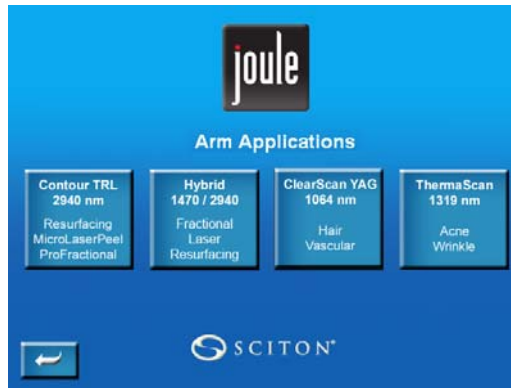
Using the theory of selective photothermolysis, onychomycosis can be treated with the 1064 nm Nd:YAG ClearSense and appropriate settings that will cause selective absorption of laser light in the toe nail. As the light travels down the nail, the absorption converts light into heat energy, which raises the temperature of the nail which destroys the fungal strains such as dermatophytes *Trichophyton rubrum* and *Trichophyton mentagrophytes*, and/or yeasts *Candida albicans*, etc. With the fungal growth arrested, visible improvement will be seen following nail growth.

ClearSense Handpiece - provides real time temperature sensing and optimum laser delivery to safely provide effective treatment for skin and nail rejuvenation.



1064 nm ClearSense Application User Screen

Attach the ClearSense handpiece to the articulated arm. Press the ClearScan YAG 1064 nm button, and then the ClearSense softkey.



This screen allows the user to adjust treatment settings. The available functions are described below.

1. Wavelength indicator
Wavelength indicator shows which wavelength is being used for the treatment.
2. Fluence indicator
Fluence indicator shows the amount of fluence or energy being delivered per spot. Fluence is measured in joules per centimeter squared, J/cm^2 .
3. Fluence adjustment softkeys
Fluence adjustment softkeys allow the user to increase or decrease fluence by $1 J/cm^2$ by tapping or holding down the up ▲ or down ▼ arrow softkeys.

4. Pulse width indicator
Pulse width indicator shows the length of time the energy is being delivered per spot. Pulse width is measured in milliseconds (ms).
5. Pulse width adjustment softkeys
Pulse width adjustment softkeys allow the user to increase or decrease pulse width by 5 ms by tapping or holding down the up ▲ or down ▼ arrow softkeys.
6. Spot placement rate
Spot placement rate is the speed at which each spot is being delivered within the scan pattern. The speed is measured in Hz. The maximum rate is automatically limited by the laser based on the fluence and pulse width.
7. Spot placement rate adjustment softkeys
Spot placement rate adjustment softkeys allow the user to increase or decrease the rate at which each spot is being delivered by 0.5 Hz by tapping or holding down the up ▲ or down ▼ arrow softkeys
8. Power Indicator
Power indicator displays the amount of power delivered in Watts.
9. Aiming beam intensity softkeys
Intensity of aiming beam may be adjusted by touching this softkey.
10. Number of accumulated pulses indicator
Number of accumulated pulses indicator shows how many pulses have been delivered since the system was turned on or since the last time the reset softkey for accumulated pulses was reset.
11. Accumulated pulses reset softkey
Accumulated pulses reset softkey allows the user to reset the number of accumulated pulses to 0 by touching the reset softkey.
12. System status softkey
System status softkey allows the user to put the system in Standby or Ready.
13. Return to 1064 nm Applications screen softkey
Touching this softkey will return the system to the previous screen.

9.3.10.1 1064 nm ClearSense Treatment of Onychomycosis

Treatment Basics

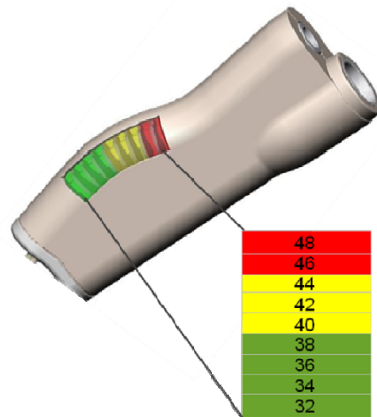


Eye protection should always be worn by everyone present in the treatment room during any laser or light based treatment.

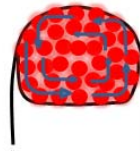
- A KOH test should be administered to affected nails to determine if condition is Onychomycosis and that ClearSense laser therapy is the appropriate treatment.
- The patient should be instructed to clip and debride affected nails and to remove any nail polish prior to treatment.
- Take baseline photographs of treatment sites to establish extent of infection based on visual assessment.
- Place white towel as backdrop for treatment area.
- Patient should be positioned so that he/she is comfortable and the treatment provider has good access to the area to be treated and the system control panel display screen.
- A mild cleanser or alcohol gauze should be used to remove any dirt or moisture from the treatment site.
- Do not apply topical anesthetic; the patient's feedback of heat sensation is an important clinical endpoint.
- Use a low lint or lint free alcohol wipe to clean the temperature sensor window. This will maximize the sensor's visibility and provide a more accurate temperature measurement.
- To properly use the temperature sensor, hold the ClearSense handpiece perpendicular to the treatment area and make sure to triangulate the laser aiming beam (solid red beam) and temperature sensing beam (flashing beam). When at the ideal distance, both beams form a single red dot.
- Select starting settings based on ClearSense Treatment Starting Parameters noted below.
- Depress the foot switch to deliver a series of consecutive pulses while moving the handpiece in a continuous painting or sweeping motion over the treatment area. Take care not to pulse stack. Stacking pulses can result in full thickness burns.



Treating Test Area: *Treating a test area prior to beginning treatment will determine the patient's response threshold and help establish safe and effective treatment parameters. During delivery of the laser pulses, observe for endpoints; patient's report of a mild to moderate heat sensation in the area being treated. If desired endpoints are observed with no adverse effects, treatment can be continued until area is completed. If endpoints are not noted, increase the Fluence or Rep Rate until the patient reports mild to moderate heat sensation in the area being treated. If reaction to test spot is too severe (excessive pain reported), the Fluence or Rep rate should be reduced so that the patient reports only mild to moderate heat sensation in the area being treated.*



- The ClearSense Accessory Handpiece has integrated temperature sensing that is displayed by 9 indicator lights and an audible tone. The tone begins when the temperature reaches 40 °C or when the yellow indicator lights are illuminated. The tone increases in frequency as temperature increases or as more lights are illuminated.



- The laser beam should be applied to the entire nail plate by slowly moving the beam in a spiral pattern, from the outside of the nail moving into the center, as shown above to cover the cuticle and nail bed completely. Listen for audible tones and watch for the visual LED signal. Recommended treatment temperature range is 40-42 °C or when the yellow LED lights are illuminated on the temperature indicator and the audible tone begins.



DO NOT TREAT IN THE RED LED LIGHT ZONE. When the red indicator lights are illuminated the temperature is higher than recommended; blistering may occur if treatment is continued in this area. Take caution when treating severe nail fungus, as the patient may not feel the heat.

- Treat all ten nails, including nails that appear healthy. Typical treatment times range from 10-20 minutes.

ClearSense Treatment Starting Parameters

Area	Handpiece	Spot Size (mm)	Fluence (J/cm ²)	Pulse Width (ms)	Rep Rate (Hz)	# of Passes
Toe/Finger Nail	ClearSense	6	5	0.3	3.5	2-3
<i>Note: Make sure that the patient has debrided the nail if there are areas that are 2 mm thick or greater.</i>						

Endpoints

- There is no visual clinical change of the treatment area.
- You must rely on audible and visual signals from the ClearSense handpiece as well as commentary from the patient.
- Patient reports mild to moderate discomfort in the entire area being treated as each series of pulses are applied. Listen to the patient and ask them to tell you when it is too hot; the temperature at which they think it is too hot may be less than 40-42 °C.

Post Treatment

- Observation – No discernable change to toenail immediately following treatment. It may take 3-6 months to see clear nails, depending on the speed of the patient's nail growth.
- Intervention – Cool compresses or ice packs can provide some comfort after treatment. If blistering occurs, aggressive wound healing measures should be implemented.
- Home care – Advise the patient to use new shoes and wash socks and footwear thoroughly in hot water. Topical anti-fungal cream may be prescribed.
- Interval – Treatments are performed 2-4 weeks apart; 3 or more treatments may be required.
- Activity – Patients may resume normal activity immediately following treatment.

9.3.11 Safe Start Protocol for 1064 nm Nd:YAG ClearSense Treatment of Warts

The theory of Selective Photothermolysis explains how wavelength, energy and pulse width, in relation to Thermal Relaxation Time (TRT), all play a role in the destruction of a target and the preservation of surrounding tissue.

Using the theory of selective photothermolysis, warts can be effectively treated with the 1064 nm Nd:YAG ClearSense handpiece. The target chromophore for the wart is the vascular component which is selectively absorbed by the laser light. The combination of appropriate energy and pulse timing will provide thermal heat leading to the destruction of the blood supply.

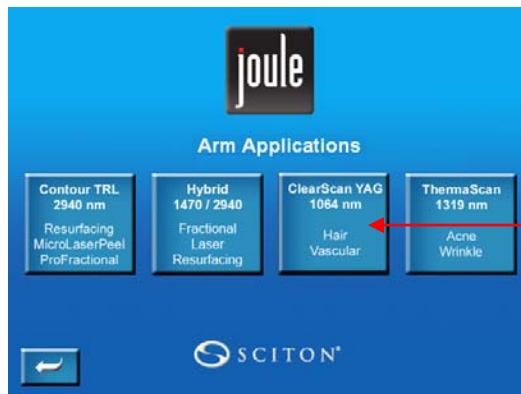
ClearSense Handpiece - optimum laser delivery to safely provide effective treatment for wart, skin and nail rejuvenation. (Indicator lights are not activate in the ClearSense Wart treatment mode, as temperature is not an endpoint)



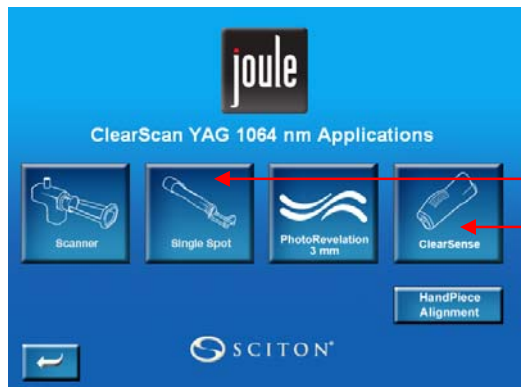
1064 nm ClearSense Application User Screen

Attach the ClearSense handpiece to the articulated arm. Press the ClearScan softkey on the 1064 nm Applications screen to enter the application screen.



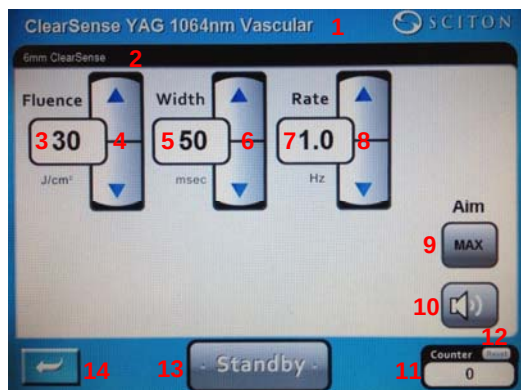


Press this soft key to enter into the ClearScan user screen



Single Spot softkey for Profile/JOULE1 Systems

1064 nm ClearSense softkey for JOULE7 systems



This screen allows the user to adjust treatment settings. The available functions are described below.

1. Wavelength indicator
Wavelength indicator shows which wavelength is being used for the treatment.
2. Handpiece Spot Size Indicator
Handpiece spot size indicates that the 6 mm spot handpiece is attached to the articulated arm.
3. Fluence indicator
Fluence indicator shows the amount of fluence or energy being delivered per spot. Fluence is measured in joules per centimeter squared, J/cm^2 .
4. Fluence adjustment softkeys
Fluence adjustment softkeys allow the user to increase or decrease fluence by $1 \text{ J}/\text{cm}^2$ by tapping or holding down the up ▲ or down ▼ arrow softkeys.
5. Pulse width indicator
Pulse width indicator shows the length of time the energy is being delivered per spot. Pulse width is measured in milliseconds (ms).

6. Pulse width adjustment softkeys
Pulse width adjustment softkeys allow the user to increase or decrease pulse width by 5 ms by tapping or holding down the up ▲ or down ▼ arrow softkeys.
7. Spot placement rate
Spot placement rate is the speed at which each spot is being delivered
8. Spot placement rate adjustment softkeys
Spot placement rate adjustment softkeys allow the user to increase or decrease the rate at which each spot is being delivered by 1 Hz by tapping or holding down the up ▲ or down ▼ arrow softkeys
9. Aiming beam intensity softkeys
Intensity of aiming beam may be adjusted by touching this softkey.
10. Audible tone
Audible tone when lasing.
11. Number of accumulated pulses indicator
Number of accumulated pulses indicator shows how many pulses have been delivered since the system was turned on or since the last time the reset softkey for accumulated pulses was reset.
12. Accumulated pulses reset softkey
Accumulated pulses reset softkey allows the user to reset the number of accumulated pulses to 0 by touching the reset softkey.
13. System status softkey
System status softkey allows the user to put the system in Standby or Ready.
14. Return to 1064 nm Applications screen softkey
Touching this softkey will return the system to the previous screen.



In poorly ventilated treatment rooms, the use of a smoke evacuator should be considered. NIOSH and OSHA recommend the use of a smoke evacuator during procedures that create smoke or plume. Therefore, it is highly recommended that a smoke evacuator be used during 1064nm Nd:YAG wart procedures.

9.3.11.1 1064 nm ClearSense Treatment of Warts

Treatment Basics

- Take baseline photographs of treatment site.
- Clean treatment area with appropriate cleanser or alcohol gauze.
- If warts need debridement, use disinfected instruments prior to treatment.
- May use topical anesthetic and/or local anesthetic infiltration.
- No coupling gel is used.
- Smoke evacuator is needed to capture plume. High filtration laser masks are recommended.

The ClearSense handpiece is foot pedal activated. Depress the foot switch and begin delivering energy. Hold the handpiece so that it is 2 cm and perpendicular from the surface of the treatment area. Apply the laser energy in one or two pulses. Treat the wart and surrounding tissue as it may be affected with the virus.

- Wart should be greater than 6 mm in size.
- One or two courses of slightly overlapping laser pulses applied to the wart covering the wart itself and a margin on the surrounding skin, as it may be affected with the virus.



Be careful when treating repeatedly in the same area or stacking pulses. Excessive pulse stacking can lead to excessive heat buildup and may result in blisters, scarring or hyperpigmentation.

- Once desired endpoints are observed as noted below, complete the area to be treated.
- Temperature sensor not engaged in the ClearSense wart mode.

ClearSense Wart Safe Start Parameters

Delivery Handpiece	Spot Size	Skin Type	Fluence (J/cm ²)	Pulse Width (ms)	Repetition Rate (Hz)
ClearSense	6 mm	I-VI	80 - 90	20	1 Hz

Endpoints

- Slight blanching or dusky immediately after.
- A blood blister is likely to form within 7-10 days, and then a crust forms and sloughs off.

Post Treatment

- Observation – Slight redness and a minimal sun burn sensation may be felt for approximately 2-12 hours.
- Intervention – Cool compresses or ice packs can provide some comfort after treatment. If blistering occurs, aggressive wound healing measures should be implemented. Clinicians may choose to prescribe topical antibiotic or soothing ointment along with non-stick dressing.
- Home care - Patients should be advised to keep the area clean. Patients should be advised to use new shoes and wash socks and footwear thoroughly if feet are the affected area.
- Interval – more than 1 treatment may be necessary 3-4 weeks apart
- Activity – Patients may resume normal or slightly altered activity immediately following procedure depending on area of treatment.

ProLipo PLUS™

9.4 1064 nm Nd:YAG and/or 1319 nm Nd:YAG ProLipo PLUS Treatment

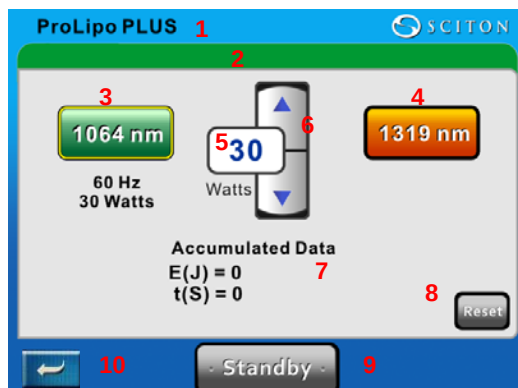
ProLipo emits mid-infrared wavelengths of 1064 nm and/or 1319 nm to liquefy fat, preparing it for gentle aspiration. The goal is to allow for the removal of pockets of body fat with minimum patient discomfort and postoperative pain, and deliver a tighter, smoother body contour. This laser assisted lipolysis device is only intended to be used on a small treatment area. A small treatment area is a small anatomical site such as a chin or upper arms (triceps) that is treated to remove a total of about 120cc of fat per anatomical site. The safety and effectiveness of laser assisted lipolysis on larger areas and laser assisted lipolysis procedures with liquefied fat remaining in the body or as an adjunct or pretreatment for standard liposuction procedures have not been evaluated or cleared by the FDA. The FDA has not evaluated clinical data demonstrating the safety and effectiveness of this device for larger volumes or areas of fat treatment such as thighs, buttocks or abdomen.

The ProLipo PLUS treatment is provided using the ProLipo PLUS User Screen which is accessed from the Fiber Applications Screen.



Press this softkey to enter Laser-Assisted Lipolysis User Screen

Pressing the Laser-Assisted Lipolysis softkey will allow the user to enter into the ProLipo PLUS user screen.



The ProLipo *PLUS* user screen allows the user to adjust treatment settings. The available functions are described below.

1. Application indicator
Application wavelength indicator shows the user is in the ProLipo *PLUS* user screen.
2. Pulse energy ratio
This bar displays the color according to the wavelength selected; green for 1064 nm and orange for 1319 nm.
3. 1064 nm softkey
1064 nm softkey allows the user to activate the 1064 nm wavelength for use during the ProLipo *PLUS* procedure.
4. 1319 nm softkey
1319 nm softkey allows the user to activate the 1319 nm wavelength for use during the ProLipo *PLUS* procedure.
5. Power indicator
Power indicator shows the rate at which power is being delivered and is displayed in Watts.
6. Power adjustment softkeys
Power adjustment softkeys allow the user to increase or decrease the power by 1 Watt by tapping or holding down the up ▲ or down ▼ arrow softkeys.
7. Accumulated Data indicator
Accumulated Data displays the total energy being delivered in Joules and the total time of the treatment in seconds.
8. Accumulated Data reset softkey
Accumulated Data reset softkey allows the user to reset the total energy delivered and the total treatment time to zero (0).
9. System status softkey
System status softkey will allow the user to put the system in Standby or Ready.
10. Return to Fiber Applications screen
Return to Fiber Applications softkey will return the system to the previous screen.

9.4.1 Indications for Use

The ProLipo *PLUS* with fiber delivery is indicated for laser assisted lipolysis.

9.4.2 Contraindications

The 1064 nm Nd:YAG and/or 1319 nm Nd:YAG ProLipo *PLUS* laser system is contraindicated for:

- Patients with coagulopathy
- Patients with collagen/scarring/connective tissue disorders
- Patients with vascular problems
- Patients with endocrine disorders
- Patients with hypertension
- Patients with depression
- Patients who are morbidly obese
- Patients with wound healing disorders
- Patients with recreational drug use or excessive alcohol consumption
- Patients who are pregnant
- Patients who have an inability to ambulate
- Patients with an active localized or systemic infection
- Patients who are immunocompromised

9.4.3 Precautions

Ensure that the patient is mentally and emotionally stable to undergo this cosmetic procedure. Patient must not have any active diseases or pre-existing medical conditions and must have realistic expectations of the outcome of their surgery.

9.4.4 Complications

Complications, though rare, occasionally occur and should be discussed and understood. The patient must understand the importance of the post care instructions and that failure to comply may increase the probability of complications.

- Bruising

- Edema
- Paresthesia
- Uncontrolled bleeding from incisions
- Uncontrolled pain
- Uncontrollable dizziness not related to pain relievers
- Necrotic fat drainage from the incision
- Necrotic tissue requiring removal
- Asymmetry
- Hyperpigmentation
- Hematoma
- Infection
- Temperature over 105°F
- Convulsions
- Gangrene

9.4.5 Warnings

Possible risks specific to ProLipo *PLUS* treatment include:

- Negative reaction to anesthesia
- Burns from laser treatment
- Excessive blood loss
- Pulmonary thromboemboli
- Fat emboli
- Pulmonary edema
- Excessive blood loss
- Collateral tissue injury, particularly neural and dermal

9.4.6 Selective Photothermolysis

ProLipo *PLUS* works on the theory of Selective Photothermolysis which is the precise targeting of a structure or tissue using a specific wavelength of light with the intention of absorbing light into that target area alone. The energy directed into the target area produces sufficient heat to damage the target while allowing the surrounding area to remain relatively untouched.

1064 nm Nd:YAG laser lipolysis

The 1064 nm wavelength is chosen for constructing the fat channels and preparing the fat for lipolysis by breaking up the more vascular superficial fat.

The 1064 nm wavelength is absorbed by oxyhemoglobin for better hemostasis and also generates thermal heating. The fat cell is ruptured and tumefaction takes place. It is an efficient wavelength for lipolysis.

1319 nm Nd:YAG laser lipolysis

The 1319 nm wavelength is used for its high absorption in water and its lower scattering in fat, so the majority of its thermal energy can be confined to the area just beyond the tip of the fiber and therefore may be preferable when treating around vital areas and thinner skin such as the submental region.

The 1319 nm wavelength is used to preferentially damage collagen in fibrous septae. This is the precursor to tissue retraction and observable improvement in skin laxity.

9.4.7 Getting Started

9.4.7.1 Consultation/Education

A consultation is essential in order to establish realistic expectations and to gain a full understanding of the patient and his/her treatment goals. The patient must understand the procedure, pre and post care instructions, expectations, contraindications and possible complications prior to beginning any treatment.

9.4.7.2 Physical Exam & Medical History

A physical exam and detailed medical history outlining any former or active medical condition or medication that is contraindicated or that could possibly affect the outcome of the treatment should be obtained prior to treatment.

9.4.7.3 Informed Consent

The process of accepting and confirming treatment must be reviewed, understood and signed by the patient prior to treatment. This document must review the topics discussed during the consultation. It acknowledges that the patient understands the procedure, possible risks and complications and that all questions have been answered.

Reference sample Informed Consent in Appendix of this manual.

9.4.7.4 Photographs

Pictures should be taken prior to each treatment to document the progress of the treatment. Photographs are useful in demonstrating efficacy of treatment to the patient.

Camera settings, distance, backdrop, and body/face angle, position and expression should be the same for each photography session to maintain similar quality.

The patient should sign a photo release form if before and after pictures are to be used for educational or marketing purposes.

9.4.7.5 Eye Protection

Eye protection should always be worn by everyone present in the treatment room during any laser or light based treatment.

9.4.8 Treatment Basics



ProLipo PLUS procedures are considered a more advanced treatment. Sciton recommends that each user attend a Preceptor training course prior to offering ProLipo PLUS procedures to their patients. Treatment specifics will be reviewed and discussed during the preceptorship.

Below are basic guidelines for ProLipo PLUS procedure. Specifics will vary with physician preference.

9.4.8.1 Assemble supplies and equipment for the procedure

- Patient treatment bed
- Procedure tray or cart
- Sterile fiber appropriately stripped and ready for use
- Tumescence anesthesia supplies
- Skin prep solutions
- 4x4 gauze sponges
- Sterile drapes and towels to create a sterile field
- Dressings

9.4.8.2 Pre-treatment

- Patient must complete and sign informed consent document(s)
- Identify and mark the areas to be treated while patient is standing
- Take photographs of the area being treated
- Oral sedation if used, should be administered as directed
- Peri-operative antibiotics should be administered as directed, if indicated

9.4.8.3 Prep and drape the patient

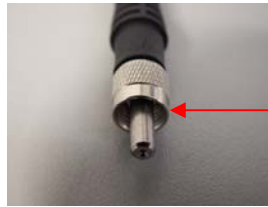
- Perform surgical skin prep using a skin disinfectant solution per standard institutional protocol
- Drape the treatment area with sterile drapes to create a sterile field

9.4.8.4 Laser Safety

- Make sure that all individuals in the treatment room have the appropriate laser eyewear protection, including the patient
- Place the laser treatment sign on all doorways entering into the treatment room
- Cover any windows in the room with material that will not allow the laser light to escape

9.4.8.5 Set up the ProLipo *PLUS* laser system

- Open the sterile laser fiber (Laser Peripherals DBLF-60-2-HP or matching specification) and place black laser handpiece and cannula onto the sterile field.



High Power SMA 905 Connector



Use only fibers that are fitted with high power SMA-905 connectors. Use of fibers without high power connectors may lead to premature failure of the laser system and void existing warranty on the system.

Handle the laser fiber with care to ensure that it has not been kinked, punctured, fractured or damaged. Do not leave fiber where it can be kinked, pulled or tightly coiled (no smaller than a 6 inch diameter). Do not clamp the fiber with a hemostat or other instrument. A damaged fiber can cause accidental laser exposure to personnel or the patient.

Always verify the presence of the aiming beam before beginning treatment. Absence or dimness of the aiming beam may indicate damage or breakage to the laser fiber. This must be done before every case!

- From the sterile field, pass the connector end of the laser fiber to the non-sterile assistant
- Remove the protective cap and connect the fiber to the laser system
- A folded towel may be used to help contain the fiber on the sterile field

9.4.8.6 Tumescence anesthesia

Tumescence prescription is based on physician preference.

9.4.8.7 Connect the laser fiber to the laser handpiece/cannula assembly



This process must be completed in the sterile field by an individual qualified to handle sterile equipment and maintain sterile technique throughout the procedure.

- Choose the sterile cannula of the appropriate length and attach it to the black ProLipo *PLUS* handpiece
- Loosen the handpiece nut at the base of the handpiece and insert the laser fiber through the nut, handpiece and cannula until the fiber extends, but no more than 2 to 3 mm, beyond the distal end of the cannula.



- Tighten the handpiece nut until it is snug around the fiber and the fiber is secure. Lightly grasp the fiber and gently push/pull the fiber to ensure there is no movement of the laser fiber.
- Observe that the aiming beam is visible at the end of the fiber/cannula assembly



Do not begin laser treatment with the fiber inside or adjacent to the tip of the cannula. Rapid heating of the cannula by the laser beam may damage the fiber or cannula and may cause damage to tissue.

9.4.8.8 Procedure

The treatment parameters may vary based on experience and preceptor visit observations.

- Select laser treatment parameters
 - Fiber size: **1000 µm core diameter**
 - Rate: **30 Hz**
 - Power: **15 Watts**
- Insert the fiber and cannula into the tumesced area
- Use a gentle back and forth movement of the laser cannula while firing the laser to achieve a smooth, uniform delivery of energy to tissue
- The physician's hand should be placed on the outside of the skin to help gauge the movement of the laser cannula and to detect heat on the surface of the skin or the TempASSURE should be utilized to measure the temperature of the treatment area.
- The patient may describe sensation and pressure but should not feel discomfort. Additional tumescent anesthesia may be needed if there is any pain in a given area.
- Continue to observe the aiming beam through the skin during the treatment. When the fiber is introduced into deep fat, it may not be visible.
- At the conclusion of the laser treatment, aspirate liquefied fat from the treatment site. The amount of fluid/tissue removed should always be documented.
- Document laser treatment parameters including wavelength, fiber type and size, Watts and Hz
 - NOTE:** All treatment data is deleted from memory after the laser is turned off. It is important to document treatment parameters prior to the laser being turned off.*
- Three options for applying a dressing to treated area(s):
 - Suture incision tightly closed
 - A single stitch, or Steri-Strips® lightly approximating tissue
 - Leave open, allowing the tissue to drain

9.4.8.9 Post-Treatment Instructions

Post-treatment care will vary with physician preference and should include instructions for:

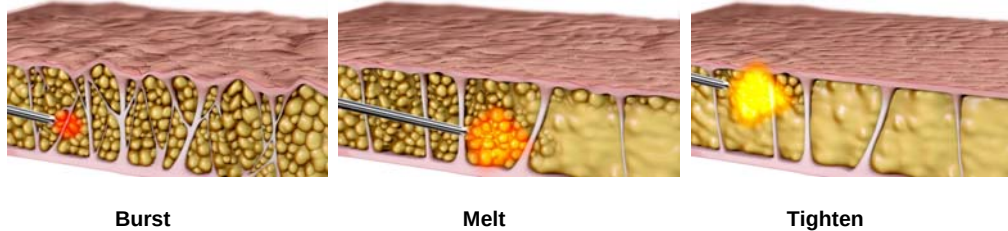
- Dressing and wound care
- Use of compression garment
- How to shower
- Activity level
- When to return for follow-up appointments
- Medications for discomfort and antibiotics, if ordered

CelluSmooth™

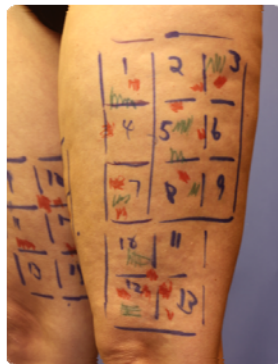
9.5 1319 nm Nd:YAG CelluSmooth Treatment

CelluSmooth is a minimally invasive procedure built on the Sciton JOULE platform. The procedure utilizes a 1319 nm laser, delivered through a fiber, in three different modes. The fiber is contained in a TempAssure cannula which measures the tissue temperature near the laser delivery point.

The three modes used for CelluSmooth are Burst, Melt, and Tighten. Each mode has a specific function: Burst mode is used to sever septae that cause dimpling, Melt mode is used to melt fat underlying bulging tissue, and Tighten mode is used to tighten the dermis by stimulating collagenesis.

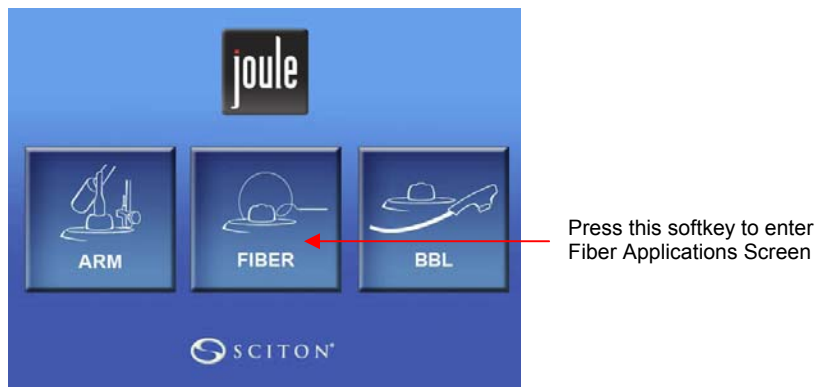


A CelluSmooth procedure will take approximately 12 minutes of laser-on time minutes for 300 cm² of skin surface and does not require general anesthesia. The skin is first marked with red and green markers, highlighting low points (septae tethering) and high points (adipose accumulation) respectively. The skin surface is then marked with a 5 cm x 5 cm grid pattern for precise application.

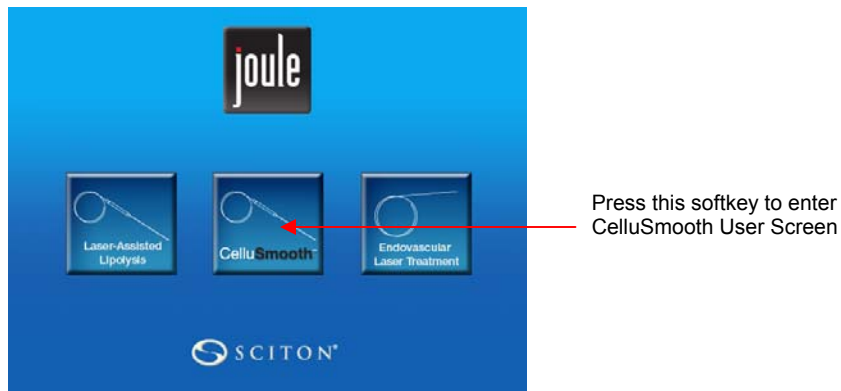


Tumescent anesthesia is then applied via 1 or 2 small incisions per each area. The laser energy is then applied via the same incisions. Approximately 15% of time and energy is spent cutting septae in Burst mode, 15% of time and energy smoothing irregularities in Melt mode, and 70% of time and energy spent tightening the skin in Tighten mode.

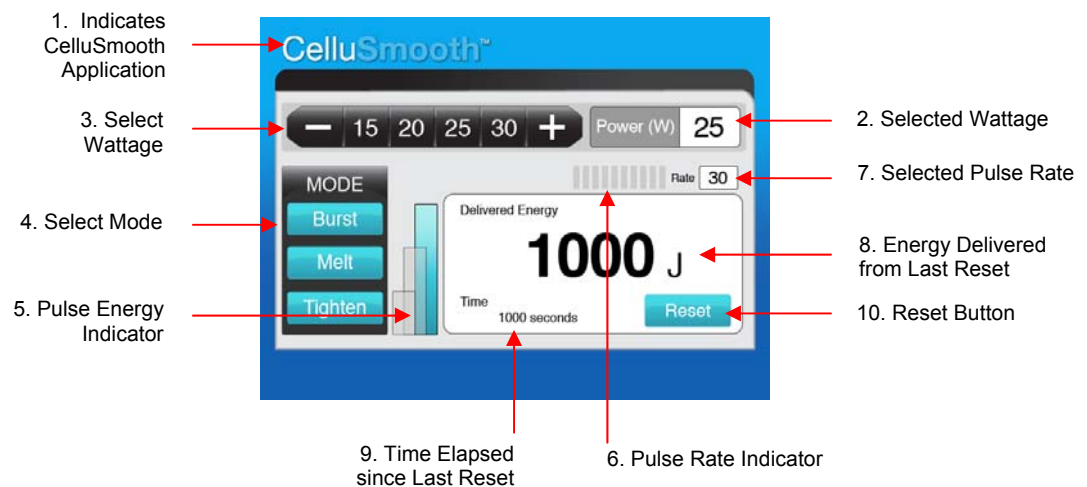
CelluSmooth is delivered via the Fiber Port. Select Fiber once your JOULE has started up to access the Fiber Applications Screen.



The CelluSmooth treatment is provided using the CelluSmooth User Screen which is accessed from the Fiber Applications Screen.



Pressing the CelluSmooth softkey will allow the user to enter into the CelluSmooth user screen.



The CelluSmooth user screen allows the user to adjust treatment settings. The available functions are described below.

1. Application indicator
Application indicator shows the user is in the CelluSmooth user screen.
2. Power indicator
Power indicator shows the rate at which power is being delivered and is displayed in Watts.
3. Power adjustment softkeys
Power adjustment softkeys allow the user to increase or decrease the power by 5 Watts by tapping or holding down the **-** or **+** softkeys.
4. Mode Selection
The Tighten, Melt or Burst mode can be selected by touching the softkey.
5. Mode Representation of Selected Modes
Tighten, Melt and Burst modes are represented by small, medium and large bars respectively.
6. Pulse Rate Indicator
Graphical representation of relative pulse rates.
7. Pulse Rate Display
Rep rate is displayed in pulses per second (Hz).
8. Accumulated Data indicator for Delivered Energy
Displays the total energy being delivered in Joules.
9. Accumulated Data indicator for Elapsed Time
Displays the total time of the treatment in seconds.
10. Accumulated Data reset softkey
Accumulated Data reset softkey allows the user to reset the total energy delivered and the total treatment time to zero (0).

9.5.1 Indications for Use

CelluSmooth with 1319 nm is intended for the surgical incision, excision, vaporization, ablation and coagulation of soft tissue.

9.5.2 Contraindications

The 1319 nm Nd:YAG CelluSmooth laser system is contraindicated for:

- Patients with coagulopathy
- Patients with collagen/scarring/connective tissue disorders
- Patients with vascular problems
- Patients with endocrine disorders
- Patients with hypertension
- Patients with depression
- Patients who are morbidly obese
- Patients with wound healing disorders
- Patients with recreational drug use or excessive alcohol consumption
- Patients who are pregnant
- Patients who have an inability to ambulate
- Patients with an active localized or systemic infection
- Patients who are immunocompromised

9.5.3 Precautions

Ensure that the patient is mentally and emotionally stable to undergo this cosmetic procedure. Patient must not have any active diseases or pre-existing medical conditions and must have realistic expectations of the outcome of their surgery.

9.5.4 Complications

Complications, though rare, occasionally occur and should be discussed and understood. The patient must understand the importance of the post care instructions and that failure to comply may increase the probability of complications.

- Bruising
- Edema
- Paresthesia
- Uncontrolled bleeding from incisions

- Uncontrolled pain
- Uncontrollable dizziness not related to pain relievers
- Necrotic fat drainage from the incision
- Necrotic tissue requiring removal
- Asymmetry
- Hyperpigmentation
- Hematoma
- Infection
- Temperature over 105°F
- Convulsions
- Gangrene

9.5.5 Warnings

Possible risks specific to CelluSmooth treatment include:

- Negative reaction to anesthesia
- Burns from laser treatment
- Excessive blood loss
- Pulmonary thromboemboli
- Fat emboli
- Pulmonary edema
- Excessive blood loss
- Collateral tissue injury, particularly neural and dermal

9.5.6 Selective Photothermolysis

CelluSmooth works on the theory of Selective Photothermolysis which is the precise targeting of a structure or tissue using a specific wavelength of light with the intention of absorbing light into that target area alone. The energy directed into the target area produces sufficient heat to damage the target while allowing the surrounding area to remain relatively untouched. Depending on the fluence, the 1319 nm wavelength can be used to preferentially ablate fibrous septae, emulsify fat, or to damage collagen as precursor to tissue retraction and observable improvement in skin laxity.

9.5.7 Getting Started

9.5.7.1 Consultation/Education

A consultation is essential in order to establish realistic expectations and to gain a full understanding of the patient and his/her treatment goals. The patient must understand the procedure, pre and post care instructions, expectations, contraindications and possible complications prior to beginning any treatment.

9.5.7.2 Physical Exam & Medical History

A physical exam and detailed medical history outlining any former or active medical condition or medication that is contraindicated or that could possibly affect the outcome of the treatment should be obtained prior to treatment.

9.5.7.3 Informed Consent

The process of accepting and confirming treatment must be reviewed, understood and signed by the patient prior to treatment. This document must review the topics discussed during the consultation. It acknowledges that the patient understands the procedure, possible risks and complications and that all questions have been answered.

Reference sample Informed Consent in Appendix of this manual.

9.5.7.4 Photographs

Pictures should be taken prior to each treatment to document the progress of the treatment. Photographs are useful in demonstrating efficacy of treatment to the patient.

Camera settings, distance, backdrop, and body/face angle, position and expression should be the same for each photography session to maintain similar quality.

The patient should sign a photo release form if before and after pictures are to be used for educational or marketing purposes.

9.5.7.5 Eye Protection

Eye protection should always be worn by everyone present in the treatment room during any laser or light based treatment.

9.5.8 Treatment Basics



CelluSmooth procedures are considered a more advanced treatment. Sciton recommends that each user attend a Preceptor training course prior to offering CelluSmooth procedures to their patients. Treatment specifics will be reviewed and discussed during the preceptorship.

Below are basic guidelines for CelluSmooth procedure. Specifics will vary with physician preference.

9.5.8.1 Patient Selection

Patient selection is very important for the CelluSmooth procedure. Lumpy and dimpled skin can present in one of two ways: volume plus or volume deficient. Patients that will achieve the best outcomes will be volume plus, while volume deficient patients may or may not be candidates for the CelluSmooth procedure. Additionally, combining lipo with CelluSmooth may be even more effective, as long as the patient is volume plus and has tight skin.

The proper candidates for CelluSmooth are volume plus patients. Volume plus patients will present with a tight skin envelope, increased fat in subcutaneous space, increased fat in deep space, etiology of dents relates to septa, and will be described as a "chunky" leg. The patients that are not a good choice for CelluSmooth are the volume deficient. Volume deficient patients will present with lax skin envelope, a thin subcutaneous fat layer, almost no deep fat, and dimples not caused by septa.

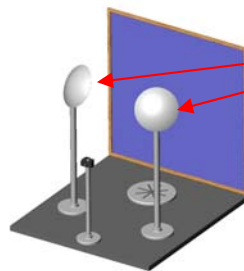
Do not treat volume depleted buttocks areas because when you cut the septa it may result in more drooping and a less appealing result.

9.5.8.2 Assemble supplies and equipment for the procedure

- Patient treatment bed
- Procedure tray or cart
- 800 or 1000 micron sterile fiber appropriately stripped and ready for use
- Tumescence anesthesia supplies
- Skin prep solutions
- 4x4 gauze sponges
- Sterile drapes and towels to create a sterile field
- Dressings

9.5.8.3 Pre-treatment

- Patient must complete and sign informed consent document(s)
- Oral sedation if used, should be administered as directed
- Peri-operative antibiotics should be administered as directed, if indicated
- Photograph the area to be treated **before** marking the patient. Dimples and bulges are obscured after markings are done.
- Photograph the area **after** marking the patient. This is important for identifying the area treated in future evaluation of CelluSmooth improvement.



Tungsten halide lamps with umbrellas at specific angles

9.5.8.4 Ultrasound Imaging (Optional)

Ultrasound identifies dimples and fat bulges through correlation between the waviness of the superficial fascia and the dermis. Pass the ultrasound over the marked bump area. The corresponding ultrasound image will show superficial fascia widens and the distance between the dermis thickens or increases. Pass the ultrasound over a marked dimpled area and the corresponding ultrasound image shows thinning or tenting of the distance between the superficial fascia and the dermis.

9.5.8.5 Marking the Patient

Patients should be examined and marked while standing in order to observe the tissue as it would normally appear.

Begin the marking process by lighting tangentially with a handheld light. The oblique light will create shadows that emphasize the dimples and brighter areas that indicate bulges.



First, mark the dimples by filling in the area with a red marker.



Second, highlight the bulges with a green marker.



Lastly, use the template to mark squares on the area to be treated. The template will outline six 5 cm by 5 cm squares.



Surgeons have observed that they find between 1 and 3 dimples per square, with an average of 1 per square. If red and green areas fall outside the 5 cm x 5 cm squares, create more squares using the template.



Additionally, it may be helpful to number each square for documentation purposes.



9.5.8.6 Prep and drape the patient

- Perform surgical skin prep using a skin disinfectant solution per standard institutional protocol
- Drape the treatment area with sterile drapes to create a sterile field

9.5.8.7 Laser Safety

- Make sure that all individuals in the treatment room have the appropriate laser eyewear protection, including the patient
- Place the laser treatment sign on all doorways entering into the treatment room
- Cover any windows in the room with material that will not allow the laser light to escape

9.5.8.8 Set up the CelluSmooth laser system

- Open the sterile laser fiber (Laser Peripherals DBLF-800-HP or matching specification for 800 micron fiber, or Laser Peripherals DBLF-1000 or matching specification for 1000 micron fiber) and place CelluSmooth laser handpiece and cannula onto the sterile field.



High Power SMA 905 Connector



For 800 micron fiber application, use only fibers that are fitted with high power SMA-905 connectors. Use of fibers without high power connectors may lead to premature failure of the laser system and void existing warranty on the system. Handle the laser fiber with care to ensure that it has not been kinked, punctured, fractured or damaged. Do not leave fiber where it can be kinked, pulled or tightly coiled (no smaller than a 6 inch diameter). Do not clamp the fiber with a hemostat or other instrument. A damaged fiber can cause accidental laser exposure to personnel or the patient.

Always verify the presence of the aiming beam before beginning treatment. Absence or dimness of the aiming beam may indicate damage or breakage to the laser fiber. This must be done before every case!

- From the sterile field, pass the connector end of the laser fiber to the non-sterile assistant
- Remove the protective cap and connect the fiber to the laser system
- A folded towel may be used to help contain the fiber on the sterile field

9.5.8.9 Connect laser fiber to TempASSURE™ assembly



CelluSmooth should always be used in conjunction with TempASSURE for maximum safety. Refer to the TempASSURE Operators Manual for instructions on assembly, usage, and sterilization.

9.5.8.10 Tumescant anesthesia

Tumescant prescription is based on physician preference.

Recommended Solution:

- One liter Ringers Lactate
- 50 cc 1% lidocaine plain
- 1 ampule epinephrine 1:1000 (1mg/ml)
- 10 cc bicarbonate 8.4%.

Recommended quantity: 30-50 cc per square depending on treatment area.

9.5.8.11 Connect the laser fiber to the laser handpiece/cannula assembly



This process must be completed in the sterile field by an individual qualified to handle sterile equipment and maintain sterile technique throughout the procedure.

- Choose the sterile cannula of the appropriate length and attach it to the CelluSmooth handpiece.
- Loosen the handpiece nut at the base of the handpiece and insert the laser fiber through the nut, handpiece and cannula until the fiber extends, but no more than 2 to 3mm mm, beyond the distal end of the cannula.



- Tighten the handpiece nut until it is snug around the fiber and the fiber is secure. Lightly grasp the fiber and gently push/pull the fiber to ensure there is no movement of the laser fiber.
- Observe that the aiming beam is visible at the end of the fiber/cannula assembly



Do not begin laser treatment with the fiber inside or adjacent to the tip of the cannula. Rapid heating of the cannula by the laser beam may damage the fiber or cannula and may cause damage to tissue.

9.5.8.12 Procedure

The treatment parameters may vary based on experience.

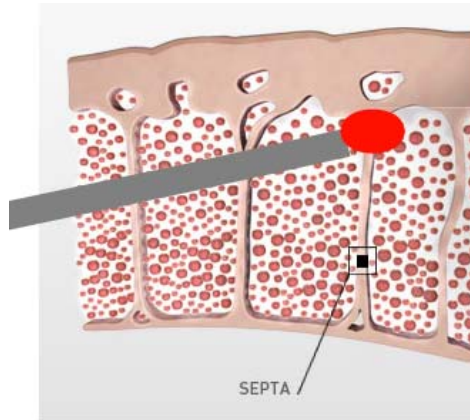
- Select laser treatment parameters.

The modes below all specify a power of "Up to 30 watts." For the shortest procedure the higher power should be used, but investigators may wish to reduce the power until they feel comfortable using the higher power.

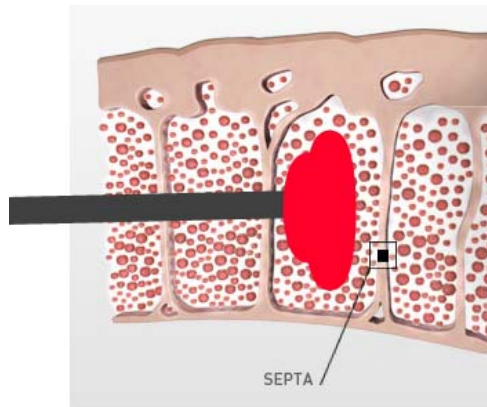
1st Mode:	<u>Burst</u>	Approximately 15% of total procedure energy
Power:	Up to 30 W	
Laser Setting:	Burst Mode: 1 Joule per pulse, 20-30 pulses per second	
Time:	5 – 6 seconds per septa	
Energy delivered:	150 – 180 Joule per septa (5 - 6 sec @ 30W)	
Average Temperature:	41 – 42 °C	
2nd Mode:	<u>Melt</u>	Approximately 15% of total procedure energy
Power:	Up to 30 W	
Laser Setting:	Melt mode: 0.75 Joule per pulse, 26-40 pulses per second.	
Time:	4 – 6 seconds per fat pocket	
Energy delivered:	150 – 180 Joule per fat pocket (5 sec @ 30W)	
Average Temperature:	46 – 48 °C	
3rd Mode:	<u>Tightening</u>	Approximately 70% of total procedure energy
Power:	Up to 30 W	
Laser Setting:	Tighten mode: 0.5 Joule per pulse, 40–60 pulses per second	
Time:	Treat to temperature 46 – 48 °C	
Energy Delivered:	700 – 1200 Joule per 5 cm x 5 cm square	
Average Temperature:	46 – 48 °C	

- Insert the fiber and cannula into the tumesced area.

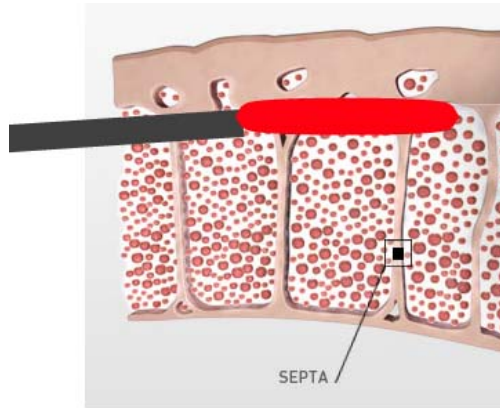
- For Burst Mode, start with each 5 cm x 5 cm square and locate the septa marked in red by placing the tip of the cannula against it. If you can observe the dimpled area depress further, you have located the septa causing the dimple. The septa should be severed superficially, close to the dermal subcutaneous junction.



- For Melt Mode, treat a 5 cm x 5 cm using the laser and cannula targeting the green marked areas with a gentle back and forth movement. Melt mode should be performed midway between the dermal subcutaneous junction and the underlying muscle.



- For Tighten mode, treat each 5 cm x 5 cm square and use a gentle back and forth movement of the laser cannula while firing the laser to achieve a smooth, uniform delivery of energy to tissue. Tighten mode should be performed at the dermal subcutaneous junction.



- The physician's hand should be placed on the outside of the skin to help gauge the movement of the laser cannula. TempASSURE should be utilized at all times to measure the temperature of the treatment area.
- The patient may describe sensation and pressure but should not feel discomfort. Additional tumescent anesthesia may be needed if there is any pain in a given area.
- Continue to observe the aiming beam through the skin during the treatment. When the fiber is introduced into deep fat, it may not be visible.
- Document laser treatment parameters including fiber type and size. For each mode, record the wattage, joules delivered, and temperature for each 5 cm x 5 cm square.
NOTE: All treatment data is deleted from memory after the laser is turned off. It is important to document treatment parameters prior to the laser being turned off.
- At completion of procedure on a treatment area, gently roll the area to express the tumescent fluid or liquefied fat
- Three options for applying a dressing to treated area(s):
 - Suture incision tightly closed
 - A single stitch, or Steri-Strips® lightly approximating tissue
 - Leave open, allowing the tissue to drain

9.5.8.13 Post-Treatment Instructions

Post-treatment care will vary with physician preference and should include instructions for:

- Dressing and wound care
- Use of compression garment
- How to shower
- Activity level
- When to return for follow-up appointments
- Medications for discomfort and antibiotics, if ordered

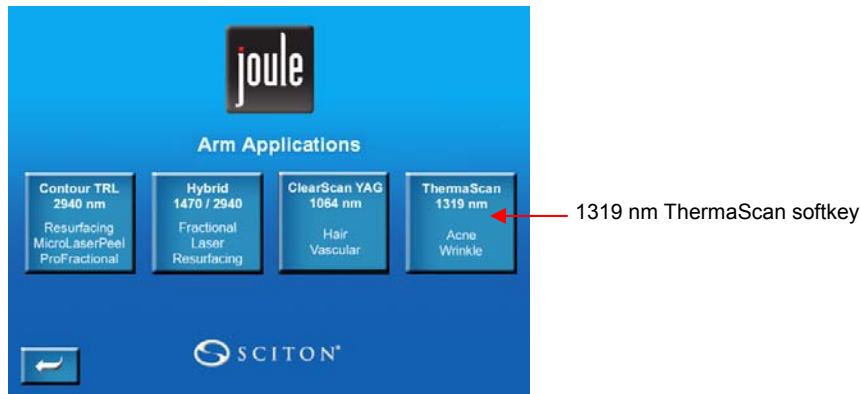
ThermaScan™

9.6 1319 nm Nd:YAG ThermaScan

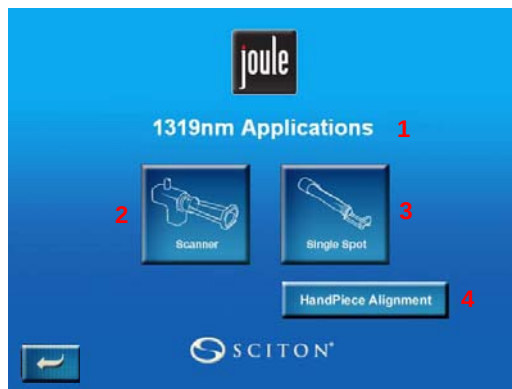
ThermaScan emits a mid-infrared beam with a wavelength of 1319 nm which coincides with a high absorption peak for water and collagen. The epidermis is less hydrated than the dermis, therefore the majority of the energy from ThermaScan is absorbed in the dermis. ThermaScan is safe and effective for all skin types. Its principal uses are for treatment of fine lines and wrinkles, and for the treatment of acne scars and active acne.

Arm Application Menu Screen

The Arm Application menu screen allows the user to enter the 1319 nm ThermaScan user application screens.



Pressing the ThermaScan softkey will allow the user to enter into the 1319 nm Applications screen.

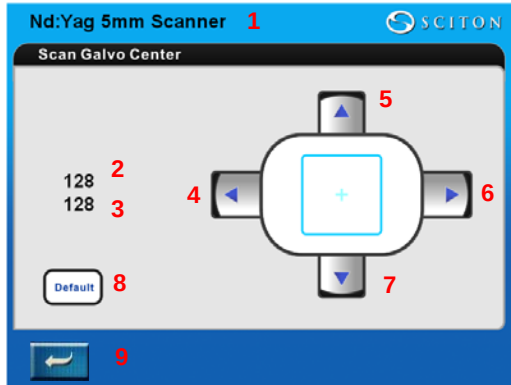


1. Application Header
Application Header displays the selected 1319 nm application.
2. Scanner application softkey.
Attach 5 mm HF Scanner with Contact Cooler connected and press the softkey to enter the Nd:YAG 1319 nm user screen.
3. Single Spot application softkey
When treating single acne lesions, attach the 6 mm single spot handpiece with either the single spot

contact cooler chill plate or paddle chill plate. Connect the external Contact Cooler to chill plate selected.

4. HandPiece Alignment softkey

The 5 mm HF Scanner has the ability to adjust the scan pattern output center. Press HandPiece Alignment softkey to access the centering screen. The X-axis and Y-axis can be adjusted and stored into memory. This adjustment should be made each time the scanner is attached to the system for the first time and any time the scan pattern output is not centered (edge of aiming beam is cut-off or is hitting the metal surrounding the chill plate window).



1. Scanner Handpiece indicator
2. Current center settings indicator for x-axis
3. Current center settings indicator for y-axis
4. Adjust pattern left softkey
5. Adjust pattern up softkey
6. Adjust pattern right softkey
7. Adjust pattern down softkey
8. Center scanner to default position softkey
9. Return to 1319 nm Applications Screen softkey

9.6.1 Indications for Use

The 1319 nm Nd:YAG ThermoScan laser module is designed for use in:

- Treatment of fine lines and wrinkles
- Treatment of atrophic acne scars
- Treatment of mild to moderate inflammatory acne vulgaris

9.6.2 Contraindications

The 1319 nm Nd:YAG ThermoScan laser system is contraindicated for:

- Patients who take medication which is known to increase sensitivity to sunlight
- Patients with infectious disease
- Patients with connective tissue disease
- Patients who have a history of keloid scar formation
- Patients who are immunocompromised
- Patients who are pregnant
- Patients who have used isotretinoin (Accutane) within the past 6 – 12 months
- Patients with a medical condition that may affect wound healing

9.6.3 Complications

Complications, though rare, occasionally occur and should be discussed and understood. The patient must understand the importance of the post care instructions and that failure to comply may increase the probability of complications.

- Scarring, though rare can occur following any laser procedure.
- Blistering during treatment may be an indication of recent sun exposure or too high a fluence for the skin type and/or incomplete placement of the chill plate on skin. Blistering can occur during the

first three days following the laser procedure. Blistered areas should be treated with care, and kept moist with an ointment until area has healed.

- Pigmentary changes: hyperpigmentation or hypopigmentation are rare when treating with a 1319 nm wavelength.

9.6.4 Warnings

- In pretreatment work-ups, screen lesions that are located in the close proximity to known arteries or veins in order to locate these circulatory structures.
- Water condensation on the upper surface of the chill plate may result in laser beam scattering and an incorrect setting for fluence. Treating the top of the plate with a surfactant, SeaDrops, will reduce scattering due to condensation.
- A dirty chill plate may lead to an incorrect setting for fluence. Clean the chill plate with a soft cotton gauze moistened with alcohol prior to each treatment and throughout extended, lengthy treatments.
- Check the chill plate temperature prior to each treatment. The risk of epidermal injury, such as blistering, increases if the temperature of the chill plate is too warm or if the chill plate is too cold.
- Tattooed areas, and the area of skin 4 - 5 mm outside of the tattoo in all directions, should not be treated. Tattoo ink may absorb laser energy resulting in a color change of the tattoo ink or a risk of epidermal damage.
- Darkened moles should not be treated. Moles may absorb laser energy causing a color change of the mole resulting in the inability to monitor the mole under ABCD guidelines for melanoma detection. Excess energy may also be absorbed into the mole resulting in the risk of epidermal damage.
- Do not stack pulses or overlap consecutive scans. Repeated pulses in the same location, improper chill plate placement, repeated scans, improper cooling temperatures, or excessive fluence may lead to a buildup of subsurface heat and a subsequent blister or burn.
- Do not allow combustibles or flammables, including drapes and paper panties, in the laser treatment area. Fire prevention/control methods should be in place.

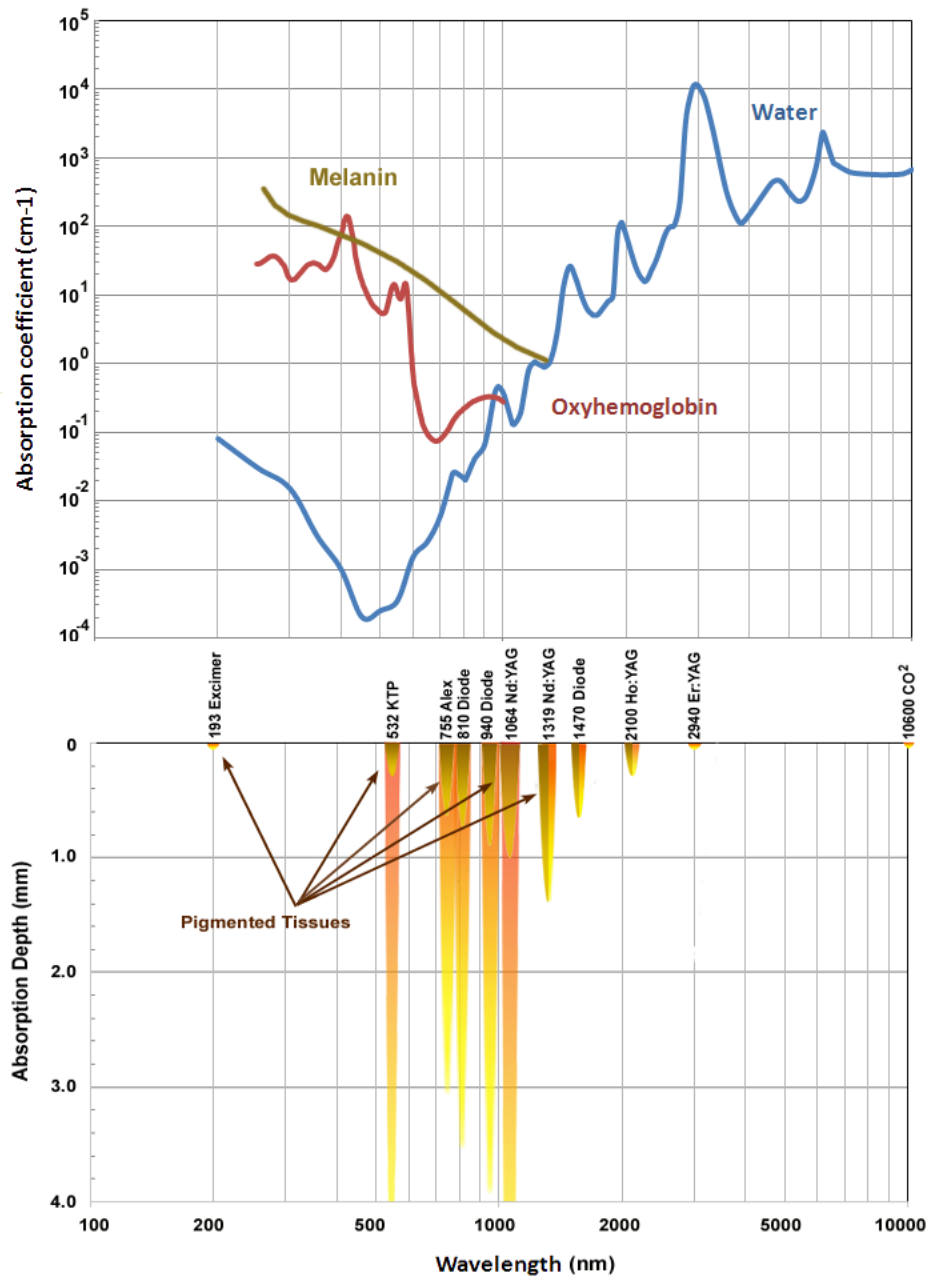
9.6.5 Laser Skin Heating

Absorption Curve

Absorption curve shows the relationship of the variation in absorbed laser light as a function of wavelength. The graphic shows absorption spectra of major intracellular absorbers. The molecular absorption coefficients of oxygenated hemoglobin, melanin and water are shown.

Depth of Penetration

Depth of penetration of laser energy for different types of lasers is also illustrated.



The thermodynamic properties of skin are very similar for all patients and a reproducible thermal response will be achieved by setting pulse width, fluence and surface cooling temperature and selecting the appropriate wavelength. Adjusting these settings will allow you to adjust the treatment to different skin conditions. When treating patients with thinner skin, more conservative settings should be selected.

Pulse width is the length of time that the target is exposed to the heat and is typically measured in milliseconds (ms). Pulse width must be less than the Thermal Relaxation Time (TRT) of the target. In other words, the pulse width must be long enough to allow heating of the target but also short enough that the target can cool so that there is no heat buildup in surrounding skin and tissue. The cooling time of a target is relative to its size, structure and density. Refer to TheraScan Treatment Starting Parameters for safe start pulse width parameters.

Fluence is the amount of heat or energy delivered into the target. Fluence is measured in units of Joules/cm². Refer to TheraScan Treatment Starting Parameters for safe start fluence parameters.

The higher the fluence selected, the higher the temperature of the target, the surrounding tissue and the epidermis. Treating with excess energy can result in adverse effects such as abnormal pigmentation, blistering and scarring.

Patient response can vary, so the fluence setting should begin low and be increased gradually after assessing the individual patient response and observation of endpoints desired.

Wavelength is the spatial period of a wave from peak of one wave to the peak of the next wave. Photons of 1319 nm are preferentially absorbed in water and collagen.

Surface Cooling

1319 nm Nd:YAG ThermoScan integrates a powerful 250 Watt external cooling system that connects to the 5 mm HF Scanner, paddle or single spot chill plates in order to keep the treatment area cool. Skin surface temperature changes of 1 °C can cause immediately observable differences in the clinical response.



External Cooling Systems: A black or white version of the external chiller may have been supplied with your system. Refer to Appendix I for operating instructions, including instructions on how to attach chiller hoses.



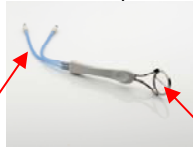
Chill Plates connected to the system

All chill plates are all made of 100% sapphire. Each chill plate consists of two sapphire plates that are sandwiched together. When connected to the external Contact Cooler, water flows from the cooler, through the chiller hose, down the chill plate tubing and between the two sapphire plates. The water continues up the opposite tube on the chill plate and then recycled back through the contact cooler.

Single spot chill plate



Paddle chill plate



Chill plate tubing

Sapphire plates

5 mm HF Scanner with chill plate



The chill plate should be in complete contact with skin throughout the entire scan or pulse to ensure that skin is protected before, during and after a pulse or scan pattern is delivered.

Although absorption of the 1319 nm Nd:YAG energy into a certain chromophore is desirable, some epidermal cooling is necessary to protect the skin. Refer to Starting Parameters for temperature setting of the external cooling system.

Continuous observation of skin during a 1319 nm Nd:YAG ClearScan treatment is critical and will ensure appropriate fluence, pulse width and temperature settings have been selected and that skin integrity has not been compromised.

9.6.6 Getting Started

9.6.6.1 Consultation/Education

A consultation is essential in order to establish realistic expectations and to gain a full understanding of the patient and his/her treatment goals. The patient must understand the procedure, pre and post care instructions, expectations, contraindications and possible complications prior to beginning any treatment.

9.6.6.2 Medical History

A detailed medical history should be obtained prior to treatment outlining any former or active medical condition or medication that is contraindicated or that could possibly affect the outcome of the treatment.

It is recommended that a brief medical history be taken before beginning any subsequent treatment with questions such as, but not limited to, any new medications, skin care, sun exposure, pregnancy etc.

9.6.6.3 Informed Consent

The process of accepting and confirming treatment must be reviewed, understood and signed by the patient prior to treatment. This document must review the topics discussed during the consultation. It acknowledges that the patient understands the procedure, possible risks and complications and that all questions have been answered.

Reference sample Informed Consent in Appendix of this manual.

9.6.6.4 Photographs

Pictures should be taken prior to each treatment to document the progress of the treatment. Photographs are useful in demonstrating efficacy of treatment to the patient.

Camera settings, distance, backdrop, and body/face angle, position and expression should be the same for each photography session to maintain similar quality.

The patient should sign a photo release form if before and after pictures are to be used for educational or marketing purposes.

9.6.6.5 Topical Anesthesia

The use of topical anesthetic is not typically recommended for 1319 nm Nd:YAG ThermaScan treatments. Patient feedback is needed to evaluate appropriate endpoints. If a patient is "numb" they may not be able to accurately assess if a treatment is too warm which could lead to a blister or a burn. However, if topical preparation is used to alleviate discomfort for highly sensitive patients or sensitive areas prior to treatment, the manufacturer's guidelines for the application and duration of the anesthetic should be read prior to topical application. Remove before treatment with mild soap and water or an alcohol swab, then plain water. Dry the area thoroughly before treatment.

Reminder: Each patient should be assessed and questioned regarding allergies or sensitivities to ingredients in topical anesthetics prior to application.



Be extremely cautious when applying topical anesthetics to large areas of the body. Lidocaine toxicity has been linked to several deaths.

9.6.6.6 Eye Protection

Eye protection should always be worn by everyone present in the treatment room during any laser or light based treatment. When treating on the face of a patient, they should always wear external, matte-finish metal goggles.

9.6.7 Safe Start Protocol for 1319 nm Nd:YAG ThermoScan for Fine Lines/Wrinkles & Acne Scar Treatment

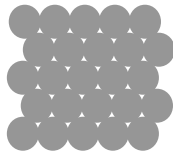
The epidermis is a robust and resilient structure at the surface of the skin. It functions as a physical barrier to protect the deeper dermis and to retain the skin's hydration. It is less hydrated than the dermis resulting in less absorption of energy at 1319 nm than in the dermis since energy at a wavelength of 1319 nm is preferentially absorbed in water and collagen. The highest absorption, and thus the highest temperature, will occur just below the epidermis in the more hydrated papillary dermis. In addition, a high degree of scattering prevents photons at 1319 nm from penetrating deep into tissue. Instead, they are absorbed before penetrating deeper into the dermis. The result is a peak temperature near the region of the papillary dermis. The energy absorbed by the targeted areas stimulates the fibroblast cells in the skin to begin to generate collagen which in return thickens the dermis and raises depressed scars and smoothes wrinkles.

5 mm HF Scanner

The 5 mm HF Scanner has a contact cooling chill plate assembly attached to it. The assembly is comprised of two sapphire plates that are separated by continuously flowing Chiller Mixture. The spot placement is achieved by using two galvanometer motors for x-axis and y-axis displacement.



5 mm HF Scanner chill plate

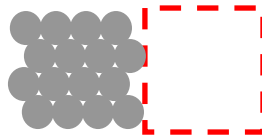


5 x 5 pattern

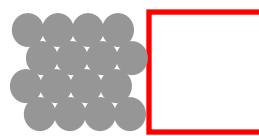
The 5 mm HF Scanner precisely places each pulse in a non-sequential pattern to eliminate improper placement of individual pulses. It also maximizes the time interval between adjacent spots and minimizes subsurface heat buildup.

The 5 mm HF Scanner allows for complete and uniform application of the laser energy by delivering 5 mm spots of energy within a designated pattern shape and size. The pattern can be adjusted from a 1 x 1 (single spot) to 6 x 6 with any variation in between. A 5 x 5 pattern is illustrated above.

Aiming beam is represented by red box and shows the user the area to be treated. The energy will be delivered inside the red box. When the red box is "dancing" the system is in Standby. When the red box is solid the system is in Ready.



Standby



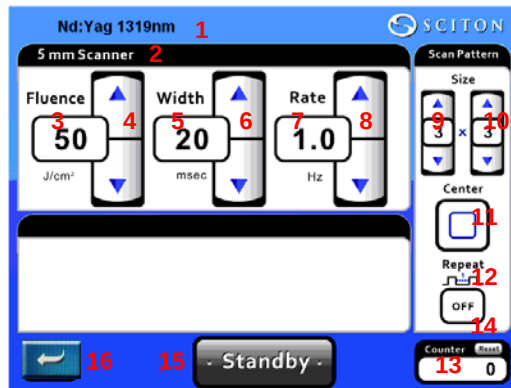
Ready

Care should be taken to apply adjoining scans without gap or excessive overlap of the previously scanned area. A mental picture of where the next scan pattern should be placed will assist in lining each scan pattern up to each other to avoid gap or overlap as shown above.

To achieve safe, uniform treatment as shown, the scanner should be held so that the red box within the chill plate window is in complete contact with the skin at all times.

1319 nm Scanner Application User Screen

Attach the 5 mm HF Scanner to the articulated arm. Press the Scanner softkey on the 1319 nm Application screen and the system will enter the Nd:YAG 1319 nm application screen.



The Nd:YAG 1319 nm user screen allows the user to adjust treatment settings. The available functions are described below.

1. Wavelength indicator
Wavelength indicator shows which wavelength is being used for the treatment.
2. Handpiece indicator
Handpiece indicator shows which handpiece is being used for the treatment.
3. Fluence indicator
Fluence indicator shows the amount of fluence or energy being delivered per 5 mm spot within whatever size or shape scan pattern has been selected. Fluence is measured in joules per centimeter squared, J/cm².
4. Fluence adjustment softkeys
Fluence adjustment softkeys allow the user to increase or decrease fluence by 1 J/cm² by tapping or holding down the up ▲ or down ▼ arrow softkeys.
5. Pulse width indicator
Pulse width indicator shows the length of time the energy is being delivered per 5 mm spot within whatever size or shape scan pattern has been selected. Pulse width is measured in milliseconds (ms).
6. Pulse width adjustment softkeys
Pulse width adjustment softkeys allow the user to increase or decrease pulse width by 5 ms by tapping or holding down the up ▲ or down ▼ arrow softkeys.
7. Spot placement rate
Spot placement rate is the speed at which each 5 mm spot is being delivered within the scan pattern. The speed is measured in Hz. The maximum rate is automatically limited by the laser based on the fluence and pulse width.
8. Spot placement rate adjustment softkey
Spot placement rate adjustment softkeys allow the user to increase or decrease the rate at which each 5 mm spot is being delivered by 0.5 Hz by tapping or holding down the up ▲ or down ▼ arrow softkeys.
9. Vertical pattern selection softkeys
The vertical pattern selection softkeys allow the user to increase or decrease the vertical size of the pattern from 1 to 6 spots.
10. Horizontal pattern selection softkeys
The horizontal pattern selection softkeys allow the user to increase or decrease the horizontal size of the pattern from 1 to 6 spots.
11. Pattern center softkey
Pattern center allows the user to offset the area to be treated to the upper left corner, upper middle, upper right corner or the center of the chill plate window.



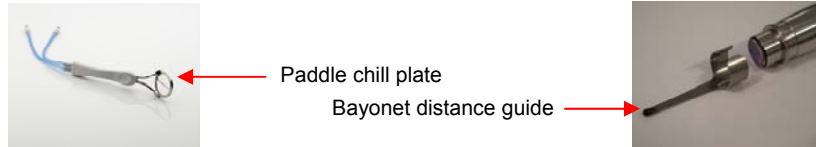
12. Pattern repeat softkey
Pattern repeat will allow the user to set an amount of time between consecutive scans of 1, 2, 3, 4, or 5 seconds by tapping the Repeat softkey. Repeat can also be turned off so that each scan pattern is delivered by lifting and depressing the footswitch.
13. Number of accumulated pulses indicator
Number of accumulated pulses indicator shows how many pulses have been delivered since the system was turned on or since the last time the reset softkey for accumulated pulses was reset.

14. Accumulated pulses reset softkey
Accumulated pulses reset softkey allows the user to reset the number of accumulated pulses to 0 by touching the reset softkey.
15. System status softkey
System status softkey will allow the user to put the system in Standby or Ready.
16. Return to 1319 nm Applications Screen
Return to 1319 nm Applications softkey will return the system to the previous screen.

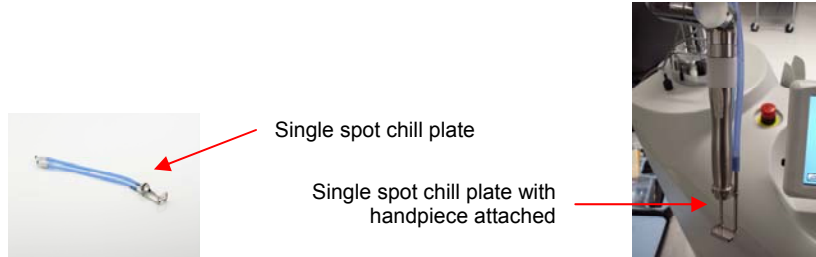
Surface Cooling

When performing 1319 nm Nd:YAG ThermoScan for Fine Lines/Wrinkles & Acne Scar Treatment, the use of a contact cooler is critical for ensuring patient safety.

Either the paddle chill plate or the single spot chill plate can be used for the treatment.



The bayonet distance guide assures that proper distance from the paddle chill plate is maintained throughout the treatment for accurate spot size delivery.



Managing patient expectations

Patients should understand that to obtain optimal results with 1319 nm Nd:YAG ThermoScan Skin Rejuvenation & Acne Scar Treatment, a minimum of 4 treatments are required. Optimal results may not be seen for 3 - 6 months after the last treatment. It takes this amount of time for dermal changes from fibroblast activity to be observed.

Treating scars

- **Fibrotic Scars** – Dense fibrotic tissue can blister at a lower temperature than normal tissue. In areas where fibrotic scars are present it is recommended that the fluence and cooling temperature be decreased by 20 - 50%.
- **Atrophic Scars** – Depressed scars can be treated less aggressively and possibly more frequently. Using a lower fluence may help avoid injury to the thinner epidermis of atrophic tissue. It is recommended that when treating over depressed areas, fluence and cooling temperature be decreased by 20-50%.

9.6.7.1 1319 nm Nd:YAG ThermaScan Fine Lines/Wrinkle or Acne Scar Treatment

Treatment Basics

- Hair that is present in the area to be treated should be shaved prior to treatment. There should be no more than 0.5 mm hair growth, or very minimal stubble, present in treatment area. The longer the hair, the greater the risk of burning the hair to the patient's skin and also "pitting" or damaging the 5 mm HF Scanner chill plate window.
- Patient should be positioned based on the area to be treated. The position should be comfortable to the patient and such that the treatment provider has good access to area to be treated and the system control panel display screen.
- A mild cleanser or alcohol gauze should be used to remove any dirt, makeup, deodorant or moisture from the treatment site.
- If topical anesthetic is to be used, apply as directed prior to treatment. Before beginning treatment, ensure that topical has been completely removed from surface of skin.
- Apply a thin layer (1 mm) of colorless gel to area to be treated. The gel should be used during the 1319 nm wavelength treatment for optimal heat removal to help protect the epidermis, as well as improved optical coupling and lubrication for sliding the chill plate over skin. The gel also simulates contact with the skin and reduces the risk of "pitting" or damage to the 5 mm HF Scanner chill plate window.
- Connect the 5 mm HF Scanner to the articulated arm.
- Water condensation on the upper surface of the chill plate may result in laser beam scattering and an incorrect setting for fluence. Apply the surfactant, Sea Drops, to the upper side of the 5 mm HF Scanner chill plate window before turning on the external Contact Cooler. Reapply as needed.
- Connect external Contact Cooler to the 5 mm HF Scanner and then turn the cooler on.
Note: Always test the chill plate window for desired level of chilling before beginning any laser treatment. The risk of epidermal injury such as blistering increases with decreased or ineffective cooling.



Eye protection should always be worn by everyone present in the treatment room during any laser or light based treatment. When treating on the patient's face, the patient should always wear external, matte-finish metal goggles.

- Select starting settings based on ThermaScan Fine Lines/Wrinkles & Acne Scar Treatment Starting Parameters referenced below.
- The 5 mm HF Scanner should be held perpendicular to the surface of the skin at all times. Move patient if necessary to accomplish this 90 degree angle. All areas of the chill plate within the red box, should be in complete contact with skin at all times throughout entire scan. For highly curved areas, select a smaller scan pattern or select Pattern Center to offset the pattern to the top edge of the chill plate to ensure that treatment area inside the red box is completely flat on the skin.
- **Treating Test Area:** Treating a test area prior to beginning treatment will determine the patient's response threshold and help establish safe and effective treatment parameters.
 - Select test settings based on ThermaScan Fine Lines/Wrinkles & Acne Scar Treatment Starting Parameters below.
 - Set the scan pattern size to 2 x 2 or 3 x 3 especially if the treatment area is small. This will allow adequate area for test spots rather than treating the entire area.
 - Depress the foot switch to deliver the entire scan pattern. Another scan pattern will not be delivered unless the footswitch is depressed again or if repeat is turned on.
 - Wipe off gel and observe test area for immediate endpoints; light, uniform erythema within a few minutes of treatment and the patient's report of a mild to moderate heat sensation in the area being treated.
 - If desired endpoints are observed with no adverse effects, treatment can be continued until area is completed.

- If endpoints are not noted, increase the intensity of treatment by the following actions, in the following order (make only one change per test pulse):
 - Increase fluence by **2 J/cm²**
 - Increase the rate by **0.5 - 1 Hz**
- If reaction to test spot is too severe (intense erythema, purpura, immediate white or grey presentation of skin), the settings should be decreased in intensity by the following actions, in the following order:
 - Decrease fluence by **2 - 4 J/cm²** depending on intensity of reaction
 - Decrease rate by **0.5 - 1 Hz** depending on intensity of reaction
- Match the trailing edge of one scan pattern to the leading edge of the next. There should be no overlap between scans. Scan patterns should "line up" right next to each other.

ThermaScan Fine Lines/Wrinkles & Acne Scar Treatment Starting Parameters

Skin Type	Fluence (J/cm ²)	Pulse Width (ms)	Repetition Rate (Hz)	Cooling (°C)
I - VI	12 - 16	50	1 - 3	12
<u>Note:</u> In areas where skin is thinner and the bone is closer to the surface (such as jaw line, cheek bones, clavicle, shins, shoulders, knees etc.) fluence should be decrease by 20%. Decrease fluence and temperature by 20 - 50% when treating over a fibrotic or depressed scar. Use a slower rep rate (1.5 Hz or less) if the scan pattern is a 2 x 2 or 2 x 3.				

Endpoints

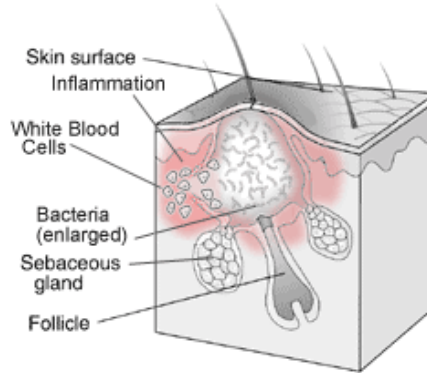
- Light, uniform erythema within a few minutes of treatment.
- Mild to moderate heat sensation in the area being treated.

Post Treatment

- Observation – Light erythema for up to several hours after treatment. Patients may feel like they have a moderate sunburn in the treatment area for up to two hours after the treatment.
- Intervention – Cool compresses or ice packs can provide some comfort after treatment. If blistering occurs, aggressive wound healing measures should be implemented.
- Interval – Treatments are performed 4 weeks apart. 4 - 5 treatments may be required.
- 1319 nm Nd:YAG ThermaScan Fine Lines/Wrinkles & Acne Scar Treatments may be given in combination with MLP, and/or ProFractional/ProFractional-XC/III.
- If performing 1319 nm Nd:YAG ThermaScan Fine Lines/Wrinkles & Acne Scar Treatment in conjunction of other procedures such as MLP or ProFractional, perform ThermaScan first.
- Check with manufacturer for guidelines on using injectables in conjunction with 1319 nm Nd:YAG ThermaScan Fine Lines/Wrinkles & Acne Scar Treatment.

9.6.8 Safe Start Protocol for 1319 nm Nd:YAG ThermoScan Acne Treatment

Acne is a disorder resulting from the action of hormones and other substances on the skin's oil glands or sebaceous glands. These factors lead to plugged pores and outbreaks of lesions commonly called pimples. Acne lesions usually occur on the face, neck, back, chest, and shoulders. Although acne is usually not a serious health threat, it can be a source of significant emotional distress. Severe acne can also lead to permanent scarring.



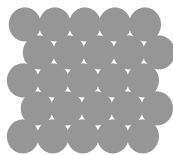
How does ThermoScan (1319 nm) work?

The epidermis is a robust and resilient structure at the surface of the skin. It functions as a physical barrier to protect the deeper dermis and to retain the skin's hydration. It is less hydrated than the dermis resulting in less absorption of energy at 1319 nm than in the dermis since energy at a wavelength of 1319 nm is preferentially absorbed in water and collagen. The energy absorbed by the targeted areas generates heat in and around the sebaceous glands. By creating a mild thermal injury just below the skin's surface, ThermoScan alters the structure and function of the sebaceous gland. This leads to a reduction of oil production and as a result, a clearance of the acne.

The 5 mm HF Scanner has a contact cooling chill plate assembly attached to it. The assembly is comprised of two sapphire plates that are separated by continuously flowing Chiller Mixture. The spot placement is achieved by using two galvanometer motors for x-axis and y-axis displacement.



5 mm HF Scanner chill plate

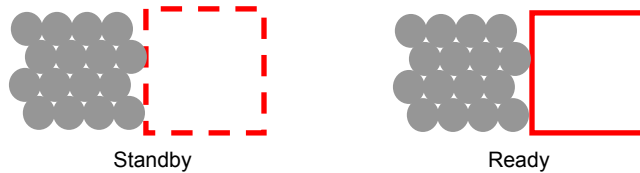


5 x 5 pattern

The 5 mm HF Scanner precisely places each pulse in a non-sequential pattern to eliminate improper placement of individual pulses. It also maximizes the time interval between adjacent spots and minimizes subsurface heat buildup.

The 5 mm HF Scanner allows for complete and uniform application of the laser energy by delivering 5 mm spots of energy within a designated pattern shape and size. The pattern can be adjusted from a 1 x 1 (single spot) to 6 x 6 with any variation in between. A 5 x 5 pattern is illustrated above.

Aiming beam is represented by red box and shows the user the area to be treated. The energy will be delivered inside the red box. When the red box is "dancing" the system is in Standby. When the red box is solid the system is in Ready.

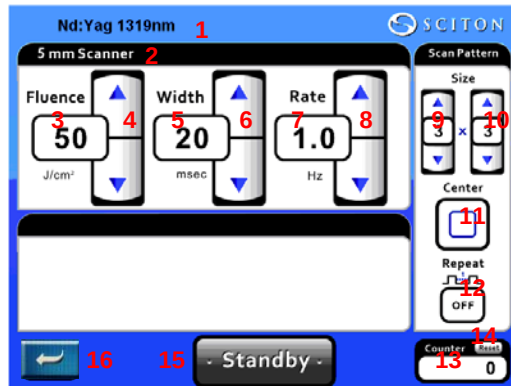


Care should be taken to apply adjoining scans without gap or excessive overlap of the previously scanned area. A mental picture of where the next scan pattern should be placed will assist in lining each scan pattern up to each other to avoid gap or overlap as shown above.

To achieve safe, uniform treatment as shown, the scanner should be held so that the red box within the chill plate window is in complete contact with the skin at all times.

1319 nm Scanner Application User Screen

Attach the 5 mm HF Scanner to the articulated arm. Press the Scanner softkey on the 1319 nm Application screen and the system will enter the Nd:YAG 1319 nm application screen.



The Nd:YAG 1319 nm user screen allows the user to adjust treatment settings. The available functions are described below.

1. Wavelength indicator
Wavelength indicator shows which wavelength is being used for the treatment.
2. Handpiece indicator
Handpiece indicator shows which handpiece is being used for the treatment.
3. Fluence indicator
Fluence indicator shows the amount of fluence or energy being delivered per 5 mm spot within whatever size or shape scan pattern has been selected. Fluence is measured in joules per centimeter squared, J/cm².
4. Fluence adjustment softkeys
Fluence adjustment softkeys allow the user to increase or decrease fluence by 1 J/cm² by tapping or holding down the up ▲ or down ▼ arrow softkeys.
5. Pulse width indicator
Pulse width indicator shows the length of time the energy is being delivered per 5 mm spot within whatever size or shape scan pattern has been selected. Pulse width is measured in milliseconds (ms).
6. Pulse width adjustment softkeys
Pulse width adjustment softkeys allow the user to increase or decrease pulse width by 5 ms by tapping or holding down the up ▲ or down ▼ arrow softkeys.
7. Spot placement rate
Spot placement rate is the speed at which each 5 mm spot is being delivered within the scan pattern. The speed is measured in Hz. The maximum rate is automatically limited by the laser based on the fluence and pulse width.
8. Spot placement rate adjustment softkey
Spot placement rate adjustment softkeys allow the user to increase or decrease the rate at which each 5 mm spot is being delivered by 0.5 Hz by tapping or holding down the up ▲ or down ▼ arrow softkeys.

9. Vertical pattern selection softkeys

The vertical pattern selection softkeys allow the user to increase or decrease the vertical size of the pattern from 1 to 6 spots.

10. Horizontal pattern selection softkeys

The horizontal pattern selection softkeys allow the user to increase or decrease the horizontal size of the pattern from 1 to 6 spots.

11. Pattern center softkey

Pattern center allows the user to offset the area to be treated to the upper left corner, upper middle, upper right corner or the center of the chill plate window.



12. Pattern repeat softkey

Pattern repeat will allow the user to set an amount of time between consecutive scans of 1, 2, 3, 4, or 5 seconds by tapping the Repeat softkey. Repeat can also be turned off so that each scan pattern is delivered by lifting and depressing the footswitch.

13. Number of accumulated pulses indicator

Number of accumulated pulses indicator shows how many pulses have been delivered since the system was turned on or since the last time the reset softkey for accumulated pulses was reset.

14. Accumulated pulses reset softkey

Accumulated pulses reset softkey allows the user to reset the number of accumulated pulses to 0 by touching the reset softkey.

15. System status softkey

System status softkey will allow the user to put the system in Standby or Ready.

16. Return to 1319 nm Applications Screen

Return to 1319 nm Applications softkey will return the system to the previous screen.

Surface Cooling

When performing 1319 nm Nd:YAG ThermoScan Acne Treatment, the use of a contact cooler is critical for ensuring patient safety.

Either the paddle chill plate or the single spot chill plate can be used for the treatment.



Paddle chill plate



Bayonet distance guide

The bayonet distance guide assures that proper distance from the paddle chill plate is maintained throughout the treatment for accurate spot size delivery.



Single spot handpiece with bayonet distance guide attached

Paddle chill plate



Single spot chill plate

Single spot chill plate with handpiece attached



Managing patient expectations

Patients should understand that to obtain optimal results with 1319 nm Nd:YAG ThermaScan Acne Treatment, a minimum of 4 - 7 treatments are required. Repeated treatments lead to an observable reduction in active acne in 2 to 4 weeks. Results of acne treatments have been reported to last up to 6 months.

Treating scars

- **Fibrotic Scars** – Dense fibrotic tissue can blister at a lower temperature than normal tissue. In areas where fibrotic scars are present it is recommended that the fluence and cooling temperature be decrease by 20 - 50%.
- **Atrophic Scars** – Depressed scars can be treated less aggressively and possibly more frequently. Using a lower fluence may help avoid injury to the thinner epidermis of atrophic tissue. It is recommended that when treating over depressed areas, fluence and cooling temperature be decreased by 20-50%.

9.6.8.1 1319 nm Nd:YAG ThermaScan Acne Treatment

Treatment Basics

- Hair that is present in the area to be treated should be shaved prior to treatment. There should be no more than 0.5 mm hair growth, or very minimal stubble, present in treatment area. The longer the hair, the greater the risk of burning the hair to the patient's skin and also "pitting" or damaging the 5 mm HF Scanner chill plate window.
- Patient should be positioned based on the area to be treated. The position should be comfortable to the patient and such that the treatment provider has good access to area to be treated and the system control panel display screen.
- A mild cleanser or alcohol gauze should be used to remove any dirt, makeup, deodorant or moisture from the treatment site.
- If topical anesthetic is to be used, apply as directed prior to treatment. Before beginning treatment, ensure that topical has been completely removed from surface of skin.
- Apply a thin layer (1 mm) of colorless gel to area to be treated. The gel should be used during the 1319 nm wavelength treatment for optimal heat removal to help protect the epidermis, as well as improved optical coupling and lubrication for sliding the chill plate over skin. The gel also simulates contact with the skin and reduces the risk of "pitting" or damage to the 5 mm HF Scanner chill plate window.
- Connect the 5 mm HF Scanner to the articulated arm.
- Water condensation on the upper surface of the chill plate may result in laser beam scattering and an incorrect setting for fluence. Apply the surfactant, Sea Drops, to the upper side of the 5 mm HF Scanner chill plate window before turning on the external Contact Cooler. Reapply as needed.
- Connect external Contact Cooler to the 5 mm HF Scanner and then turn the cooler on. *Note: Always test the chill plate window for desired level of chilling before beginning any laser treatment. The risk of epidermal injury such as blistering increases with decreased or ineffective cooling.*



Eye protection should always be worn by everyone present in the treatment room during any laser or light based treatment. When treating on the patient's face, the patient should always wear external, matte-finish metal goggles.

- Select starting settings based on ThermaScan Acne Treatment Starting Parameters referenced below.
- The 5 mm HF Scanner should be held perpendicular to the surface of the skin at all times. Move patient if necessary to accomplish this 90 degree angle. All areas of the chill plate within the red box, should be in complete contact with skin at all times throughout entire scan. For highly curved areas, select a smaller scan pattern or select Pattern Center to offset the pattern to the top edge of the chill plate to ensure that treatment area inside the red box is completely flat on the skin.
- **Treating Test Area:** Treating a test area prior to beginning treatment will determine the patient's response threshold and help establish safe and effective treatment parameters.
 - Select test settings based on ThermaScan Acne Treatment Starting Parameters below.
 - Set the scan pattern size to 2 x 2 or 3 x 3 especially if the treatment area is small. This will allow adequate area for test spots rather than treating the entire area.
 - Depress the foot switch to deliver the entire scan pattern. Another scan pattern will not be delivered unless the footswitch is depressed again or if repeat is turned on.
 - Wipe off gel and observe test area for immediate endpoints; light, uniform erythema within a few minutes of treatment and the patient's report of a mild to moderate heat sensation in the area being treated.
 - If desired endpoints are observed with no adverse effects, treatment can be continued until area is completed.
 - If endpoints are not noted, increase the intensity of treatment by the following actions, in the following order (make only one change per test pulse):

- Increase fluence by **2 J/cm²**
- Increase the rate by **0.5 - 1 Hz**
- If reaction to test spot is too severe (intense erythema, purpura, immediate white or grey presentation of skin), the settings should be decreased in intensity by the following actions, in the following order:
 - Decrease fluence by **2 - 4 J/cm²** depending on intensity of reaction
 - Decrease rate by **0.5 - 1 Hz** depending on intensity of reaction
- Match the trailing edge of one scan pattern to the leading edge of the next. There should be no overlap between scans. Scan patterns should “line up” right next to each other.

ThermaScan Acne Treatment Starting Parameters

Skin Type	Fluence (J/cm ²)	Pulse Width (ms)	Repetition Rate (Hz)	Cooling (°C)	Passes
I - VI	12	50 - 200	0.5 - 3	5 - 12	1 - 2
<u>Note:</u> In areas where skin is thinner and the bone is closer to the surface (such as jaw line, cheek bones, clavicle, shins, shoulders, knees etc.) fluence should be decrease by 20%. Decrease fluence and temperature by 20 - 50% when treating over a fibrotic or depressed scar. Use a slower rep rate (1.5 Hz or less) if the scan pattern is a 2 x 2 or 2 x 3.					

Endpoints

- Light, uniform erythema within a few minutes of treatment.
- Mild to moderate heat sensation in the area being treated.

Post Treatment

- Observation – Light erythema for up to several hours after treatment. Patients may feel like they have a moderate sunburn in the treatment area for up to two hours after the treatment.
- Intervention – Cool compresses or ice packs can provide some comfort after treatment. If blistering occurs, aggressive wound healing measures should be implemented.
- Interval – Treatments are performed 4 weeks apart. 4 - 5 treatments may be required.
- 1319 nm Nd:YAG ThermaScan Acne Treatments may be given in combination with MLP, and/or ProFractional/ProFractional-XC/III.
- If performing 1319 nm Nd:YAG ThermaScan Acne Treatments in conjunction of other procedures such as MLP or ProFractional, perform ThermaScan first. If using the 420 nm filter with the BBL in combination with the ThermaScan (1319 nm) Acne treatment, the 420 nm filter can be used before or after the 1319 nm.
- Check with manufacturer for guidelines on using injectables in conjunction with 1319 nm Nd:YAG ThermaScan Acne Treatments.

9.6.9 Safe Start Protocol for 1319 nm Nd:YAG ThermaScan Single Acne Lesion Treatments

The 1319 nm Nd:YAG ThermaScan Acne Treatment protocol is utilized when treating individual acne lesions.

The 6 mm single spot handpiece is used for 1319 nm Nd:YAG ThermaScan Single Acne Lesion treatments.



6 mm Single Spot Handpiece

1319 nm Single Spot Application User Screen

Attach the 6 mm single spot handpiece to the articulated arm. Press the Single Spot softkey on the 1319 nm Application screen and the system will enter the Nd:YAG 1319 nm application screen.



The Nd:YAG (1319 nm) user screen allows the user to adjust treatment settings. The available functions are described below.

1. Wavelength indicator
Wavelength indicator shows which wavelength is being used for the treatment.
2. Handpiece spot size indicator
Handpiece spot size indicates that 6 mm single spot handpiece is attached to the articulated arm.
3. Fluence indicator
Fluence indicator shows the amount of fluence or energy being delivered. Fluence is measured in joules per centimeter squared, J/cm^2 .
4. Fluence adjustment softkeys
Fluence adjustment softkeys allow the user to increase or decrease fluence by $1 \text{ J}/\text{cm}^2$ by tapping or holding down the up ▲ or down ▼ arrow softkeys.
5. Pulse width indicator
Pulse width indicator shows the length of time the energy is being delivered per 6 mm spot. Pulse width is measured in milliseconds (ms) and depending upon fluence setting can be adjusted from 10 to 200 ms.
6. Pulse width adjustment softkeys
Pulse width adjustment softkeys allow the user to increase or decrease pulse width by 5 ms by tapping or holding down the up ▲ or down ▼ arrow softkeys.
7. Repetition rate indicator
Repetition rate is the amount of time between each single spot delivery when the footswitch is held down continuously. 1319 nm Nd:YAG ThermaScan Single Acne Lesion treatment is always performed in the shot mode.
8. Repetition rate adjustment softkeys
Repetition rate adjustment softkeys allow the user to increase or decrease each single spot

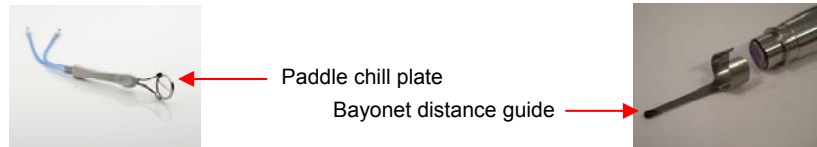
delivery from a single shot to 0.3 Hz up to 6.6 Hz (15 spots per second) by tapping or holding down the up ▲ or down ▼ arrow softkeys.

9. Aiming beam intensity softkey
Aiming beam intensity allows the user to make the aiming beam dimmer or brighter in intensity. MIN, 1, 2, 3, 4, 5 or MAX intensity can be selected by tapping the Aim softkey.
10. Number of accumulated pulses indicator
Number of accumulated pulses indicator shows how many pulses have been delivered since the system was turned on or since the last time the reset softkey for accumulated pulses was reset.
11. Accumulated pulses reset softkey
Accumulated pulses reset softkey allows the user to reset the number of accumulated pulses to 0 by touching the reset softkey.
12. System status softkey
System status softkey will allow the user to put the system in Standby or Ready.
13. Return to 1319 nm Applications screen softkey
The Return to 1319 nm Applications softkey will return the system to the previous screen.

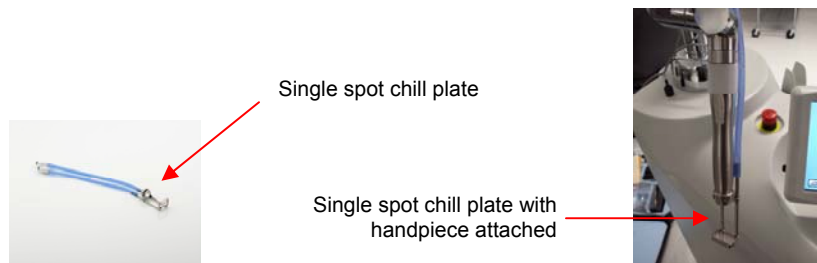
Surface Cooling

When performing 1319 nm Nd:YAG ThermoScan Single Acne Treatments, the use of a contact cooler is critical for ensuring patient safety.

Either the paddle chill plate or the single spot chill plate can be used for the treatment.



The bayonet distance guide assures that proper distance from the paddle chill plate is maintained throughout the treatment for accurate spot size delivery.



Refer to 1319 nm Nd:YAG ThermoScan Acne treatment protocol for Treatment Basics.

ThermoScan Single Lesion Acne Treatment Starting Parameters

Skin Type	Fluence (J/cm ²)	Pulse Width (ms)	Repetition Rate (Hz)	Cooling (°C)	Passes
I - VI	12	50 - 200	shot	5 - 12	1

Note:

In areas where skin is thinner and the bone is closer to the surface (such as jaw line, cheek bones, clavicle, shins, shoulders, knees etc.) fluence should be decrease by 20%.

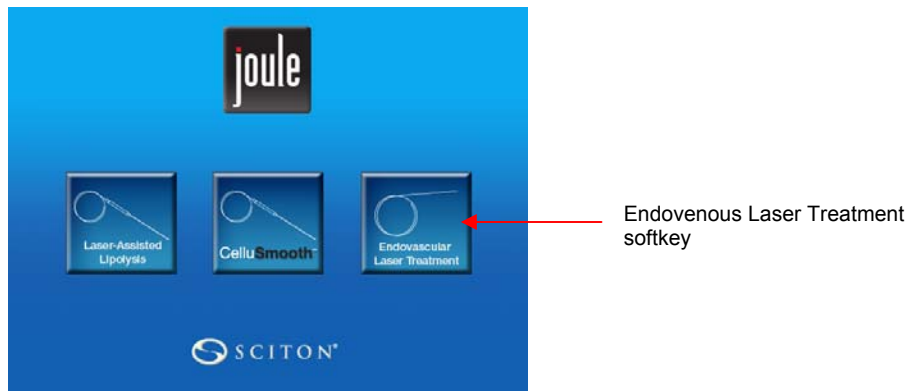
Decrease fluence and temperature by 20 - 50% when treating over a fibrotic or depressed scar.

Endovenous Treatment

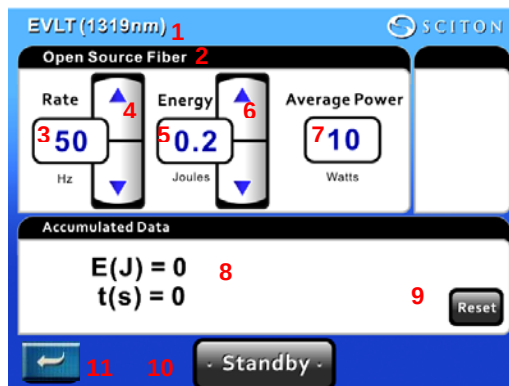
9.7 1319 nm Nd:YAG Pro-V Endovenous Ablation Treatment

Pro-V emits a mid-infrared wavelength of 1319 nm to heat water within the vein, limiting damage to the vein itself, causing it to contract and collapse. This enables the Pro-V to treat veins without contact of the vein wall, minimizing the risk of bruising, discomfort, and perforation of veins.

The Pro-V treatment is provided using the endovenous laser treatment EVLT (1319 nm), User Screen which is accessed from the Fiber Applications Screen.



Pressing the Endovascular Laser Treatment softkey will allow the user to enter into the EVLT (1319 nm) user screen.



The EVLT (1319 nm) user screen allows the user to adjust treatment settings. The available functions are described below.

1. Application and wavelength indicator
Application and wavelength indicator shows the user is in the EVLT user screen and that the 1319 nm wavelength is being used for the treatment.
2. Open source fiber indicator
An open source fiber with 600 μm core diameter, which is fitted with a high power SMA-905 connector, can be used to perform endovenous treatment.



Use only fibers that are fitted with high power SMA-905 connectors.
Use of fibers without high power connectors may lead to premature failure of the laser system and void existing warranty on the system.

3. Rate indicator
Rate indicator displays the repetition rate at which the energy is being delivered and is measured in Hz.
4. Rate adjustment softkeys
Rate adjustment softkeys allow the user to increase or decrease the rate by 1 Hz by tapping or holding down the up ▲ or down ▼ arrow softkeys.
5. Energy indicator
Energy indicator shows the amount of energy being delivered. Energy is measured in Joules.
6. Energy adjustment softkeys
Energy adjustment softkeys allow the user to increase or decrease energy by 0.025 Joules by tapping or holding down the up ▲ or down ▼ arrow softkeys.
7. Average power indicator
Average power indicator shows the amount of power being delivered in Watts.
8. Accumulated Data indicator
Accumulated Data displays the total energy being delivered in Joules and the total time of the treatment in seconds.
9. Accumulated Data reset softkey
Accumulated Data reset softkey allows the user to reset the total energy delivered and the total treatment time to zero (0).
10. System status softkey
System status softkey will allow the user to put the system in Standby or Ready.
11. Return to Fiber Applications screen
Return to Fiber Applications softkey will return the system to the previous screen.

9.7.1 Indications for Use

The Pro-V endovenous platform with fiber delivery is indicated for the treatment of reflux of great and small saphenous veins associated with varicose veins and varicosities, and for treatment of incompetence and reflux of superficial veins in the lower extremity.

9.7.2 Contraindications

The 1319 nm Nd:YAG Pro-V laser system is contraindicated for:

- Patients with coagulopathy
- Patients who have arteriovenous malformations in the vein segment being treated
- Patients with ongoing deep vein thrombosis
- Patients who have non-palpable pedal pulses
- Patients with peripheral arterial disease indicated by ankle-brachial index (ABI) of < 0.7
- Patients who are pregnant
- Patients with the inability to ambulate
- Patients with active localized or systemic infection
- Patients who are immunocompromised

9.7.3 Precautions

POSSIBLE NEURAL AND CUTANEOUS INJURY: Treatment of the vein in the leg below the knee is associated with an increased risk of neural and cutaneous injury.

9.7.4 Complications

Complications, though rare, occasionally occur and should be discussed and understood. The patient must understand the importance of the post care instructions and that failure to comply may increase the probability of complications, such as:

- Pain
- Edema
- Ecchymosis
- Paresthesia
- Hematoma
- Phlebitis
- Thrombus
- Skin thermal injury, pigmentary changes and infection

9.7.5 Warnings

Possible complications specific for Pro-V endovenous ablation include:

- Vascular disruption
- Inadequate deep vein penetration and thrombosis, particularly at the saphenofemoral junction
- Collateral tissue injury, particularly neural and dermal

9.7.6 Causes of Varicose Veins

Most patients develop varicose veins from the hydrostatic forces produced by reflux that results from primary valvular insufficiency.

Arteries carry blood from your heart to the rest of your tissues. Veins return blood from the rest of your body to your heart, so the blood can be recirculated. To return blood to the heart, the veins in legs must work against gravity. Muscle contractions in the lower legs act as pumps, and elastic vein walls help blood return to the heart. Tiny valves in the veins open as blood flows toward the heart then close to stop blood from flowing backward.

Age - As one gets older, the veins can lose elasticity causing them to stretch. The valves in the veins may become weak, allowing blood that should be moving toward your heart to flow backward. Blood pools in the veins, and the veins enlarge and become varicose.

Pregnancy - Some pregnant women develop varicose veins. Pregnancy increases the volume of blood in the body, but decreases the flow of blood from the legs to your pelvis. This circulatory change is designed to support the growing fetus, but it can produce an unfortunate side effect - enlarged veins in the legs. Varicose veins may surface for the first time or may worsen during late pregnancy, when the uterus exerts greater pressure on the veins in the legs. Changes in the hormones during pregnancy also may play a role. Varicose veins that develop during pregnancy generally improve without medical treatment within three months after delivery.

9.7.7 Getting Started

9.7.7.1 Consultation/Education

A consultation is essential in order to establish realistic expectations and to gain a full understanding of the patient and his/her treatment goals. The patient must understand the procedure, pre and post care instructions, expectations, contraindications and possible complications prior to beginning any treatment.

9.7.7.2 Physician Exam & Medical History

A physical exam and detailed medical history outlining any former or active medical condition or medication that is contraindicated or that could possibly affect the outcome of the treatment should be obtained prior to treatment.

9.7.7.3 Informed Consent

The process of accepting and confirming treatment must be reviewed, understood and signed by the patient prior to treatment. This document must review the topics discussed during the consultation. It acknowledges that the patient understands the procedure, possible risks and complications and that all questions have been answered.

Reference sample Informed Consent in Appendix of this manual.

9.7.7.4 Photographs

Pictures should be taken prior to each treatment to document the progress of the treatment. Photographs are useful in demonstrating efficacy of treatment to the patient.

Camera settings, distance, backdrop, and body/face angle, position and expression should be the same for each photography session to maintain similar quality.

The patient should sign a photo release form if before and after pictures are to be used for educational or marketing purposes.

9.7.7.5 Eye Protection

Eye protection should always be worn by everyone present in the treatment room during any laser or light based treatment.

9.7.8 1319 nm Nd:YAG Varicose Vein Treatment

Treatment Basics

Pro-V procedures are considered a more advanced treatment. Sciton recommends that each user attend a Preceptor training course prior to offering Pro-V procedures to their patients. Treatment specifics will be reviewed and discussed during the preceptorship.

Below are basic guidelines for any Pro-V procedure. Specifics will vary with physician preference.

9.7.8.1 Patient Selection and Examination

1. Obtain description and intensity of symptoms from the patient.
2. Perform a physical examination of the extremities.
3. Determine the origin of reflux and map the greater saphenous vein (GSV) using continuous wave Doppler and duplex ultrasound imaging.
4. Make transverse measurements of the GSV, 2-3 cm below the saphenofemoral junction (SFJ) and along the course of the GSV.
5. Obtain hard copy documentation of GSV diameter and reflux.
6. Note length of vein to be treated.
7. Take photograph of the leg.
8. Obtain signed informed consent document from patient.

9.7.8.2 The Procedure

1. After sterile prepping and draping of the leg, the ultrasound probe is placed into a sterile probe cover.
2. Administer local anesthesia to the treatment site.
3. Using ultrasound guidance make percutaneous entry with a 21-gauge 7cm needle into the GSV, around the knee level.
4. Insert a 0.018" diameter guide wire into the vein through the needle.
5. Remove and discard the needle.
6. Introduce the coaxial catheter pair.
7. Remove and discard inner catheter and guide wire.
8. Insert 0.035" diameter guide wire.
9. Insert a 5 French 45 cm introducer sheath over the guide wire. Advance the sheath to at least the SFJ.
10. Confirm placement of sheath at the SFJ using ultrasound and then remove the guide wire.
11. Wear safety glasses appropriate for 1319 nm; patient as well as all staff in treatment room.
12. Insert the sterile laser fiber into the sheath and advance. The fiber is positioned with its tip 2 cm below the SFJ.



Laser fibers are inherently fragile and so care should be exercised in handling them.

13. Visualize the aiming beam through the patient's skin.
14. Administer peri-venous local anesthesia along the GSV.
Note: The choice of local anesthetic regime may vary from physician to physician.
15. Confirm the laser fiber tip position using ultrasound and pull the introducer sheath out of the vein, leaving only the proximal tip in the skin edge.



Do not begin laser treatment with the fiber inside the introducer sheath. Intravascular burning of the sheath by the laser beam may damage the sheath and/or cause a patient reaction.

16. Set laser treatment parameters.

The treatment parameters may vary based on experience and preceptor visit observations.

Fiber size: **600 µm core diameter**
 Rate: **40 Hz**
 Energy: **0.200 Joules**
 Average Power: **8.0 Watts**

- Set laser system to READY mode.

17. Begin the laser treatment by steadily pulling back the laser fiber at the rate appropriate for the patient's condition. **0.5 mm/sec to 1 mm/sec** are common pullback rates. Observe tissue response on ultrasound for the following:

- Slowing or stopping of forward movement of flow.
- Thickening of the vein wall
- Contraction of the vein
- Decrease in size of the vein lumen

***Note:** If use of pullback device is desired, set up the pull-back device by adjusting the height and position of the pull-back so that the fiber has a straight, unobstructed pathway to the device. Make sure that the pull-back device is positioned so that the arrows indicate the correct direction of the fiber movement. Insert the fiber into the pull-back device, ensuring that the fiber is positioned over the roller wheel. Remove the slack in the fiber so that it is taut and close the device lid. Run the device at 1 mm/sec during treatment.*



Inserting Fiber into Pull-Back Device



Stop the pull-back device if laser treatment is interrupted to avoid untreated segments of the vein. Not doing so may result in under-treatment or no treatment for some segments.

Do not continue laser treatment unless the aiming beam is present and fiber movement is confirmed.

18. Place fingers on either side of the fiber at the exit point from the skin to verify movement and to support the fiber as it is being pulled out.
19. When the fiber is a few centimeters from the access site, stop laser treatment and turn off the pull-back device. Remove the introducer sheath completely from the vein and resume laser treatment with a manual pull back of the fiber until the fiber exits the vein.
20. Following the treatment, observe the appearance of the vein with the ultrasound:
 - Vein appears more dense and thickened (more echogenic)
 - Vein is less compressible with pressure from the ultrasound probe
 - Vein lumen is noticeably smaller in size
 - Vein does not demonstrate spontaneous flow
21. Document laser treatment parameters including:
 - Fiber size, Watts and Hz
 - Pull-back speed and treatment length.
22. Apply dressing at the completion of the procedure
 - Steri-Strips®

- Absorbent dressing over access site
- 3 inch conform tape wrap
- Elastic bandage with E-Z clips.

9.7.8.3 Post Treatment Instructions

1. The patient should begin walking immediately after dressings are in place.
2. Post treatment care will vary with physician preference and should include instructions for:
 - Dressing and wound care
 - Use of compression stockings
 - Activity level
 - When to return for follow-up appointments

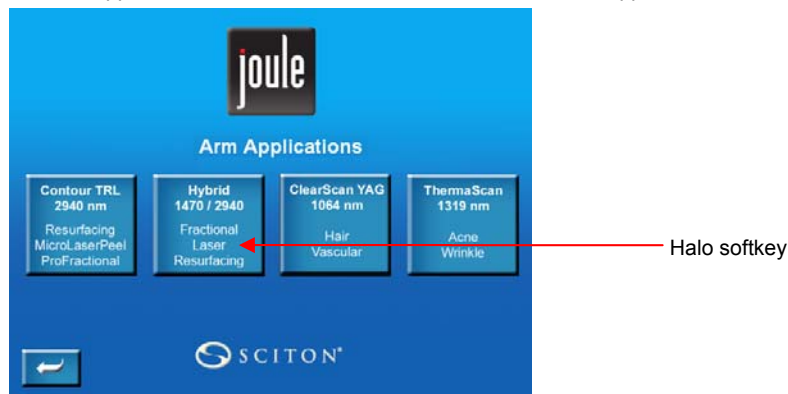
Halo™ Hybrid Fractional Laser (HFL)

9.8 1470/2940 nm Halo Hybrid Fractional Laser

Halo Pro is a hybrid fractional resurfacing system that can sequentially utilize two wavelengths in its delivery, non-ablative 1470 nm and ablative 2940 nm. 1470 nm wavelength is absorbed by water making it ideal for non-ablation of soft tissue and creating controlled zones of coagulation to chosen depths into the dermis. Treating with Halo 1470 nm laser alone produces non-ablative channels only. Halo also uses 2940 nm for it is high absorption in water which results in precision ablation as desired in the epidermis. This combination allows for fractionated non-ablative and ablative skin resurfacing resulting in a cosmetic improvement in pigmentation, tone and texture of skin as well as other effects of photoaging.

Arm Application Menu Screen

The Arm Application menu screen allows the user to enter Halo application screen.



Pressing the Halo or Halo Pro softkey will allow the user to enter the appropriate application screens.



1. Application Header
The Application Header displays the selected Halo application.
2. Halo application softkey
Press the softkey to enter Halo user screen.
3. Halo Pro application softkey
Press the softkey to enter Halo Pro user screen.
4. Return to Arm Applications screen softkey
Touching this key will return the system to the previous screen

9.8.1 Indications for Use

1470 nm Indications for Use:

The JOULE 1470 nm Multi-Platform Systems and delivery accessories are intended for delivery of laser light to soft tissue for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue.

The JOULE 1470 nm Multi-Platform Systems with its handpiece and delivery system is intended for use in dermatological procedures requiring skin resurfacing and coagulation of soft tissue.

2940 nm Indications for Use:

The JOULE 2940 nm Multi-Platform Systems with delivery accessories are designed for use in surgical applications requiring the excision, incision, ablation, vaporization, and coagulation of soft tissue, and for skin resurfacing and treatment of wrinkles.

The JOULE 2940 nm Multi-Platform Systems with its handpiece and delivery system is intended for use in dermatological procedures requiring skin resurfacing, and ablation and coagulation of soft tissue.

9.8.2 Considerations

Halo (1470 nm) and Halo Pro (1470 nm and 2940 nm) have the following medical judgment considerations:

- Patients who use anticoagulant medications that may hinder coagulation or have predisposition of bruising
- Patients who are actively tanning, UV exposure
- Patients with undefined lesions
- Patients who are susceptible to Post Inflammatory Hyperpigmentation (PIH)
- Patients who have filler or injectables

9.8.3 Precautions

- Patients must be carefully evaluated by the physician for their risk of scarring versus treatment benefit.
- Treatment should be done in a conservative fashion in areas where the skin is thin, such as the temple and forehead areas.
- Post-treatment hyperpigmentation may occur after 3-4 weeks.
- Direct and intentional sun exposure should be avoided for 2 weeks post treatment. Daily use of sun block immediately after treatment, and for at least the next 30 days, is recommended to avoid pigment related complications.
- Patients who smoke may experience delayed healing and decreased benefit.
- Patients should avoid the use of Clarisonic™ skin care brushes and any other form of manual exfoliation of skin for at least 2 weeks after the treatment.
- Selection of patients must include evaluation of Fitzpatrick Skin Type (I-VI). The Halo and Halo Pro procedure is a fractionated non-ablative and ablative treatment that uses heat to vaporize the water in the dermal layer in the skin. The residual heat could lead to undesirable pigment related issues in darker skin types. Therefore, Halo and Halo Pro procedure should be used cautiously in the treatment of skin types V and VI.
- Halo and Halo Pro on non-facial tissues. The epidermis of the neck, chest, hands, and general body surfaces is thinner than that of the face and has fewer adnexal healing structures. Follow suggested parameters in protocol.

9.8.4 Contraindications

Halo (1470 nm) and Halo Pro (1470 nm and 2940 nm) is contraindicated for:

- Patients who are intolerant to anesthetic based agents
- Patients with infectious disease
- Patients with connective tissue disease
- Patients with propensity for keloid scar formations
- Patients who are immunocompromised or have compromised healing
- Patients who are on long-standing systemic steroids (e.g. Prednisone, Dexamethasone)
- Patients who are pregnant
- Patients who have used isotretinoin (Accutane) within the past year
- Patients with a medical condition that may affect wound healing

9.8.5 Complications

Complications, though rare, occasionally occur and should be discussed and understood. The patient must understand the importance of the post care instructions and that failure to comply may increase the probability of complications.

The potential complications of Halo are:

- Scarring- hypertrophic and non-hypertrophic
- Burns- from superficial to full thickness
- Extensive tissue destruction
- Ulceration
- Hyperpigmentation
- Hypopigmentation
- Induced bruising or petechiae formation
- Severe edema

9.8.6 Warnings

- In pretreatment work-ups, screen lesions that are located in proximity to known arteries or veins in order to locate these circulatory structures.
- Flammable inhalation general anesthetics must not be used. "Flash Fire" may occur. Oxygen levels in the direct operative area must not be higher than 30%.
- Do not allow combustibles or flammables, including drapes and paper gowns in the laser treatment area. Fire prevention/control methods should be in place.

9.8.7 Selective Photothermolysis

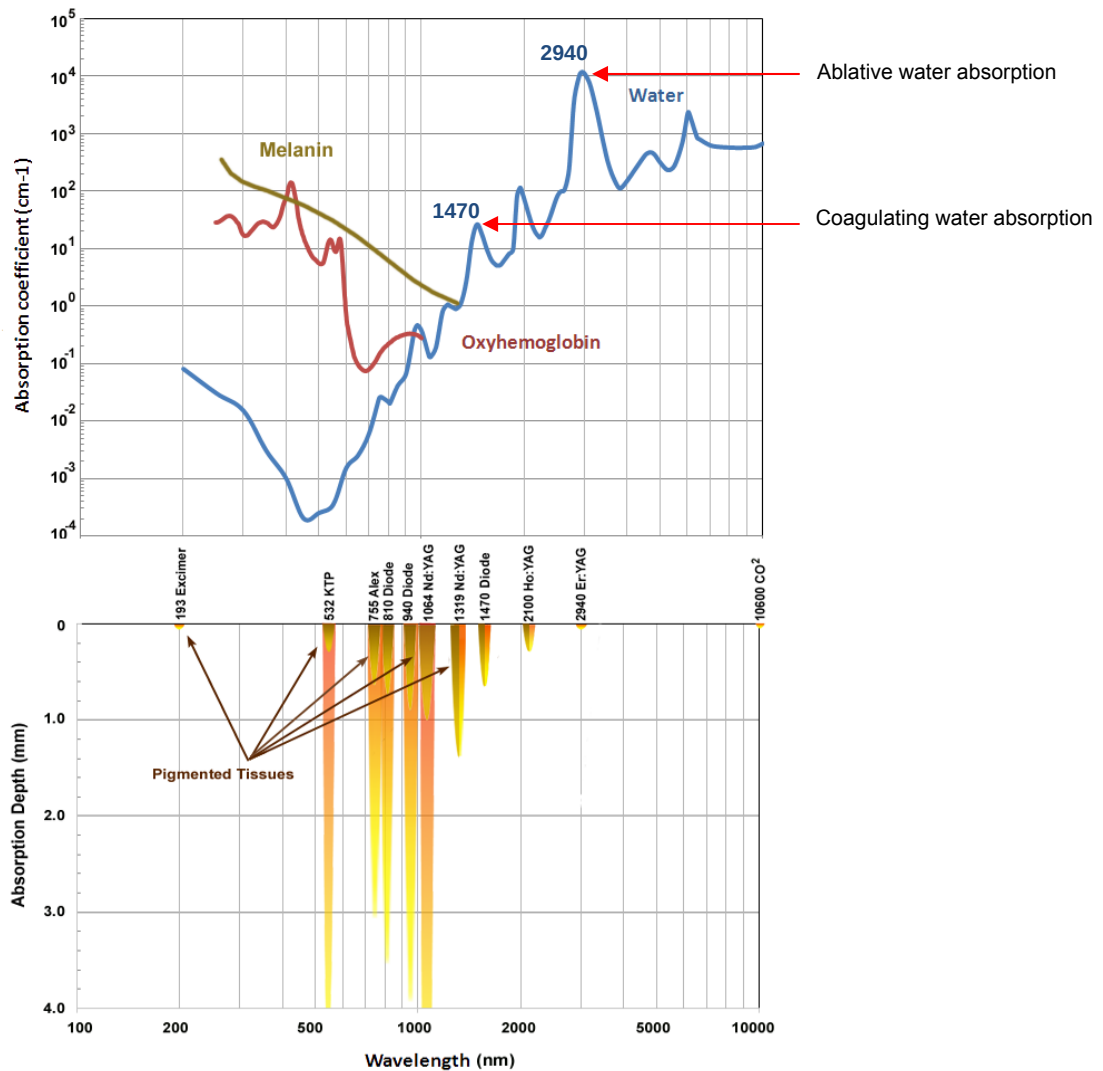
This technique relies on selective absorption of laser light to generate and confine heat at certain cellular targets. The goal of Selective Photothermolysis is to have sufficient energy penetrate to and be absorbed by the desired target while minimizing the effect on the surrounding tissue.

Absorption Curve

Absorption curve shows the relationship of the variation in absorbed laser light as a function of wavelength. The graphic shows absorption spectra of major intracellular absorbers. The molecular absorption coefficients of oxygenated hemoglobin, melanin and water are shown.

Depth of Penetration

Depth of penetration of laser energy for different types of lasers is seen illustrated.



- Based upon the principles of selective fractionated photothermolysis, Halo's use of 1470 nm laser wavelength selectively targets dermal tissue containing water and hemoglobin. It does not cause the water in the tissue to vaporize (ablate) but rather the laser energy heats the tissue in a controlled manner. This creates microscopic columns of wounded tissue that stimulate neocollagenesis, a process in which new collagen is produced by the body. The sequential use of 2940 nm wavelength selectively targets epidermis containing water and hemoglobin to precisely vaporize (ablate) tissue in a controlled manner. This hybrid use addresses both non-ablative and ablative delivery modalities.

9.8.8 Getting Started

9.8.8.1 Consultation/Education

A consultation is essential in order to establish realistic expectations and to gain a full understanding of the patient and his/her treatment goals. The patient must understand the procedure, pre and post care instructions, expectations, contraindications and possible complications prior to beginning any treatment.

9.8.8.2 Medical History

A detailed medical history should be obtained prior to treatment outlining any former or active medical condition or medication that is contraindicated or that could possibly affect the outcome of the treatment.

It is recommended that a brief medical history be taken before beginning any subsequent treatment by reviewing clinical information such as any new medications, skin care, sun exposure, pregnancy etc.

9.8.8.3 Skin Typing

Accurate skin typing is critical to treatment success and the avoidance of complications. It is important to know that in most situations an individual's previous response and genetic tendency to sun exposure will be the biggest indicators in establishing skin type. Some patients, such as Asians and Hispanics, may appear to be a skin type II or III and never tan but react to laser energy like a IV or V skin type. Hence, it is very important not to base skin type on appearance alone.

The skin type of a patient does not change. Do not confuse skin type with a tan. A person's skin type is something they are born with and it does not change, but the degree of tan can change.

Type	Hair Color	Skin Color and Ethnic Background	Eye Color	Sun Reaction
I	Red, White Blonde	Very fair <i>Scandinavian, Nordic, and North European</i>	Blue	Always burns, never tans
II	Red, Blonde, light brown	Fair <i>North European, Celtic (Scottish, Irish)</i>	Blue, green	Always burns, tans with difficulty and tends to be freckled
III	Sandy Blonde, Brown	Medium <i>Southern Europe</i>	Hazel, green, blue,	Burns initially, tans fairly well and evenly
IV	Brown, Black	Moderate brown, Olive <i>Mediterranean, Latin (Italian, Hispanic)</i>	Hazel, brown	Burns are rarely evident, tans easily
V	Black	Dark Brown <i>(Asian, Middle Eastern, American Indian)</i>	Dark brown, black	Burns are never evident, tans always <i>*some Asian skin always burns and never tans</i>
VI	Black	Black <i>(African-American, Indonesian)</i>	Dark brown, black	Burns are never evident, tans always



Skin type V is the most under-typed skin. Often Asians will look very light and have no history of sun exposure. Occasionally they have "bleached" their skin with hydroquinone. Treating them as a III or IV (based on look and reaction to sun) could result in higher risk of complications. Initially, all Asian skins should be treated as a Skin Type V until reaction to laser light has been determined.

Similarly, not all black skins are of the same degree of darkness and there may be the temptation to type these patients as a lower type.

9.8.8.4 Informed Consent

The process of accepting and confirming treatment must be reviewed, understood and signed by the patient prior to treatment. This document must review the topics discussed during the consultation. It acknowledges that the patient understands the procedure, possible risks and complications and that all questions have been answered.

Reference sample Informed Consent in Appendix of this manual.

9.8.8.5 Medication

To prevent the activation of a herpes simplex virus infection, it is recommended that an antiviral medication be prescribed.

Corticosteroid therapy may be considered to reduce significant post treatment swelling.

9.8.8.6 Photographs

Pictures should be taken prior to each treatment to document the progress of the treatment. Photographs are useful in demonstrating efficacy of treatment to the patient. Additionally, the use of UV photography and imaging is beneficial to demonstrate before and after effects.

Camera settings, distance, backdrop, and body/face angle, position and expression should be the same for each photography session to maintain similar quality.

The patient should sign a photo release form if before and after pictures are to be used for educational or marketing purposes.

9.8.8.7 Topical Anesthesia

Use a topical preparation to alleviate discomfort for sensitive patients or sensitive areas prior to treatment. The manufacturer's guidelines for the application and duration of the anesthetic should be read prior to topical application. Remove before treatment with mild soap and water or an alcohol swab, then plain water. Dry the area thoroughly before treatment.

Reminder: Each patient should be assessed and questioned regarding allergies or sensitivities to ingredients in topical anesthetics prior to application.



Be extremely cautious when applying topical anesthetics to large areas of the body. Lidocaine toxicity has been linked to several deaths.

9.8.8.8 Eye Protection

Eye protection should always be worn by everyone present in the treatment room during any laser or light based treatment. When treating on the patient's face, they should always wear non-reflective laser approved metal or disposable eye shields. Anytime a procedure is performed on the upper eyelid, internal corneal shields must be worn by the patient.

9.8.8.9 Smoke Evacuator

During surgical procedures using a laser or electrosurgical unit, the thermal destruction of tissue creates a smoke by-product. Research studies have confirmed that this smoke plume can contain toxic gases and vapors such as benzene, hydrogen cyanide, and formaldehyde, bio-aerosols, dead and live cellular material (including blood fragments), and viruses. At high concentrations the smoke causes ocular and upper respiratory tract irritation in health care personnel, and creates visual problems for the clinician. The smoke has unpleasant odors and has been shown to have mutagenic potential.

All medical personnel should consider the vaporized tissue plume to be potentially hazardous both in terms of the particulate matter and infectivity. A smoke evacuator should be used at all times when smoke is created in order to collect the plume. Surgical masks with 0.1µm filtration can be worn in addition to the use of a smoke evacuator. Halo Pro smoke evacuation tubing and adapter is used. One end of the hose is attached directly to the Halo disposable adapter. The other end is secured to the adapter to fit snugly on the smoke evacuator (see photo in treatment basics). A high level of suction is used of around 80%. Before treatment, with the Zimmer chiller unit, test adequate smoke evacuation and chilled airflow.

A Smoke Evacuator contains a suction unit (vacuum pump), a filter, a hose, and an inlet nozzle. A smoke evacuator should have high efficiency in airborne particle reduction and should be used in accordance with the manufacturer's recommendations to achieve maximum efficiency:

- The suction should have a high flow volume with frequent filter changes being made to optimize suction and filter capabilities.
- Filters should be chosen which allow for maximum filtering efficiency.
- Expired filters and uses hoses should be treated as a bio-hazard. Surgical masks and gloves should be worn when red-bagging.

9.8.8.10 Skin Thickness

It is important to avoid ablation of the full thickness of both the epidermis and dermis (E+D). Full thickness ablation markedly increases the risk of scarring and long term tissue.

Skin Thickness Chart

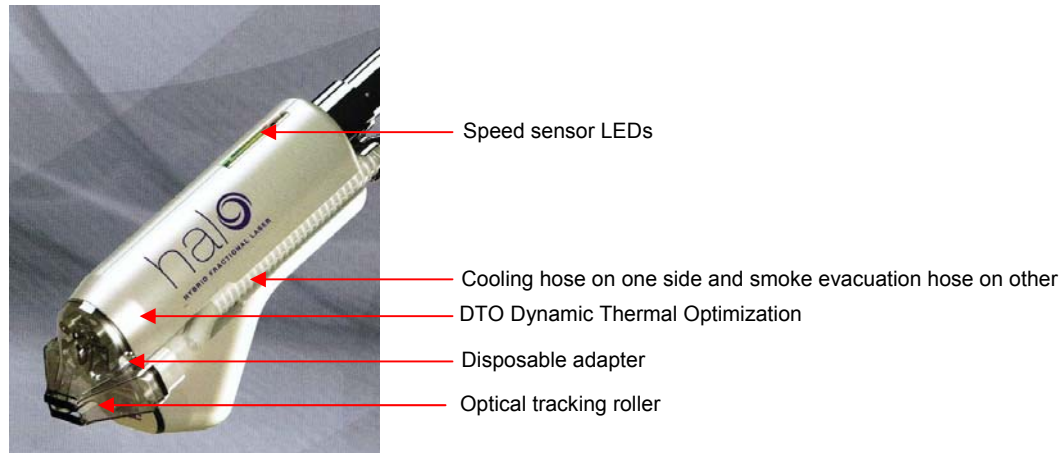
Anatomical Region	Epidermis μm	Dermis μm	E+D μm	Hypodermis μm	Total μm
Mental	149	1375	1524	1020	2544
Forehead	202	969	1171	1210	2381
Upper lip	156	1061	1217	931	2148
Lower lip	113	973	1086	829	1915
Tip of nose	111	918	1029	735	1764
Neck	115	138	253	544	797
Cheek	141	909	1050	459	1509
Glabella	144	324	468	223	691
Eyelids	130	215	345	248	593

Note: These measurements can vary from patient to patient and are intended to be used only as a guideline.

9.8.9 Safe Start Protocol for Halo and Halo Pro

Halo Pro is a hybrid fractionated 2940 nm (ablative) and 1470 nm (non-ablative) laser peel that heats the water and hemoglobin in the epidermis and dermal layer of the skin resulting in Microscopic Treatment Zones (MTZ) of thermal necrosis which forms Microscopic Epidermal Necrotic Debris (MENDS). During the first day after a treatment, new epidermis proliferates underneath the necrotic epidermal tissue and the MENDS appear at the top of the epidermis. The action of the vaporized MTZ from the 2940 nm acts to create a faster release of the MENDS and completes this process within 3-4 days. The epidermal tissue responds immediately to the initial ablative process allowing for quicker healing and minimal downtime. These wounds stimulate neocollagenesis and help to reduce the signs of photoaging. Halo without 2940 nm does not create vaporized tissue.

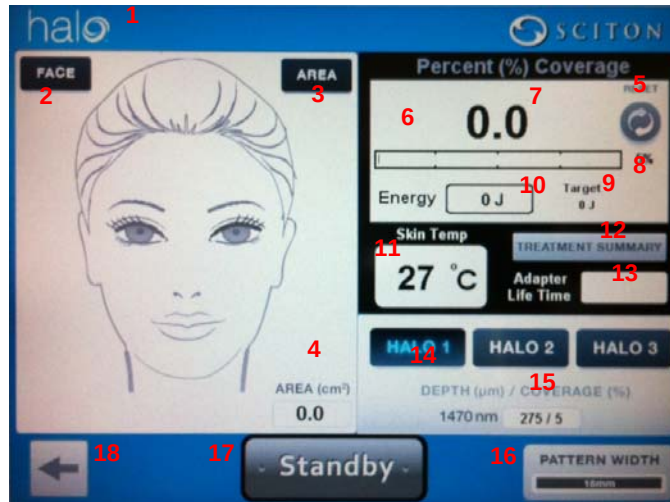
Halo / Halo Pro Scanner



Delivering energy to zones

Halo's disposable adapters have optical tracking rollers that must be kept in contact with the skin. Using slight pressure begin rolling Halo back and forth in the measured zone without gaps. The direction can be changed to uniformly complete coverage. The LED Speed Sensor will monitor the speed of delivery. The speed will light up the LED lights. Maintain a speed or rhythm to keep lights lit in the yellow color range.

Halo User Screen

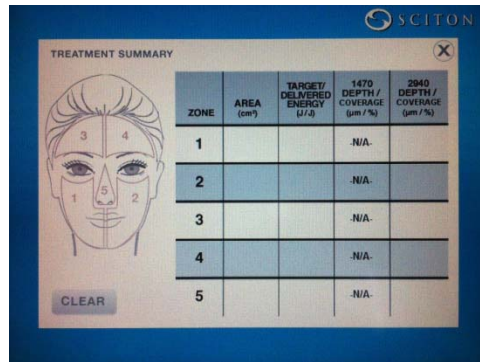


1. Application indicator
Application indicator shows the application the user is in.
2. Face treatment area zone measure softkey
There are five facial zones that comprise the treatment area. Pressing this softkey brings user to the data entry screen for entering the length and width for these zones in cm². The dimensions can be entered by simply running the Halo handpiece along the length (and width) with the footswitch pressed, or by physically measuring the dimensions and entering them by using the "+" or "-" softkeys. *The face treatment area screen is shown below.*
3. Fixed treatment area measure softkey
Pressing this softkey brings the user to the data entry screen for entering the length and width for the fixed zone. The dimensions can be entered by simply running the Halo handpiece along the length (and width) with the footswitch pressed, or by physically measuring the dimensions and entering them by using the "+" or "-" softkeys. *The fixed treatment area screen is shown below.*
4. Area (cm²) indicator
For each measured zone, area is populated in this box in cm².
5. Reset softkey
Resets this subscreen to for the treatment zone being displayed.
6. % Accumulated coverage completed bar
This bar provides graphical representation of the fraction of the selected percent coverage.
7. % Accumulated coverage value
This number represents the current percentage of coverage of the treatment area.
8. Target % of coverage
Target % of coverage selected for the treatment.
9. Target energy display
Based upon the Target % coverage selected, the target energy to be delivered is displayed here.
10. Energy display
The total energy delivered is displayed here.
11. Skin Temp
Automatic display of skin temperature during treatment.
12. Treatment Summary softkey
Touching this softkey permits the user to enter the Treatment Summary screen where the treatment area, target/delivered energy and 1470 depth/coverage are displayed for the five treatment zones. *The treatment summary screen is shown below.*
13. Adapter Life Time indicator
The indicator displays the time of use of the disposable adapter. The disposable adapter has lifetime use of 90 minutes. Indicator will monitor time used.
14. Halo 1, Halo 2 & Halo 3 preset Depth (um) / Coverage (%) softkey
Touching one of these three softkeys permits the user to select preset Depth (um) / Coverage or Density (%).

Halo 1 – Depth (um) / Coverage (%) is 275/5
Halo 2 – Depth (um) / Coverage (%) is 275/10
Halo 3 – Depth (um) / Coverage (%) is 350/10

15. Depth and coverage display
This is a display of the depth and % coverage selected for treatment with Halo 1, Halo 2 or Halo 3..
16. Pattern Width
Pattern width for Halo disposable adapter is displayed in mm.
17. Standby softkey
System is in idle or standby mode. Pressing this softkey will bring user to Ready mode and system will be active.
18. Return softkey
Touching this softkey will return the user to the 1470nm/2940nm Applications screen .

Treatment Summary Screen

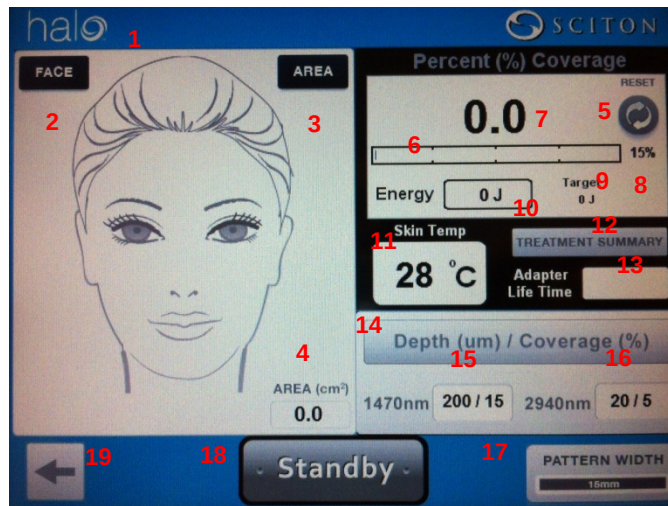


Halo User Screen (after length and width of the treatment zones are entered)

Zone 1 is ready for treatment.



Halo Pro User Screen

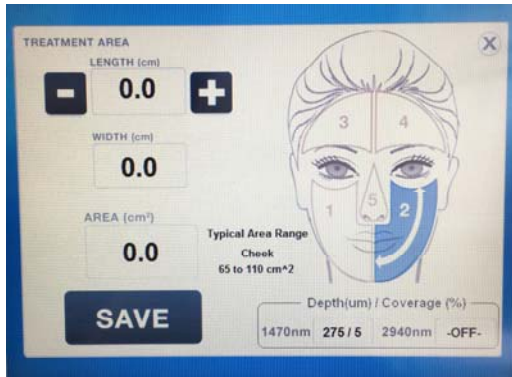


Note: This application will produce a fractionated pattern.

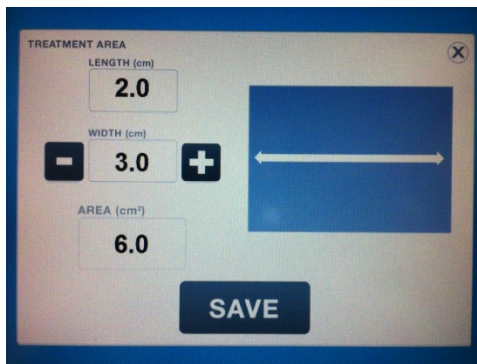
1. Application indicator
Application indicator shows the application the user is in.
2. Face treatment area zone measure softkey
There are five facial zones that comprise the treatment area. Pressing this softkey brings user to the data entry screen for entering the length and width for these zones in cm². The dimensions can be entered by simply running the Halo handpiece along the length (and width) with the footswitch pressed, or by physically measuring the dimensions and entering them by using the "+" or "-" softkeys. *The face treatment area screen is shown below.*
3. Fixed treatment area measure softkey
Pressing this softkey brings the user to the data entry screen for entering the length and width for the fixed zone. The dimensions can be entered by simply running the Halo handpiece along the length (and width) with the footswitch pressed, or by physically measuring the dimensions and entering them by using the "+" or "-" softkeys. *The fixed treatment area screen is shown below.*
4. Area (cm²) indicator
For each measured zone, area is populated in this box in cm².
5. Reset softkey
Resets this subscreen to for the treatment zone being displayed.
6. % Accumulated coverage completed bar
This bar provides graphical representation of the fraction of the selected percent coverage.
7. % Accumulated coverage value
This number represents the current percentage of coverage of the treatment area.
8. Target % of coverage
Target % of coverage selected for the treatment.
9. Target energy display
Based upon the Target % coverage selected, the target energy to be delivered is displayed here.
10. Energy display
The total energy delivered is displayed here.
11. Skin Temp
Automatic display of skin temperature during treatment.
12. Treatment Summary softkey
Touching this softkey permits the user to enter the Treatment Summary screen where the treatment area, target/delivered energy, 1470 depth/coverage and 2940 depth/coverage are displayed for the five treatment zones. *The treatment summary screen is shown below.*
13. Adapter Life Time indicator
The indicator displays the time of use of the disposable adapter. The disposable adapter has lifetime use of 90 minutes. Indicator will monitor time used.
14. Depth (um) / Coverage (%) softkey
Touching this softkey permits the user to enter the Depth (um) / Coverage or Density (%) screen where depth of treatment and the percent coverage can be selected. *The Depth/Coverage screen is shown below.*
15. 1470nm depth and coverage display
This is a display of the depth and % coverage selected for treatment with 1470nm.
16. 2940nm depth and coverage display
This is a display of the depth and % coverage selected for treatment with 2940nm.

17. Pattern Width
Pattern width for Halo disposable adapter is displayed in mm.
18. Standby softkey
System is in idle or standby mode. Pressing this softkey will bring user to Ready mode and system will be active.
19. Return softkey
Touching this softkey will return the user to the 1470nm/2940nm Applications screen .

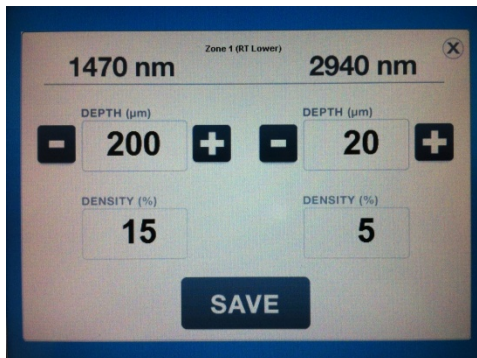
Face Treatment Area Screen



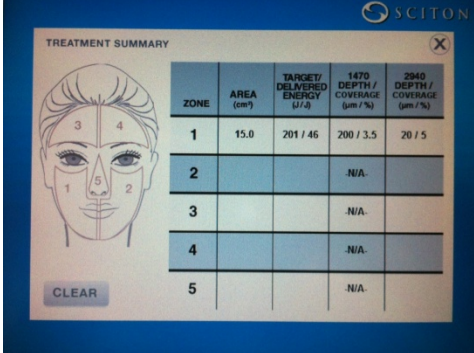
Fixed Treatment Area Screen



Depth (um) / Coverage (%) Screen



Treatment Summary Screen



ZONE	AREA (cm²)	TARGET/ DELIVERED ENERGY (J / J)	1470 DEPTH / COVERAGE (µm / %)	2940 DEPTH / COVERAGE (µm / %)
1	15.0	201 / 46	200 / 3.5	20 / 5
2			N/A	
3			N/A	
4			N/A	
5			N/A	

CLEAR

Halo Pro User Screen (after length and width of the treatment zones are entered)
Zone 1 is ready for treatment.



halo SCITON

FACE AREA

Percent (%) Coverage

Zone 1 (RT Lower)

0.0

Energy 0 J Target 1 J

Skin Temp 25 °C

Adapter Life Time

TREATMENT SUMMARY

Depth (µm) / Coverage (%)

1470nm 275 / 5 2940nm --OFF--

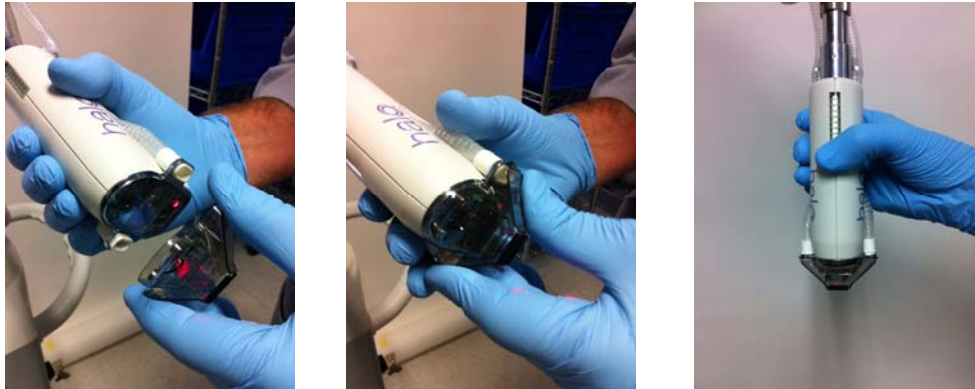
AREA (cm²) 0.8

Standby

PATTERN WIDTH

9.8.9.1 Halo and Halo Pro Treatment Basics

- If oral medications are prescribed, they should be given at least 30 minutes prior to procedure.
- A mild cleanser should be used to remove any dirt, makeup, or moisture from the treatment site. Follow with an alcohol gauze. Allow alcohol to evaporate before treatment. Use special care around the eyes.
- If topical anesthetic is to be used, apply as directed prior to treatment. Before beginning treatment, ensure that topical has been completely removed from the skin surface.
- Patient should be positioned based on the area to be treated. The position should be comfortable to the patient and such that the treatment provider has good access to area to be treated and the control panel display screen.
- Attach the Halo scanner with a new single use adapter to articulated arm as shown.

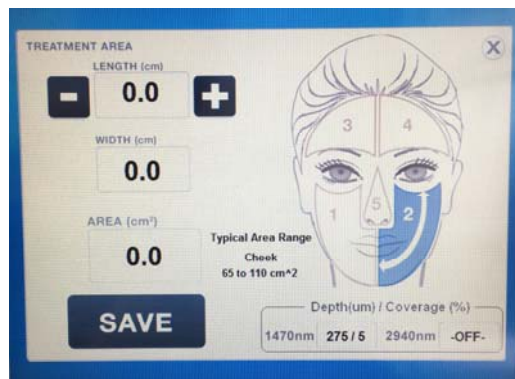


• Measure face or area:

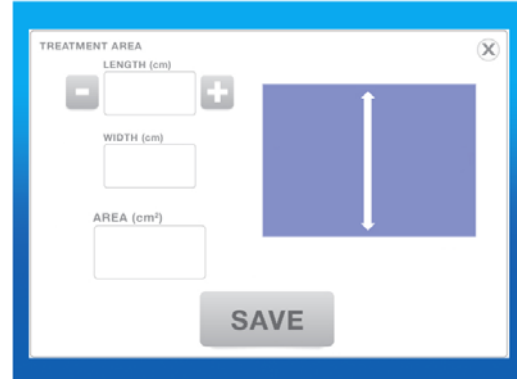
The Halo scanner has an internal measuring feature that automatically populates the user screen after measuring each of the five zones of the face or if a fixed area is selected.

- From the Halo or Halo Pro User Input Data Screen, press the Face softkey to enter the Face Treatment measuring screen as seen below left. If choosing a fixed area, press the Area softkey to enter the fixed area measuring screen as seen below right.

Face area measuring data screen



Fixed area measuring data screen



- Select length or width softkey for desired direction.

- To activate the Halo measuring feature, the foot pedal is depressed simultaneously as the roller closest to the illuminated red light of the device is in constant contact with the skin being measured.

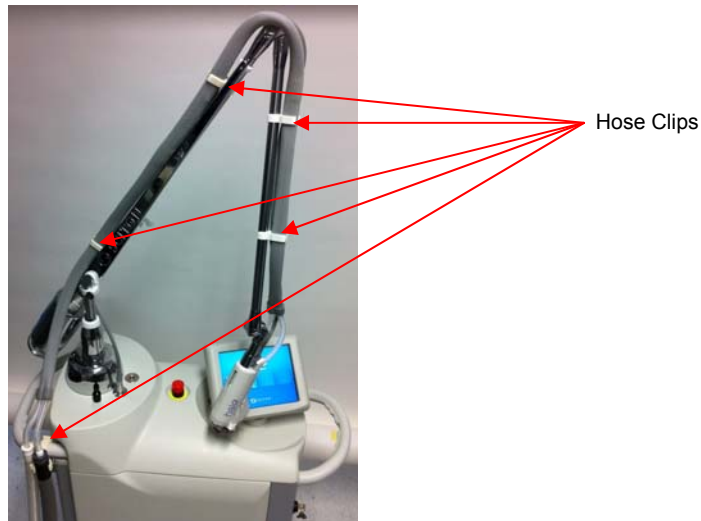


- Begin rolling the device at the start of a zone from one arrow direction to the next to measure length, next tap on the screen to measure the width box and repeat the process. These two measurements will be calculated to give the total area measurement in cm^2 and will be shown in the area box. Repeat until all areas are completed. For the fixed area, measure in the same method above, length and width.
- Press "Save" after each measured treatment area. To clear data, tap on footswitch. Use the same measurements for a series of treatments.
- Prepare for adequate smoke evacuation. Halo Pro smoke evacuation tubing and adapter is used. One end of the hose is attached directly to the Halo single use disposable adapter. The other end is secured to the adapter to fit snugly on the smoke evacuator. The hose is routed as shown below using hose clips as shown below. A high level of suction is used of around 80%. Before treatment, with the Zimmer chiller unit, test adequate smoke evacuation and chilled airflow.



Single Use Disposable Adapter





- Prepare for cooling using Zimmer and Halo adapter hose a few minutes prior to the procedure. Attach end to Halo device at disposable adapter. Attach the opposite end to Zimmer unit.

Disposable Adapter End

Zimmer side more square



Halo Cooling/Smoke Evacuator Hose

Chiller/Smoke Evacuator End

Small round connector for Zimmer chiller

Large round connector for smoke evacuator

- Recommended level setting is "maximum".



Each patient will require a new single use adapter prior to procedure. Adapters cannot be disinfected. Failure to use a new adapter will risk infection and cross contamination.

Treatment Parameters

- Enter appropriate settings into the control panel display screen based on condition and area to be treated.
- If using Halo, select 1, 2, or 3 for preset level desired.
- Depress the foot pedal and deliver complete amount of energy that has been calculated for the zone or area. An audible tone will be heard when the calculated joules has been reached to indicate completion.

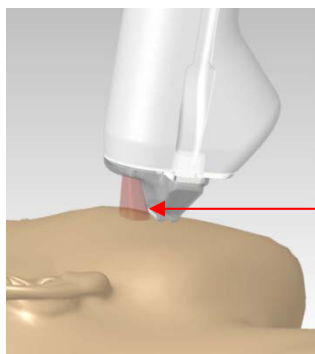
Safe Start Treatment Parameters

Halo				
Application	Skin Type	Presets	1470 nm Depth um (non-ablative)	Density %
Facial Pigment/ Light texture/tone	I-V	Level 1	275	5
	I-IV	Level 2	275	10
	I-IV	Level 3	350	10
Body Pigment/ Light texture/tone	I-V	Level 1	275	5
	I-IV	Level 2	275	10
	I-III	Level 3	350	10

Halo Pro (Independent Wavelength Selection Control)					
Application	Skin Type	1470 nm (non-ablative)		2940 nm (ablative)	
		Depth µm	Density %	Depth µm	Density %
Facial Pigment/ Texture/tone	I-III	250 – 350	5 – 30	0 – 20	5 – 20
	IV-VI	250 – 350	5 – 15	0 – 20	5 – 15
Facial Texture/ Remodeling scars	I-III	300 – 400	5 – 30	0 – 40	5 – 20
	IV-VI	300 – 400	5 – 15	0 – 40	5 – 15
Body Pigment/ Texture/tone	I-III	200 – 300	5 – 20	0 – 20	5 – 20
	IV-VI	200 – 300	5 – 10	0 – 20	5 – 10
Body texture/ Remodeling scars	I-III	250 – 350	5 – 20	0 – 40	5 – 20
	IV-VI	250 – 350	5 – 10	0 – 40	5 – 10

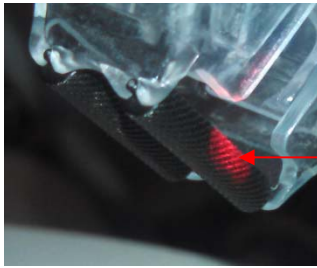
Treatment Technique

- Halo incorporates DTO Dynamic Thermal Optimization. This unique thermal sensor constantly monitors the epidermal skin temperature before each pulse to optimize the fluence and spot size ensuring the exact depth entered on the screen. Feedback automatically adjusts energy and spot size.



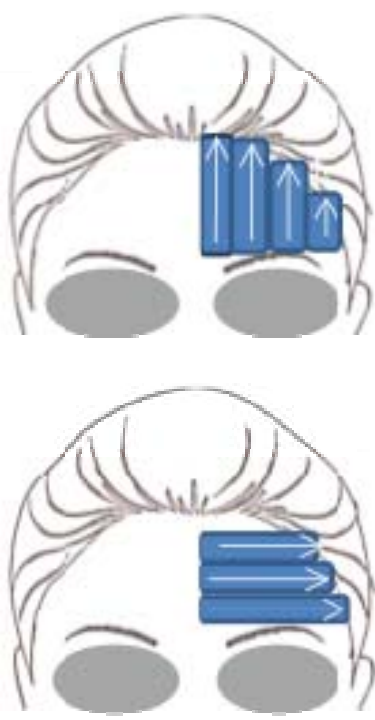
DTO (Dynamic Thermal Optimization)

- The Halo scanner must be held perpendicular and in full contact with the skin, with the rollers in constant communication with the device and with red light visible. To navigate the zone being treated, gently roll the scanner starting in a single pass technique.



Roller with red light is the roller being tracked.

Halo Cross Hatch Roller Technique

	1. Begin making vertical passes within a treatment zone • Roll Halo as arrows indicate and lay down pass • Lift halo and begin again at start position 2. Next move to adjacent row and repeat 3. Next repeat process until this treatment zone has been treated with 2 vertical passes 4. After vertical passes given alternate with horizontal passes within the treatment zone • Roll Halo as arrows indicate and lay down pass • Lift halo and begin again at start position • Repeat another pass 5. Next move to adjacent row and repeat 6. Next repeat process until this treatment zone has been treated with 2 horizontal passes 7. Continue cross hatching alternating vertical and horizontal until recommended energy is reached indicated by accumulated energy bar and audible sound
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- Use deliberate, controlled sweeping movements and at a speed monitored by the LED lights.
- Lay each pass as shown in diagram until cosmetic unit has been covered. The energy will be deposited and a sound will let the user know that the recommended total energy has been completed. The horizontal bar on the Percent (%) Coverage will be completely filled to indicate that the Accumulated % Coverage has reached the Target % Coverage.
- When finished with all 5 zones or fixed area treated, the Treatment Summary Screen will provide the data from the procedure.
- If treating in a small area, e.g. underneath eyes or lesion, make 1 pass and then wait several seconds before repeating.



The optical lens may need to be checked for debris and cleaned after each zone. May use cotton tipped applicator moistened with alcohol to cleanse lens.

Endpoints

The desired endpoint is the complete delivery of the total accumulated joules recommended for each treatment area. Visually, erythema will be seen within a few minutes of laser application. The redness and healing (often similar in appearance to varying degrees of sunburn) will increase with the ablation depth and coverage, and will vary by patient.

Post-Treatment

- Observation – erythema, localized edema, sun burn sensation, and tightness of skin. Bronzing and sand paper texture to the skin MENDS (microscopic epidermal necrotic debris) begins at day 2-3 and will be almost clear by day 4-5 (depending on aggressiveness of treatment and whether ablation versus coagulation alone).
- Intervention – cool compresses or ice packs can provide immediate comfort after treatment. A light balm e.g. Elta MD or Cicalfate will provide protection and comfort to treated area and should be used until skin has exfoliated. Tinted sunscreen may be applied on top of products. Use gentle cleanser. Do not pick or rub prematurely to exfoliate MENDS (microscopic epidermal necrotic debris) that begin on day 2-3.
- Interval – approximately 4-8 weeks depending on depth and coverage area of the treatment and the health and integrity of the skin being treated. May be part of a series.
- Non-invasive light-based BBL treatments may occur prior to procedure.
- Check with manufacturer of injectable for their guidelines on using injectables in conjunction with Halo procedure.

diVa™



The Strengthened Quartz Dilator (SQD) is a single use device.

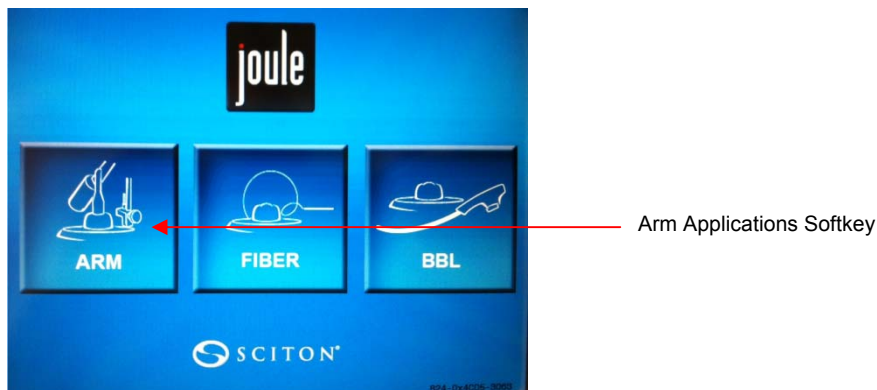
**Quartz is inherently brittle and can break if not handled with care.
Reference "Maintenance" section on how to disinfect the diVa handpiece.**

9.9 1470/2940 nm diVa Hybrid Fractional Vaginal Laser

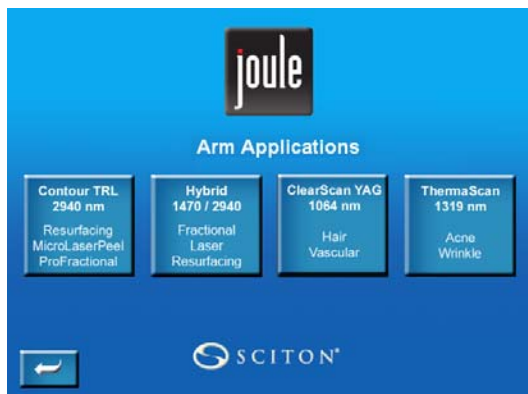
diVa™ is a hybrid fractional vaginal resurfacing system that can coincidentally and independently utilize two wavelengths in its delivery, non-ablative 1470 nm and ablative 2940 nm. The 1470 nm wavelength is absorbed by water making it ideal for heating of soft tissue to create controlled zones of coagulation to chosen depths into the vaginal mucosa. Treating with 1470 nm laser alone produces non-ablative channels only. diVa also uses 2940 nm for its high absorption in water, which results in precise ablation as desired in the mucosa epithelial layer. This combination allows for fractionated non-ablative and ablative resurfacing for an improvement to vaginal tissue.

Arm Application Menu Screen

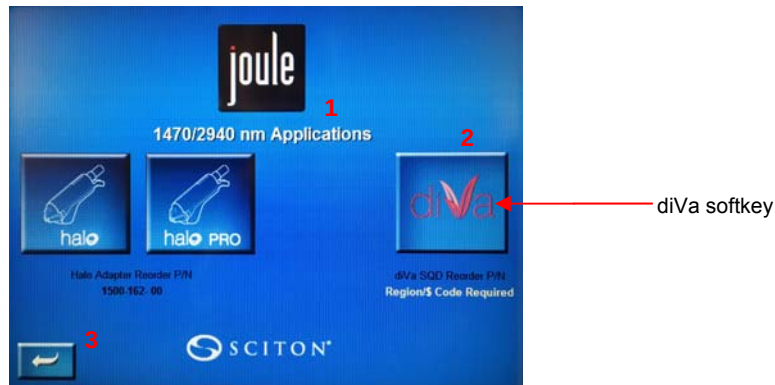
The Arm Application menu screen allows the user to enter diVa application screen.



Touching the 1470/2940 softkey will allow the user to access the 1470/2940 applications.



Touching the diVa softkey will allow the user to enter the diVa application screen.



1. Application Header
The Application Header displays the selected diVa application.
2. diVa application softkey
Press the softkey to enter diVa user screen.
3. Return to Arm Applications screen softkey
Touching this key will return the system to the previous screen

9.9.1 Indications for Use

1470 nm Indications for Use:

The JOULE 1470 nm Multi-Platform Systems and delivery accessories are intended for delivery of laser light to soft tissue for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue. The JOULE 1470 nm Multi-Platform Systems with its handpiece and delivery system is intended for use in procedures requiring skin resurfacing and coagulation of soft tissue.

2940 nm Indications for Use:

The JOULE 2940 nm Multi-Platform Systems with delivery accessories are designed for use in surgical applications requiring the excision, incision, ablation, vaporization, and coagulation of soft tissue, and for tissue resurfacing.

The JOULE 2940 nm Multi-Platform Systems with its handpiece and delivery system is intended for use in procedures requiring skin resurfacing, and ablation and coagulation of soft tissue.

9.9.2 Considerations

diVa (1470 nm and 2940 nm) has the following medical judgment considerations:

- Patients who use anticoagulant medications that may hinder coagulation or have predisposition of bruising
- Patients with undefined lesions
- Patients that have prolapse of the vaginal wall
- Patients with an active infection
- Patients who have undergone previous pelvic floor reconstructive surgery
- Patients with more than Grade II prolapse using the POP-Q measurement system
- Patients who have used vaginal topical estrogen within one month

9.9.3 Precautions

- Patients must be carefully evaluated by the physician for their risk of scarring versus treatment benefit
- Patients who smoke may experience delayed healing and decreased benefit
- Patients who are intolerant to anesthetic based agents

9.9.4 Contraindications

diVa (1470 nm and 2940 nm) is contraindicated for:

- Patients with infectious disease
- Patients with connective tissue disease
- Patients with propensity for keloid formations
- Patients who are immunocompromised or compromised healing
- Patients who are on long-standing systemic steroids (e.g. Prednisone, Dexamethasone)
- Patients who are pregnant or lactating
- Patients who have used isotretinoin (e.g. Accutane, Sotret, Claravis, Amnesteem) within the past year
- Patients with a medical condition that may affect wound healing
- Patients who are not using a medically approved method of contraception
- Patients who have acute or recurrent urinary tract infections, active sexually transmitted diseases, use of vaginal topical antibiotics or antifungal agents within one week
- Patients who have known collagen disorder, known vascular disease, scleroderma, history of immunosuppression, history of bleeding disorder or significant concurrent illness such as diabetes
- Patients who are on medications known to affect sexual function, and clinically significant anxiety, depression, or psychosexual disorder
- Patients who have inability to confirm, prior to treatment, clean pelvic exam by GYN in the past year
- Patients who have a pelvic exam in the past year that was positive for any contraindication or related condition

9.9.5 Complications

Complications, though rare, may occur and should be discussed and understood. The patient must understand the importance of the post care instructions and that failure to comply may increase the probability of complications.

The potential complications of diVa are:

- Scarring, hypertrophic and non-hypertrophic
- Burn, from superficial to full thickness
- Extensive tissue destruction
- Ulceration
- Induced bruising or petechiae formation
- Severe edema

9.9.6 Warnings

- In pretreatment work-ups, screen lesions that are located in the close proximity to known arteries or veins in order to locate these circulatory structures
- Flammable inhalation general anesthetics must not be used. "Flash Fire" may occur. Oxygen levels in the direct operative area must not be higher than 30%.
- Do not allow combustibles or flammables, including drapes and paper gowns in the laser treatment area. Fire prevention/control methods should be in place.

9.9.7 Selective Photothermolysis

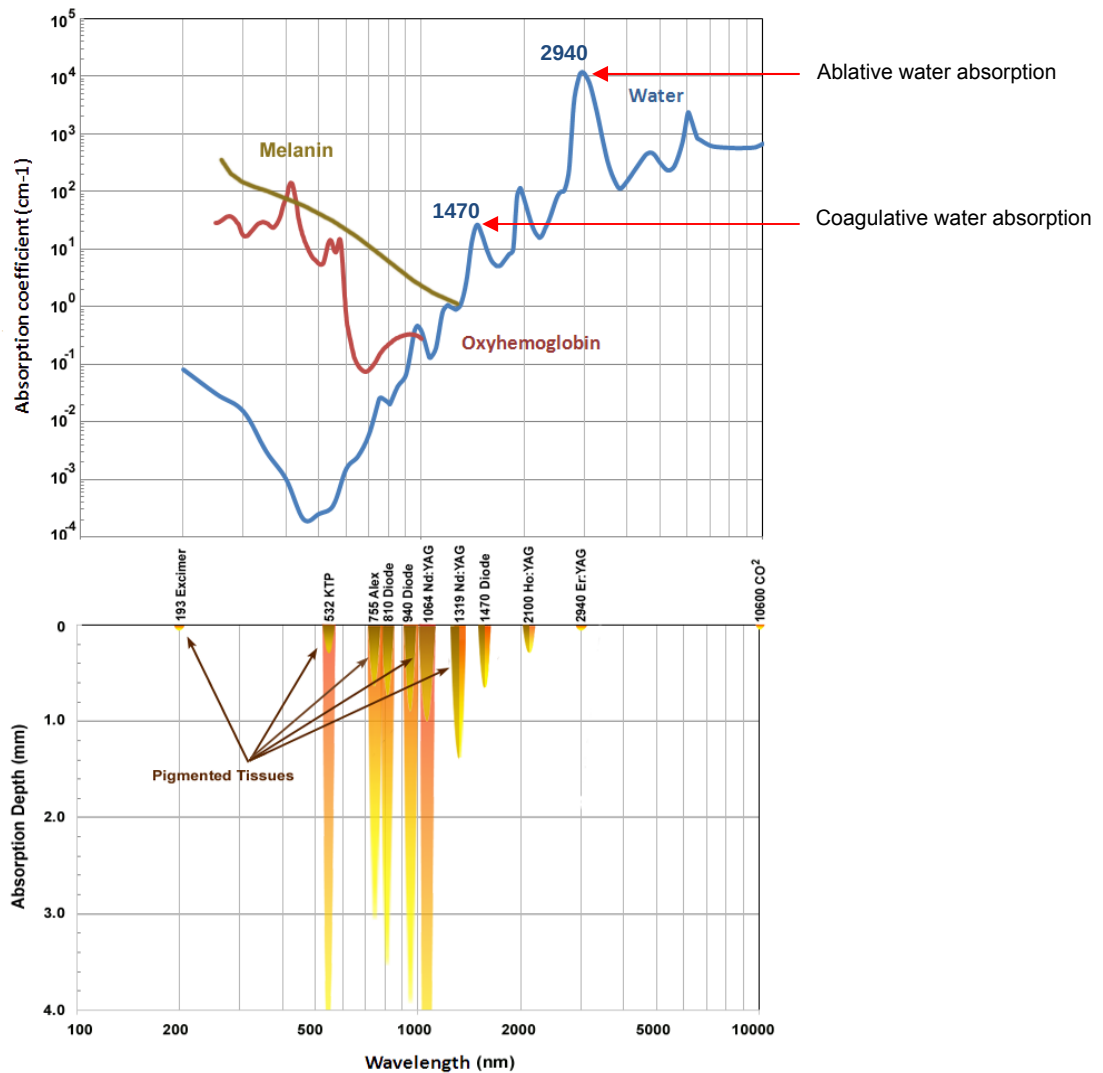
This technique relies on selective absorption of laser light to generate and confine heat at certain cellular targets. The goal of Selective Photothermolysis is to have sufficient energy penetrate to and be absorbed by the desired target while minimizing the effect on the surrounding tissue.

Absorption Curve

Absorption curve shows the relationship of the variation in absorbed laser light as a function of wavelength. The graphic shows absorption spectra of major intracellular absorbers. The molecular absorption coefficients of oxygenated hemoglobin, melanin and water are shown.

Depth of Penetration

Depth of penetration of laser energy for different types of lasers is seen illustrated.



- Based upon the principles of selective fractionated photothermolysis, diVa's use of 1470 nm laser wavelength selectively targets dermal tissue containing water and hemoglobin. It does not cause the water in the tissue to vaporize (ablate) but rather the laser energy heats the tissue in a controlled manner. The coincident and independent use of 2940 nm wavelength selectively targets the mucosal epithelial layer containing water and hemoglobin to precisely vaporize (ablate) tissue in a controlled manner. This hybrid use addresses both non-ablative and ablative delivery modalities.

9.9.8 Getting Started

9.9.8.1 Consultation/Education

A consultation is essential in order to establish realistic expectations and to gain a full understanding of the patient and her treatment goals. The patient must understand the procedure, pre and post care instructions, expectations, contraindications and possible complications prior to beginning any treatment.

9.9.8.2 Medical History

A detailed medical history should be obtained prior to treatment outlining any former or active medical condition or medication that is contraindicated or that could possibly affect the outcome of the treatment.

It is recommended that a brief medical history be taken before beginning any subsequent treatment by reviewing clinical information such as any new medications, pertinent change from last treatment, pregnancy etc.

9.9.8.3 Informed Consent

The process of accepting and confirming treatment must be reviewed, understood and signed by the patient prior to treatment. This document must review the topics discussed during the consultation. It acknowledges that the patient understands the procedure, possible risks and complications and that all questions have been answered.

Reference sample Informed Consent in Appendix of this manual.

9.9.8.4 Medication

To prevent the activation of a herpes simplex virus infection, it is recommended that an antiviral medication be prescribed.

9.9.8.5 Topical Anesthesia

Use a topical preparation to alleviate discomfort for sensitive patients or sensitive areas prior to treatment. Each patient should be assessed and questioned regarding allergies or sensitivities to ingredients in topical anesthetics prior to application. The manufacturer's guidelines for the application and duration of the anesthetic should be read prior to topical application. Remove excess before treatment.



Be extremely cautious when applying topical anesthetics to large areas of the body. Lidocaine toxicity has been linked to several deaths.

9.9.8.6 Eye Protection

Eye protection should always be worn by everyone present in the treatment room during any laser or light based treatment.

9.9.9 Safe Start Protocol for diVa

diVa is a hybrid fractionated vaginal 2940 nm (ablative) and 1470 nm (non-ablative) laser therapy that heats the water and hemoglobin in the mucosal epithelial layer and lamina propria of the vagina resulting in Microscopic Treatment Zones (MTZ) of thermal necrosis. During the first day after a treatment, new mucosal epithelial cells proliferate underneath the necrotic tissue. The mucosal epithelial layer tissue responds immediately to the initial ablative process allowing for quicker healing and minimal downtime. diVa without 2940 nm does not create vaporized tissue.

9.9.9.1 diVa Hybrid Fractional Vaginal Laser device



High Precision Automated (HPA) Handpiece

Guide rings

Dual wavelength energy delivery window



Single-Use Strengthened Quartz Dilator (SQD)

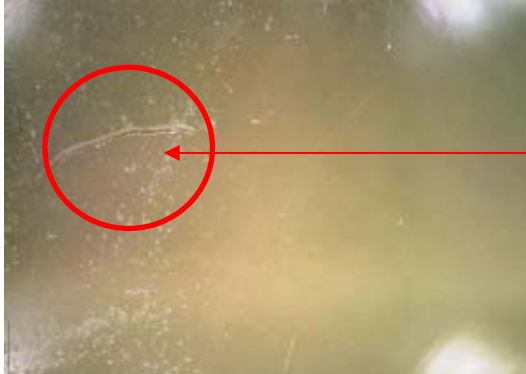


SQD handle

SQD tip



The outside surface of the diVa handpiece, including the window should be gently wiped with Isopropyl alcohol swab or non-shredding gauze prior to use. It is not recommended to use hospital grade disinfectant containment cloths, such as CaviWipe™ Towlettes. The deposits left behind by the CaviWipes may absorb either of the two wavelengths used by diVa. This could result in the diminishing of the laser effect and producing less than the desired effect. In the case of the 2940 nm wavelength, which has a high peak power, damage to the window could result.



Deposits left behind by CaviWipe

The deposits will absorb laser light and cause scatter of transmission



Clean surface of window after cleaning with alcohol swab



diVa delivery window

Recommended cleaning of diVa

9.9.9.2 diVa User Screen



1. Application indicator
Application indicator shows the application the user is in.
2. 1470 nm wavelength
Below this indicator are the controls for the 1470 nm wavelength
3. 1470 nm depth
The plus (+) and minus (-) buttons allow for control of the depth of coagulation of the diVa treatment. Each button press increases or decreases the coagulation depth by 25 microns from 200 microns to 700 microns.
4. 1470 nm density
The plus (+) and minus (-) buttons control the density of the 1470 nm coagulation. The 1470 nm coagulation has 3 levels of coagulation, 0 density (1470 nm is not activated), a low density (from 2 to 9, depending on depth) and a high density (from 4 to 18, depending on depth).
5. 2940 nm wavelength
Below this indicator are the controls for the 2940 nm wavelength.
6. 2940 nm depth
The plus (+) and minus (-) buttons allow for control of the depth of ablation of the diVa treatment. Each button press increases or decreases the ablation depth by 25 microns from 100 microns to 800 microns.
7. 2940 nm density
The plus (+) and minus (-) buttons control the density of the 2940 nm ablation. The 2940 nm wavelength has 3 levels of ablation, 0 density (2940 nm is not activated), 7% density, and 14% density.
8. Treatment Distance indicator
The distance indicator shows how far the handpiece has traveled inside of the vaginal canal from the last time the distance has been reset or the beginning of the treatment.
9. Total Energy Delivered
The energy delivery indicator shows how much energy has been delivered for each of the 1470 nm and 2940 nm wavelengths, measured in Joules.
10. Treatment Angle Button
Most treatments will use the 360 degree option, which treats the entire circumference of the vaginal canal. For more targeted treatments, the 90 degree or 180 degree option may be used. The treatment energy will be delivered as it appears on the screen. Each press of the 90 or 180 degree softkey will change the position of the treatment.
11. Zero Button
If treating at 90 degrees or 180 degrees, the handpiece must be calibrated to center the guide beam at the midpoint of the treatment angle before treatment. This can be accomplished by rotating the handpiece in standby mode. (The handpiece will rotate in standby, but will not fire.) Once the midpoint of the treatment angle is reached, pressing the zero button will calibrate the system.
12. Reset Button
The reset button will reset the distance and energy delivery values, but will not change treatment settings.

13. Return softkey
Touching this softkey will return the user to the Hybrid 1470nm/2940nm Applications screen.
14. Standby softkey
System is in idle or standby mode. Pressing this softkey will bring user to Ready mode and system will be active.
15. Shot Cnt
The shot count during the treatment is displayed here.
16. Status Display
This alerts "New SQD Validation Required," or if the SQD is validated, the time remaining for the activated SQD.

9.9.9.3 diVa Treatment Basics

- Position patient table so that end of table (vaginal exposure) is not facing door.
- Patient should be positioned in dorsal recumbant position with feet on corners of table with buttocks even with edge of table. The position should be comfortable to the patient and such that the treatment provider has good access to the vagina and the control panel display screen. Drape placed in diamond-shaped fashion for privacy and comfort. If available, stirrups are recommended.
- If oral medications are prescribed, they should be given at least 30 minutes prior to procedure.
- If topical anesthetic is to be used, apply as directed prior to treatment, usually left on at least 10 minutes. Gently remove excess from patient before treatment and ensure there is no foreign object inside the vaginal canal.
- Attach the diVa handpiece to articulated arm as shown.



- Plug the diVa cable to the outlet on the console as shown.



- To remove the cable, hold the metal housing of the cable and pull up.

9.9.9.4 Treatment Parameters

- Enter appropriate settings into the control panel display screen.
- Input the treatment settings using the plus (+) and minus (-) buttons on the user screen.

diVa Laser Vaginal Therapy (Independent Wavelength Selection Control with 360° rotation)					
Application	Treatment Number	1470 nm (non-ablative)		2940 nm (ablative)	
		Depth μm	Density %	Depth μm	Density %
Pre-Menopausal	1	500	6	300	7
	2	600	15	350	14
	3	700	18	400	14
Post-Menopausal	1	400	4	200	7
	2	500	12	250	14
	3	600	15	300	14

9.9.9.5 Treatment Technique

diVa's single-use Strengthened Quartz Dilator expands the vaginal walls for delivery of energy. The tip remains stationary in the vagina. diVa also has High Precision Automation (HPA). This is a motorized guidance system that has precisely calibrated 360° rotation. The rotation allows delivery of energy to a new window of the dilator, ensuring homogenous pulsing all along the vaginal canal.

1. To activate the diVa treatment, connect the microchip on the SQD to the connector on the handpiece (as seen below). Magnets will help guide the connection. Allow a few seconds for the treatment to activate.
2. Activating the diVa treatment will start a 15 minute timer. The timer will begin to count down from the first time the footswitch is activated in READY mode. Rotating the handpiece in standby mode will not start the timer.



3. Insert SQD into vaginal canal, using a small amount of lubrication at the tip of the SQD, if necessary.

4. Insert the metal ruler (PN1001-070-00) all the way into the SQD, with the round end inside the SQD.



5. Measurement of the treatment length is indicated by the length (cm) to the urethral meatus.
6. Note the measured length (cm) in the Treatment Log.
7. Remove the ruler from the SQD and remove the SQD from the vaginal canal.
8. Slide SQD onto the handpiece.



9. Ensure the SQD is completely engaged with the handpiece but able to rotate freely around the threaded shaft of the handpiece.



10. Insert the handpiece into patient's vaginal canal.
11. Gently hold SQD handle with one hand and the handpiece housing with the other hand to prevent rotation but allow axial outward movement of the handpiece during treatment.
12. Place the system in the Ready mode by touching the Standby soft-key.



13. Depress footswitch to begin treatment.

14. Verify that the handpiece is slowly moving outwards as the patient is being treated.

Note: If the handpiece is not moving outwards, stop treatment. Place system in Standby and verify that the SQD is properly engaged as noted in Section 7 above. Depress footswitch to verify axial movement of the SQD as the handpiece screw rotates. After verifying axial movement return the system to Ready mode and continue treatment.

15. Monitor the distance gauge on the treatment screen until you are 2-3 cm from measured distance.

16. Guide rings will appear and provide a visual indication of treatment progress

Green ring: 3 cm from laser beam to introitus

Blue ring: 2 cm from laser beam to introitus.

Red ring: 1 cm from laser beam to introitus



17. Stop the treatment when the red ring is visible.

18. Remove the handpiece from the vaginal canal.

19. Remove the SQD from the handpiece and discard as medical waste.

9.9.10 Endpoints

The desired endpoint is the complete delivery of the total accumulated joules recommended from measured treatment length in the vaginal canal in centimeters.

9.9.11 Post-Treatment

- Observation – Visually, the patient may have varying degrees of pinpoint bleeding.
- Intervention – A sanitary pad is given for spotting or pinkish discharge. This typically lasts for 24-48 hours. Some cramping may be experienced that lasts for 24-48 hours. Return of normal daily activity can start immediately. No sexual activity for 48 hours. No douching for 48 hours.
- Interval – Between 1 to 3 sessions, 4 weeks apart.

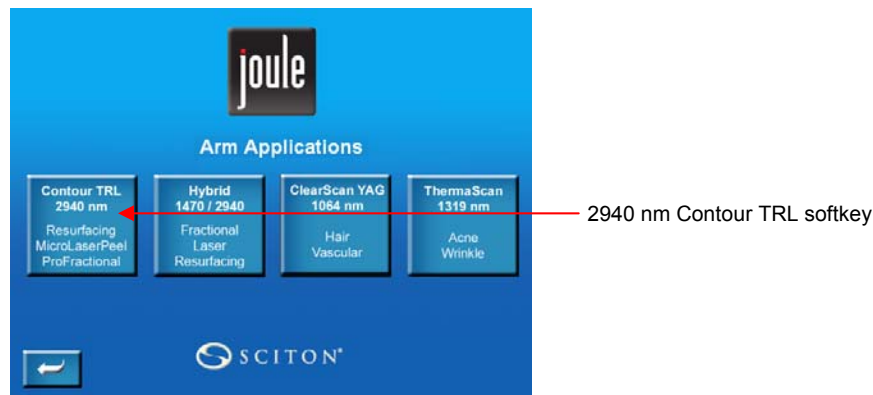
Contour TRL™

9.10 2940 nm Er:YAG Contour TRL

Often referred to as the "Erbium" laser, it emits a mid-infrared beam at 2940 nm, which coincides with the highest absorption peak for water. Its principal use is to ablate tissue for a cosmetic improvement of wrinkles and other effects of photoaging.

Arm Application Menu Screen

The Arm Application menu screen allows the user to enter the different 2940 nm Contour TRL user application screens.

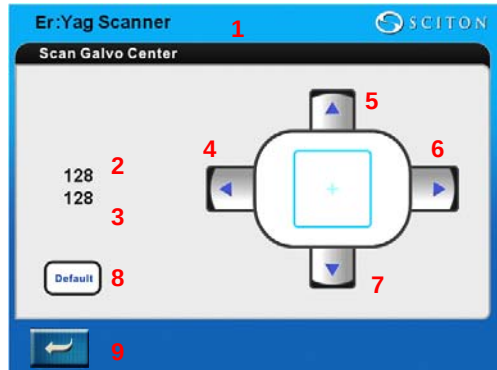


Pressing the ContourTRL softkey will allow the system to enter into the 2940 nm Applications screen.



1. Application Header
The Application Header displays the selected 2940 nm application.
2. MicroLaserPeel application softkey
Attach Contour Scanner and press the softkey to enter the MLP (2940 nm) user screen.
3. Resurfacing application softkey
Attach Contour Scanner and press the softkey to enter the TRL (2940 nm) user screen.

4. Single Spot softkey
Attach the 2 mm or 4 mm single spot handpiece and press the single spot softkey to enter the Single Spot user screen. Attach the Focused Single Spot handpiece and press the Single Spot softkey to enter the Focused Single Spot user screen.
5. Fractional Resurfacing softkey
Attach the ProFractional-XC/III or ProFractional scanner and press the Fractional Resurfacing softkey to enter the ProFractional-XC (2940 nm) or ProFractional (2940 nm) user screens.
6. Handpiece Alignment softkey
The Contour, ProFractional-XC/III and ProFractional scanning handpieces have the ability to adjust the scan pattern output center. Press HandPiece Alignment softkey to access the centering screen. The X-axis and Y-axis can be adjusted and stored into memory. This adjustment should be made each time a scanner is attached to the system for the first time and any time the scan pattern output is not centered (edge of aiming beam is cut-off).



1. Scanner Handpiece indicator
 2. Current center settings indicator for x-axis
 3. Current center settings indicator for y-axis
 4. Adjust pattern left softkey
 5. Adjust pattern up softkey
 6. Adjust pattern right softkey
 7. Adjust pattern down softkey
 8. Center scanner to default position softkey
 9. Return to 2940 nm Applications Screen softkey
7. Return to Arm Applications screen softkey.

9.10.1 Indications for Use

The 2940 nm Er:YAG Contour TRL is designed for use in surgical applications requiring the excision, incision, ablation, vaporization, and coagulation of soft tissue, and for skin resurfacing.

Aesthetic Surgery: Skin resurfacing and treatment of wrinkles.

Dermatology & Plastic Surgery: Indications include epidermal nevi, actinic cheilitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision, debulking benign tumors, and decubitus ulcers. It is also used for laser assisted site preparation for hair transplantation.

2940 nm Er:YAG Contour TRL with ProFractional/ProFractional-XC/III handpiece and delivery system is intended for use in dermatological procedures requiring skin 2940 nm Er:YAG Contour TRL Resurfacing and coagulation of soft tissue.

9.10.2 Contraindications

The 2940 nm Er:YAG Contour TRL is contraindicated for:

- Patients who are intolerant to anesthesia
- Patients with infectious disease
- Patients with connective tissue disease
- Patients with propensity for keloid formations
- Patients who are immunocompromised

- Patients who are pregnant
- Patients who have used isotretinoin (Accutane) within the past year
- Patients with a medical condition that may affect wound healing
- Patients who use anticoagulant medications

9.10.3 Complications

Complications, though rare, occasionally occur and should be discussed and understood. The patient must understand the importance of the post care instructions and that failure to comply may increase the probability of complications.

The potential complications of 2940 nm Er:YAG Contour TRL are:

- Scarring- hypertrophic and non-hypertrophic
- Burns- from superficial to full thickness
- Extensive tissue destruction
- Ulceration
- Hyperpigmentation
- Hypopigmentation
- Induced hemorrhage
- Edema

9.10.4 Warnings

- In pretreatment work-ups, screen lesions that are located in the close proximity to known arteries or veins in order to locate these circulatory structures.
- Flammable inhalation general anesthetics must not be used. "Flash Fire" may occur. Oxygen levels in the direct operative area must not be higher than 50%.
- Do not allow combustibles or flammables, including drapes and paper panties, in the laser treatment area. Fire prevention/control methods should be in place.

9.10.5 Selective Photothermolysis

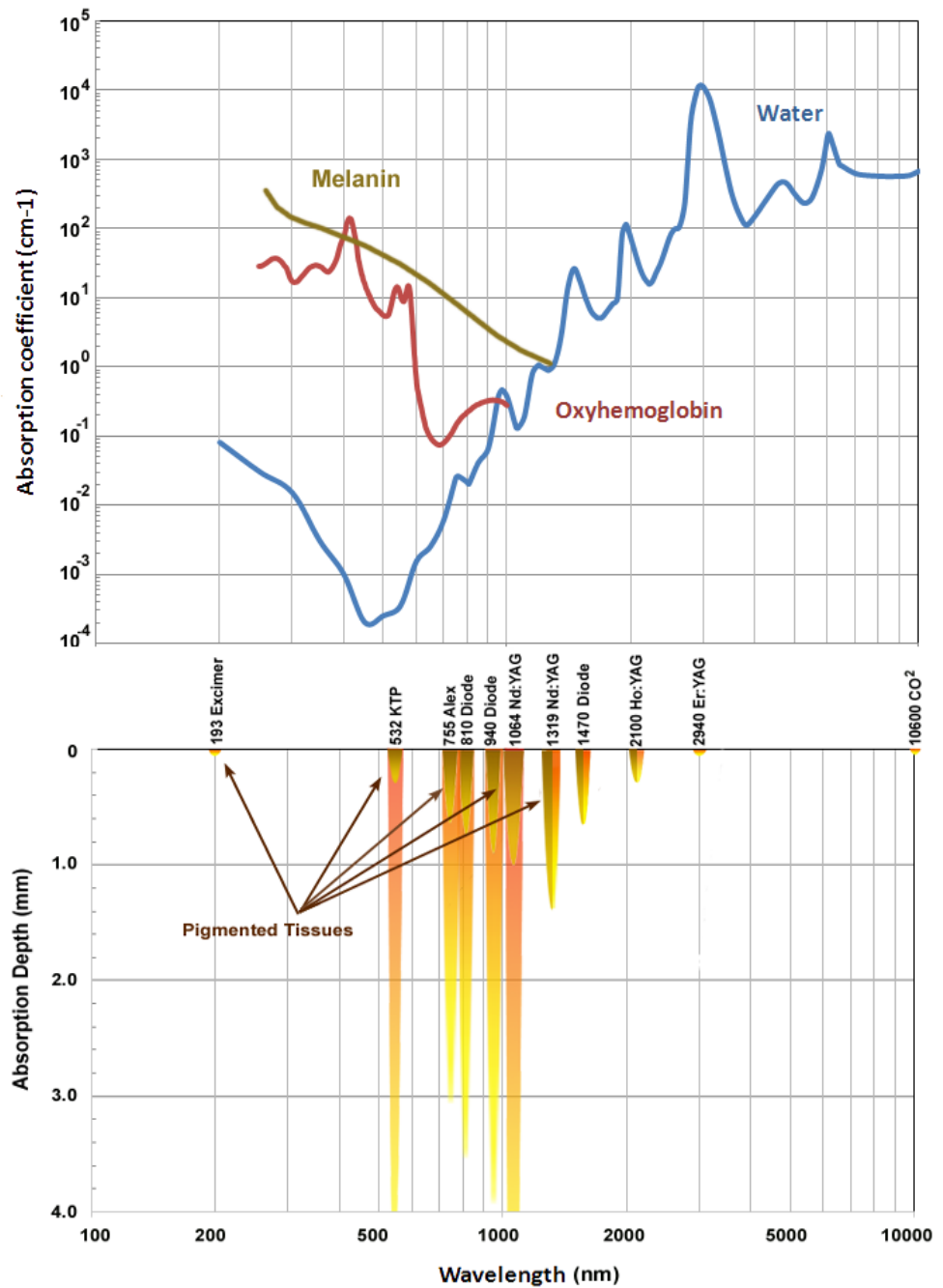
This technique relies on selective absorption of laser light to generate and confine heat at certain cellular targets. The goal of Selective Photothermolysis is to have sufficient energy penetrate to and be absorbed by the desired target while minimizing the effect on the surrounding tissue.

Absorption Curve

Absorption curve shows the relationship of the variation in absorbed laser light as a function of wavelength. The graphic shows absorption spectra of major intracellular absorbers. The molecular absorption coefficients of oxygenated hemoglobin, melanin and water are shown.

Depth of Penetration

Depth of penetration of laser energy for different types of lasers is also illustrated.



Based upon the principles of selective photothermolysis, erbium lasers selectively target tissue containing water resulting in controlled tissue vaporization. The 2940 nm Er:YAG wavelength very closely matches the highest peak of the absorption spectrum for water. Because of the selective properties of 2940 nm Er:YAG, almost all of the energy created by the laser is taken up by heating water. The resulting tissue vaporization leaves very little laser energy that can scatter into the skin and produce nonspecific heating.

9.10.6 Getting Started

9.10.6.1 Consultation/Education

A consultation is essential in order to establish realistic expectations and to gain a full understanding of the patient and his/her treatment goals. The patient must understand the procedure, pre and post care instructions, expectations, contraindications and possible complications prior to beginning any treatment.

9.10.6.2 Medical History

A detailed medical history should be obtained prior to treatment outlining any former or active medical condition or medication that is contraindicated or that could possibly affect the outcome of the treatment.

It is recommended that a brief medical history be taken before beginning any subsequent treatment by reviewing clinical information such as any new medications, skin care, sun exposure, pregnancy etc.

9.10.6.3 Skin Typing

Accurate skin typing is critical to treatment success and the avoidance of complications. It is important to know that in most situations an individual's previous response and genetic tendency to sun exposure will be the biggest indicators in establishing skin type. Some patients, such as Asians and Hispanics, may appear to be a skin type II or III and never tan but react to laser energy like a IV or V skin type. Hence, it is very important not to base skin type on appearance.

The skin type of a patient does not change. Do not confuse skin type with a tan. A person's skin type is something they are born with and it does not change, but the degree of tan can change.

Type	Hair Color	Skin Color and Ethnic Background	Eye Color	Sun Reaction
I	Red, White Blonde	Very fair <i>Scandinavian, Nordic, and North European</i>	Blue	Always burns, never tans
II	Red, Blonde, light brown	Fair <i>North European, Celtic (Scottish, Irish)</i>	Blue, green	Always burns, tans with difficulty and tends to be freckled
III	Sandy Blonde, Brown	Medium <i>Southern Europe</i>	Hazel, green, blue,	Burns initially, tans fairly well and evenly
IV	Brown, Black	Moderate brown, Olive <i>Mediterranean, Latin (Italian, Hispanic)</i>	Hazel, brown	Burns are rarely evident, tans easily
V	Black	Dark Brown <i>(Asian, Middle Eastern, American Indian)</i>	Dark brown, black	Burns are never evident, tans always <i>*some Asian skin always burns and never tans</i>
VI	Black	Black <i>(African-American, Indonesian)</i>	Dark brown, black	Burns are never evident, tans always



Skin type V is the most under-typed skin. Often Asians will look very light and have no history of sun exposure. Occasionally they have "bleached" their skin with hydroquinone. Treating them as a III or IV (based on look and reaction to sun) could result

in higher risk of complications. Initially, all Asian skins should be treated as a Skin Type V until reaction to laser light has been determined. Similarly, not all black skins are of the same degree of darkness and there may be the temptation to type these patients as a lower type.

9.10.6.4 Informed Consent

The process of accepting and confirming treatment must be reviewed, understood and signed by the patient prior to treatment. This document must review the topics discussed during the consultation. It acknowledges that the patient understands the procedure, possible risks and complications and that all questions have been answered. *Reference sample Informed Consent in Appendix of Sciton Operator Manual.*

9.10.6.5 Antiviral Medication

To prevent the activation of a herpes simplex virus infection, it is recommended that an antiviral medication be prescribed.

9.10.6.6 Photographs

Pictures should be taken prior to each treatment to document the progress of the treatment. Photographs are useful in demonstrating efficacy of treatment to the patient.

Camera settings, distance, backdrop, and body/face angle, position and expression should be the same for each photography session to maintain similar quality.

The patient should sign a photo release form if before and after pictures are to be used for educational or marketing purposes.

9.10.6.7 Topical Anesthesia

Use a topical preparation, as needed, to alleviate discomfort for sensitive patients or sensitive areas prior to treatment. The manufacturer's guidelines for the application and duration of the anesthetic should be read prior to topical application. Remove before treatment with mild soap and water or an alcohol swab, then plain water. Dry the area thoroughly before treatment.

Reminder: Each patient should be assessed and questioned regarding allergies or sensitivities to ingredients in topical anesthetics prior to application.



Be extremely cautious when applying topical anesthetics to large areas of the body. Lidocaine toxicity has been linked to several deaths.

9.10.6.8 Eye Protection

Eye protection should always be worn by everyone present in the treatment room during any laser or light based treatment. When treating on the patient's face, they should always wear non-reflective, metal goggles or laser approved disposable eye shields. Anytime a procedure is performed on the upper eyelid, internal corneal shields must be worn by the patient.

9.10.6.9 Smoke Evacuator

During surgical procedures using a laser or electrosurgical unit, the thermal destruction of tissue creates a smoke by-product. Research studies have confirmed that this smoke plume can contain toxic gases and vapors such as benzene, hydrogen cyanide, and formaldehyde, bio-aerosols, dead and live cellular material (including blood fragments), and viruses. At high concentrations the smoke causes ocular and upper respiratory tract irritation in health care personnel, and creates visual problems for the clinician. The smoke has unpleasant odors and has been shown to have mutagenic potential.

All medical personnel should consider the vaporized tissue plume to be potentially hazardous both in terms of the particulate matter and infectivity. A smoke evacuator should be used at all times when smoke is created in order to collect the plume. Surgical masks with 0.1µm filtration can be worn in addition to the use of a smoke evacuator.

A Smoke Evacuator contains a suction unit (vacuum pump), a filter, a hose, and an inlet nozzle. A smoke evacuator should have high efficiency in airborne particle reduction and should be used in accordance with the manufacturer's recommendations to achieve maximum efficiency:

- The suction should have a high flow volume with frequent filter changes being made to optimize suction and filter capabilities.

- Filters should be chosen which allow for maximum filtering efficiency.
- The distal end of the smoke evacuator should be as close as possible to the treated area. Smoke evacuator hoses not within one inch of the area treated will capture less than 50% of the smoke and debris created at the ablative site.
- Evacuator suction tips should be cleaned (preferable sterilized) after each procedure.
- Expired filters and used hoses should be treated as a bio-hazard. Surgical masks and gloves should be worn when red-bagging.

9.10.6.10 Skin Thickness

It is important to avoid ablation of the full thickness of both the epidermis and dermis (E+D). Full thickness ablation markedly increases the risk of scarring and long term tissue.

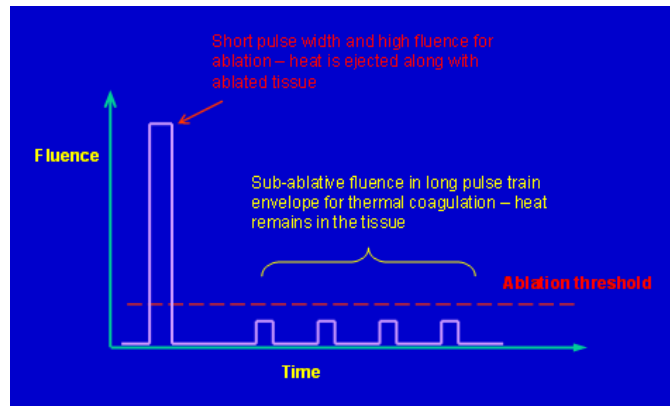
Skin Thickness Chart

Anatomical Region	Epidermis μm	Dermis μm	E+D μm	Hypodermis μm	Total μm
Mental	149	1375	1524	1020	2544
Forehead	202	969	1171	1210	2381
Upper lip	156	1061	1217	931	2148
Lower lip	113	973	1086	829	1915
Tip of nose	111	918	1029	735	1764
Neck	115	138	253	544	797
Cheek	141	909	1050	459	1509
Glabella	144	324	468	223	691
Eyelids	130	215	345	248	593

Note: These measurements can vary from patient to patient and are intended to be used only as a guideline.

9.10.6.11 Use of COAG

Resurfacing, 4 mm Single Spot and ProFractional-XC/III treatments can deliver high energy erbium pulses interleaved with low-energy erbium pulses to sequentially vaporize and coagulate tissue. By delivering long, low energy, sub-ablative pulses, heat can be deposited into tissue without vaporizing the tissue. Resurfacing, 4 mm Single Spot and ProFractional-XC/III treatments can deliver energy in very short pulses so that the laser can deposit enough energy to rapidly ablate tissue. Resurfacing, 4 mm Single Spot and ProFractional-XC/III treatments can also deliver energy at a rate such that heat is carried to lower depths by conduction faster than the laser is depositing it so that the exposed tissue never accumulates enough energy to vaporize. This can result in deep coagulation. By precisely setting the high energy pulse and the low energy long pulse a range of ablation and coagulation depths can be achieved.



9.10.7 Safe Start Protocol for 2940 nm Er:YAG Contour TRL MicroLaserPeel (MLP)

MicroLaserPeel (MLP) is an epidermal laser peel (4 - 50 microns) that precisely ablates or removes the outermost layers of the skin resulting in an improvement of fine lines and wrinkles, reduction of superficial brown spots and an overall improvement in the appearance of skin.

The epidermis is a robust and resilient structure with an average thickness, on the face, of about 110 microns. It functions as a physical barrier to protect the deeper dermis, and retain the skin's hydration. It is often the source of fine lines and discolorations in aging skin. The MLP, 4-50 microns in selected depth, will not fully penetrate the epidermal barrier of the skin. Therefore the safety, shortened recovery time, and ease of care with these procedures produce a treatment that is preferred by many patients and physicians.

Contour Scanner

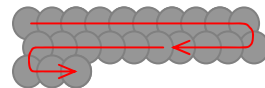


Contour TRL Scanner
(4 mm)

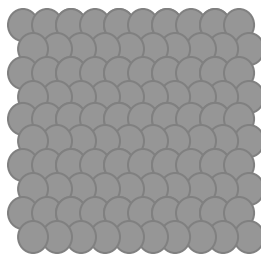


Zoom Scanner
(4/6 mm)

The Contour or Zoom Scanner is used for both MLP and Resurfacing treatments. The scanner handpiece consists of 2 galvanometers and collimating optics contained in a housing. The galvanometers allow the beam to be scanned to form two dimensional spots on the skin surface.

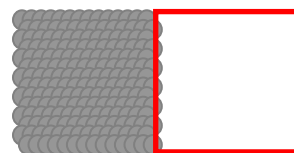
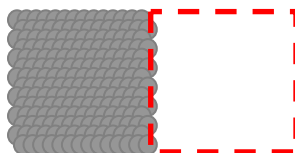


Spots are scanned in a serpentine manner.



Complete scan with 30% overlap.
Spot size equals 4 mm.
Scanned area shown is a pattern size 8 which is 27 mm x 27 mm.

The Contour Scanner allows for complete and uniform application of the laser energy by delivering 4 mm spots of energy within a designated pattern shape and size. Aiming beam is represented by red square and shows the user the area to be treated. The energy will be delivered inside the red square. When the red square is "dancing" the system is in Standby. When the red square is solid the system is in Ready.



Standby

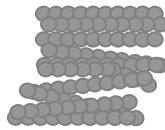
Ready

Care should be taken to apply adjoining scans without gap or excessive overlap of the previously scanned area. Align each scan pattern up to each other to avoid gap or overlap as shown above.

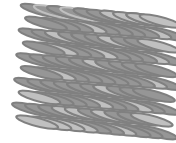
To achieve uniform treatment as shown, the scanner should always be:

- (a) held with a steady hand during the scanning process, and
- (b) held perpendicular and within 6 inches of the skin surface.

Examples of incorrect scanning:



Scanner not held steadily

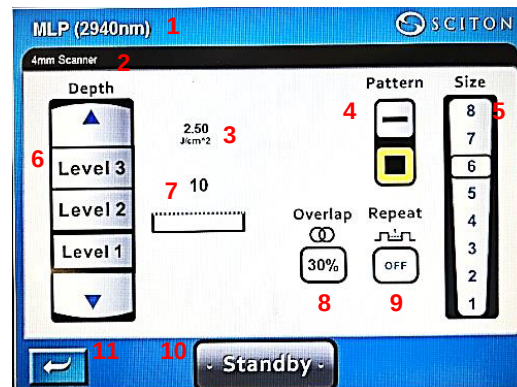


Scanner not held perpendicular to skin surface

Many physicians divide the total ablation evenly between two passes to avoid the presence of scanner patterns on the skin (i.e., 40 micron ablation performed as two 20 micron passes). If two passes are performed, the scanner should be rotated on the 2nd pass to avoid the presence of scanner patterns on the skin.

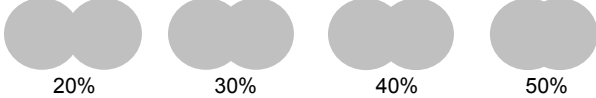
MLP (2940 nm) User Screen

Attach the standard Contour or Zoom Scanner to the articulated arm. Press the MicroLaserPeel softkey on the 2940 nm application screen and the system will enter the MLP (2940 nm) application screen.



Note: This application covers 100% of the skin within the scanned pattern; it does not produce a "fractional" effect.

1. Application and wavelength indicator
Application and wavelength indicator shows which treatment screen the user is in and which wavelength is being used for the treatment.
2. Handpiece indicator
Handpiece indicator shows which handpiece is being used for the treatment.
Note: Zoom Scanner allows use of 6 mm spot size in addition to standard 4 mm spot size. A weight will need to be added to the end of the counterweight to balance the Zoom handpiece.
3. Ablation fluence indicator
Ablation fluence indicator shows the amount of fluence or energy being delivered based on the depth of the ablation selected. $1\text{J}/\text{cm}^2 = 4\text{ microns of ablation}$.
4. Pattern shape softkeys
Pattern shape can be adjusted from a square to a rectangle to assist in more complete coverage of a treatment area by tapping either the rectangle or square softkey.

5. Pattern size adjustment softkeys
Pattern size can be adjusted from 1 to 8; 8 x 8 mm to 30 x 30 mm square or 12 x 6 mm to 27 x 6 mm rectangle by tapping the desired numbered softkey.
 6. Ablation depth softkeys
Ablation depth relates to the amount of tissue to be removed. The ablative depth may be set by tapping the softkeys: Level One = 10 microns, Level Two = 20 microns or Level Three = 30 microns. The laser may also be set manually from 4 -50 micron ablation depth by tapping or holding down the up ▲ or down ▼ arrow softkeys.
 7. Tissue diagram indicator
Tissue diagram gives the user a quick reference to the amount of ablative energy being delivered to tissue. The more superficial the depth of treatment the smaller the tissue diagram and the deeper the treatment depth the bigger the tissue diagram.
 8. Pattern spot overlap softkeys
Spot overlap within the scanned pattern may be adjusted from 20 - 50% (30% is default) by tapping the overlap softkey.
- 

20% 30% 40% 50%
9. Pattern repeat softkey
Pattern repeat allows the user to set an amount of time between consecutive scans of 0.5, 1.0, 1.5 or 2.0 seconds by tapping the repeat softkey. Repeat can also be turned off so that each scan pattern is delivered by lifting and depressing the footswitch.
 10. System status softkey
System status softkey will allow the user to put the system in Standby or Ready mode.
 11. Return to 2940 nm Applications screen softkey
Return to 2940 nm application softkey will return the system to the previous screen.

9.10.7.1 Precautions

- Patients must be carefully evaluated by the physician for their risk of scarring versus the treatment benefit.
- Treatment should be done in a conservative fashion in areas where the skin is thin, such as the temple and forehead areas.
- Post-treatment hyperpigmentation may occur after 3-4 weeks.
- Direct and intentional sun exposure should be avoided for 7-10 days, then daily use of sun block is recommended to avoid pigment related complications.
- Patients who smoke may experience delayed healing and decreased benefit.
- Particulate debris on the lens of the scanner may result in laser beam scattering and an incorrect setting for depth of treatment. Cleaning the lens prior to, and during treatment, is essential to ensure accurate treatment settings.
- Treating with overlapping scans or at settings much higher than those recommended by the protocol may lead to undesirable outcomes. Attention to technique and conservative treatment is recommended.
- Selection of patients must include evaluation of Fitzpatrick Skin Type (I-VI). The MicroLaserPeel is a purely ablative procedure without the coagulation mode that may lead to long term or permanent hypo- or hyper-pigmentation issues. However, darker skin types may have transient pigmentary loss with more aggressive MicroLaserPeel (40-50 micron) treatment. The transitory loss can be a natural healing phenomenon with a potential period of 3 to 30 days.

MLP on non-facial tissues: The epidermis of the neck, chest, hands and general body surfaces is thinner than that of the face and has fewer adnexal healing structures. Peels beyond 20 microns are not recommended in a single treatment. Retreatment may occur as early as 8 weeks. This procedure may not be ideal for patients with known healing deficiencies.

9.10.7.2 2940 nm Er:YAG Contour TRL MicroLaserPeel

Treatment Basics

- Patient should be positioned based on the area to be treated. The position should be comfortable to the patient and such that the treatment provider has good access to area to be treated and the control panel display screen.
- A mild cleanser should be used to remove any dirt, makeup or moisture from the treatment site. Follow with an alcohol gauze. Allow alcohol to evaporate before treatment. Use special care around the eyes.
- If topical anesthetic is to be used, apply as directed prior to treatment. Before beginning treatment, ensure that topical has been completely removed from surface of skin.
- Prepare for adequate smoke evacuation.
- Attach the Contour Scanner that has previously been cleaned with an alcohol gauze to the articulated arm.
- Enter settings into the control panel display screen based on condition and area to be treated.



Verify that scanner preview pattern is centered prior to treatment. If pattern is not centered, refer to Section 7.6 for instructions on how to center the scan pattern.

Treatment Starting Parameters

Application	Indication	Ablation Depth (µm)	% of Overlap
MicroLaserPeel	Fine lines and wrinkles, minor lesions, and superficial hyperpigmentation	Up to 50 microns	10 - 50%

- The Contour Scanner should be held perpendicular and to within 6 inches of the skin surface at all times for efficient and uniform ablation. Move patient if necessary to accomplish a 90 degree angle.
- To confirm that laser and accessories are performing normally, it is useful for the operator to first test on a nonflammable inanimate object like a wooden tongue depressor. Treating a test area prior to beginning treatment will determine the patient's response threshold and help them understand the audible and sensory components of the treatment.
- Match the trailing edge of one scan pattern to the leading edge of the next. There should be no overlap between scans. Patterns should "line up" right next to each other. Refer to Section 7.6.6.1. Ablative depth can be divided into two equal passes to cover accidental missed or overlapped scans and for greater patient comfort.
- Particulate debris on the optics of the scanner may result in laser beam scattering and an incorrect setting for fluence. Scanner optics should be cleaned throughout treatment with a gauze moistened with water. If alcohol is used, clean with the water gauze first and then the alcohol and allow to dry completely before continuing with the treatment.
- The desired endpoint is erythema within a few minutes of laser application. The redness and healing (often similar in appearance to varying degrees of sunburn) will increase with the ablation depth and will vary by patient.

Post-Treatment

- **OBSERVATIONS**
Some possible side effects: erythema, localized edema, urticaria, sun burn sensation, flaking and tightness of skin.
Side effects after MLP can be observed for 12-48 hours after treatment, depending upon depth of peel.

- **INTERVENTION**
Cool compresses or ice packs can provide immediate comfort after treatment.
An occlusive barrier such as Aquaphor will provide protection and comfort to treated area and should be used until skin has re-epithelialized.
- **INTERVAL** between 2940 nm Er:YAG Contour TRL MicroLaserPeel is approximately 4-8 weeks depending upon depth of peel and the health and integrity of skin being treated.

Concurrent Procedures

Noninvasive light-based treatments like hair reduction or collagen stimulation may occur prior to a 2940 nm Er:YAG Contour TRL MicroLaserPeel.
Check with manufacturer for guidelines on using injectables in conjunction with 2940 nm Er:YAG Contour TRL MicroLaserPeel.

9.10.8 Safe Start Protocol for 2940 nm Er:YAG Contour TRL Resurfacing

2940 nm Er:YAG Contour TRL Resurfacing is a dermal laser peel (50 microns and beyond) that precisely ablates or removes layers of the skin resulting in an improvement of deeper lines and wrinkles, acne scars and an overall improvement in the appearance of skin.

The dermis is a thick layer of fibrous and elastic tissue (made mostly of collagen, elastin, and fibrillin) that gives the skin its flexibility and strength. The dermis lies immediately underneath the epidermis and is about four times thicker. The dermis contains nerve endings, sweat glands and oil glands, hair follicles, and blood vessels.

Scanner

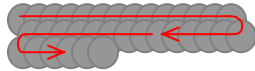


Contour TRL Scanner
(4 mm)

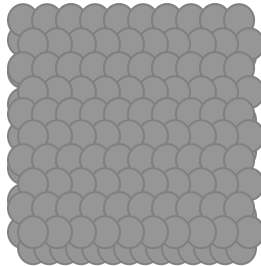


Zoom Scanner
(4/6 mm)

The Contour or Zoom Scanner is used for both MLP and Resurfacing treatments. The scanner handpiece consists of 2 galvanometers and collimating optics contained in a housing. The galvanometers allow the beam to be scanned to form two dimensional spots on the skin surface.

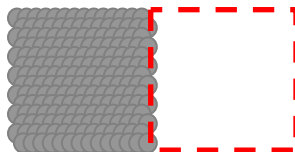


Spots are scanned in a serpentine manner.

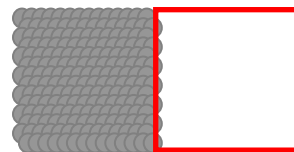


Complete scan with 50% overlap.
Spot size equals 4 mm.
Scanned area shown is a pattern size 8 which is 30 mm x 30 mm.
To achieve uniform treatment as shown, the scanner should be:
(a) held with a steady hand during the scanning process, and
(b) held perpendicular and within 6 inches of the skin surface at all times.

The Contour Scanner allows for complete and uniform application of the laser energy by delivering 4 mm spots of energy within a designated pattern shape and size. Aiming beam is represented by red square and shows the user the area to be treated. The energy will be delivered inside the red square. When the red square is "dancing" the system is in Standby. When the red square is solid the system is in Ready.



Standby



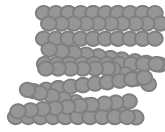
Ready

Care should be taken to apply adjoining scans without gap or excessive overlap of the previously scanned area. Align each scan pattern up to each other to avoid gap or overlap as shown above.

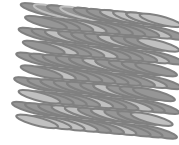
To achieve uniform treatment as shown, the scanner should always be:

- (a) held with a steady hand during the scanning process, and
- (b) held perpendicular and within 6 inches of the skin surface.

Examples of incorrect scanning:



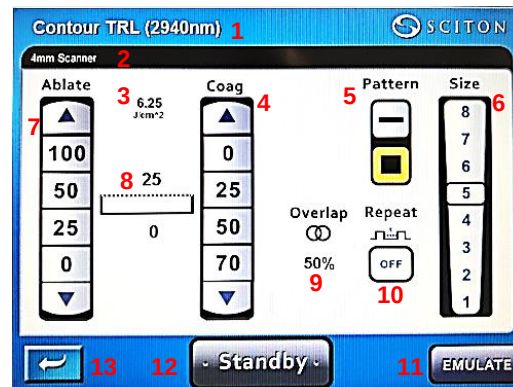
Scanner not held steadily



Scanner not held perpendicular to skin surface

Resurfacing User Screen

Attach the Contour Scanner to the articulated arm. Press the Resurfacing softkey on the 2940 nm application screen and the system will enter the TRL (2940 nm) application screen.



Note: This application covers 100% of the skin within the scanned pattern; it does not produce a "fractional" effect.

1. Application and wavelength indicator
Application and-wavelength indicator shows which treatment screen the user is in and which wavelength is being used for the treatment.
2. Handpiece indicator
Handpiece indicator shows which handpiece is being used for the treatment.
Note: For Zoom Scanner, only 4mm spot size is available.
3. Ablation fluence indicator
Ablation fluence indicator shows the amount of fluence or energy being delivered based on the depth of the ablation selected. $1\text{J}/\text{cm}^2 = 4$ microns of ablation.
4. Coagulation depth softkeys
Coagulation depth may be set by tapping the default softkeys of 0, 25, 50 or 70 microns and can also be adjusted from 0 - 130 microns by tapping or holding down the up ▲ or down ▼ arrow softkeys. See Section 8.6.5.11 for explanation of COAG.
5. Pattern shape softkeys
Pattern shape can be adjusted from a square to a rectangle to assist in more complete coverage of a treatment area by tapping softkeys.
6. Pattern size adjustment softkeys
Pattern size can be adjusted from 1 to 8; 8 x 8 mm to 30 x 30 mm square and 6 x 6 mm to 30 x 6 mm rectangle by tapping softkeys.
7. Ablation depth adjustment softkeys
Ablation depth relates to the amount of tissue to be removed. The ablative depth may be set by tapping the default softkeys of 0, 25, 50 or 100 microns. The laser may also be set manually from 0 - 200 microns by tapping or holding down the up ▲ or down ▼ arrow softkeys.
8. Tissue diagram indicator
Tissue diagram gives the user a quick reference to the amount of ablative and COAG (if selected) energy being delivered to tissue. The deeper the treatment depth the bigger

the tissue diagram. The amount of COAG selected is represented under the tissue diagram in dark shade and will increase in size as the COAG depth is increased.

9. Pattern spot overlap indicator

Spot overlap within the scanned pattern is fixed at 50%.



50% spot overlap

10. Pattern repeat softkey

Pattern repeat allows the user to set an amount of time between consecutive scans of 0.5, 1.0, 1.5 or 2.0 seconds by tapping the repeat softkey. Repeat can also be turned off so that each scan pattern is delivered by lifting and depressing the footswitch.

11. Emulate softkey for Er:YSGG or CO₂ preset settings

Emulate softkey allows the user to choose settings that would emulate either a YSGG treatment with 20 microns of ablation and 20 microns of COAG or a CO₂ like treatment with 50 microns of ablation and 70 microns of COAG by tapping the emulate softkey.

12. System status softkey

System status softkey allows the user to put the system in Standby or Ready

13. Return to 2940 nm Applications screen softkey

Return to 2940 nm application softkey will return the system to the previous screen.

9.10.8.1 Precautions

- Patients must be carefully evaluated by the physician for their risk of scarring versus the treatment benefit, especially with selection of coagulation setting when using the Contour TRL.
- Treatment should be done in a conservative fashion in areas where the skin is thin, such as the temple and forehead areas.
- Post-treatment hyperpigmentation may occur after 3-4 weeks.
- Direct and intentional sun exposure should be avoided for 7-10 days, then daily use of sun block is recommended to avoid pigment related complications.
- Patients who smoke may experience delayed healing and decreased benefit.
- Particulate debris on the lens of the scanner may result in laser beam scattering and an incorrect setting for depth of treatment. Cleaning the lens prior to, and during treatment, is essential to ensure accurate treatment settings.
- Treating with overlapping scans or at settings much higher than those recommended by the protocol may lead to undesirable outcomes. Attention to technique and conservative treatment is recommended.
- Selection of patients must include evaluation of Fitzpatrick Skin Type (I-VI). 2940 nm Er:YAG Contour TRL Resurfacing is an ablative procedure selected with or without the coagulation mode.
Note that using coagulation mode while ablating the epidermis may lead to long term or permanent hypo or hyper-pigmentation issues in skin types IV-VI. However, darker skin types may have transient pigmentary loss in the more aggressive pure ablative resurfacing (50+ microns). This transitory loss is a natural healing phenomenon with a potential period of 3 to 30 days.
- **Anesthesia:** Ablation of more than 50 microns usually requires the use of general anesthesia, conscious sedation, or injection of local anesthesia. Proper safety protocols should be followed for all anesthesia types.
- **2940 nm Er:YAG Contour TRL Resurfacing on non-facial tissues:** The epidermis of the neck, chest, hands and general body surfaces is thinner than that of the face and has fewer adnexal healing structures.
Peels beyond 20 microns are not recommended in a single treatment. COAG should not be added to treatments performed on non-facial tissue. Retreatment may occur as early as 8 weeks. This procedure may not be ideal for patients with known healing deficiencies.

9.10.8.2 2940 nm Er:YAG Contour TRL Resurfacing

Treatment Basics

2940 nm Er:YAG Contour TRL Resurfacing is considered a more advanced treatment. Sciton recommends that each user attend a Preceptor training course prior to offering 2940 nm Er:YAG Contour TRL Resurfacing treatments to their patients. Treatment specifics will be reviewed and discussed during the preceptorship.



Verify that scanner preview pattern is centered prior to treatment. If pattern is not centered, refer to Section 7.6 for instructions on how to center the scan pattern.

Treatment Starting Parameters

Application	Indication	Ablation Depth (µm)
Resurfacing	moderate wrinkles, lesions and shallow scars	100
	deep wrinkles and scars	400 - 800
<i>Tissue coagulation is the addition of heat to produce a zone of thermal necrosis. As an option, Contour TRL scanner allows the user to select coagulation depths of 0-130 microns.</i>		

Post-Treatment

- **OBSERVATIONS**

Some possible side effects: erythema, edema, urticaria, sun burn sensation, oozing and crusting, flaking and tightness of skin.
Side effects 2940 nm Er:YAG Contour TRL Resurfacing can be observed for 7-10 days after treatment, depending upon depth of peel.

- **INTERVENTION**

Intervention measures will be discussed during preceptorship.

- **INTERVAL** between 2940 nm Er:YAG Contour TRL Resurfacing treatments is approximately 8-12 weeks depending upon depth of peel.

Concurrent Procedures

Noninvasive light-based treatments like hair reduction or collagen stimulation may occur prior to a 2940 nm Er:YAG Contour TRL Resurfacing procedure. All other procedures should not be performed concurrently.

Check with manufacturer for guidelines on using injectables in conjunction with 2940 nm Er:YAG Contour TRL Resurfacing treatments.

9.10.9 Safe Start Protocol for 2940 nm Er:YAG Contour TRL Single Spot Treatment

The 2 mm or 4 mm single spot handpiece can be used to treat unwanted lesions such as Actinic Keratoses (AK) or Seborrheic Keratoses (SK), acne scars and hypertrophic scars. The handpiece can also be used to treat missed spots of a full face treatment.

Single Spot Handpiece

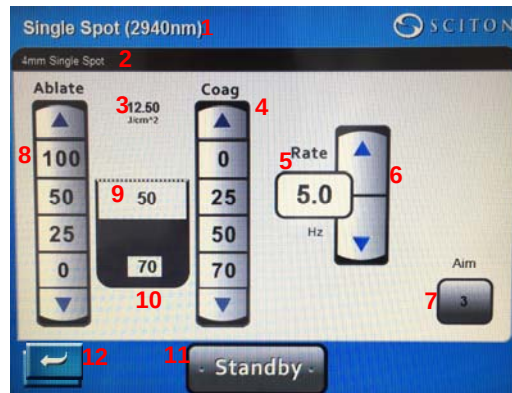
The Single Spot handpiece consists of a hollow tube housing two lenses and a removable bayonet. The bayonet distance guide assures appropriate distance to tissue and accurate spot size delivery.

2 mm & 4 mm Handpieces



4 mm Single Spot Screen

Attach the 4 mm single spot handpiece to the articulated arm. Press the Single Spot softkey on the 2940 nm application screen and the system will enter the TRL (2940 nm) application screen.

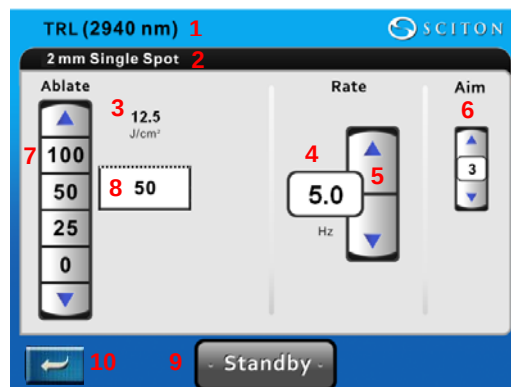


Note: This application covers 100% of the skin within the 4 mm single spot treated; it does not produce a "fractional" effect.

1. Application and wavelength indicator
Application and-wavelength indicator shows which treatment screen the user is in and which wavelength is being used for the treatment.
2. Handpiece Spot Size indicator
Handpiece spot size indicates that the 4 mm single spot handpiece is attached to the articulated arm.
 4 mm spot size
3. Ablation fluence indicator
Ablation fluence indicator shows the amount of fluence or energy being delivered based on the depth of the ablation selected. $1\text{J}/\text{cm}^2 = 4\text{ microns}$ of ablation.
4. Coagulation depth softkeys
Coagulation depth may be set by tapping the default softkeys of 0, 25, 50 or 70 microns and can also be adjusted from 0 - 70 microns by tapping or holding down the up ▲ or down ▼ arrow softkeys. See earlier section for explanation of COAG.

5. Repetition rate indicator
Repetition rate is the length of time between each single spot delivery when the footswitch is held down continuously. The rate is measured in Hz.
6. Repetition rate adjustment softkeys
Repetition rate adjustment softkeys allow the user to increase or decrease each single spot delivery 1 Hz (1 spot per second) up to 43 Hz (42 spots per second) by tapping or holding down the up ▲ or down ▼ arrow softkeys.
7. Aiming beam intensity softkey
Aiming beam intensity allows the user to make the aiming beam lighter or brighter in intensity. MIN, 2, 3, 4 or MAX intensity can be selected by tapping the Aim softkey.
8. Ablation depth softkeys
Ablation depth relates to the amount of tissue to be removed. The ablative depth may be set by tapping the default softkeys of 0, 25, 50 or 100 microns. The laser may also be set manually from 0 - 100 microns by tapping or holding down the up ▲ or down ▼ arrow softkeys.
9. Tissue diagram indicator
Tissue diagram gives the user a quick reference to the amount of ablative and COAG (if selected) energy being delivered to tissue. The deeper the treatment depth the bigger the tissue diagram.
10. COAG indicator
The amount of COAG selected is represented under the tissue diagram in black and will increase in size as the COAG depth is increased.
11. System status softkey
System status softkey allows the user to put the system in Standby or Ready.
12. Return to 2940 nm applications screen softkey
Return to 2940 nm application softkey will return the system to the previous screen.

2 mm Single Spot Screen



Note: This application covers 100% of the skin within the 2 mm single spot treated; it does not produce a "fractional" effect.

1. Application and wavelength indicator
Application and-wavelength indicator shows which treatment screen the user is in and which wavelength is being used for the treatment.
2. Handpiece Spot Size indicator
Handpiece spot size indicates that the 2 mm single spot handpiece is attached to the articulated arm.
● 2 mm spot size
3. Ablation fluence indicator
Ablation fluence indicator shows the amount of fluence or energy being delivered based on the depth of the ablation selected. $1\text{J}/\text{cm}^2 = 4\text{ microns}$ of ablation.
4. Repetition rate indicator
Repetition rate is the length of time between each single spot delivery when the footswitch is held down continuously. The rate is measured in Hz.
5. Repetition rate adjustment softkeys
Repetition rate adjustment softkeys allow the user to increase or decrease each single spot delivery 1 Hz (1 spot per second) up to 42 Hz (42 spots per second) by tapping or holding down the up ▲ or down ▼ arrow softkeys.

6. Aiming beam intensity softkey
Aiming beam intensity allows the user to make the aiming beam lighter or brighter in intensity. MIN, 1, 2, 3, 4, 5 or MAX intensity can be selected by tapping the Aim softkey.
7. Ablation depth softkeys
Ablation depth relates to the amount of tissue to be removed. The ablative depth may be set by tapping the default softkeys of 0, 25, 50 or 100 microns. The laser may also be set manually from 0 - 200 microns by tapping or holding down the up ▲ or down ▼ arrow softkeys.
8. Tissue diagram indicator
Tissue diagram gives the user a quick reference to the amount of ablative energy being delivered to tissue.
9. System status softkey
System status softkey allows the user to put the system in Standby or Ready.
10. Return to 2940 nm applications screen softkey
Return to 2940 nm application softkey will return the system to the previous screen.

9.10.9.1 Precautions

- Patients must be carefully evaluated by the physician for their risk of scarring versus the treatment benefit, especially with selection of coagulation setting when using the single spot handpiece.
- Treatment should be done in a conservative fashion in areas where the skin is thin, such as the temple and forehead areas.
- Post-treatment hyperpigmentation may occur after 3 - 4 weeks.
- Direct and intentional sun exposure should be avoided for 7 - 10 days, then daily use of sun block is recommended to avoid pigment related complications.
- Patients who smoke may experience delayed healing and decreased benefit.
- Particulate debris on the lens of the handpiece may result in laser beam scattering and an incorrect setting for depth of treatment. Cleaning the lens prior to, and during treatment, is essential to ensure accurate treatment settings.
- Treating at settings much higher than those recommended by the protocol may lead to undesirable outcomes. Attention to technique and conservative treatment is recommended.
- Selection of patients must include evaluation of Fitzpatrick Skin Type (I-VI). The 2940 nm Er:YAG Contour TRL Single Spot treatment is an ablative procedure selected with or without the coagulation mode. Note that using coagulation mode (available only with 4 mm handpiece) while ablating the epidermis may lead to long term or permanent hypo or hyper-pigmentation issues in skin types IV-VI. However, darker skin types may have transient pigmentary loss in the more aggressive pure ablative single spot treatments (50+ microns). This transitory loss is a natural healing phenomenon with a potential period of 3 to 30 days.

9.10.9.2 2940 nm Er:YAG Contour TRL Single Spot Treatment

Treatment Basics

- Patient should be positioned based on the area to be treated. The position should be comfortable to the patient and such that the treatment provider has good access to area to be treated and the control panel display screen.
- A mild cleanser should be used to remove any dirt, makeup or moisture from the treatment site. Follow with an alcohol gauze. Allow alcohol to evaporate before treatment. Use special care around the eyes.
- If topical anesthetic is to be used, apply as directed prior to treatment. Before beginning treatment, ensure that topical has been completely removed from surface of skin.
- Prepare for adequate smoke evacuation.
- Attach the 2 mm or 4 mm single spot handpiece that has been cleaned with an alcohol gauze, to the articulated arm.
- Enter settings into the control panel display screen based on condition and area to be treated. When treating with 2940 nm Er:YAG Contour TRL Single Spot in combination with a MLP, the single spot treatment can be performed before or after the MLP.

Treatment Starting Parameters

Application	Indication	Ablative Depth (µm)	Repetition Rate (Hz)
2 mm single spot	Actinic Keratoses, Seborrheic Keratoses, Acne Scars	10	1 - 5
4 mm single spot	Actinic Keratoses, Seborrheic Keratoses, Acne Scars	10 - 20	1 - 5
<i>Tissue coagulation is the addition of heat to produce a zone of thermal necrosis. As an option, the 4 mm single spot handpiece allows the user to select coagulation depths of 0 - 70 microns.</i>			

- The single spot handpiece should be held perpendicular. Move patient if necessary to accomplish a 90 degree angle. Use the bayonet distance guide to help achieve this angle and proper distance to tissue for efficient and uniform ablation.
- To confirm that laser and accessories are performing normally, it is useful for the operator to first test on a nonflammable inanimate object like a wooden tongue depressor. Treating a test area prior to beginning treatment will determine the patient's response threshold and help them understand the audible and sensory components of the treatment.
- Particulate debris on the optics of the handpiece may result in laser beam scattering and an incorrect setting for fluence. Handpiece optics should be cleaned throughout treatment with a moistened wipe. If alcohol is used, allow the alcohol to dry completely before continuing with the treatment.

Epidermal Lesions

When treating for Actinic Keratoses (AK) or Seborrheic Keratoses (SK), the goal is to remove the epidermis to the appropriate depth of the lesion.

Using either the 2 mm spot or 4 mm spot choose the 10 micron setting and a repetition rate of 1 - 5 hertz. Ablate the area by making a pass covering the entire lesion. Use a 4 x 4 gauze sponge and wipe any residue from the area to assess the lesion clearance. Make additional passes until the lesion is gone. Pinpoint bleeding indicates that the papillary dermis has been reached and further passes should be avoided.

Acne Scars

These are generally assessed as if histology is mid papillary to upper reticular. It is better to avoid treatment into the reticular dermis.

Select either the 2 mm or 4 mm single spot handpiece based on the size of the lesion being treated, set the ablative depth to 10 microns and the repetition rate to 1 - 5 Hz. Trace the outer margins of the acne scars to smooth down the ridges. The idea is to decrease the highly demarcated ridges to blend into the valleys. After smoothing down the ridges in an area, use the Contour Scanner and set the laser to the appropriate depth (extending to the papillary dermis) and treat the entire area to promote uniform healing.

Post-Treatment

- **OBSERVATIONS**

Some possible side effects: erythema, localized edema, urticaria, sun burn sensation, flaking and tightness of skin.

Side effects after single spot treatment can be observed for 12 - 48 hours after treatment, depending upon depth of treatment.

- **INTERVENTION**

Cool compresses or ice packs can provide immediate comfort after treatment.

An occlusive barrier such as Aquaphor will provide protection and comfort to treated area and should be used until skin has re-epithelialized.

- **INTERVAL** between single spot treatments is approximately 4 - 8 weeks depending upon depth of treatment and the health and integrity of skin being treated.

Concurrent Procedures

Noninvasive light-based treatments like hair reduction or collagen stimulation may occur prior to a single spot treatment. When treating with the 2940 nm Er:YAG Contour TRL Single Spot in combination with a MLP, the single spot treatment can be performed before or after the MLP.

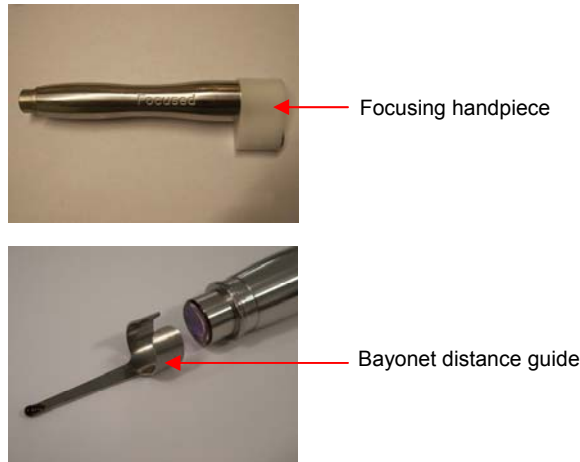
Check with manufacturer for guidelines on using injectables in conjunction with 2940 nm Er:YAG Contour TRL Single Spot treatments.

9.10.10 Safe Start Protocol for using the 2940 nm Er:YAG Contour TRL Focused Spot Treatment

The Focused handpiece is designed for use in surgical applications requiring the excision, incision, ablation, vaporization and coagulation of soft tissue.

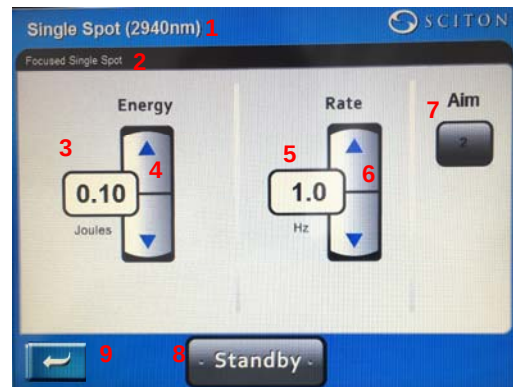
9.10.10.1 Focused Handpiece

The Focused Single Spot handpiece consists of a hollow tube housing a lens and a removable bayonet. The bayonet distance guide assures appropriate distance to tissue and accurate spot size delivery. The spot size becomes larger away from the focal point. The handpiece uses specialized optics to generate an approximately 0.7 mm diameter spot. The spot size is determined by the energy, repetition rate (Hz) and the distance. This spot size is desirable for precise tissue ablation.



9.10.10.2 Focused Single Spot Screen

Attach the Focused Single Spot handpiece to the articulated arm. Press the Single Spot softkey on the 2940 nm application screen and the system will enter the TRL (2940 nm) application screen.



1. Application and wavelength indicator
Application and-wavelength indicator shows which treatment screen the user is in and which wavelength is being used for the treatment.
2. Handpiece Spot Size indicator
Handpiece spot size indicates that the Focused Single Spot handpiece is attached to the articulated arm.
3. Energy indicator
Energy indicator shows the amount of energy being delivered in Joules.

4. Energy adjustment softkeys
Energy adjustment softkeys allow the user to increase or decrease energy by 0.05 Joules by tapping or holding down the up ▲ or down ▼ arrow softkeys.
5. Repetition rate indicator
Repetition rate is the amount of time between each single spot delivery when the footswitch is held down continuously. The rate is measured in Hz
6. Repetition rate adjustment softkeys
Repetition rate adjustment softkeys allow the user to increase or decrease each single spot delivery from 1 Hz (1 spot per second) up to 50 Hz (50 spots per second) by tapping or holding down the up ▲ or down ▼ arrow softkeys.
7. Aiming beam intensity softkey
Aiming beam intensity allows the user to make the aiming beam lighter or brighter in intensity. MIN, 2, 3, 4 or MAX intensity can be selected by tapping the Aim softkey.
8. System status softkey
System status softkey allows the user to put the system in Standby or Ready.
9. Return to 2940 nm Applications screen softkey
Return to 2940 nm application softkey will return the system to the previous screen.

9.10.10.3 Precautions

- Patients must be carefully evaluated by the physician for their risk of scarring versus the treatment benefit.
- Treatment should be done in a conservative fashion in areas where the skin is thin, such as the temple and forehead areas.
- Post-treatment hyperpigmentation may occur.
- Direct and intentional sun exposure should be avoided for 7 - 10 days, then daily use of sun block is recommended to avoid pigment related complications.
- Patients who smoke may experience delayed healing and decreased benefit.
- Particulate debris on the lens of the handpiece may result in laser beam scattering and an incorrect setting for depth of treatment. Cleaning the lens prior to, and during treatment, is essential to ensure accurate treatment settings.
- Treating at settings much higher than those recommended by the protocol may lead to undesirable outcomes. Attention to technique and conservative treatment is recommended.
- Selection of patients must include evaluation of Fitzpatrick Skin Type (I - VI). The Focused Single Spot treatment is an ablative procedure. Darker skin types may have transient pigmentary loss in the more aggressive single spot treatments (50+ microns). This transitory loss is a natural healing phenomenon.

9.10.10.4 2940 nm Er:YAG Contour TRL Focused Single Spot Treatment

Treatment Basics

- Patient should be positioned based on the area to be treated. The position should be comfortable to the patient and such that the treatment provider has good access to area to be treated and the control panel display screen.
- A mild cleanser should be used to remove any dirt, makeup or moisture from the treatment site. Follow with an alcohol gauze. Allow alcohol to evaporate before treatment.
- If topical anesthetic is to be used, apply as directed prior to treatment. Before beginning treatment, ensure that topical has been completely removed from surface of skin.
- Prepare for adequate smoke evacuation.
- After cleaning the Focused Single Spot Handpiece with alcohol gauze, attach to the articulated arm.
- Enter settings into the control panel display screen based on condition and area to be treated.

Treatment Starting Parameters

Application	Indication	Energy (J)	Repetition Rate (Hz)	Ablative Depth* (μm)
Focused Single Spot	Surgical applications requiring the excision, incision, ablation and coagulation of soft tissue	0.1 - 0.5	1 - 10	120 – 600

- The Focused Single Spot Handpiece should be held perpendicular. Move patient if necessary to accomplish a 90 degree angle. Use the bayonet distance guide to help achieve this angle and proper distance to tissue for efficient and uniform ablation.
- To confirm that laser and accessories are performing normally, it is useful for the operator to first test on a nonflammable inanimate object like a wooden tongue depressor. Treating a test area prior to beginning treatment will determine the patient's response threshold and help them understand the audible and sensory components of the treatment.
- To gain comfort of delivering pulses with this handpiece, it is suggested to practice on a stack of Post-it notes or a tongue blade for determining speed, accuracy, and approximation of degree of depth. The Focused Handpiece will provide a spot size of approximately 0.7 mm. The spot size is controlled by the speed, energy and the distance used.
** Note: As an example, choosing 0.1 J at 1 Hz will approximate a fluence of 30 J/cm² and an ablation depth of 120 μm . Choosing 0.5 J will approximate a fluence of 150 J/cm² and an ablation depth of 600 μm .*
- Particulate debris on the optics of the handpiece may result in laser beam scattering and an incorrect setting for fluence. Handpiece optics should be cleaned throughout treatment with a gauze moistened with alcohol.

Post-Treatment

- **OBSERVATIONS**
 Some possible side effects: erythema, localized edema, urticaria, sun burn sensation, flaking and tightness of skin.
 Side effects after Focused Single Spot treatment can be observed for 12 - 48 hours after treatment, depending upon depth of treatment.
- **INTERVENTION**
 Cool compresses or ice packs can provide immediate comfort after treatment.
 An occlusive barrier such as Aquaphor will provide protection and comfort to treated area and should be used until skin has reepithelialized.

- **INTERVAL**

If treated area requires touch up or additional treatment, this may be done in approximately 4-8 weeks depending upon the status of the healing process of the treated.

Concurrent Procedures

Noninvasive light-based treatments like hair reduction or collagen stimulation may occur prior to a 2940 nm Er:YAG Contour TRL Focused Single Spot Treatment . When treating with the 2940 nm Er:YAG Contour TRL Focused Single Spot in combination with a MLP, Focused Single Spot can be performed before or after the MLP.

Check with manufacturer for guidelines on using injectables in conjunction with 2940 nm Er:YAG Contour TRL Focused Single Spot treatments.

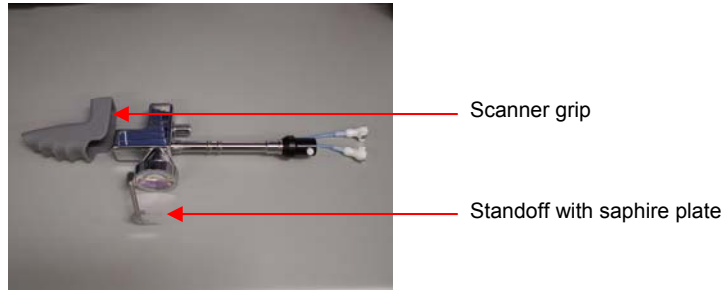
9.10.11 Safe Start Protocol for 2940 Er:YAG Contour TRL ProFractional/ProFractional-XC/III

ProFractional/ProFractional-XC/III works on the principle of fractionated photothermolysis. Due to the efficient water absorption characteristics of 2940 nm Er:YAG laser, the ProFractional/ProFractional-XC/III is able to ablate deeply into the dermis by vaporizing clean channels of tissue to a selected depth and instantly removing the tissue within the channel. It heats the water in the epidermis and dermal layer of the skin resulting in Microscopic Treatment Zones (MTZ) of ablated tissue. These channels are surrounded by healthy tissue, speeding healing time and reducing downtime for the patient. During the first day after a treatment, new epidermis proliferates into the channels and the entire area reepithelializes. The epidermal tissue responds immediately to the initial ablative process allowing for quicker healing and minimal downtime. These would simulate neocollagenesis and help to reduce the signs of photoaging.

ProFractional energy delivery is limited to the channels, minimizing patient discomfort.

9.10.11.1 ProFractional Scanner (250 µm spot delivery)

The ProFractional Scanner Handpiece consists of 2 galvanometers and collimating optics contained in a housing. The galvanometers allow the beam to be scanned to form two dimensional spots on the skin surface.

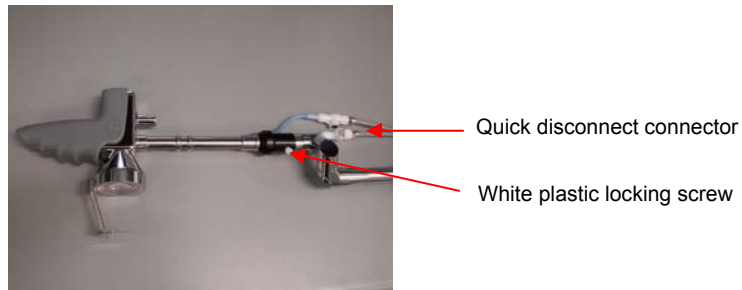


Scanner grip provides for a more comfortable hold while using the scanner. The grip is an option for the user and can be used with any Sciton scanner.

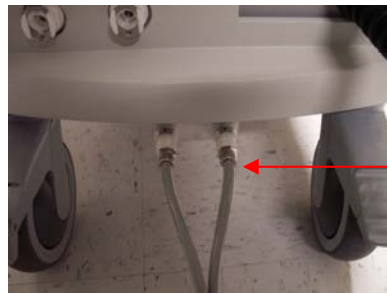
Note: When using scanner grip, make sure it fits tightly on the scanner housing.

Standoffs permit the user to position the focal plane of the laser energy onto the skin surface for consistent results. The user has an option of a standoff with or without a glass plate.

Water from the laser system is circulated through the end of the scanner to help keep the handpiece cool for the user during scanner use.



A white plastic locking screw is used to lock the handpiece in place after it is screwed to the end of the articulated arm.



ProFractional quick disconnect connector

Attach the quick disconnect connectors on the end of the handpiece to the tubing connected to the back of the laser.

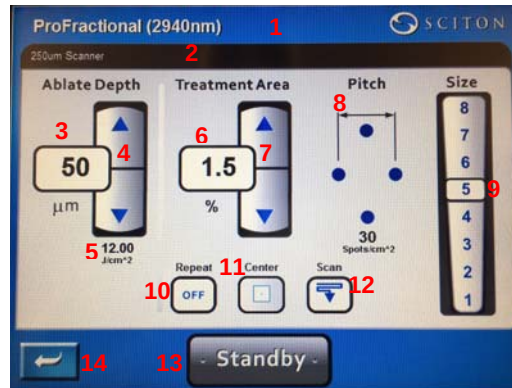
The ProFractional Scanner allows fractional application of the laser energy by delivering 250 μm spots of energy within a pattern that ranges from 1.5 mm x 1.5 mm to 15 mm x 15 mm in size. Aiming beam is represented by red square and shows the user the area to be treated. The energy will be delivered inside the red square. When the red square is "dancing" the system is in Standby. When the red square is solid the system is in Ready.



Care should be taken to apply adjoining scans without gap or excessive overlap of the previously scanned area. Line each scan pattern up to each other to avoid gap or overlap as shown above.

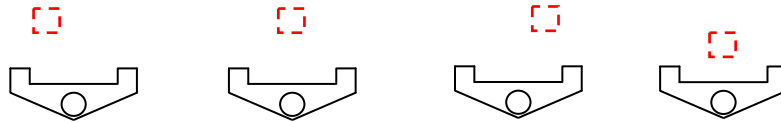
9.10.11.2 ProFractional Screen

Attach the ProFractional Scanner to the articulated arm. Press the Fractional Resurfacing softkey on the 2940 nm application screen and the system will enter the ProFractional (2940 nm) application screen.



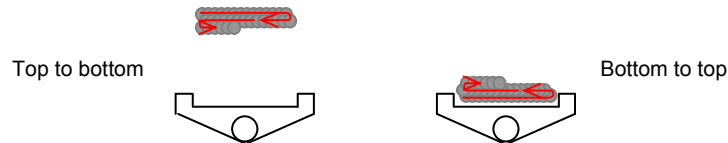
- Application and wavelength indicator
Application and wavelength indicator shows which treatment screen the user is in and which wavelength is being used for the treatment.
- Handpiece indicator
Handpiece indicates that which handpiece is attached to the articulated arm.
- Ablation depth indicator
Ablation depth relates to the amount of tissue to be removed.
- Ablation depth adjustment softkeys
Ablation depth may be set by tapping or holding down the up ▲ or down ▼ arrow softkeys.

5. Ablation fluence indicator
Ablation fluence indicator shows the amount of fluence or energy being delivered based on the depth of the ablation selected. $1\text{J}/\text{cm}^2 = 4\text{ microns}$ of ablation.
6. Treatment area percentage indicator
Treatment area percentage shows what percentage of the tissue is being treated.
7. Treatment area percentage adjustment softkeys
Treatment area percentage can be adjusted from 1.5% up to 30% by tapping or holding down the up ▲ or down ▼ arrow softkeys.
8. Pitch indicator
Pitch relates to the distance between adjacent treated zones. When the percentage of area treated is changed, pitch is automatically adjusted. The higher the percentage of area treated the smaller the distance between treated zones.
9. Pattern size adjustment softkeys
Pattern size can be adjusted from a size 1 which is 1.5 mm x 1.5 mm to an 8 which is 15 mm x 15 mm by tapping the desired numbered softkey.
10. Pattern repeat softkey
Pattern repeat will allow the user to set an amount of time between consecutive scans of 0.5, 1.0, 1.5 or 2.0 seconds by tapping the Repeat softkey. Repeat can also be turned off so that each scan pattern is delivered by lifting and depressing the footswitch.
11. Pattern center adjustment softkey
Pattern center allows the user to offset the area to be treated to the upper left corner, upper middle or upper right corner of the standoff by tapping the Center softkey.



Offset to upper left Offset to upper middle Offset to upper right Offset to center

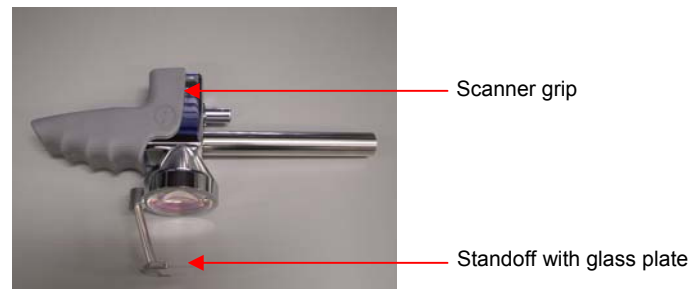
12. Scan Pattern direction softkey
Scan pattern direction allows the user to change the direction of the scan being delivered from the top to bottom or bottom to top of the standoff.



13. System status softkey
System status softkey will allow the user to put the system in Standby or Ready.
14. Return to 2940 nm applications screen
Return to 2940 nm application softkey will return the system to the previous screen.

9.10.11.3 ProFractional-XC or ProFractional III Scanner (430µm spot delivery)

The ProFractional-XC/III Scanner Handpiece consists of 2 galvanometers, a micro lens array and focusing optics contained in a housing.



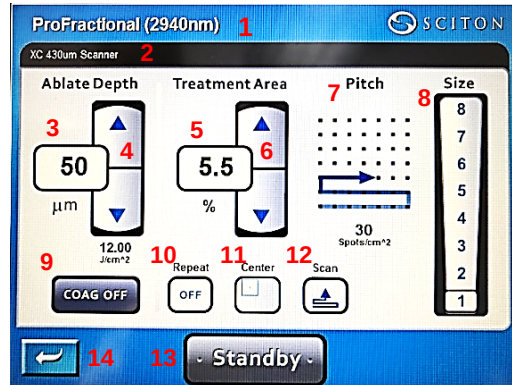
The scanner grip provides for a more comfortable hold while using the scanner. The grip is an option for the user and can be used with any Joule scanner.

Note: When using scanner grip, make sure it fits tightly on the scanner housing.

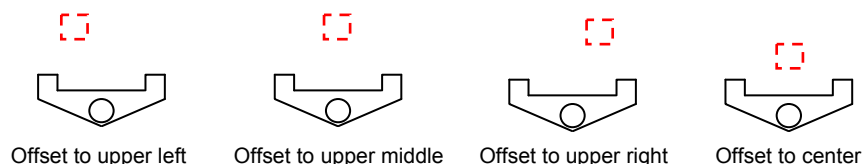
Standoffs permit the user to position the focal plane of the laser energy onto the skin surface for consistent results. The user has an option of a standoff with or without a glass plate.

9.10.11.4 ProFractional-XC Screen (430µm spot delivery)

Attach the ProFractional-XC Scanner to the articulated arm. Press the Fractional Resurfacing softkey on the 2940 nm application screen and the system will enter the ProFractional-XC (2940 nm) application screen.

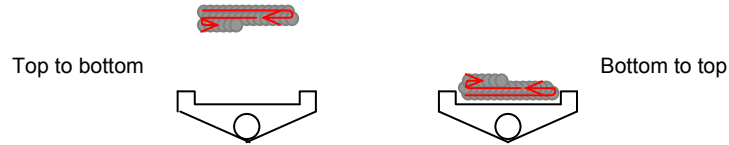


1. Application and wavelength indicator
Application and wavelength indicator shows which treatment screen the user is in and which wavelength is being used for the treatment.
2. Handpiece indicator
Handpiece indicates which handpiece is attached to the articulated arm.
3. Ablation depth indicator
Ablation depth refers to the depth of the micro-column of ablated tissue.
4. Ablation depth adjustment softkeys
Ablation depth may be set by tapping or holding down the up ▲ or down ▼ arrow softkeys.
5. Treatment area percentage indicator
Treatment area percentage shows what percentage of the tissue is being treated.
6. Treatment area percentage adjustment softkeys
Treatment area percentage can be adjusted to 5.5%, 11% or 22% by tapping the up ▲ or down ▼ arrow softkeys.
7. Pitch indicator
Pitch relates to the distance between adjacent treated zones. When the percentage of area treated is changed, pitch is automatically adjusted. The higher the percentage of area treated the smaller the distance between treated zones.
8. Pattern size adjustment softkeys
Pattern size can be adjusted from a size 1 which is 1.3 mm x 1.3 mm to an 8 which is 20 mm x 20 mm by tapping the desired numbered softkey.
9. Coagulation depth adjustment softkey
COAG depth can be turned off or adjusted to three levels by tapping the COAG softkey; COAG-1 equals approximately 50 µm, COAG-2 equals approximately 100 µm and COAG-3 equals approximately 150 µm. Refer to earlier section for explanation of COAG.
10. Pattern repeat softkey
Pattern repeat will allow the user to set an amount of time between consecutive scans of 0.5, 1.0, 1.5 or 2.0 seconds by tapping the Repeat softkey. Repeat can also be turned off so that each scan pattern is delivered by lifting and depressing the footswitch.
11. Pattern center adjustment softkey
Pattern center allows the user to offset the area to be treated to the upper left corner, upper middle upper right corner or center of the standoff by tapping the Center softkey.



12. Scan Pattern direction softkey

Scan pattern direction allows the user to change the direction of the scan being delivered from the top to bottom or bottom to top of the standoff.



13. System status softkey

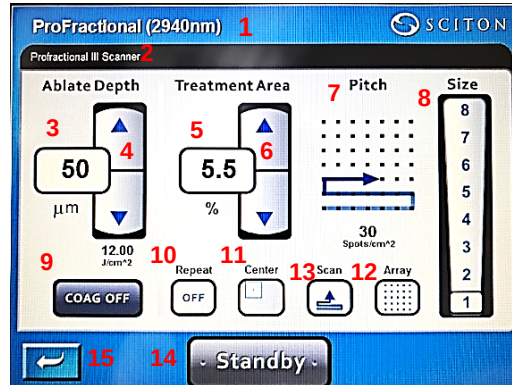
System status softkey will allow the user to put the system in Standby or Ready.

14. Return to 2940 nm applications screen

Return to 2940 nm application softkey will return the system to the previous screen.

9.10.11.5 ProFractional-III Screen (430µm spot delivery)

Attach the ProFractional III Scanner to the articulated arm. Press the Fractional Resurfacing softkey on the 2940 nm application screen and the system will enter the ProFractional III (2940 nm) application screen.



1. Application and wavelength indicator

Application and wavelength indicator shows which treatment screen the user is in and which wavelength is being used for the treatment.

2. Handpiece indicator

Handpiece indicates which handpiece is attached to the articulated arm.

3. Ablation depth indicator

Ablation depth refers to the depth of the micro-column of ablated tissue.

4. Ablation depth adjustment softkeys

Ablation depth may be set by tapping or holding down the up ▲ or down ▼ arrow softkeys.

5. Treatment area percentage indicator

Treatment area percentage shows what percentage of the tissue is being treated.

6. Treatment area percentage adjustment softkeys

Treatment area percentage can be adjusted to 5.5%, 11% or 22% by tapping the up ▲ or down ▼ arrow softkeys.

7. Pitch indicator

Pitch relates to the distance between adjacent treated zones. When the percentage of area treated is changed, pitch is automatically adjusted. The higher the percentage of area treated the smaller the distance between treated zones.

8. Pattern size adjustment softkeys

Pattern size can be adjusted from a size 1 which is 1.3 mm x 1.3 mm to an 8 which is 20 mm x 20 mm by tapping the desired numbered softkey.

9. Coagulation depth adjustment softkey

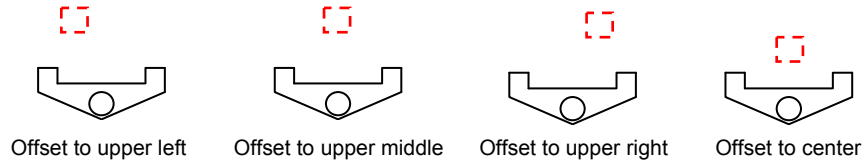
COAG depth can be turned off or adjusted to three levels by tapping the COAG softkey; COAG-1 equals approximately 50 µm, COAG-2 equals approximately 100 µm and COAG-3 equals approximately 150 µm. Refer to earlier section for explanation of COAG.

10. Pattern repeat softkey

Pattern repeat will allow the user to set an amount of time between consecutive scans of 0.5, 1.0, 1.5 or 2.0 seconds by tapping the Repeat softkey. Repeat can also be turned off so that each scan pattern is delivered by lifting and depressing the footswitch.

11. Pattern center adjustment softkey

Pattern center allows the user to offset the area to be treated to the upper left corner, upper middle, upper right corner, or center of the standoff by tapping the Center softkey.

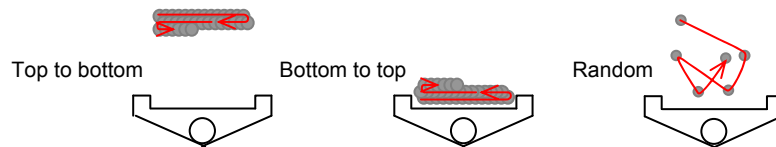


12. Array Pattern softkey

Array pattern allows the user to change the pattern of the scan being delivered. Uniform array allows the scan option of top to bottom or bottom to top of the standoff. Randomized array allows a random scan pattern to be delivered.

13. Scan Pattern direction softkey

Scan pattern direction allows the user to change the direction of the scan being delivered from the top to bottom or bottom to top of the standoff.



14. System status softkey

System status softkey will allow the user to put the system in Standby or Ready.

15. Return to 2940 nm applications screen

Return to 2940 nm application softkey will return the system to the previous screen.

9.10.11.6 Precautions

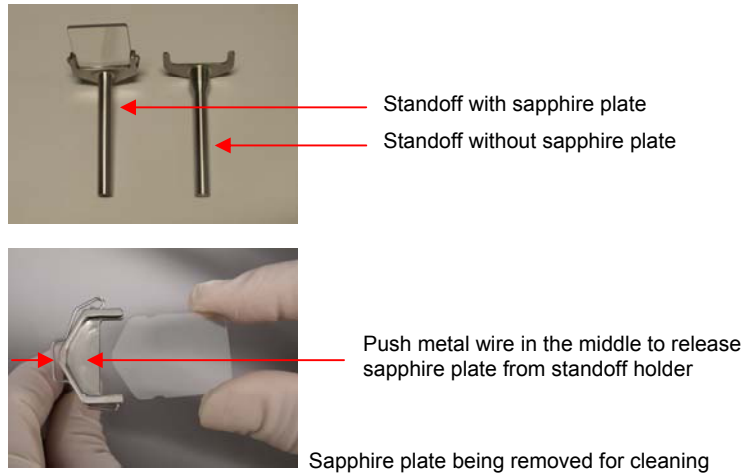
- Patients must be carefully evaluated by the physician for their risk of scarring versus the treatment benefit, especially with selection of coagulation setting when using the ProFractional-XC and ProFractional-III.
- Treatment should be done in a conservative fashion in areas where the skin is thin, such as the temple and forehead areas.
- Post-treatment hyperpigmentation may occur after 3-4 weeks.
- Direct and intentional sun exposure should be avoided for 7-10 days, then daily use of sun block is recommended to avoid pigment related complications.
- Patients who smoke may experience delayed healing and decreased benefit.
- Selection of patients must include evaluation of Fitzpatrick Skin Type (I-VI). ProFractional, ProFractional-XC/III without COAG, can safely and comfortably treat patients with Fitzpatrick skin types I through VI without pigmentary changes but it is recommended that a test spot be done on darker skin type patients first. Some patients may experience transitory lines of demarcation with more aggressive ProFractional and ProFractional-XC/III treatments. These lines resolve in a few days after treatment.
- If COAG is used with ProFractional-XC/III it may pose a risk of long term or permanent hypo or hyper-pigmentation, especially in darker skin types. Therefore, the COAG option with ProFractional-XC/III is not recommended for use in Skin Types IV-VI.
- Particulate debris on the lens of the scanner and/or glass plate standoff may result in laser beam scattering and an incorrect setting for depth of treatment. Cleaning the lens and glass plate standoff prior to, and during treatment, is essential to ensure accurate treatment settings.

- Treating with overlapping scans or at settings much higher than those recommended by the protocol may lead to undesirable outcomes. Attention to technique and conservative treatment is recommended.

9.10.11.7 ProFractional & ProFractional-XC/III Standoffs

The removable ProFractional and ProFractional-XC/III standoffs are used to position the focal plane of the laser energy onto the skin surface. The scanner should always be held perpendicular to the skin surface for consistent results. The disinfected standoff should be attached to the handpiece and held gently with continuous skin contact during the entire treatment for precise focus and uniform delivery of energy.

The standoff with or without a sapphire plate can be used for ProFractional and ProFractional-XC/III treatment. The two different standoffs are supplied to provide options for the treatment provider.



9.10.11.7.1 Standoff Disinfection

Standoffs should be removed from scanner, and cleaned and disinfected in a high-level disinfectant or autoclaved after each use.

Suggested high-level disinfectants are:

- Cidex® High-Level Disinfectant Solution
- Metricide® High-Level Disinfectant/Sterilant
- Sporicidin® Sterilizing and Disinfecting Solution

More disinfectants are available by referencing FDA website at:
<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm437347.htm>

- Follow the manufacturer's instructions for a high-level disinfection or autoclave procedure.
- Gloves should always be worn when handling a standoff during and after the treatment.

9.10.11.7.2 Treating Body Tissue

The epidermis of body skin is thinner than that of the face and has fewer adnexal healing structures. Peels beyond 100 microns in depth and more than 5% ProFractional or 5.5% ProFractional-XC/III in treatment area percentage are not recommended in a single treatment. Re-treatment may occur as early as 8 weeks. Treating body skin may not be ideal for patients with known healing deficiencies.

- *Note: COAG is not recommended on body skin.*

9.10.11.7.3 Device Tissue Effects

The following table summarizes ablative and thermal damage at various depth settings:

Expected Depth (μm)	Measured Depth (μm)	Measured Width (μm)	Lateral Thermal Damage (μm)	Deep Thermal Damage (μm)
100 μm	207	343	42	67
300 μm	337	313	67	100
1000 μm	702	367	117	283

9.10.11.8 2940 Er:YAG Contour TRL ProFractional/ProFractional-XC/III

Treatment Basics

- Patient should be positioned based on the area to be treated. The position should be comfortable to the patient and such that the treatment provider has good access to area to be treated and the control panel display screen.
- A mild cleanser should be used to remove any dirt, makeup or moisture from the treatment site. Wipe the area with an alcohol gauze. Allow alcohol to evaporate before treatment. Use special care around the eyes.
- If topical anesthetic is to be used, apply as directed prior to treatment. Before beginning treatment, ensure that topical has been completely removed from surface of skin.
- Prepare for adequate smoke evacuation when using a standoff without a sapphire plate.
- Attach clean handpiece with highly disinfected or autoclaved standoff to articulated arm.
- Enter settings into the control panel display screen based on condition and area to be treated.

ProFractional Treatment Starting Parameters

Application	Ablation Depth	Fluence	Treatment Area
Skin Resurfacing	25 - 100 μm	6.3 - 25 J/cm^2 (displayed only)	1.5 - 30%

ProFractional-XC/III Treatment Starting Parameters

Application	Ablation Depth	Coagulation Depth	Fluence	Treatment Area
Skin Resurfacing and coagulation	25 - 100 μm	COAG-1 approx 50 μm	5 - 25 J/cm^2 (displayed only)	5.5 - 22%
<i>Tissue coagulation is the addition of heat to produce a zone of thermal necrosis. As an option, ProFractional-XC/III device provides three levels of coagulation:</i> COAG-1 equals approximately 50 μm COAG-2 equals approximately 100 μm COAG-3 equals approximately 150 μm				

- ProFractional/ProFractional-XC/III handpiece should be held perpendicular to the skin surface at all times. Move patient if necessary to accomplish this 90 degree angle. The disinfected standoff should be attached to the handpiece and held in continuous contact with tissue during the entire treatment for precise focus and uniform delivery of energy.
- To confirm that laser and accessories are performing normally, it is useful for the operator to first test on a nonflammable inanimate object like a wooden tongue depressor. Treating a test area prior to beginning treatment will determine the patient's response threshold and help them understand the audible and sensory components of the treatment.
- Match the trailing edge of one scan pattern to the leading edge of the next. There should be no overlap between scans. Patterns should "line up" beside each other.
- Patient response can vary. Generally, treating at deeper depths (higher energy delivery) and a greater treatment area percentage (% of skin) both result in greater efficacy, but also a longer healing time.
- Ablation depth and treatment area percentage should be selected based on the condition treated, expected outcome, patient pain tolerance, and expected downtime for healing after assessing the individual patients needs.
- Because skin is thinner on the forehead, it is recommended that depth and treatment area percentage settings be more conservative in that area.
- The desired endpoint is erythema within a few minutes of laser application. Incidental pinpoint to punctuate bleeding may occur during the treatment but usually resolves within a few minutes to hours after the completion of treatment. Redness (often similar in

appearance to varying degrees of sunburn) and healing time will be greater the deeper the ablation depth, the greater the treatment area percentage (% of skin), and with the addition of COAG and will vary from patient to patient.

- ProFractional/ProFractional-XC/III pattern marks are typically very transient and usually resolve within 2-3 days after treatment. However, in rare cases this patterning can be seen for up to 4 weeks post treatment and usually completely resolves without intervention.
- Particulate debris and blood on the optics of the scanner and glass plate standoff may result in laser beam scattering and an incorrect setting for fluence. Scanner optics and glass plate standoff should be cleaned throughout treatment with a moistened wipe. If alcohol is used, allow the alcohol to dry completely before continuing with the treatment.

Post-Treatment

- **OBSERVATIONS**
Pinpoint or punctuate bleeding during and immediately following treatment.
Erythema and edema noted for approximately 12-48 hours after treatment depending on depth and percentage of area treated.
- **INTERVENTION**
Cool compresses or ice packs can provide immediate comfort after treatment.
An occlusive barrier such as Aquaphor will provide protection and comfort to treated area and should be used until skin has reepithelialized.
- **INTERVAL** between ProFractional/ProFractional-XC/III treatments is 2 - 6 weeks depending upon depth, treatment area percentage and level of COAG, if used.

Concurrent Procedures

2940 Er:YAG Contour TRL ProFractional/ProFractional-XC/III treatments may be given in combination with other procedures. If a patient is undergoing a BBL or MLP procedure, these treatments should be performed before the ProFractional/ProFractional-XC/III. Check with manufacturer for guidelines on using injectables in conjunction with 2940 Er:YAG Contour TRL ProFractional/ProFractional-XC/III treatments.

BBL™

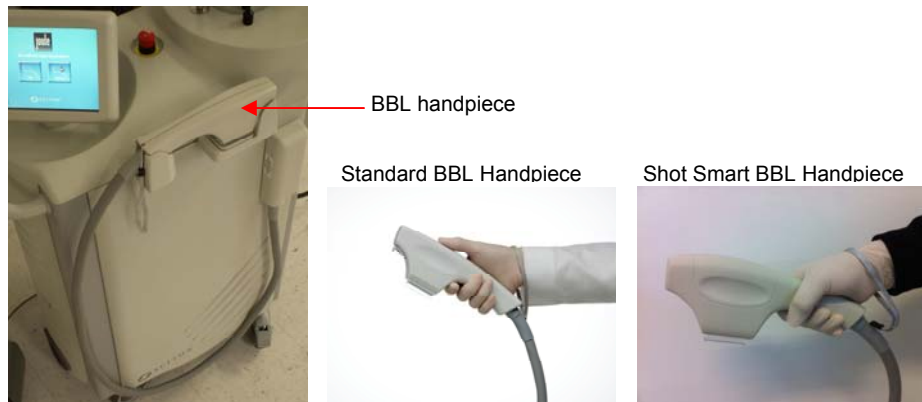
9.11 Broadband Light (BBL)

Broadband Light or BBL is a comprehensive phototherapy system that incorporates dual flashlamp technology, interchangeable filters, snap on adapters and a precise thermoelectric cooling system for safe, effective and easy use.

BBL is innovative technology that sets new standards for the treatment of skin conditions associated with aging, active lifestyles, and sun damage. Broadband Light energy can be used to treat age spots, small facial veins (telangiectasias), rosacea, solar lentigines (freckles), brown spots, poikiloderma, skin laxity, acne and remove hair.

BBL Operation

System functions are adjusted and selected via the control panel display screen. Press softkeys to select application and treatment parameters. The BBL handpiece shown below is used to perform treatment. The BBL handpiece is available in two versions, the standard BBL handpiece or the Shot Smart BBL handpiece. The Shot Smart BBL handpiece has a built-in energy meter which counts the energy in megajoule (MJ) units and allows the handpiece to be used for two additional applications – SkinTyte and ForeverBare BBL Motion.

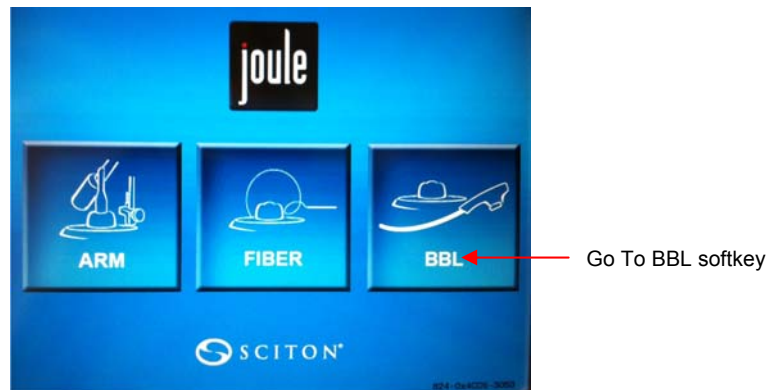


User Interface

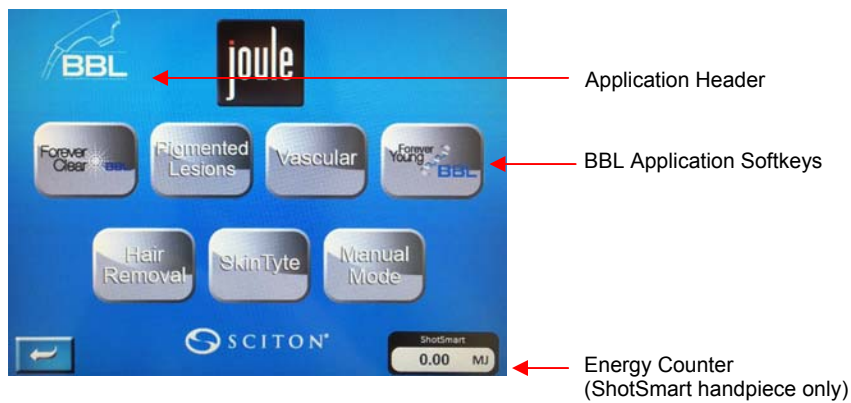
BBL has multiple user interface screens for different uses. The application screens are accessed via the Arm Application menu screen. Access to user screens also requires the appropriate filter to be inserted in the handpiece. Each screen and its functions are outlined as follows.

BBL Applications Menu Screen

The BBL application can be accessed from the main screen.



Pressing the Go To BBL softkey will allow the user to enter into the Broadband Light Applications screen.



Application Header

Application Header displays the available Broadband Light Applications.

BBL Application Softkey

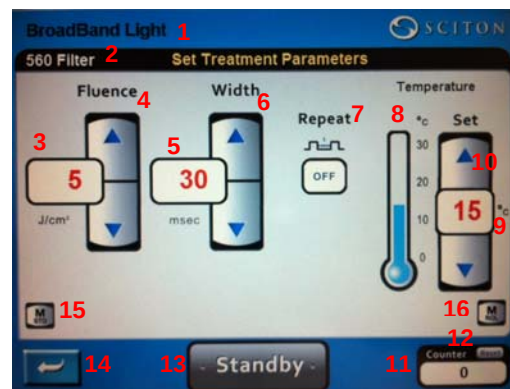
Insert appropriate filter into the BBL handpiece to enter the desired application.

Energy Counter

This window displays the total energy in megajoule (MJ) delivered through the ShotSmart handpiece.

BBL User Screen

BBL User screen allows the user to adjust a wide range of treatment settings. The available functions are described below, using the 560 filter screen as an example. Settings for all treatments performed with the BBL will be set using the screen below with the exception of SkinTyte™ and Forever Bare BBL™. Refer to the SkinTyte™ and Forever Bare BBL™ protocols for a pictures and explanation of user screens.



Manual Mode User Screen

1. Application indicator
Application indicator shows which application is being used for treatment.
2. Filter wavelength indicator
Filter wavelength indicator shows which wavelength is being used for the treatment.
3. Fluence indicator
Fluence indicator shows the amount of fluence or energy being delivered per pulse of BBL light. The fluence is measured in joules per centimeter squared (J/cm^2).
4. Fluence adjustment softkeys
Fluence adjustment softkeys allows the user to increase or decrease fluence by $1 \text{ J}/\text{cm}^2$ by tapping or holding down the up ▲ or down ▼ arrow softkeys.
5. Pulse width indicator
Pulse width indicator shows the length of time the energy is being delivered per pulse of BBL light. Pulse width is measured in milliseconds (ms).
6. Pulse width adjustment softkeys
Pulse width adjustment softkeys allows the user to increase or decrease pulse width by 1 ms by tapping or holding down the up ▲ or down ▼ arrow softkeys.
7. Pulse repeat softkey
Pulse repeat softkey allows the user to set an amount of time between consecutive pulses of 1, 2, 3, 4 or 5 seconds by tapping the Repeat softkey. Repeat can also be turned off so that each pulse is delivered by lifting and depressing the footswitch.
8. Cooling thermometer indicator
Cooling thermometer provides a pictorial representation of the cooling temperature of the BBL crystal.
9. Cooling numerical temperature indicator
Cooling numerical temperature shows the degree of cooling selected by numerical value. The temperature is measured in degrees Celsius ($^{\circ}\text{C}$).
10. Cooling adjustment softkeys
Cooling adjustment softkeys allows the user to increase or decrease the temperature of the BBL crystal by 1°C by tapping or holding down the up ▲ or down ▼ arrow softkeys. Temperature can be set from 0 to 30°C depending on the target and area being treated.
11. Number of accumulated pulses indicator
Number of accumulated pulses indicator shows how many pulses have been delivered since the system was turned on or since the last time the reset softkey for accumulated pulses was reset.
12. Accumulated pulses reset softkey
Accumulated pulses reset softkey allows the user to reset the number of accumulated pulses to 0 by touching the reset softkey.
13. System status softkey
System status softkey allows the user to put the system in Standby or Ready.
14. Return to Broadband Light Applications screen softkey
Return to Broadband Light Applications softkey will return the system to the previous screen.
15. Memory Store
Permits the storage of up to 3 preset settings.
16. Memory Recall
Permits recall of up to 3 preset settings

9.11.1 Indications for Use

The BBL system is designed for use in:

- The treatment of benign pigmented lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles) (515 nm, 560 nm)
- The treatment of cutaneous lesions including warts, scars and striae (515 nm, 560 nm)
- The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations (560 nm, 590 nm)
- Mild to moderate inflammatory and pustular inflammatory acne vulgaris (420 nm, 515 nm, 560 nm, 590 nm)

Note: BBLs is not authorized for sale in Canada for the treatment of mild to moderate inflammatory and pustular inflammatory acne vulgaris.

- The removal of unwanted hair from all skin types, and to effect stable long-term, or permanent, hair reduction (590 nm, 640 nm, 695 nm)
- Topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles. In addition, it may also help muscle spasms, minor sprains and strains, and minor muscular back pain. (SkinTyte™ - 800 nm)

Note: BBLs is not authorized for sale in Canada for topical heating for the purpose of elevating tissue temperature to promote increased blood flow for temporary relief of joint pain.

The BBL handpiece is designed to include a thermo-electric cooler that is indicated for use in cooling the epidermis at the treatment site prior to, during and after light or laser treatment:

- Reduce pain during and/or associated with light treatment (via partial anesthesia from cooling);
- Reduce discomfort during and/or associated with light treatment;
- Minimize thermal injury, including thermal necrosis, to non-target skin and skin structures during and/or associated with light treatment, thus reducing possible complications such as scabbing, scarring, hyper- and/or hypopigmentation;
- Allow the use of higher light fluences for light treatments (such as for the treatment of vascular or pigmented lesions); and
- Reduce potential side effects of light treatments (such as for the treatment of vascular or pigmented lesions).

9.11.2 Contraindications

The BBL system is contraindicated for:

- Patients who have a history of abnormal response to sunlight
- Patients who use photo-sensitizing medications or drugs
- Patients who have used isotretinoin (Accutane) within the last 6-12 months
- Patients who are pregnant
- Patients who have medical conditions that may affect wound healing
- Patients who use anticoagulant medication or heavy aspirin use
- Patients with active infections and/or compromised immune systems
- Patients with tanned skin
- Patients with a history of skin cancer, especially malignant melanoma
- Patients who have a history of keloid scar formation
- Patient who are Skin Type VI

9.11.3 Precautions

- Performing a test spot or spots is indicated for assessing clinical responses of the epidermis. Be sure to allow enough "wait time" for this observational process. This step should precede performing a treatment to a whole area or when moving from one area to another such as face to chest.
- Treat areas of non-facial tissue (neck, chest, hands, etc.) more conservatively to avoid excessive patient discomfort and to minimize the risk of striping, blisters, burns and scarring. Off face tissue tends to be thinner and more sensitive to heat. In these areas, decrease fluence by 2-3J/cm², maintain cooler temperatures and lengthen the pulse width.
- Settings may need to be altered depending on the epidermal temperature and moisture content, the room temperature, physiology, chronological age, degree of photo aging, skin type, background color, etc. Increase fluence with caution only after observing the clinical response of the epidermis.
- Use more conservative settings when treating over hypertrophic scars.
- Do not overlap or stack pulses which could result in burns or blisters.
- Use caution treating areas where permanent hair loss is not desired, such as a man's beard area and/or over eyebrows.
- Ensure that entire BBL crystal is in complete contact of treated area throughout entire pulse

9.11.4 Complications

Complications, though rare, can occur and should be discussed and understood. The patient must understand the importance of the post care instructions, and that failure to comply may increase the potential for complications.

- Scarring, though rare, can occur following any intense light procedure.
- Histamine/Hives: some patients develop raised urticaria similar to hives. This irritation usually subsides in a few hours.
- Pigmentary changes: hyperpigmentation or hypopigmentation may occur. There is a higher risk in darker skin types.
- Purpura, which is purplish bruising, may occur in the treated area and may appear to be the size and shape of the BBL crystal. These bruises may last for 1-2 weeks. Purpura usually results from having the pulse width too short and/or fluence too high during the treatment. Purpura could also occur from the concomitant use of anticoagulant medications.
- Swelling around the eyes and bridge of nose may occur immediately after a BBL treatment and may remain for 24-48 hours.

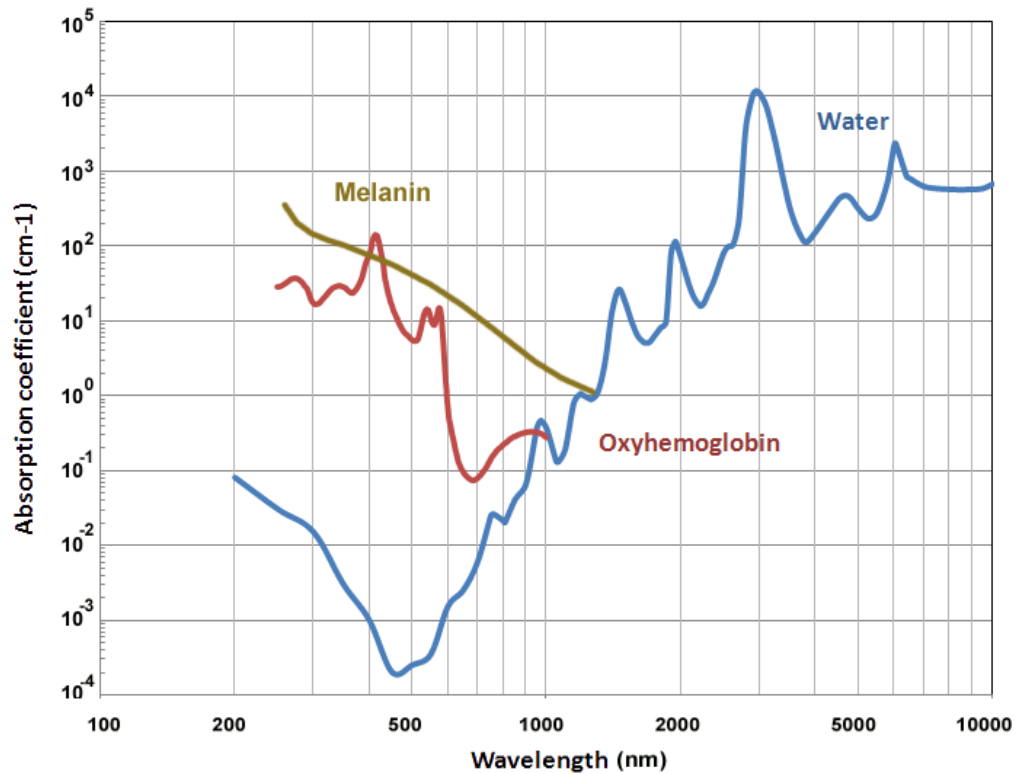
9.11.5 Warnings

- Tattooed areas, and the area of skin 4-5 mm outside of the tattoo in all directions, should not be treated. Tattoo ink may absorb energy resulting in a color change in tattoo ink or risk a burn, blister and/or scarring.
- Darkened moles should not be treated. Moles may absorb energy resulting in a color change creating a risk of epidermal damage and the inability to monitor the lesion under ABCD guidelines for melanoma detection.
- There is a risk of “paradoxical effect” resulting from the activation of dormant hair follicles in untreated areas close to hirsute-treated areas in subjects with facial hirsutism, which is diagnosed with polycystic ovarian syndrome and presenting ovarian hyperandrogenism. Basically, treatment with BBL could stimulate hair growth.
- BBL should not be used on mucosal tissue such as inside the mouth, nose, ears, vagina or anus.

9.11.6 Selective Photothermolysis

The light or heat that is released from the BBL which strikes the target tissue is more attracted to certain chromophores or skin pigments. There are basically three chromophores in skin which are targets when treating with lasers or BBL light; hemoglobin, melanin and water. Each one of these chromophores has a certain absorption spectrum and wavelengths of light that are more selectively absorbed by them than that of other chromophores at the same wavelength.

Absorption Curve shows the relationship of the variation in absorbed radiation as a function of wavelength. The graphic shows absorption spectra of major intracellular absorbers. The molecular absorption coefficients of oxygenated hemoglobin, melanin and water are shown.



The goal when treating with BBL light energy is to heat the target to a temperature that is sufficient to destroy it, but not to the point that the heat damages skin and surrounding tissue. This is termed Selective Photothermolysis and relies on 3 critical parameters:

- Pulse width
- Fluence
- Wavelength

Pulse width is the length of time that the target is exposed to the heat and is typically measured in milliseconds (ms). Pulse width must be less than the Thermal Relaxation Time (TRT) of the target. In other words, the pulse width must be long enough to allow heating of the target but also short enough that the target can cool so that there is no heat buildup in surrounding skin and tissue. The cooling time of a target is relative to its size, structure and density. Larger targets take longer to cool than smaller ones. Likewise, a very densely pigmented target will cool down slower than a target with less concentrated pigment. Refer to Treatment Starting Parameters for safe start pulse width settings.

Fluence is the amount of heat or energy delivered into the target. Fluence is measured in units of Joules/cm². Refer to Treatment Starting Parameters for safe start fluence settings.



The higher the fluence selected, the higher the temperature of the target, the surrounding tissue and the epidermis. Treating with excess energy can result in adverse effects such as abnormal pigmentation, blistering and scarring. Patient response can vary, so the fluence setting should begin low and be increased gradually after assessing the individual patient response and observation of endpoints desired.

BBL Filters

Sciton cut-off filters used for BBL treatments are 420, 515, 560, 590/590ST, 640, 695/695ST and ST/800ST wavelengths. Each filter blocks out wavelengths of light below the filter number selected and allows only those wavelengths of light above the filter number to pass through. The exception to this is the 420 nm filter, which is only a band of blue light.



BBL Filters

When a filter has been chosen based on the particular treatment being provided, it is gently inserted into the opening located on the top of the BBL handpiece.



Partially and full inserted BBL Filters

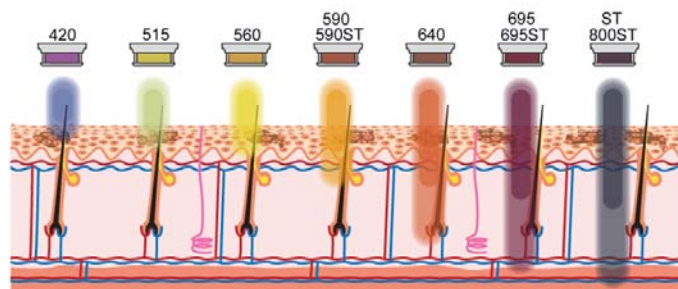


Care should be taken not to touch or scratch the BBL filters. If the filters become dirty or covered with fingerprints, an alcohol gauze may be used to clean the filter. DO NOT soak or submerge BBL filters in water or any other liquid.

When choosing a filter for a specific treatment, remember that the shorter the wavelength (or smaller the number on the filter) the more superficial the light or heat is deposited into tissue and the longer the wavelength (the larger the number on the filter) the deeper into tissue the light or heat is delivered. The longer the wavelength, less heat is deposited in skin and epidermis. Therefore, when treating darker skins or tissue with excess target present, a longer wavelength is recommended. Knowing what depth in tissue the target resides is critical when selecting the appropriate filter. A Wood's lamp or a camera with skin analysis software is a useful tool for making depth determinations. Refer to Treatment Starting Parameter for filter selection.

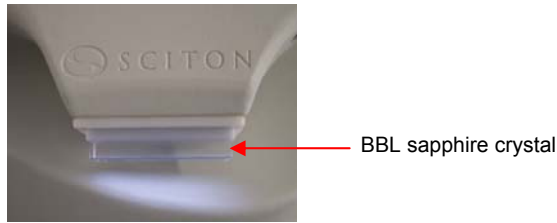
Depth of Penetration

The following illustration provides a comparison of depth of penetration for various wavelengths of light.



Surface Cooling

BBL has an integrated Thermo Electric cooled sapphire crystal that keeps the treatment area cool.



Skin surface temperature changes of 1 °C can cause immediately observable differences in the clinical response.

Although absorption of the BBL light into a certain chromophore may be desirable, some epidermal cooling is necessary to protect the skin. The amount of cooling required will vary depending upon the patient's skin type, and the fluence and pulse width selected. The lighter the skin type the less cooling is necessary, while the darker the skin type more cooling will be necessary. Higher fluences and shorter pulse widths may also require more epidermal cooling.

Surface cooling before, during and immediately after a BBL pulse, or after the light is converted to heat, can quench heat from the surface and protect the epidermis from undesirable heating. Refer to Treatment Starting Parameters for temperature settings.

Continuous observation of skin during a BBL treatment is critical and will ensure appropriate fluence, pulse width and temperature settings have been selected and that skin integrity has not been compromised.

9.11.7 Getting Started

9.11.7.1 Consultation/Education

A consultation is essential in order to establish realistic expectations and to gain a full understanding of the patient and his/her treatment goals. The patient must understand the procedure, pre and post care instructions, expectations, contraindications and possible complications prior to beginning any treatment.

9.11.7.2 Medical History

A detailed medical history should be obtained prior to treatment outlining any former or active medical condition or medication that is contraindicated or that could possibly affect the outcome of the treatment.

It is recommended that a brief medical history be taken before beginning any subsequent treatment by reviewing clinical information such as any new medications, skin care, sun exposure, pregnancy etc.

9.11.7.3 Skin Typing

Accurate skin typing is critical to treatment success and the avoidance of complications. It is important to know that in most situations an individual's previous response and genetic tendency to sun exposure will be the biggest indicators in establishing skin type. Some patients, such as Asians and Hispanics, may appear to be a skin type II or III and never tan but react to laser energy like a IV or V skin type. Hence, it is very important not to base skin type on appearance.

The skin type of a patient does not change. Do not confuse skin type with a tan. A person's skin type is something they are born with and it does not change, but the degree of tan can change.

Type	Hair Color	Skin Color and Ethnic Background	Eye Color	Sun Reaction
I	Red, White Blonde	Very fair <i>Scandinavian, Nordic, and North European</i>	Blue	Always burns, never tans
II	Red, Blonde, light brown	Fair <i>North European, Celtic (Scottish, Irish)</i>	Blue, green	Always burns, tans with difficulty and tends to be freckled
III	Sandy Blonde, Brown	Medium <i>Southern Europe</i>	Hazel, green, blue,	Burns initially, tans fairly well and evenly
IV	Brown, Black	Moderate brown, Olive <i>Mediterranean, Latin (Italian, Hispanic)</i>	Hazel, brown	Burns are rarely evident, tans easily
V	Black	Dark Brown <i>(Asian, Middle Eastern, American Indian)</i>	Dark brown, black	Burns are never evident, tans always <i>*some Asian skin always burns and never tans</i>
VI	Black	Black <i>(African-American, Indonesian)</i>	Dark brown, black	Burns are never evident, tans always



Skin type V is the most under-typed skin. Often Asians will look very light and have no history of sun exposure. Occasionally they have "bleached" their skin with hydroquinone. Treating them as a III or IV (based on look and reaction to sun) could result

in higher risk of complications. Initially, all Asian skins should be treated as a Skin Type V until reaction to laser light has been determined. Similarly, not all black skins are of the same degree of darkness and there may be the temptation to type these patients as a lower type.

9.11.7.4 Informed Consent

The process of accepting and confirming treatment must be reviewed, understood and signed by the patient prior to treatment. This document must review the topics discussed during the consultation. It acknowledges that the patient understands the procedure, possible risks and complications and that all questions have been answered. *Reference sample Informed Consent in Appendix of this manual.*

9.11.7.5 Photographs

Pictures should be taken prior to each treatment to document the progress of the treatment. Photographs are useful in demonstrating efficacy of treatment to the patient.

Camera settings, distance, backdrop, and body/face angle, position and expression should be the same for each photography session to maintain similar quality.

The patient should sign a photo release form if before and after pictures are to be used for educational or marketing purposes.

9.11.7.6 Topical Anesthesia

The use of topical anesthetic is not typically recommended for BBL treatments. Patient feedback is needed to evaluate appropriate endpoints. If a patient is “numb” they may not be able to accurately assess if a treatment is too warm which could lead to a blister or a burn. However, if topical preparation is used to alleviate discomfort for highly sensitive patients or sensitive areas prior to treatment, the manufacturer’s guidelines for the application and duration of the anesthetic should be read prior to topical application. Remove before treatment with mild soap and water or an alcohol swab, then plain water. Dry the area thoroughly before treatment. Reminder: Each patient should be assessed and questioned regarding allergies or sensitivities to ingredients in topical anesthetics prior to application.



Be extremely cautious when applying topical anesthetics to large areas of the body. Lidocaine toxicity has been linked to several deaths.

9.11.7.7 Eye Protection

Eye protection should always be worn by everyone present in the treatment room during a BBL treatment. When treating on the face of a patient, they should always wear metal, non-reflective goggles. Because the BBL light is very bright to your patient, especially when treating on their face and even when they are wearing the metal goggles, it is helpful to inform them about the brightness prior to treatment.

9.11.7.8 Treatment Basics

Please refer to the specific treatment protocol for settings and information based on condition being treated.

- Prior to beginning any BBL treatment, patients should be evaluated for any evidence of recent self-tanner, sun, or tanning bed exposure in the area being treated. Treating tanned skin can lead to a high incidence of epidermal reactions, blistering and pigmentation abnormalities. Patient should have had no direct sun exposure to the area being treated for 3 - 4 weeks and no self tanner use for 7 - 10 days. Patients need to understand that presenting with a tan will result in cancellation of treatment.
- Hair that is present in the area to be treated should be shaved prior to treatment. There should be no more than 0.5 mm hair growth, or very minimal stubble, present in treatment area.
- Patient should be positioned based on the area to be treated. The position should be comfortable to the patient and such that the treatment provider has good access to area to be treated and the control panel display screen.

- A mild cleanser should be used to remove any dirt, makeup or moisture from the treatment site.
- Select settings based on specific protocol settings. Reference Clinical Protocols.
- If topical anesthetic is to be used, apply as directed prior to treatment. Before beginning treatment, ensure that topical has been completely removed from surface of skin.
- Apply 2 - 3 mm thickness of colorless gel to area to be treated. The gel should be used in conjunction with the BBL for better heat removal, improved optical coupling and lubrication for sliding the BBL crystal over skin.
- BBL handpiece should be held perpendicular to the surface of the skin at all times. Move patient if necessary to accomplish this 90 degree angle. All edges of the BBL crystal should be in complete contact with skin at all times throughout entire BBL pulse. For highly curved areas, such as the forehead, chin and cheeks, where maintaining complete contact with the large rectangle BBL crystal is not possible, the smaller snap on adapter may yield a better result. A small bead of gel should be placed on the sapphire glass on the underside of the adapter, prior to snapping it on to the full crystal. This will allow for better light transmission. A small bead of gel should be placed on the sapphire glass on the underside of the adapter, prior to snapping it on to the full crystal. This will allow for better light transmission.

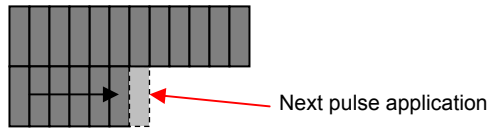


Snap On Adapters



- **Treating Test Area:** Treating a test area prior to beginning treatment will determine the patient's response threshold and help establish safe and effective treatment parameters.
 - Select test settings. Starting settings are based on specific protocol settings. Refer to a specific Clinical Protocol for safe start settings.
 - If treating on the face, begin testing in the pre-auricular area with handpiece aligned vertical to skin.
 - Depress the foot switch to deliver a pulse.
 - Wipe off gel and observe test area for 10 - 15 minutes for endpoints. Non-facial skin may take longer to react; therefore more time will be needed for observation of test area. Endpoints will be specific for each condition treated (Refer to Clinical Protocol).
 - If desired endpoints are observed with no adverse effects, treatment can be continued until area is completed.
 - If endpoints are not noted, increase the intensity of treatment by the following actions, in the following order (make only one change per test pulse):
 - Increase fluence by **1 J/cm²**
 - Decrease pulse width by **5 ms**
 - Increase (make warmer) cooling temperature by **2 - 5 °C**
 - If reaction to test spot is too severe (intense erythema, purpura, immediate white or grey presentation of skin), the settings should be decreased in intensity by the following actions, in the following order:
 - Decrease fluence by **1 - 5 J/cm²** depending on intensity of reaction
 - Increase pulse width by **5 - 10 ms** depending on intensity of reaction
 - Decrease cooling temperature **5 - 10 °C** depending on intensity of reaction
 - Use a filter with a longer wavelength

- For “Static, Corrective” treatments, match the trailing edge of one pulse to the leading edge of the next. There should be no overlap between pulses. Pulses should “line up” right next to each other.



- In areas where skin is thinner; forehead, chin, jaw, clavicle, hands etc., fluence should be decreased by 20%.



Use caution treating areas where permanent hair loss is not desired, such as a man's beard area and/or over eyebrows.

*•Tattooed areas, and the area of skin 4 - 5 mm outside of the tattoo in all directions, should not be treated. Tattoo ink may absorb energy from the BBL and result in a color change of the tattoo or a burn/blister to the skin.
Darkened moles should not be treated. Moles may absorb heat from the BBL resulting in a color change creating a risk of a burn or blister and the inability to monitor the mole under ABCD guidelines for melanoma detection.*

- BBL treatments may be given in combination with other procedures. If a patient is undergoing a MLP, Halo treatment and/or ProFractional or other resurfacing procedure, the BBL should be performed first.
- Check with manufacturer for guidelines on using injectables in conjunction with BBL treatments.

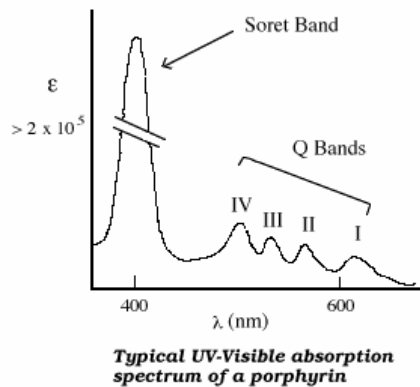
9.11.8 Safe Start Protocol for Forever Clear BBL™ Acne Treatment

The pathogenesis of acne is multifactorial and can be associated with four contributors: follicular plugging, excess sebum, inflammation, and the presence of *Propionibacterium acnes* (*P. acnes*).

P. acnes are a naturally occurring bacterium that is present on the skin, as well as within pores and sebaceous glands, at all times. When dead skin and sebum become trapped and block the pores, *P. acnes* rapidly multiply, causing follicle damage and inflammation. Once inflammation develops, the degree of acne evolves, forming papules, pustules, nodules, and cysts.

Light Therapy

BBL visible light takes advantage of the photosensitivity of porphyrins. The porphyrins are produced by the *P. acnes*. The blue light will cause photo excitation of these *P. acnes* porphyrins. This will form singlet oxygen within the microorganism itself, leading to the selective destruction of bacteria. Shorter wavelengths (blue light – 420 nm) are capable of the greatest absorption that specifically target bacteria; whereas longer wavelengths (red light – 590 nm) produce deeper penetration into the skin, targeting inflammation. The following graph illustrates excitation of porphyrin in Soret Band and Q Bands.



Considering that *P. acnes* is rarely present without concomitant inflammation, the treatment combination of blue and red light has demonstrated considerable success in treating mild to severe inflammatory acne.

Forever Clear BBL is an acne treatment that uses the power of light to comfortably and effectively clear acne without oral drugs in most cases and to maintain healthy, clear skin with minimal to no risk of complications.

Forever Clear BBL uses a unique three-step process:

- Skin is first treated with **blue** BBL light to eliminate acne-causing bacteria. This step helps reduce and improve the appearance of active acne as well as prevent new breakouts.
- Skin is then treated with **yellow/red** BBL light to reduce the inflammation and redness associated with acne. This step helps resolve active inflammatory acne and reduce scarring.
- Skin is then treated with SkinTyte using visible and **infra-red** BBL light. This step helps complement the results of the first two steps and facilitates treatment of large areas quickly.

Fluence

Refer to Forever Clear BBL Acne Treatment Parameters for appropriate fluence selection.

The goal when treating with the BBL for acne is the use of porphyrin as a photosensitizer – not as a heat inducer. Due to the fact that BBL acne treatment is not a thermal treatment, fluence is important to the extent that it be at the appropriate level, in combination with the right pulse width, to equal a sufficient dose of light needed to penetrate the skin and stimulate the destruction of *P. acnes* bacteria.

Fluence should not need to be adjusted from protocol settings since heat is not a desired endpoint.

Pulse Width

Refer to Forever Clear BBL Acne Treatment Parameters for appropriate pulse width selection.

The appropriate dose of light will ensure destruction of P.acnes bacteria. Long pulse widths will allow the treatment to remain photochemical vs. photothermal.

Pulse Width should not need to be adjusted from protocol settings since heat is not a desired endpoint.

Cooling

Refer to Forever Clear BBL Acne Treatment Parameters for appropriate cooling selection.

The BBL contact cooling crystal ensures that the epidermis is adequately protected as the 420nm, 560nm, 590nm, 640nm and 800nm light passes through the skin.

Managing Patient Expectations

Patients should understand that to see optimal results with BBL acne treatments a minimum of 6 treatments at 2 week intervals are recommended.

9.11.8.1 Treatment Basics - Forever Clear BBL™ Acne Treatment



Appropriate protective eyewear should be worn by both the patient and practitioner throughout the duration of the treatment. Permanent hair loss may occur in the area treated with BBL. Do not proceed with the treatment if hair growth is desired in the treatment area.

The following 2 steps outlined below should be followed at each treatment. The 3rd step helps complement the results of the first two steps and facilitates treatment of large areas quickly.

Treatment

- Apply thin layer of colorless gel.
- Select appropriate settings.
- Complete area to be treated.

Touching the following Forever Clear BBL softkey permits the user to enter the Forever Clear BBL Application.



Forever Clear BBL softkey
(Allowed filters: 420nm, 560nm and 590nm, 640nm, 590ST and 800ST)

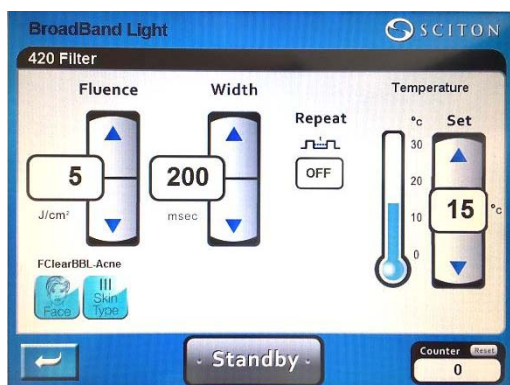


Step 1 Acne Parameters:

Skin Type	Filter	Fluence (J/cm ²)	Pulse Width (ms)	Temperature (°C)	Passes
I-V	420 nm	4-6	200-300	15	3

Note:

On sensitive patients and patients with more severe acne, the use of a small snap on adapter focused on individual acne lesions may help to minimize discomfort and allow for all passes to be completed.

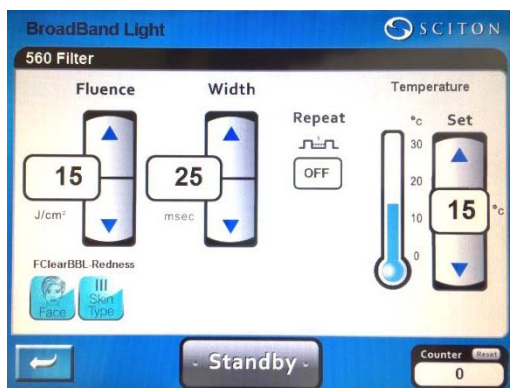


Step 2 Redness Parameters:

Skin Type	Filter	Fluence (J/cm ²)	Pulse Width (ms)	Temperature (°C)	Passes
I-III	560 nm	15	15-40	15	2
IV	590 nm	15	15-40	15	2
V	640 nm	15	15-40	15	2

Note:

We recommend the use of the square adaptor and the use of the Zimmer Chiller (or equivalent) if available for enhanced cooling and patient comfort.



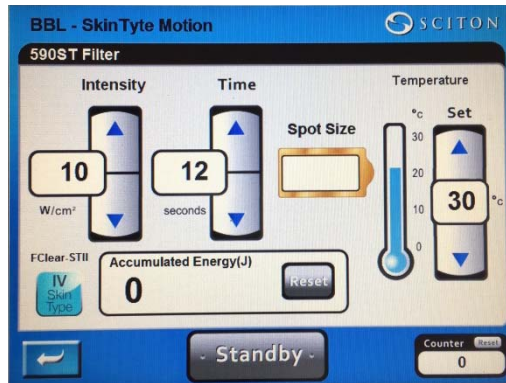
Step 3 SkinTyte Parameters:

(Optional treatment to complement the results of the first two steps and facilitate treatment of large areas quickly)

Skin Type	Filter	Irradiance (Watts/cm ²)	Pulse Width	Temperature (°C)
I-IV	590 ST nm	8-12	12 seconds	30
V	800ST	8-12	12 seconds	30

Note:

Use of the large spot size and constant motion for 10 pulses of 12 seconds each (about 2 minutes) per side is recommended. Please continuously check for patient comfort and adjust to a higher filter if necessary.



Endpoints

There are no definitive endpoints. The treatment goal is to pack the skin with light. Patients may feel a slight tingling sensation. If area treated begins to get warm, pause treatment until area cools down.

Post Treatment

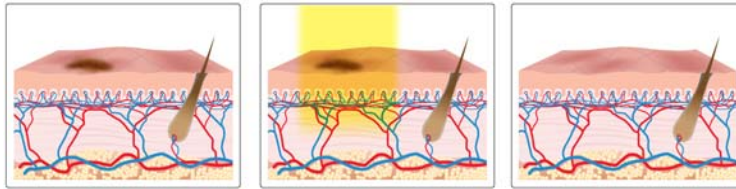
- Observation – Possible slight erythema for several hours after treatment.
- Intervention – Cool compresses or ice packs, though rarely needed, can provide some comfort after treatment. If blistering occurs, aggressive wound healing measures should be implemented.
- Interval – Treatments are performed 1 - 2 times per weeks. A minimum of 6 treatments are recommended. Destruction of *P.acnes* continues for a few weeks following the last BBL treatment and the effects of the treatment will be maintained until bacterial populations rebuild to their initial concentration. Some patients may require a maintenance treatment within 3 - 6 months of the initial series of treatments.
- If performing an acne treatment in conjunction with other procedures such as MLP or ProFractional, perform the acne treatment first.
- Check with manufacturer for guidelines on using injectables in conjunction with acne treatments.

9.11.9 Safe Start Protocol for BBL/BBLs Non-Ablative Pigmented Lesion/Skin Treatment

The BBL Non-Ablative Pigmented Lesion/Skin Treatment Protocol is effective for treating hyperpigmentation, sun damage, brown spots, age spots, liver spots, brown pigmented scars, birthmarks, melasma, and freckles.

The theory of Selective Photothermolysis explains how wavelength, energy and pulse width in relation to Thermal Relaxation Time (TRT) all play a role in the destruction of a target and the preservation of surrounding tissue.

Using the theory of selective photothermolysis, benign pigmented lesions can be treated with the appropriate BBL filter and settings that will cause selective absorption of light in melanin. The absorption converts light into heat energy, which raises the temperature of the pigmented lesion. This heat is used to destroy the parts of the cells in which the melanin is stored, resulting in slow elimination of the pigmented lesion by the *macrophages of the immune system*. All of this should happen selectively and without damage being done to the epidermis or surrounding tissue.



Filter selection

Refer to Pigmented Lesion Treatment Starting Parameters for appropriate filter selection.

For pigmented lesions that reside deeper in tissue and for lesions that are more densely populated in an area, a deeper penetrating filter should be chosen.

Melanin in the skin competes with the target lesions for absorption of the BBL light. Therefore, a deeper penetrating filter should be chosen for patients with darker skin types.

Fluence

Refer to Pigmented Lesion Treatment Starting Parameters for appropriate fluence selection.

Darker targets absorb more energy/heat and will reach higher temperatures. Therefore, darker, more concentrated pigmented lesions require less fluence than lighter colored, less concentrated pigmented lesions to reach the same therapeutic level.

Pulse Width

Refer to Pigmented Lesion Treatment Starting Parameters for appropriate pulse width selection.

Pulse width should be shorter than the cooling time of the target to make sure that all the energy is confined to the target. Smaller objects cool faster than larger ones. Therefore, the smaller the lesion being treated, the less time on or a shorter pulse width needed. Conversely, when treating a larger lesion, a longer pulse width should be selected to provide for a longer period of heat delivery.

Pigmented lesions with low concentrations of pigment will cool down quicker than densely pigmented ones. Therefore, "lighter", less concentrated areas of lesions should be treated with shorter pulse widths and "darker", more concentrated areas of lesions should be treated with longer pulse widths.

Darker skin absorbs more light and heats to a higher temperature, therefore pulse width should be longer for darker skin.

Cooling

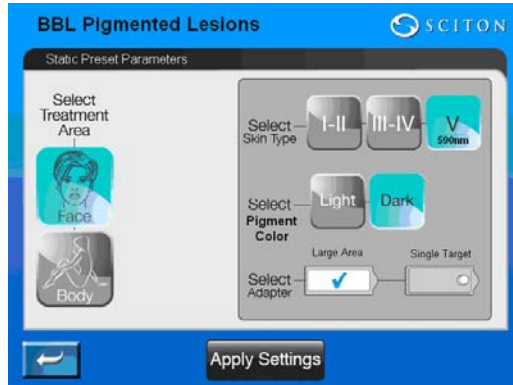
Refer to Pigmented Lesion Treatment Starting Parameters for appropriate temperature selection.

Although absorption of the BBL light in melanin is desirable, some epidermal cooling is essential to protect the skin. The amount of cooling required will vary with skin type, amount of target present, and area treated.

The temperature of the BBL crystal should be colder when treating areas of darker and/or more densely populated pigment. *When treating body tissue, temperature should be colder*, as well as when treating darker skin types.

Treatment

- Apply thin layer of colorless gel
- Select appropriate settings
- Treat test area to establish safe treatment parameters and desired endpoint.
- Once appropriate settings are selected, complete treatment area.



BBL Pigmented Lesion Treatment Starting Parameters – FACIAL Tissue with Large Area Spot



+

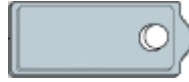


Skin Type	Pigment Color	Fluence (J/cm ²)	Pulse Width (ms)	Temperature (°C)
	Light	12	10	25
	Dark	9	20	20
	Light	9	20	22
	Dark	8	25	18
	Light	7	30	15
	Dark	6	35	10

BBL Pigmented Lesion Treatment Starting Parameters – FACIAL Tissue with Round Spot

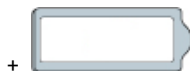


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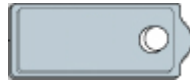
Skin Type	Pigment Color	Fluence (J/cm ²)	Pulse Width (ms)	Temperature (°C)
	Light	15	15	15
	Dark	12	15	20
	Light	12	15	15
	Dark	10	15	20
	Light	10	20	15
	Dark	10	20	15

BBL Pigmented Lesion Treatment Starting Parameters – BODY Tissue with Large Area Spot



Skin Type	Pigment Color	Fluence (J/cm ²)	Pulse Width (ms)	Temperature (°C)
	Light	10	15	22
	Dark	7	20	18
	Light	7	20	18
	Dark	7	25	15
	Light	5	30	15
	Dark	5	35	10

BBL Pigmented Lesion Treatment Starting Parameters – BODY Tissue with Round Spot



Skin Type	Pigment Color	Fluence (J/cm ²)	Pulse Width (ms)	Temperature (°C)
	Light	15	15	15
	Dark	12	15	20
	Light	12	15	18
	Dark	10	15	15
	Light	10	20	15
	Dark	10	20	15



The following verification message for the use of small adapter will be displayed prior to display of the pigmented lesion application screen. Please ensure that the small adapter is attached to the BBL handpiece. A small bead of gel should be placed on the sapphire glass on the underside of the adapter, prior to snapping it on to the full crystal. This will allow for better light transmission.



Endpoints

- Darkening and scattering of the pigmented lesion
- Erythema of surrounding skin
- Possible edema of the pigmented lesion
- Slight tingling sensation in area treated

Post Treatment

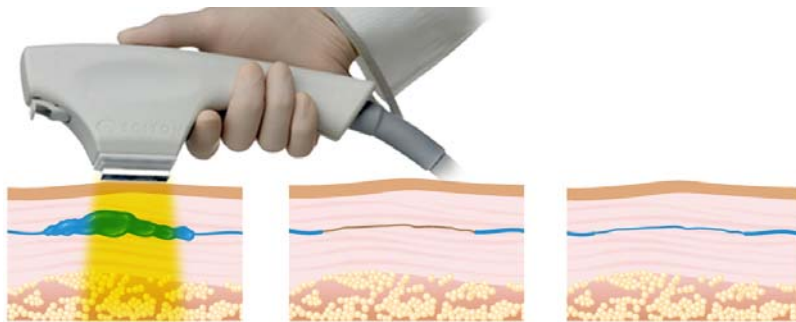
- Observation – Erythema for several hours after treatment
- Intervention – Cool compresses or ice packs can provide some comfort after treatment. If blistering occurs, aggressive wound healing measures should be implemented.
- Interval – Treatments are performed 3 - 4 weeks apart. 3 - 5 treatments may be required.
- If performing a BBL Pigmented Lesion treatment in conjunction of other procedures such as MLP or ProFractional, perform the pigmented lesion treatment first.
- Check with manufacturer for guidelines on using injectables in conjunction with BBL pigmented Lesion treatments.

9.11.10 Safe Start Protocol for BBL Non-Ablative Vascular/Skin Treatment

The BBL Non-Ablative Vascular/Skin Treatment Protocol is effective for treating redness, flushing, blushing, rosacea, red scars and broken capillaries.

The theory of Selective Photothermolysis explains how wavelength, energy and pulse width in relation to Thermal Relaxation Time (TRT) all play a role in the destruction of a target and the preservation of surrounding tissue.

Using the theory of selective photothermolysis, benign vascular lesions can be treated with the appropriate BBL filter and settings that will cause selective absorption of light in the blood that is flowing through the targeted vessel. The absorption converts light into heat energy, which raises the temperature of the blood. Heat is conducted to the lining of the vessel wall leading to its injury. This results in slow elimination of the vascular lesion by the macrophages of the immune system. All of this should happen selectively and without damage being done to the epidermis or surrounding tissue.



Filter Selection

Refer to Vascular/Skin Treatment Starting Parameters for appropriate filter selection.

For vascular lesions, flushing, blushing and/or rosacea that resides deeper in tissue and for areas where these conditions are more densely populated, a deeper penetrating filter should be chosen.

Melanin in the skin competes with the targeted vascular lesions for absorption of the BBL light. Therefore, a deeper penetrating filter should be chosen for patients with darker skin types.

Fluence

Refer to Vascular/Skin Treatment Starting Parameters for appropriate fluence selection.

Targets that have more dense vascularity absorb more energy/heat and will reach higher temperatures. Therefore, redder, more concentrated areas of vascular lesions require less fluence than lighter colored, less concentrated areas of vascular lesions to reach the same therapeutic level.

Pulse Width

Refer to Vascular/Skin Treatment Starting Parameters for appropriate pulse width selection.

Pulse width should be shorter than the cooling time of the target to make sure that all of the energy is confined to the target. Smaller objects cool faster than larger ones. Therefore, the smaller the vascular lesion being treated the less time on, or a shorter pulse width. Conversely, when treating a larger vascular lesion, a longer pulse width should be selected to provide for a longer period of heat delivery.

Vascular lesions with less dense vascularity will cool down quicker than more densely pigmented ones. Therefore, "lighter", less concentrated vascular lesions should be treated with shorter pulse widths and "redder", more concentrated lesions should be treated with longer pulse widths.

Darker skin absorbs more light and heats to a higher temperature, therefore pulse width should be longer for darker skin.

Cooling

Refer to Vascular/Skin Treatment Starting Parameters for appropriate temperature selection.

Although absorption of the BBL light in vascular lesions is desirable, some epidermal cooling is essential to protect the skin. The amount of cooling required will vary with skin type, amount of target present, and area treated.

The temperature of the BBL crystal should be colder when treating areas where more redness is present and areas where there are more densely populated vascular lesions. When treating body tissue, temperature should be colder, as well as when treating darker skin types.

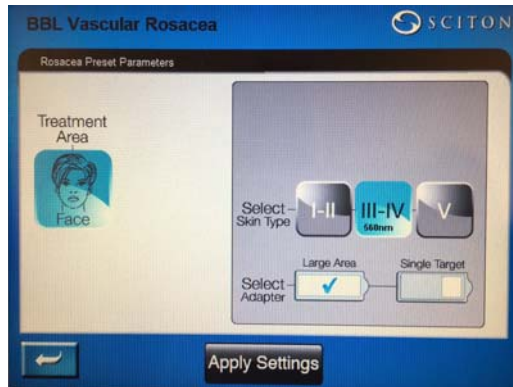
Air chillers, such as a Zimmer, should not be used during BBL vascular treatments. Prolonged cold air on skin can cause vasoconstriction of the targeted vessels resulting in an ineffective treatment.

Treatment

- Apply thin layer of colorless gel
- Select appropriate settings
- Treat test area to establish safe treatment parameters and desired endpoint.
- Once appropriate settings are selected, complete area to be treated
- Be careful not to apply pressure to the skin with the BBL handpiece. Complete contact with the entire BBL crystal and skin should be maintained at all times throughout a pulse; however pressure should be avoided to prevent possible blanching of the vessels in the treated area. If vessels are blanched there is no longer a target for the BBL light.



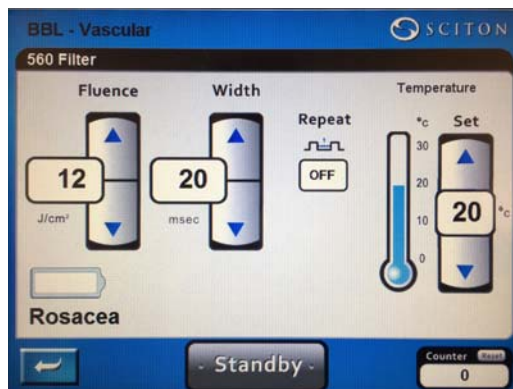
Vascular Rosacea Treatment



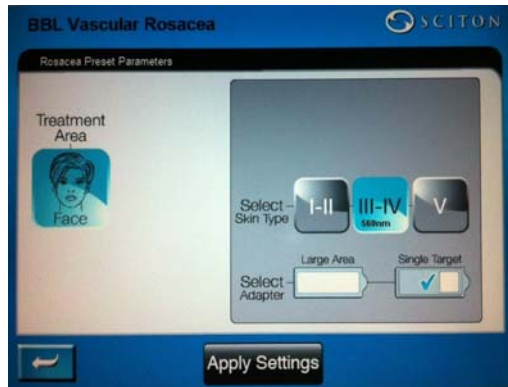
BBL Vascular Rosacea Treatment Starting Parameters – FACIAL Tissue with Large Area Spot



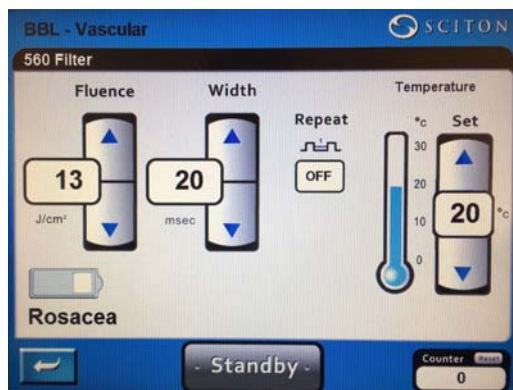
Skin Type	Fluence (J/cm ²)	Pulse Width (ms)	Temperature (°C)
I-II 560nm	14	20	20
III-IV 560nm	12	20	20
V 590nm	10	30	15



BBL Vascular Rosacea Treatment Starting Parameters – FACIAL Tissue with Small Area Spot



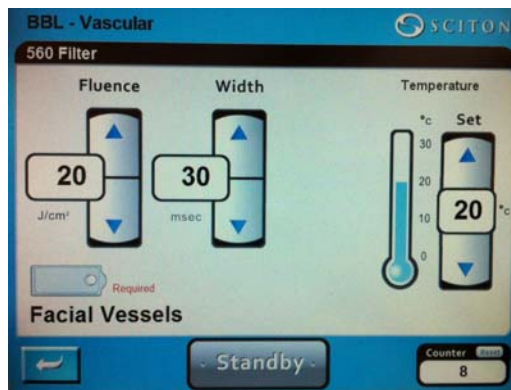
Skin Type	Fluence (J/cm ²)	Pulse Width (ms)	Temperature (°C)
I-II 560nm	15	20	20
III-IV 560nm	13	20	20
V 590nm	11	30	15



BBL Vascular Facial Vessels Treatment Starting Parameters – Round Spot

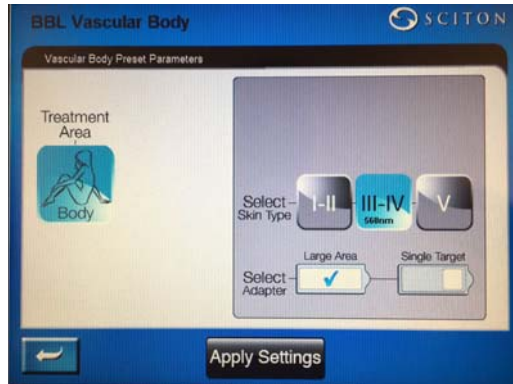


The following verification message for the use of small adapter will be displayed prior to display of the Facial Vessels application screen. Please ensure that the small adapter is attached to the BBL handpiece. A small bead of gel should be placed on the sapphire glass on the underside of the adapter, prior to snapping it on to the full crystal. This will allow for better light transmission.

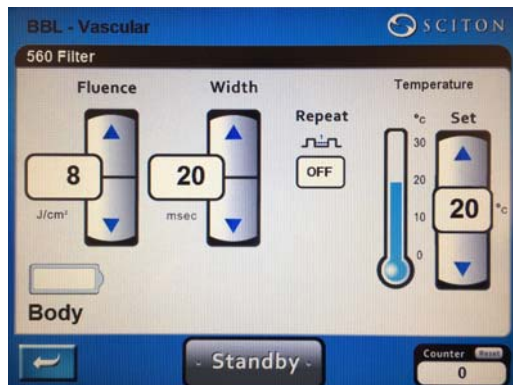


Body Vascular Treatment

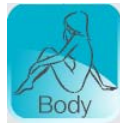
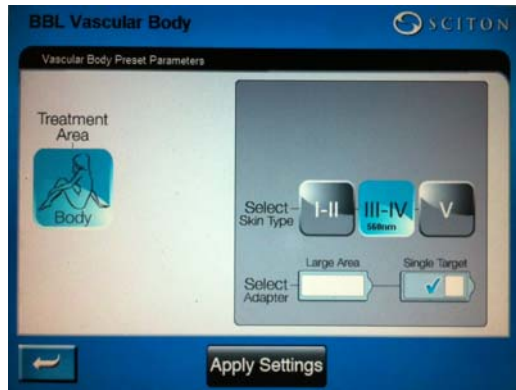
BBL Vascular Body Treatment Starting Parameters – BODY Tissue with Large Area Spot



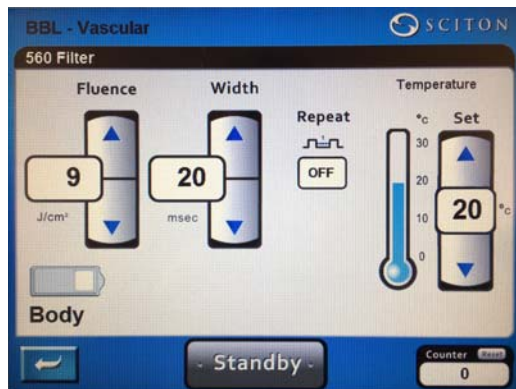
Skin Type	Fluence (J/cm ²)	Pulse Width (ms)	Temperature (°C)
I-II 560nm	10	20	20
III-IV 560nm	8	20	20
V 590nm	8	30	15



BBL Vascular Body Treatment Starting Parameters – BODY Tissue with Small Area Spot



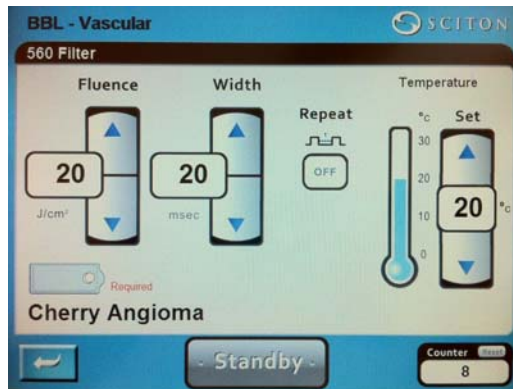
Skin Type	Fluence (J/cm ²)	Pulse Width (ms)	Temperature (°C)
I-II 560nm	11	20	20
III-IV 560nm	9	20	20
V 590nm	9	30	15



BBL Vascular Cherry Angioma Treatment Starting Parameters – Round Spot



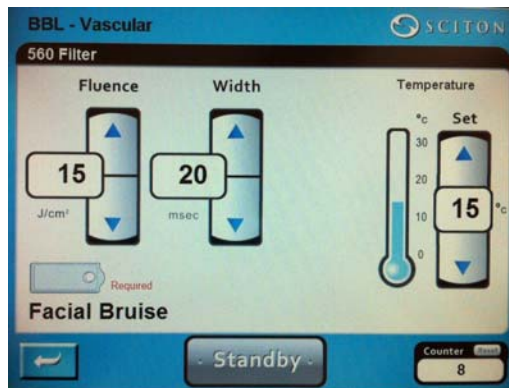
The following verification message for the use of small adapter will be displayed prior to display of the Cherry Angioma application screen. Please ensure that the small adapter is attached to the BBL handpiece. A small bead of gel should be placed on the sapphire glass on the underside of the adapter, prior to snapping it on to the full crystal. This will allow for better light transmission.



BBL Vascular Facial Bruise Treatment Starting Parameters – Round Spot



The following verification message for the use of small adapter will be displayed prior to display of the Rosacea application screen. Please ensure that the small adapter is attached to the BBL handpiece. A small bead of gel should be placed on the sapphire glass on the underside of the adapter, prior to snapping it on to the full crystal. This will allow for better light transmission.



Endpoints for Vascular/Skin Treatment

- Erythema
- Vessels may disappear, darken, lighten or appear unchanged but fade over time. When capillary refill test is performed, blood flow is static.
- Urticaria or a “cat scratch” appearance to the treated vessel.
- Possible purpura

Post Treatment

- Observation – Erythema for several hours after treatment.
- Intervention – Cool compresses or ice packs can provide some comfort after treatment. If blistering occurs, aggressive wound healing measures should be implemented.
- Interval – Treatments are performed 2 - 4 weeks apart. 5 - 7 treatments may be required.
- If performing a BBL Vascular/Skin treatment in conjunction of other procedures such as MLP or ProFractional, perform the vascular treatment first.
- Check with manufacturer for guidelines on using injectables in conjunction with BBL Vascular/Skin treatments.

9.11.11 Safe Start Protocol for BBL Hair Reduction

The theory of Selective Photothermolysis explains how wavelength, energy and pulse width in relation to Thermal Relaxation Time (TRT) all play a role in the destruction of a target and the preservation of surrounding tissue.

Using the theory of Selective Photothermolysis, unwanted hair can be treated with the appropriate BBL filter and settings that will cause selective absorption of light in the melanin of a hair. The light travels down the hair shaft and into the bulb of the follicle where the blood supply to the follicle is located. The absorption converts light into heat energy, which raises the temperature of the bulb causing the blood vessels that supply blood and other necessary nutrients to the follicle to be cauterized. As a result, hair growth is no longer possible. This process should happen selectively and without damage being done to the epidermis or surrounding tissue.

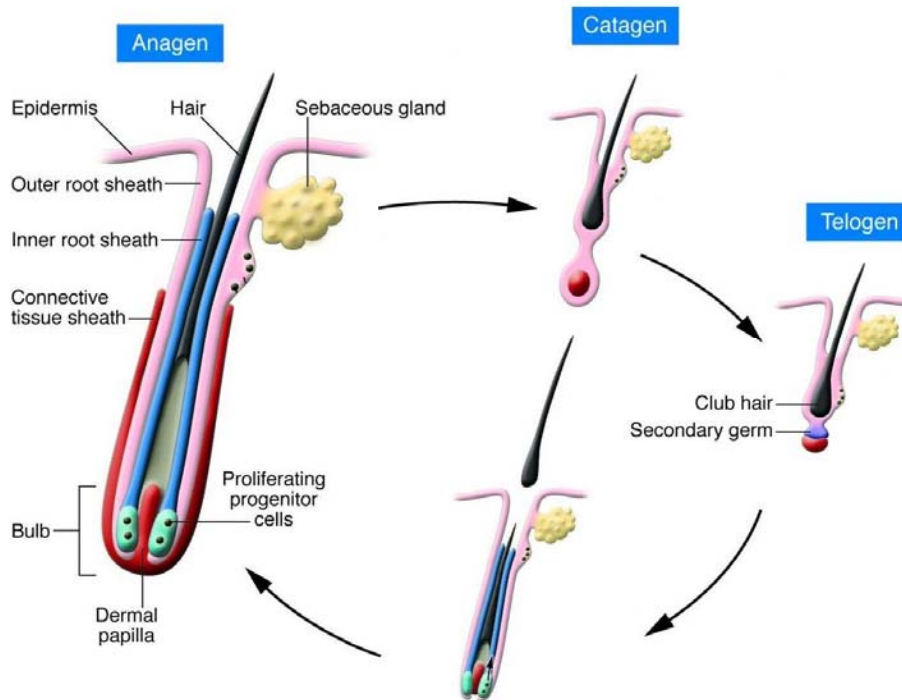
Hair revolves through three phases of growth: anagen, catagen and telogen. It is only during the growing phase, anagen, that hair reacts to BBL light. Not all hair present in an area is in the anagen phase at the same time. Duration of hair growth cycles depends on the body location being treated. Multiple treatments are necessary over a time span of typically 4-8 week intervals to remove hair from most areas. *Reference Richards-Merhag Chart in the Appendix of this manual.*

Hair Growth Cycle

anagen: the phase of the hair cycle during which synthesis of hair takes place. This is the active growing phase in which the hair bulb is intact.

catagen: brief intermediate phase between anagen and telogen. During this phase, the body absorbs the lower third of the follicle.

telogen: this is the resting phase. The hair bulb is no longer present. It is now a club hair, which will fall out or be pushed out of the follicle by a new anagen growing hair.



Filter Selection

Refer to Hair Reduction Treatment Starting Parameters for appropriate filter selection.

Melanin in the skin competes with the targeted hair for absorption of the BBL light. Therefore, a deeper penetrating filter should be chosen for patients with darker skin types.

Fluence

Refer to Hair Reduction Treatment Starting Parameters for appropriate fluence selection.

Targets that are darker absorb more energy/heat and will reach higher temperatures. Therefore darker more concentrated areas of hair growth require less fluence than lighter colored, less concentrated areas of hair growth to reach the same therapeutic level.

Pulse Width

Refer to Hair Reduction Treatment Starting Parameters for appropriate pulse width selection.

Pulse width should be shorter than the cooling time of the target to make sure that all the energy is confined to the target. Smaller objects cool faster than larger ones. Therefore, the smaller or finer the hair being treated the less time on, or a shorter pulse width. Conversely, the larger or coarser the hair being treated the more time on with the heat, or a longer pulse width should be selected.

Areas of hair growth that are less densely populated will cool down quicker than more densely populated ones. Therefore hair that is finer and in areas with less dense growth should be treated with shorter pulse widths and coarser more concentrated areas of hair growth should be treated with longer pulse widths.

Darker skin absorbs more light and heats to a higher temperature, therefore pulse width should be longer for darker skin.

Cooling

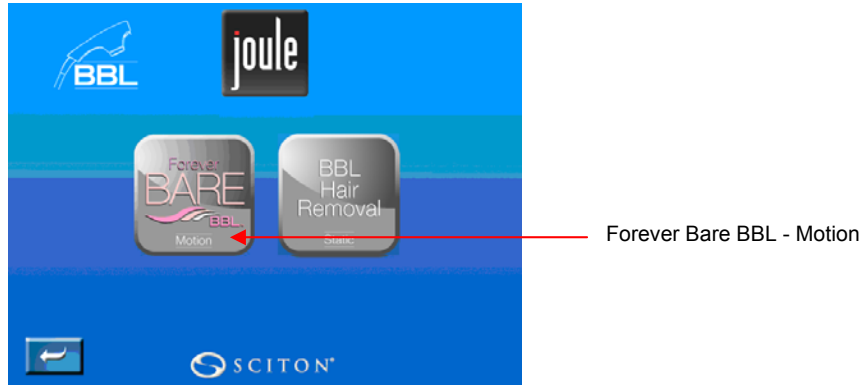
Refer to Treatment Starting Parameters for appropriate temperature selection.

Although absorption of the BBL light in the hair follicle is desirable, some epidermal cooling is essential to protect the skin. The amount of cooling required will vary with skin type, amount of target present, and area treated.

The temperature of the BBL crystal should be colder when treating areas where hair is darker and more densely populated.

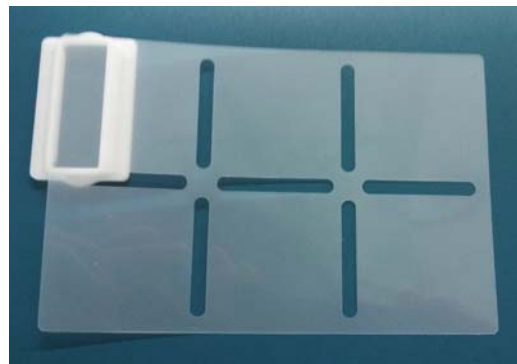
When treating darker skin types temperature should be colder.

9.11.11.1 Treatment Basics – Forever Bare BBL - MOTION



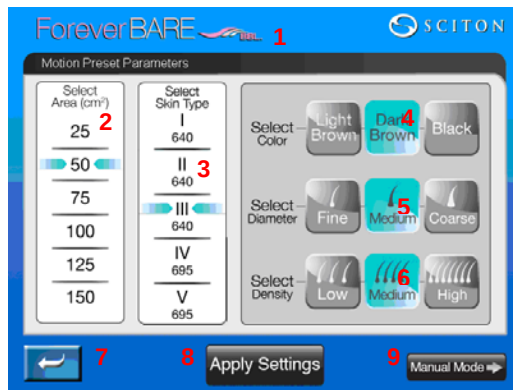
- Hair to be treated should be shaved 0 - 24 hours prior to treatment. Hair should not be waxed or plucked for 4 weeks prior to treatment.
- Measure treatment area using the template as a guide. The template below has 6 squares that are each 25 cm² (size of a 2"x 2" sticky note). The template sizes also correlate to the *Preset Parameters*. There are 6 Area Size Selections: 25 cm², 50 cm², 75 cm², 100 cm², 125 cm² and 150 cm².

Treatment Size	Template Squares	Number of Crystal Widths
25 cm ²	1	3
50 cm ²	2	6
75 cm ²	3	9
100 cm ²	4	12, or 2 rows of 6
125 cm ²	5	15
150 cm ²	6	18, or 2 rows of 9



Each square is 25 sq cm.
Use 1-6 squares
depending on size of
treatment area. 3 crystal
widths fit in 1 square.

- Apply a 4-5 mm layer of colorless ultrasound gel to clean, dry skin. Be sure length of hair is no more than 0.5mm
- Attach smoothie to the large rectangle crystal. The size of the treatment area should be at least 25 sq cm
- Select the Forever Bare BBL Motion to display the Preset Parameters Screen.



16. Forever Bare BBL Selection Screen

This indicates that hair (motion) application has been selected.

17. Treatment Selection Area

The treatment area may be selected from 25 - 150 sq cm.

18. Skin Type Selection

Skin types I – V may be selected. Skin types I – III require 640 nm filter whereas IV – V require 695 nm filter.

19. Hair Color Selection

Light brown, dark brown or black may be selected as hair color.

20. Hair Diameter Selection

Fine, medium or coarse may be selected as hair diameter.

21. Hair Density Selection

Low, medium or high may be selected as hair density.

22. Return to Previous Screen

Touching this softkey permits the user to return to the previous screen.

23. Apply Settings

Touching this softkey will permit the user to apply the selected preset parameters and advance to the next screen.

24. Manual Mode

This softkey permits the user to bypass selected preset parameters and enter desired parameters manually.

- Select approximate working size of area, skin type, hair color, diameter and density. Input this information by pressing corresponding softkey in the above Preset Parameter Screen.

Note: Forever Bare BBL Motion technique for hair removal utilizes easy-to-use Preset Parameters. This information will populate the proper treatment settings into the Forever Bare BBL Treatment Screen.

In the example above from the Forever Bare BBL Motion Preset Parameters Screen, a 50 cm² area was selected for a Skin Type III patient with dark brown, medium diameter hair at medium density growth.

- Press the Apply Settings softkey.



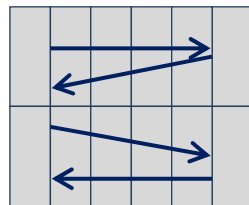
This screen displays the parameters derived from preset selection.

1. Forever Bare BBL Selection Screen
This indicates that hair (motion) application has been selected.
2. Filter Display
This displays the type of filter being used.
3. Treatment Area
Selected treatment area size is displayed.
4. Preset Parameters
The selected preset options are displayed.
5. Rate
The frequency of pulses in Hz.
6. Temp
The temperature of the sapphire crystal.
7. Accumulated Energy
The total energy delivered in Joules (J).
8. Target Energy
This displays the range of target energy required to be delivered based upon the preset selection.
The Target Energy range is calculated by the computer. In the Accumulated Energy (J) section in the treatment screen above it recommends 1633 to 2333 J for the 50 cm² selected area. The lower end of the range is for more comfortable application of energy whereas the higher end is for more efficacious treatment.
Once the Target Energy has been achieved, an audible tone will sound to signal the completion of treatment of that area.
9. Reset
Resets the current accumulated energy counter to zero.
10. Average Power
Average power output in Watts (W).
11. Counter
This counter displays the total number of shots since last reset to zero.
12. Reset
To reset the counter to zero, touch the reset softkey until the system beeps 4 times. Turning off the system also resets this counter to zero.
13. Standby/Treatment
Touch this key to switch between Treatment and Standby modes.
14. Return to Previous Screen
Touching this softkey permits the user to return to the previous screen.

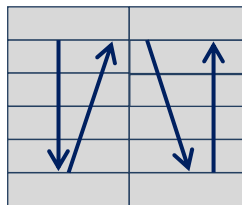
- A common working size for areas such as the axilla, neck, and/or bikini is 100 cm² and would measure out to 4 of the squares (25 cm² each) in the template. This 100 cm² size is also similar to a 4" x 4" gauze. When treating the patient, move the handpiece from one end of the treatment area, to the other end of the treatment area, while keeping the handpiece in contact with the skin, moving 2 - 3 crystal widths per second. Once the other side of the treatment area is reached, reverse the direction and begin moving from the top of the treatment area to the bottom. When the bottom is reached reverse again as being moving back to the top. When the Accumulated Energy (J) has reached half of the Target Energy, the process can be repeated but this time changing orientation direction of handpiece to blend coverage and slight overlap. Continue until Target Energy is reached.

Note: An audible tone will signal completion of treatment of the area selected.

First Direction



Second Direction



Moving the handpiece too slowly within a treatment area may cause a burn or dermal injury. If the handpiece is not moved quickly enough, the epidermis is being heated without efficient or effective delivery of the heat to the dermis.

- Once that area is completed move on to the next measured 100 cm² or 4" x 4" area and treat in the same manner.

- Repeat until entire treatment area is completed.

Endpoints

- It is important to gauge the patient's response during the procedure. Patients routinely find the motion procedure more comfortable than other Hair Removal technology. However, if the patient is uncomfortably warm in the treatment area and the recommended Total Energy has not been delivered, then adjustments to the speed, temperature, or rate should be considered. If the patient is uncomfortable and the target energy has not been reached, proceed to the next area. Forever Bare BBL technology makes treating areas where hair is dense, dark, and/or coarse more tolerable for the patient.
- Smell of success (SOS) – hair has a unique and very noticeable odor when it is heated during the light pulsing.
- Slight follicular edema and erythema that resolves within 1 - 4 hours of treatment.

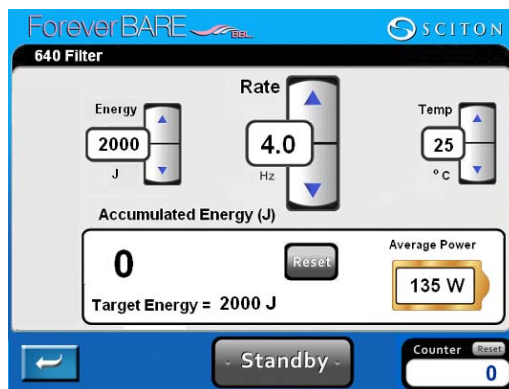
Post Treatment

- Observation – Erythema for several hours after treatment. Treated hairs can take up to 7 - 14 days to exfoliate from the follicle and may appear to be "growing" during this time.
- Intervention – While usually not an issue with Forever Bare motion technique, cool compresses or ice packs can provide some comfort after treatment. If blistering occurs, aggressive wound healing measures should be implemented.
- Sunscreen with at least SPF 30 is recommended on body locations that have exposure to the sun for at least 2 weeks after treatment to avoid burning or post inflammatory hyperpigmentation (PIH).
- Interval – Treatments are performed 4 - 8 weeks apart. Typically, 4-6 weeks for face and neck and 6-8 weeks for body locations. 5 - 7 or more treatments may be required. Consistency of the interval is critical to hair removal success.
- If performing hair removal treatments in conjunction of other procedures such as MLP® or ProFractional™, perform hair removal first.

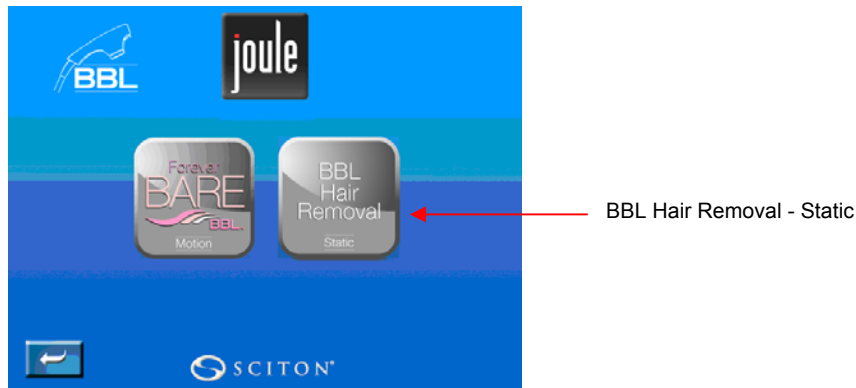
***Note:** Check with manufacturer for guidelines on using injectables in conjunction with hair removal treatment.*

Manual Mode

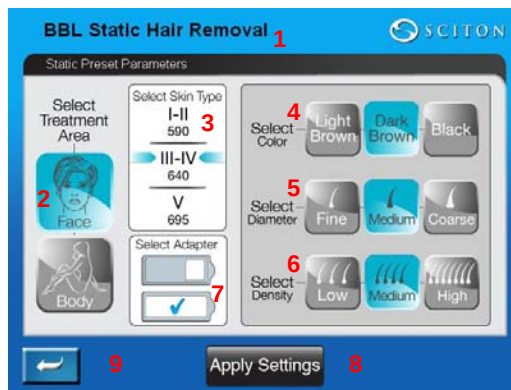
The preset parameters can be bypassed by the user. Touching the Manual Mode softkey allows the user to set the energy, rate and temperature as desired.



9.11.11.2 Treatment Basics – BBL Hair Removal - STATIC



BBL Hair (Static) Preset Parameters

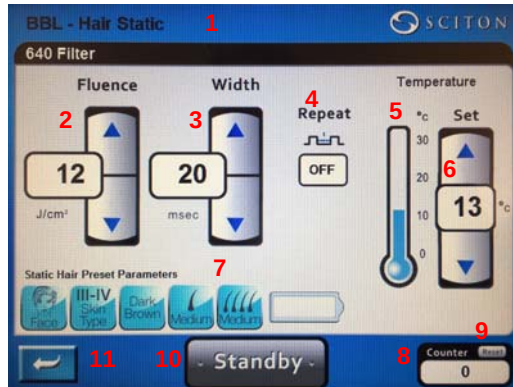


1. BBL Static Hair Removal Selection Screen
This indicates that hair (static) application has been selected.
 2. Treatment Selection Area
The treatment area may be selected: Face or Body
 3. Skin Type Selection
Skin types I – V may be selected. Skin types I – II require 590 nm filter, III-IV require 640 nm filter and V require 695 nm filter.
 4. Hair Color Selection
Light brown, dark brown or black may be selected as hair color.
 5. Hair Diameter Selection
Fine, medium or coarse may be selected as hair diameter.
 6. Hair Density Selection
Low, medium or high may be selected as hair density.
 7. Apply Settings
Touching this softkey will permit the user to apply the selected preset parameters and advance to the next screen.
 8. Return to Previous Screen
Touching this softkey permits the user to return to the previous screen.
- Select the treatment area (face or body), skin type, hair color, diameter and density, and the type of adaptor. Input this information by pressing corresponding softkey in the above Preset Parameter Screen.

***Note:** The BBL Static Hair Removal utilizes easy-to-use Preset Parameters. This information will populate the proper treatment settings into the BBL – Hair Static Treatment Screen.*

In the example above from the BBL Static Hair Removal Preset Parameters Screen, face is selected for treatment for a Skin Type III-IV patient with dark brown, medium diameter hair at medium density growth.

- Press the Apply Settings softkey.



This screen displays the parameters derived from preset selection.

1. BBL - Hair Static Selection Screen
This indicates that hair (static) application has been selected.
 2. Fluence Display
This displays the preselected fluence. It may be changed by touching the up or down key. ~~Pulse Width. It can be manually selected between 5 and 17 J/cm².~~
 3. Pulse Width
It can be manually selected between 5 and 500 msec.
 4. Repeat
Default is off. A repeat rate may be selected between 1 and 5 seconds.
 5. Temperature Indicator
This provides a visual gauge of the temperature of the sapphire crystal.
 6. Temperature Setpoint
It can be manually selected between 0 and 30 °C.
 7. Static Hair Preset Parameters
The preset parameters for hair treatment are displayed.
 8. Counter
This counter displays the total number of shots since last reset to zero.
 9. Reset
To reset the counter to zero, touch the reset softkey until the system beeps 4 times. Turning off the system also resets this counter to zero.
 10. Standby/Treatment
Touch this key to switch between Treatment and Standby modes.
 11. Return to Previous Screen
Touching this softkey permits the user to return to the previous screen.
- Hair to be treated should be shaved 0 - 24 hours prior to treatment. Hair should not be waxed or plucked for 4 weeks prior to treatment.
 - Apply thin layer of colorless gel.
 - Select appropriate settings.
 - Treat test area to establish safe treatment parameters and desired endpoint.
-  *Do not overlap pulses. Doing so may result in skin blister.*
- Once appropriate settings are selected, complete treatment area.

Endpoints

- Smell of success (SOS) – hair has a unique and very noticeable odor when it is heated during the light pulse.
- Slight follicular edema and erythema that resolves within 1 - 4 hours of treatment.
- Slight patient discomfort.

Post Treatment

- Observation – Erythema for several hours after treatment. Treated hairs can take up to 7 - 14 days to exfoliate from the follicle and may appear to be “growing” during this time.
- Intervention – Cool compresses or ice packs can provide some comfort after treatment. If blistering occurs, aggressive wound healing measures should be implemented.
- Interval – Treatments are performed 4 - 8 weeks apart. 5 - 7 treatments may be required.
- If performing hair reduction treatments in conjunction of other procedures such as MLP or ProFractional, perform hair reduction first.
- Check with manufacturer for guidelines on using injectables in conjunction with hair reduction treatments.

Note: Check with manufacturer for guidelines on using injectables in conjunction with hair removal treatment.

Safe Start Protocol for BBL SkinTyte

Protocol Introduction

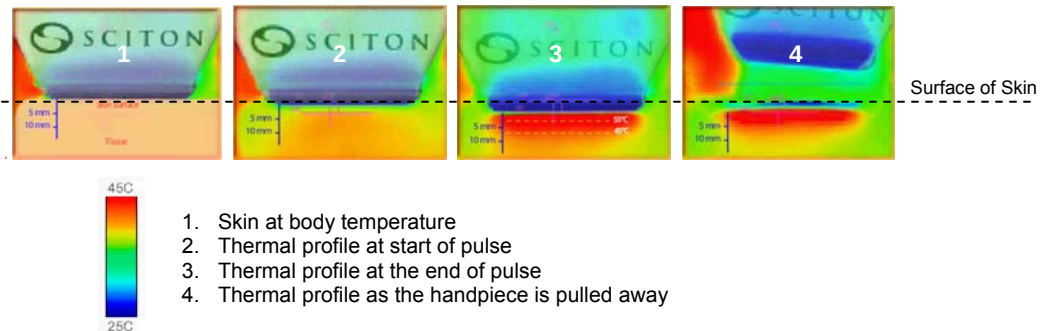
SkinTyte™ is a fast intense pulsed light non-invasive skin firming treatment. SkinTyte treatments utilize optimized cut-off filters which emit energy with wavelengths in the visible to infrared spectrum, and provide dermal heating for the purpose of elevating tissue temperature for firmer skin. This proprietary technology is used to selectively heat the water within the dermal collagen matrix.

Note: BBL is not cleared in Canada for the treatment of non-invasive skin firming.

The SkinTyte Protocol will:

1. Discuss selective heating of skin using photothermal energy and the factors that determine safe start parameters
2. Provide details and requirements corresponding to the safe use of each specialized ST filter
3. Display screen shots with key descriptions
4. Provide instruction in the performance of the two different SkinTyte techniques; one the "Static" Technique and the other, the "Motion Technique"

Selective Heating of Skin with Photothermal Energy



Tight, firm skin requires good elasticity. Elasticity means the ability of the skin to snap back or tighten after it has been displaced or pulled away from the body. Good elasticity depends on healthy collagen and elastin fibers that lie very deep, near the bottom of the dermis. Collagen and elastin fibers act like small rubber bands that hold the skin tight against our body, and pull the loose tissue back when it is stretched or pulled.

Aging, sun damage from ultraviolet (UV) light, smoking, stress, excessive alcohol intake and an unhealthy diet and lifestyle all destroy collagen and elastin in the dermis and cause the skin to loosen and sag. Although it is located beneath the epidermis, it is changes to the dermis that cause the outer skin to wrinkle and lose elasticity. As we grow older, the amount of fat found in our lower layer of skin decreases, our glands produce less oil, and collagen and elastin fibers lose their elasticity. The natural process of cell reproduction in the dermal layer also decreases, resulting in a slower rejuvenation of our skin cells.

SkinTyte deposits heat into the dermis. The epidermis is a robust and resilient structure that is at the surface of the skin. It functions as a physical barrier to protect the deeper dermis, and to retain the skin's hydration. As a result of cooling by the sapphire crystal the highest temperature will occur below the epidermis in the more hydrated dermis. The result is a higher temperature within the dermis. The immediate response to this thermal exposure is a contraction of the collagen and elastin fibrils. Longer term, fibroblasts are activated stimulating the production of new collagen, elastin and other components of the extracellular matrix in response to wound healing which takes place up to six months after the initial heating. This tissue remodeling results in a thickening of the dermis and the shrinking of the elastin fibers, resulting in improvement of skin firmness.

Fluence

In light based medicine, fluence is referred to as radiant exposure or the measurement of energy over area. The area is usually the spot size of the light device. The energy is thermal. Collagen strands are denatured and elastin will contract in response to high temperatures. Ideally, the peak temperature is

just above the threshold for initiating collagen remodeling, but not enough to cause full thickness necrosis. SkinTyte "Static Technique" uses J/cm^2 (joules per centimeter squared) as a measurement of thermal energy and SkinTyte "Motion Technique" uses W/cm^2 (watts per centimeter squared) or Intensity as a measurement of thermal energy. When assessing for the appropriate amount of fluence, test pulses should be performed and fluence or intensity should be adjusted incrementally until appropriate endpoints are met.

Pulse Width

Pulse width is the length of the pulse measured in time. The pulse width used in the SkinTyte procedure is measured in seconds for both "Static" and "Motion" techniques. In the "Static" technique the longer pulse width reduces the power, whereas the shorter pulse width increases power for a given fluence setting. In the "Motion" technique the average power delivered is set by the intensity; the pulse width determines the energy delivered.

Cooling

Skin is naturally cooler at the surface. SkinTyte modifies the normal temperature gradient in skin by heating a subsurface layer while cooling the surface. Elastin and collagen lie very deep in the dermis. The major challenge when trying to heat this area in tissue is to get enough heat deep down in the dermis without burning the surface of the skin as the heat passes through the more superficial layers. A thermally controlled sapphire crystal on the BBL handpiece is used to control the skin surface temperature to a precise temperature. All patients and areas treated will then have similar temperature profiles regardless of their normal skin temperature. Infrared light from SkinTyte is applied to the surface of the skin and penetrates down below. The pre-cooled region stays cool while a layer several millimeters below the surface is preferentially heated.

Managing Patient Expectations

Patients should understand that to experience optimal results with SkinTyte a minimum of 4 treatments are required and that optimal results are not seen for 3 - 6 months after the last treatment. It takes this amount of time for dermal changes from fibroblast activity to be evident.

BBL SkinTyte Filters

SkinTyte treatments use three optimized cut-off filters; 590ST, 695ST, and 800ST. Each filter blocks out wavelengths of light below the filter number selected and allows only those wavelengths of light above the filter number to pass through. As an example, the 800ST filter blocks out wavelengths of light below 800 nm and allows only those wavelengths above 800 nm to pass through.



The three filters are skin type specific and have tissue recommendations for use:

- 590ST filter – Skin types I-III
- 695ST filter – Skin types IV-VI
- 800ST filter – Skin types I-VI.

The three filters are technique specific for use:

- 590ST filter - used in "Motion Technique" only
- 695ST filter - used in "Motion Technique" only
- 800ST filter – used in both "Static and Motion Techniques"

The 590ST and 695ST filters have a wider range of light that permits greater transfer of heat thus heating the treatment area faster than the 800ST filter.

9.11.12 Safe Start Protocol for BBL SkinTyte II – Motion Technique (590/695/800ST)



590ST and 695ST filters can only be used with the Motion Technique. 800ST can be used for both Static and Motion Technique.

The goal when treating with SkinTyte using the Motion Technique is to heat the target to a temperature that is sufficient to stimulate collagen, but not to the point that the heat damages skin and surrounding tissue. The SkinTyte Motion treatment uses intensity which is Watts/cm² to measure energy over an area of treatment (different from 800ST Static Technique that uses J/cm²). The following are performance factors when providing a SkinTyte motion technique procedure.

- Intensity
- Time
- Wavelength
- Spot size
- Accumulated energy
- Motion (continual movement of the BBL handpiece during each measured cycle)
- Epidermal temperature monitoring

Time indicates the length of time the energy is being delivered per pass of BBL light.

Intensity is the amount of energy delivered into the target. Intensity is measured in units of Watts/cm². Refer to Treatment Starting Parameters for safe start intensity settings.



The higher the intensity selected, the higher the temperature of the target, the surrounding tissue and the epidermis. Treating with excess energy can result in adverse effects such as abnormal pigmentation, blistering and scarring. Patient response can vary, so the intensity setting should begin low and be increased gradually after assessing the individual patient response and observation of endpoints desired. Reference treatment endpoints at the end of this section.



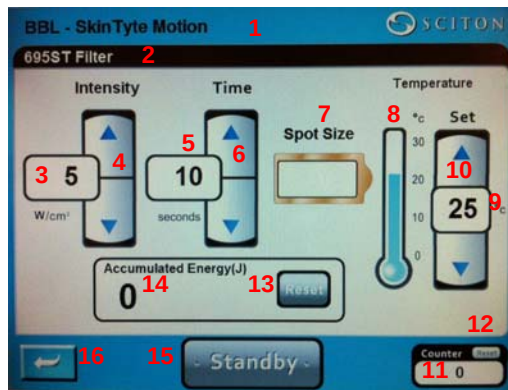
Permanent hair loss may occur in the area treated with BBL. Do not proceed with the treatment if hair growth is desired in the treatment area.

SkinTyte User Screen – Motion Technique

Insert the appropriate filter into the BBL handpiece. Press the Motion SkinTyte softkey on the Broadband Light Application screen and the system will enter the SkinTyte application screen.



Motion SkinTyte II softkey



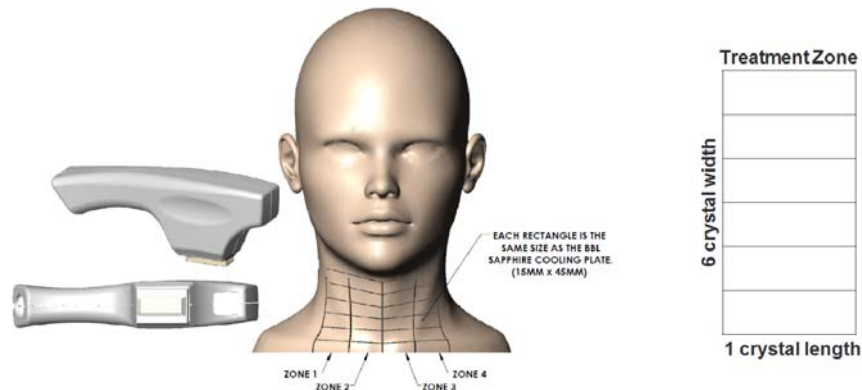
1. Application indicator
Application indicator shows which application is being used for the treatment.
2. Filter wavelength indicator
Filter wavelength indicator shows which wavelength is being used for the treatment.
3. Intensity indicator
Intensity indicator shows the amount of power being delivered per second of BBL light. Intensity is measured in watts per centimeter squared, W/cm².
4. Intensity adjustment softkeys
Intensity adjustment softkeys allow the user to increase or decrease intensity by 1W/cm² by tapping or holding down the up ▲ or down ▼ arrow softkeys.
5. Time indicator
Time indicator shows the length of time the energy is being delivered per pass of BBL light. Time is measured in seconds (s).
6. Time adjustment softkeys
Time adjustment softkeys allow the user to increase or decrease the time on with the energy by 1 second (s) by tapping or holding down the up ▲ or down ▼ arrow softkeys.
7. Spot size adjustment softkey
Spot size adjustment softkey allows the user to toggle between the 15x45 mm spot and the 15x15 mm spot.
8. Cooling thermometer indicator
Cooling thermometer provides a pictorial representation of the cooling temperature of the BBL crystal.
9. Cooling numerical temperature indicator
Cooling numerical temperature indicator shows the degree of cooling selected by numerical value. The temperature is measured in degrees Celsius (°C).
10. Cooling adjustment softkeys
Cooling adjustment softkeys allow the user to increase or decrease the temperature of the BBL crystal by 1 °C by tapping or holding down the up ▲ or down ▼ arrow softkeys. Temperature can be set from 0 to 30 °C depending on the target and area being treated.
11. Number of accumulated pulses indicator
Number of accumulated pulses indicator shows how many pulses have been delivered since the system was turned on or since the last time the reset softkey for accumulated pulses was reset.
12. Accumulated pulses reset softkey
Accumulated pulses reset softkey allows the user to reset the number of accumulated pulses to 0 by touching the reset softkey.
13. Accumulated data reset softkey
Accumulated data reset softkey allows the user to reset the total energy delivered to 0 by touching the reset softkey
14. Accumulated Data
The accumulated data is the total energy delivered. When the 15x15 mm spot is activated the accumulated data is approximately 1/3 less.
15. System status softkey
System status softkey allows the user to put the system in Standby or Ready.
16. Return to Broadband Light Applications screen softkey
Return to Broadband Light Applications soft key will return the system to the previous screen

Treatment Basics:



SkinTyte treatment may be performed on all skin types. 590ST is used for treating skin types I-III, 695ST is for skin types IV-V and 800ST can be used on all skin types, I-VI. When treating darker skin, technique and parameters remain the same, however, patient feedback and temperature monitoring should be performed more frequently on skin type V & VI.

- Select your treatment zones. Use the below diagram as a guidance.



- Apply a thin layer of colorless, room temperature gel.
- Using an external digital thermometer, take 2-3 temperature readings of the area to be treated to establish a baseline. See below for instructions on how to accurately take an external temperature.
- Select appropriate settings.
- The BBL handpiece should be held parallel to the surface of the skin at all times. Move patient if necessary to accomplish this 90 degree angle. All edges of the BBL crystal should be in complete contact with skin at all times throughout entire BBL pulse. For highly curved areas, such as the forehead, chin and cheeks, where maintaining complete contact with the large rectangle BBL crystal is not possible, the smaller snap on adapter may yield a better result. A small bead of gel should be placed on the sapphire glass on the underside of the adapter, prior to snapping it onto the full crystal. This will allow for better light transmission.



Snap On Adapter

- When moving the BBL handpiece, there is a risk that the corners of the full crystal and the square snap on adapter can scratch the patient's skin and cause injury. A snap on Smoothie adapter is recommended to prevent injury and to allow for greater patient comfort.

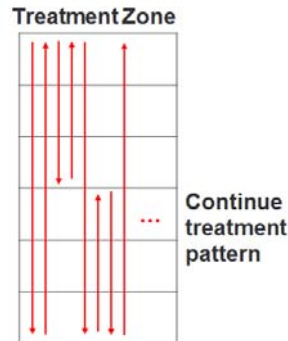


Snap On Smoothie Adapters

- Keep the BBL handpiece in constant, steady motion in a 6 x 1 sized pattern during the entire duration of the pulse.

Treatment Step 1:

- Heat the treatment zone to target temperature of 40-42 °C by moving the handpiece 6 crystal widths in one continuous direction, then reverse the direction 6 crystal widths as seen below to achieve desired temperature endpoint.



Multiple passes are applied by moving the handpiece back and forth in the direction shown.

- Perform one pass to test patient response to the heat, if the heat is tolerable then continue to perform 2-3 passes over the treatment area and then take an external temperature to gauge heat buildup. Continue passes until a temperature of 40-42 °C is reached.

Treatment Step 2:

- Once target temperature is reached, to maintain patient comfort and avoid over-heating, lower energy by 2-3 Watts and continue to maintain target temperature for two to four minutes.



Moving the handpiece too slowly within a treatment area may cause a burn or dermal injury. If the handpiece is not moved quickly enough, the epidermis is being heated without efficient or effective delivery of the heat to the dermis.

External Temperature Measurement:

- Position:** Hold the external temperature device perpendicular to the treatment area.
- Distance:** Refer to the temperature device's directions for information on the distance the device should be held away from the treatment area to register an accurate temperature reading.
- Frequency of taking external temperature:** A baseline temperature should be taken after gel application in the area to be treated and then again after 2-5 passes in the same area. Be aware that thinner tissue will heat up more quickly than thicker tissue.
- Time:** The temperature of the epidermis should be taken within 2-3 seconds after a pass to get an accurate reading.

BBL/BBLs SkinTyte Motion Technique Safe Start Parameters

Skin Type	Filter	Intensity Per Pass (W/cm ²)	Time (sec)	Cooling (°C)	Target Temperature (°C)	Reach Target Temperature then lower energy 2-3 Watts and maintain Temperature for:
I-III	590ST	10-15	10-12	30	40 - 42	2-4 min*
IV-V	695ST	10-13	10-12	30	40 - 42	2-4 min*
I - VI	800ST	9-12	10-12	30	40 - 42	2-4 min*

* Smaller cosmetic units should maintain temperature of 40-42 degrees for two mins

* Larger cosmetic units should maintain temperature of 40-42 degrees for four mins

BBL/BBLs SkinTyte Motion Technique Safe Start Parameters for Delicate Areas (under eyes, backs of hands, bony prominences, etc.) using the 15 x 15 square snap-on adapter

Skin Type	Filter	Intensity Per Pass (W/cm ²)	Time (sec)	Cooling (°C)	Target Temperature (°C)	Reach Target Temperature then lower energy 2-3 Watts and maintain temperature for:
I-III	590ST	8-12	12	20	40 - 42	2 mins
IV-V	695ST	8-12	12	20	40 - 42	2 mins
I-VI	800ST	6-12	12	20	40 - 42	2 mins

Endpoints

- The temperature of the epidermis should read between 40 - 42 °C immediately after a pass, using the external handpiece device.
- Patients report moderate amount of deep heat in the area being treated. The area being treated should be moderately warm throughout the entire pass with the intensity of the heat escalating as temperature of the skin gets to 40-42 °C. In some cases, the patient will indicate the need to move to the next area due to the intense heat sensation even prior to external skin temperatures reaching 40-42 °C.
- Slight to moderate erythema.
- Maintain external temperature: To ensure a reproducible treatment, after reaching the target temperature of 40-42 °C treat the adjacent tissue to maintain the target temperature. Area treated should be warm to the touch for 1-3 minutes after treatment.

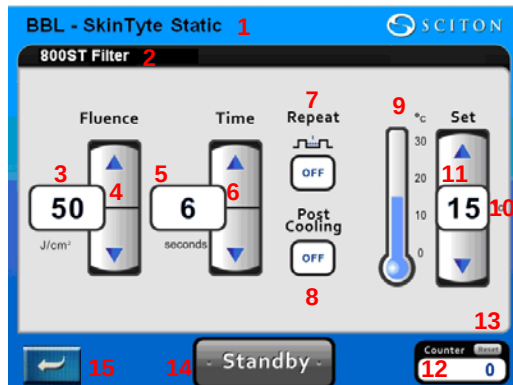
Post Treatment

- Observation – Possible erythema and a palpable change (firmness) may be felt in the treated area for several hours after treatment. Patients may report a feeling of tightness in the area treated.
- Intervention – Cool compresses or ice packs, though rarely needed, can provide some comfort after treatment. If blistering occurs, aggressive wound healing measures should be implemented.
- Interval – Treatments are performed 2 - 4 weeks apart. A minimum of 4 treatments are recommended with optimal results not being evident for 3 - 6 months after last treatment.
- If performing SkinTyte procedure in conjunction of other procedures such as Halo™, MLP® or ProFractional™, perform SkinTyte first.
- Check with manufacturer for guidelines on using injectables in conjunction with SkinTyte treatments.

9.11.13 Safe Start Protocol for BBL SkinTyte II – StaticTechnique (800ST)

Insert the 800ST filter into the BBL handpiece. Press the Static SkinTyte softkey on the Broadband Light Application screen and the system will enter the Static SkinTyte application screen.

SkinTyte User Screen – Static Technique



1. Application indicator
Application indicator shows which application is being used for the treatment.
2. Filter wavelength indicator
Filter wavelength indicator shows which wavelength is being used for the treatment.
3. Fluence indicator
Fluence indicator shows the amount of fluence or energy being delivered per pulse of BBL light. Fluence is measured in joules per centimeter squared, J/cm².
4. Fluence adjustment softkeys
Fluence adjustment softkeys allow the user to increase or decrease fluence by 5 J/cm² by tapping or holding down the up ▲ or down ▼ arrow softkeys.
5. Time indicator
Time indicator shows the length of time the energy is being delivered per pulse of BBL light. Time is measured in seconds (s).
6. Time adjustment softkeys
Time adjustment softkeys allow the user to increase or decrease the time on with the energy by 1 second (s) by tapping or holding down the up ▲ or down ▼ arrow softkeys.
7. Treatment pulse repeat softkey
Treatment pulse repeat softkey will allow the user to set an amount of time between consecutive pulses of 1, 2, 3, 4 or 5 s by tapping the Repeat softkey. Repeat can also be turned off so that each scan pattern is delivered by lifting and depressing the footswitch.

8. Post Cooling softkey
Post cooling softkey allows the user to select OFF, 1.0 s, 2.0 s or 3.0 s of cooling to be delivered after the pulse of BBL light is delivered.
9. Cooling thermometer indicator
Cooling thermometer provides a pictorial representation of the cooling temperature of the BBL crystal.
10. Cooling numerical temperature indicator
Cooling numerical temperature shows the degree of cooling selected by numerical value. The temperature is measured in degrees Celsius (°C).
11. Cooling adjustment softkeys
Cooling adjustment softkeys allow the user to increase or decrease the temperature of the BBL crystal by 1 °C by tapping or holding down the up ▲ or down ▼ arrow softkeys. Temperature can be set from 0 to 30 °C depending on the target and area being treated.
12. Number of accumulated pulses indicator
Number of accumulated pulses indicator shows how many pulses have been delivered since the system was turned on or since the last time the reset softkey for accumulated pulses was reset.
13. Accumulated pulses reset softkey
Accumulated pulses reset softkey allows the user to reset the number of accumulated pulses to 0 by touching the reset softkey.
14. System status softkey
System status softkey allows the user to put the system in Standby or Ready.
15. Return to Broadband Light Applications screen softkey
Return to Broadband Light Applications softkey will return the system to the previous screen.

Treatment Basics



SkinTyte treatment with the 800ST filter may be performed on all skin types. Patient feedback should be performed more frequently on skin type V & VI. When treating darker skin, technique and parameters remain the same, however, patient feedback and temperature monitoring should be performed more frequently on skin type V & VI.

- Apply thin layer of room temperature, colorless gel.
- Select appropriate settings.
- BBL handpiece should be held parallel to the surface of the skin at all times. Move patient if necessary to accomplish this 90 degree angle. All edges of the BBL crystal should be in complete contact with skin at all times throughout the entire BBL pulse. For highly curved areas, such as the forehead, chin and cheeks, where maintaining complete contact with the large rectangle BBL crystal is not possible, the smaller snap on adapter may yield a better result. A small bead of gel should be placed on the sapphire glass on the underside of the adapter, prior to snapping it on to the full crystal. This will allow for better light transmission.



Snap On Adapter

- Perform one pass of test pulses. A pass is no more than 4 pulses in a given area. Until appropriate endpoints are observed, increase fluence by 5 J/cm² and repeat test pass.



A pass of 4 pulses applied in the direction shown.

- Once appropriate settings are selected, complete treatment area.

BBL/BBLs SkinTyte Static Technique Safe Start Parameters

Skin Type	Filter	Fluence (J/cm ²)	Pulse Width/Duration (sec)	Cooling (°C)	Post Cooling (sec)	Passes
I – VI	800ST	40	5	12	2	4 - 5
<i>Note: Decrease fluence 15-20% over bony areas such as forehead, clavicles, etc.</i>						

Endpoints

- Patients report moderate amount of deep heat in the area being treated. Typically a scale of 1 - 10 is used to evaluate heat. 1 is equivalent to almost no heat being felt and 10 is equivalent to the most intense heat ever experienced or imagined. Patients should be at a 5 or 6 on this scale throughout most of the pulse delivery with it escalating towards a 10 on the last second of the pulse. The area being treated should be moderately warm throughout the entire pulse with the intensity of the heat escalating towards the end of the pulse and with each successive pass.
- Slight to moderate erythema.

Post Treatment

- Observation – Possible erythema and a palpable change (firmness) may be felt in the treated area for several hours after treatment. Patients may report a feeling of tightness in the area treated.
- Intervention – Cool compresses or ice packs, though rarely needed, can provide some comfort after treatment. If blistering occurs, aggressive wound healing measures should be implemented.
- Interval – Treatments are performed 3 - 4 weeks apart. A minimum of 4 treatments are recommended with optimal results not being evident for 3 - 6 months after last treatment.
- If performing SkinTyte procedure in conjunction of other procedures such as MLP® or ProFractional™, perform SkinTyte™ first.
- Check with manufacturer for guidelines on using injectables in conjunction with SkinTyte treatments.

9.11.14 Safe Start Protocol for BBL diVaTyte™



BBL diVaTyte is only performed in motion technique with 695ST & 800ST filters.

diVaTyte, is a light-based treatment using selected wavelengths of light to penetrate deep into external vaginal skin. The sapphire quartz adapter is gently massaged on the treatment area to deliver the therapeutic light that heats the dermal layer and elevates tissue temperature, resulting in a more pleasing appearance and a feeling of improved tone and skin firmness. diVaTyte is the companion technology with diVa™ Laser Vaginal Therapy; the synergy optimizes both internal and external tissue to provide a total solution in feminine health.

diVaTyte exterior vaginal skin treatment is based on the same, non-ablative BBL technology for SkinTyte™, which is used on other body skin, such as face, neck, and abdomen. diVaTyte utilizes powerful contact-cooling to protect the epidermis while allowing the therapeutic target-specific infrared energy to volumetrically yet gently heat deep into the layers of skin where collagen and elastin reside to raise tissue temperatures and initiate the body's natural repair and rebuild responses.

The following are performance factors when providing a diVaTyte motion technique procedure.

- Intensity
Intensity is the amount of energy delivered into the target. Intensity is measured in units of watts/cm². Refer to Treatment Starting Parameters for safe start intensity settings.
- Time
Time indicates the length of time the energy is being delivered per pass of light.
- Wavelength
- Spot size
- Accumulated energy
- Motion (continual movement of the BBL handpiece during each measured cycle)
- Epidermal temperature monitoring



The higher the intensity selected, the higher the temperature of the target, the surrounding tissue and the epidermis. Treating with excess energy can result in adverse effects such as abnormal pigmentation, blistering and scarring. Patient response can vary, so the intensity setting should begin low and be increased gradually after assessing the individual patient response and observation of endpoints desired.

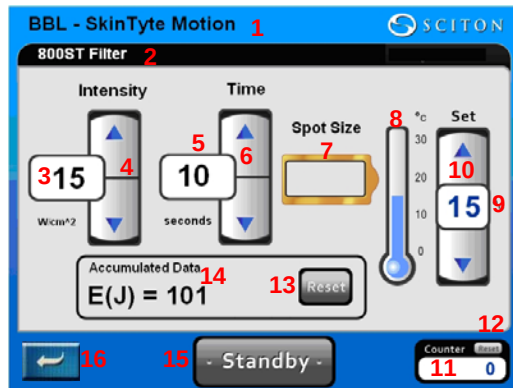
Reference treatment endpoints at the end of this section.

diVaTyte Utilizes the SkinTyte User Screen – Motion Technique

Insert the appropriate filter into the BBL handpiece. Press the Motion SkinTyte softkey on the Broadband Light Application screen and the system will enter the SkinTyte application screen.



Motion SkinTyte II softkey



1. Application indicator
Application indicator shows which application is being used for the treatment.
2. Filter wavelength indicator
Filter wavelength indicator shows which wavelength is being used for the treatment.
3. Intensity indicator
Intensity indicator shows the amount of power being delivered per second of BBL light. Intensity is measured in watts per centimeter squared, W/cm².
4. Intensity adjustment softkeys
Intensity adjustment softkeys allow the user to increase or decrease intensity by 1W/cm² by tapping or holding down the up ▲ or down ▼ arrow softkeys.
5. Time indicator
Time indicator shows the length of time the energy is being delivered per pass of BBL light. Time is measured in seconds (s).
6. Time adjustment softkeys
Time adjustment softkeys allow the user to increase or decrease the time on with the energy by 1 second (s) by tapping or holding down the up ▲ or down ▼ arrow softkeys.
7. Spot size adjustment softkey
Spot size adjustment softkey allows the user to toggle between the 15x45 mm spot and the 15x15 mm spot.
8. Cooling thermometer indicator
Cooling thermometer provides a pictorial representation of the cooling temperature of the BBL crystal.
9. Cooling numerical temperature indicator
Cooling numerical temperature indicator shows the degree of cooling selected by numerical value. The temperature is measured in degrees Celsius (°C).
10. Cooling adjustment softkeys
Cooling adjustment softkeys allow the user to increase or decrease the temperature of the BBL crystal by 1 °C by tapping or holding down the up ▲ or down ▼ arrow softkeys. Temperature can be set from 0 to 30 °C depending on the target and area being treated.
11. Number of accumulated pulses indicator
Number of accumulated pulses indicator shows how many pulses have been delivered since the system was turned on or since the last time the reset softkey for accumulated pulses was reset.
12. Accumulated pulses reset softkey
Accumulated pulses reset softkey allows the user to reset the number of accumulated pulses to 0 by touching the reset softkey.
13. Accumulated data reset softkey
Accumulated data reset softkey allows the user to reset the total energy delivered to 0 by touching the reset softkey
14. Accumulated Data
The accumulated data is the total energy delivered. When the 15x15 mm spot is activated the accumulated data is approximately 1/3 less.
15. System status softkey
System status softkey allows the user to put the system in Standby or Ready.
16. Return to Broadband Light Applications screen softkey
Return to Broadband Light Applications softkey will return the system to the previous screen

Treatment Basics



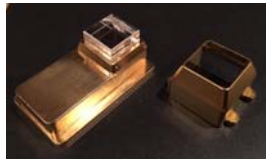
diVaTyte external vaginal skin treatment may be performed on all skin types. 695ST is used for skin types I-IV and 800ST is used for skin types V-VI. When treating darker skin, technique and parameters remain the same, however, patient feedback and temperature monitoring should be performed more frequently.

- Patient is placed in dorsal recumbent position with frog leg configuration.
- Patient is free of vulvar hair.
- Treatment area measurement:
Use a white make-up pencil to mark 1 cm below *clitoral glans* to the crease of the thigh, follow the crease to the *posterior labial commissure*. Treatment area will include the *labia majora* and *labia minora*.
- Apply a generous layer of colorless, room temperature ultrasound gel.
- Using an external digital thermometer, take 2-3 temperature readings of the area to be treated to establish a baseline. See below for instructions on how to accurately take an external temperature.
- Select appropriate setting.
- Place a small bead of gel on the sapphire glass on the underside of the adapter prior to snapping it on to the full crystal. This will allow for better light transmission.



Snap On Adapter

- Use Snap On Smoothie Adapter to prevent injury and to allow for greater patient comfort.



Snap On Smoothie Adapter



Snap On Smoothie Adapter attached

- The BBL handpiece should be held parallel to the surface of the skin at all times. Move patient if necessary to accomplish this 90° angle. The entire surface of the BBL crystal should be in complete contact with skin at all times throughout entire BBL pulse. Pay attention to curved areas, such as the mons pubis.
- Keep the BBL handpiece in constant, steady motion during the entire duration of the pulse.



Moving the handpiece too slowly within a treatment area may cause a burn or dermal injury. If the handpiece is not moved quickly enough, the epidermis is being heated without efficient or effective delivery of the heat to the dermis.

Move the handpiece approximately 6 square crystal widths in one continuous vertical direction, and then reverse the direction 6 square crystal widths as seen below.



Multiple passes are applied by moving the handpiece back and forth in the direction shown.

- Perform one pass to test patient response to the heat, if the heat is tolerable then take an external temperature to gauge heat buildup. Continue passes until a temperature of 38-42°C is reached. Ideally, 42 °C is desired; however, some tissue may be thin, and 38°C is acceptable.
- Use vertical motion passes starting 1 cm below *clitoris* to the *posterior labial commissure*.
- Perform 2 complete motion passes per side. Consider 3 passes if large surface area.
- Once 38-42 °C is reached, decrease the intensity to 7W and maintain with additional passes for 90 seconds.

diVaTyte Utilizes BBL/BBLs SkinTyte Motion Technique Safe Start Parameters

Skin Type	Filter	Intensity Per Pass (W/cm ²)	Time (Sec)	Cooling (°C)	Accumulated Data J/cm ² Per area	Target Temperature (°C)
I-IV	695ST	10W	15	30	10,000-15,000	42
V-VI	800ST	12W	15	30	10,000-15,000	42

External Temperature Measurement:

- Position: Hold the external temperature device perpendicular to the treatment area.
- Distance: Refer to the temperature device's directions for information on the distance the device should be held away from the treatment area to register an accurate temperature reading.
- Frequency of taking external temperature: A baseline temperature should be taken after gel application in the area to be treated and then again after 2-5 passes in the same area. Be aware that thinner tissue will heat up more quickly than thicker tissue.
- Time: The temperature of the epidermis should be taken within 2-3 seconds after a pass to get an accurate reading.

Endpoints

- Patients report moderate amount of deep heat in the area being treated. The area being treated should be moderately warm throughout the entire pass with the intensity of the heat escalating as temperature of the skin gets to 38-42 °C. In some cases, the patient will indicate the need to move to the next area due to the intense heat sensation even prior to external skin temperatures reaching 38-42 °C.
- Slight to moderate erythema.

Post Treatment

- Observation – Possible erythema and a palpable change (firmness) may be felt in the treated area for several hours after treatment. Patients may report a feeling of tightness in the area treated.
- Intervention – Cool compresses or ice packs, though rarely needed, can provide some comfort after treatment. If blistering occurs, aggressive wound healing measures should be implemented.
- Interval – Treatments are performed 2 - 3 weeks apart. A minimum of 5 treatments are recommended with optimal results not being evident for 3 - 6 months after last treatment.

9.11.15 Safe Start Protocol for Forever Young BBL™

The goal of the Forever Young BBL Protocol is to maintain healthy skin and delay the appearance of skin aging safely, effectively, and with minimal to no risk of complications. For greater improvement in skin laxity, Sciton's SkinTyte™ procedure can be performed immediately after the Forever Young BBL treatment.

Forever Young BBL treatments are effective for keeping skin healthy and slowing the signs of skin aging (e.g. laxity, pigmented and vascular lesions, uneven pigmentation and textural changes). BBL treatments at regular intervals appear to promote the maintenance of epidermal structures, contributing to the preservation of healthy skin and a youthful appearance.

Forever Young BBL has shown to be safe and efficacious in skin types I-V. The benefits of BBL treatment are the same for patients of many skin types, including maintaining skin tone, clarity, smoothness, and delaying the development of rhytids and laxity.

Treatments for the purpose of delaying skin aging employ the use of lower fluence and more conservative parameters than corrective BBL treatments (ie. treatment of vascular conditions and pigmented lesions). Forever Young BBL uses multiple passes and requires coverage of the entire cosmetic zone (i.e. the full face). It is recommended to perform 2-4 treatments per year. These treatments are generally initiated with a separate session after successful application of desired corrective treatments.

The theory of Selective Photothermolysis explains how wavelength, energy and pulse width in relation to Thermal Relaxation Time (TRT) all play a role in the destruction of a target and the preservation of surrounding tissue. In the case of a Forever Young BBL treatment, there may be little or no visible target due to clearance of pigment and vascular lesions during previous corrective BBL sessions. In these cases, the goal is to preserve the health of the skin, promote collagen neogenesis and promote a youthful appearance with BBL energy. The use of multiple passes at a lower fluence (J/cm^2) helps to preserve patient comfort while achieving the desired result.

Skin that is free of visible targets will benefit from the application of multiple passes at a lower fluence. Corrective spot treatments can be used on any visible targets such as pigmented or vascular lesions that remain after the completion of two Forever Young BBL passes (see appropriate corrective BBL protocol).

In cases where patients have completed a series of corrective BBL treatments but have experienced a recurrence of visible targets, it is recommended they undergo additional corrective treatments prior to commencing a Forever Young BBL regimen (see applicable BBL protocol).

Filter selection

Refer to Forever Young BBL Treatment Starting Parameters for appropriate filter selection.

Melanin in the skin competes with the target lesions for absorption of the BBL energy. Therefore, a deeper penetrating filter should be chosen for patients with darker skin types.

Fluence

Refer to Forever Young BBL Treatment Starting Parameters for appropriate fluence selection.

Darker targets absorb more energy and will reach higher temperatures, therefore lower fluences should be selected for darker skin.

Pulse Width

Refer to Forever Young BBL Treatment Starting Parameters for appropriate pulse width selection.

Darker skin absorbs more light and heats to a higher temperature, therefore pulse width should be longer for darker skin. A longer pulse width allows the skin to gradually and safely absorb BBL energy.

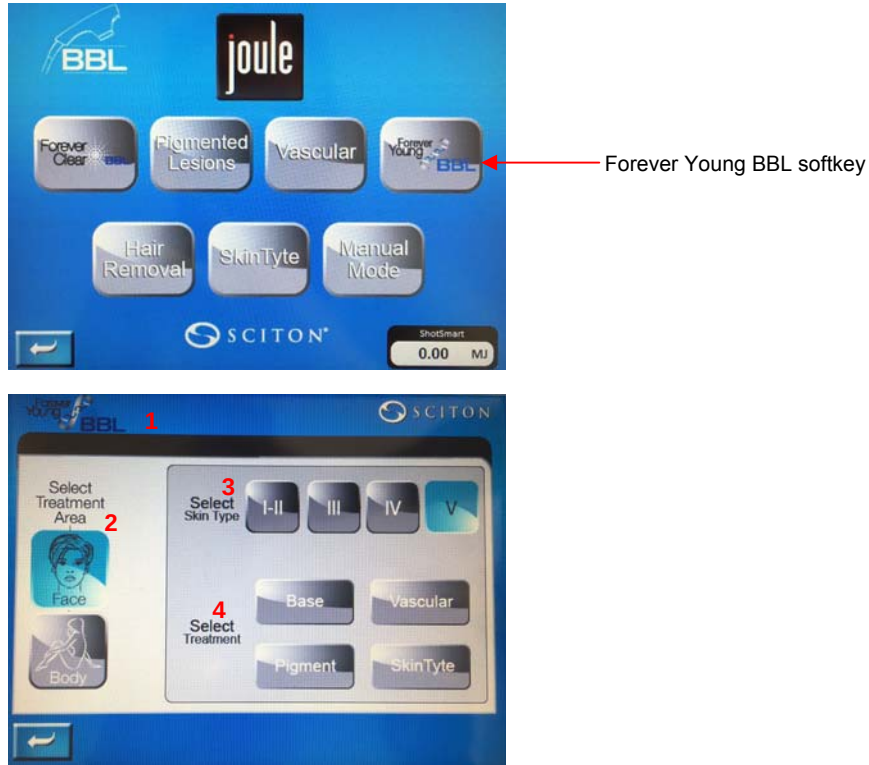
Cooling

Refer to Forever Young BBL Treatment Starting Parameters for appropriate temperature selection.

Some epidermal cooling is essential to protect the skin. The amount of cooling required will vary with skin type and area treated. *When treating body tissue, temperature should be colder*, as well as when treating darker skin types.

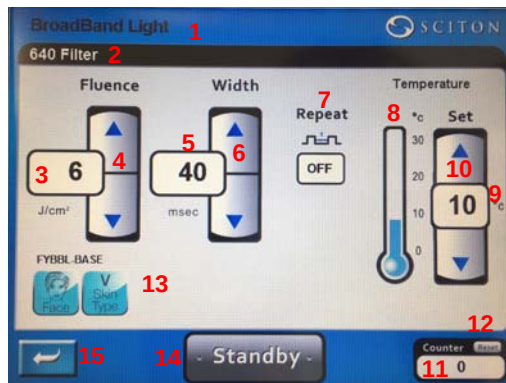
Forever Young User Screen

Press the Forever Young softkey on the Broadband Light Application. Insert the appropriate filter into the BBL handpiece. The screen and the system will enter the Forever Young selection screen.



1. Forever Young BBL Selection Screen
This indicates that Forever Young BBL application has been selected.
 2. Select Treatment Area
The treatment area may be selected for face or body.
 3. Skin Type Selection
Skin types I – V may be selected.
 4. Treatment Type Selection Area
The treatment area may be selected for Base, Vascular, Pigment or SkinTyte.
- Select appropriate working skin type, treatment area and type of treatment. Input this information by pressing corresponding softkey in the above Preset Parameter Screen.
Note: Forever Young BBL utilizes easy-to-use Preset Parameters. This information will populate the proper treatment settings into the Forever Young BBL Treatment Screen. In the example above from the Forever Young BBL Preset Parameters Screen, the Face treatment area was selected for a Skin Type V patient.

In the example below from the Forever Young BBL Preset Parameters Screen, the Base treatment area for the face was selected for a Skin Type V patient.



1. BBL – Application Selection Screen
Application indicator shows which application is being used for the treatment.
2. Filter Wavelength Indicator
Filter wavelength indicator shows which wavelength is being used for the treatment.
3. Fluence Indicator
Fluence indicator shows the amount of power being delivered per second of BBL light. Fluence is measured in joules per centimeter squared, J/cm².
4. Fluence Adjustment Softkeys
Fluence adjustment softkeys allow the user to increase or decrease fluence by 1 J/cm² by tapping or holding down the up ▲ or down ▼ arrow softkeys.
5. Pulse Width Indicator
Pulse width indicator shows the length of time the energy is being delivered per pass of BBL light. Time is measured in milliseconds.
6. Pulse Width Adjustment Softkeys
Pulse width adjustment softkeys allow the user to increase or decrease the width of energy by 1 millisecond(s) by tapping or holding down the up ▲ or down ▼ arrow softkeys.
7. Treatment Pulse Repeat Softkey
Treatment pulse repeat softkey will allow the user to set an amount of time between consecutive pulses of 1, 2, 3, 4, or 5 by tapping the Repeat softkey. Repeat can also be turned off so that each scan pattern is delivered by lifting and depressing the footswitch.
8. Cooling thermometer indicator
Cooling thermometer provides a pictorial representation of the cooling temperature of the BBL crystal.
9. Cooling numerical temperature indicator
Cooling numerical temperature indicator shows the degree of cooling selected by numerical value. The temperature is measured in degrees Celsius (°C).
10. Cooling adjustment softkeys
Cooling adjustment softkeys allow the user to increase or decrease the temperature of the BBL crystal by 1 °C by tapping or holding down the up ▲ or down ▼ arrow softkeys. Temperature can be set from 0 to 30 °C depending on the target and area being treated.
11. Number of accumulated pulses indicator
Number of accumulated pulses indicator shows how many pulses have been delivered since the system was turned on or since the last time the reset softkey for accumulated pulses was reset.
12. Accumulated pulses reset softkey
Accumulated pulses reset softkey allows the user to reset the number of accumulated pulses to 0 by touching the reset softkey.
13. Forever Young BBL Preset Parameters
The preset parameters for base treatment are displayed.
14. System status softkey
System status softkey allows the user to put the system in Standby or Ready.
15. Return to Broadband Light Applications screen softkey
Return to Broadband Light Applications soft key will return the system to the previous screen.

9.11.15.1 Treatment Basics - Forever Young BBL™

If desired, patients may have an anesthetic cream applied 30 minutes prior to the procedure. The topical anesthetic is removed before commencing treatment. The appropriate starting parameters (refer to the Forever Young BBL Parameters) are selected and programmed into the system in Manual mode.

For male patients, the beard area is an important consideration. It is crucial to inform patients that there may be partial or complete loss of dark beard hair in BBL treated areas. For the first pass on female patients (and male patients who are willing to risk loss of beard hair) the full sapphire crystal is used (no Finesse spot adapter should be attached at this time except for areas where the full crystal cannot be placed flat on the skin).



Appropriate protective eyewear should be worn by both the patient and practitioner throughout the duration of the treatment.

Technique

- Apply thin layer of colorless gel.
- Select appropriate settings.
- Treat test area to establish safe treatment parameters and desired endpoint. Treat test area to establish safe treatment parameters. Erythema may be visible and with varying degrees of warmth may be felt.
- Once appropriate settings are selected, complete treatment area.
- Treatment is started near the ear (the right side of the face is pictured in this example). A series of pulses are delivered, with the operator moving the handpiece with up to a 10% overlap over the previously treated area after each pulse. The first row of pulses moves along the jawline and ends mid-chin (Figure 1). The next row of pulses begins in front of the ear just above and slightly overlapping the first row of pulses. Rows of pulses are continued until the entire right cheek including the right upper lip and right chin have been treated. Turn the handpiece to a horizontal orientation if necessary to comfortably treat the lip and chin.

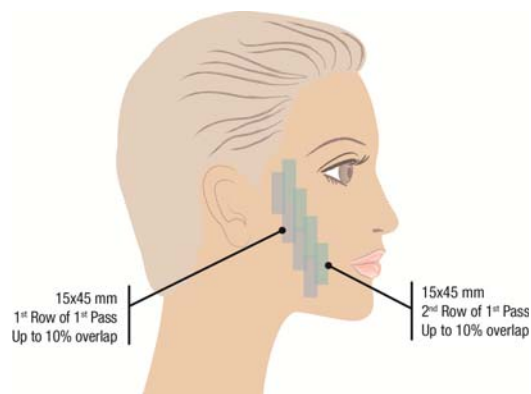


Figure 1

- For male patients who choose to not have the beard area treated, the 15 x 15 mm spot adapter is used, and treatment begins in the pre-trichial (non-beard area) of the cheek. Increase the amount of energy by one or two joules when using the 15 x 15 mm square Finesse spot adapter. The non-beard portion of the cheek is treated with two passes, followed by the forehead. In most male patients, the upper lip or the goatee area is not treated.
- Female patients, and male patients who are willing to risk loss of beard hair, will require approximately 25 pulses with the full BBL crystal for the first pass on the cheek. The second pass is made perpendicular to the direction of the first pass (Figure 2).

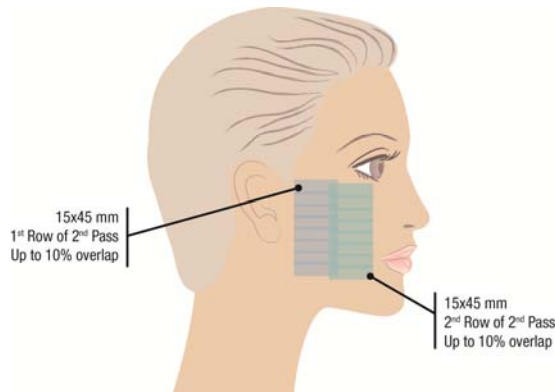


Figure 2

- Two full passes of approximately 50 pulses are delivered to the lower half of the face. This process is repeated on the opposite cheek. The forehead is treated with the square 15 x 15 mm spot adapter using the same parameters as the cheek. There is a tendency for greater epidermal heating to occur because there is less soft tissue on the forehead compared to the cheek. Keeping the fluence the same as the cheeks when treating the forehead with the smaller adapter will help avoid superficial burns.
- Treatment of the forehead begins at the glabella and moves towards the frontal hairline with up to a 10% overlap of each adjacent pulse. Pulsing is continued towards the lateral canthus and returns towards the mid forehead in both directions for two full passes. The forehead requires approximately 80-100 pulses.
- Using the same parameters and the square 15 x 15 mm spot adapter, two passes are delivered in the under eye area including the lower eyelid skin. Protective eyewear is kept in place at all times throughout the procedure, but to ensure safety instruct the patient to keep their eyes closed. The protective goggles are gently pulled superiorly to expose and tighten the lower eyelid skin and keep the eyelashes away from the treatment field. Pulses are made over the exposed lower eyelid skin as close to the goggle as possible. Alternatively, the 11 mm round adapter can be used to easily treat lower eyelid skin safely.
- While maintaining the same parameters, the square 15 x 15 mm spot adapter is used for one additional pass on the upper and lower lip up to the vermillion border. Two full passes are then made over the nose (Figure 3).

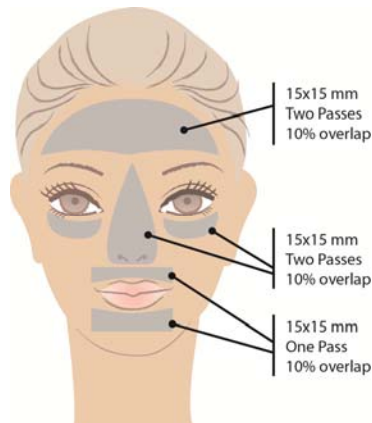


Figure 3

- Approximately 200-240 pulses are required to complete a full-face Forever Young BBL procedure. A spot treatment can be performed over any areas where the patient may need additional treatment and/or where laxity is evident. The appropriate parameters and spot adapter can be used to perform one or two additional pulses to correct areas with new or recurring benign hyperpigmentation, erythema, or telangiectasias (see appropriate corrective BBL protocol).

A SkinTyte™ procedure may be performed immediately after a Forever Young BBL session (Refer to the Table of Parameters).

See Forever Young BBL parameters for "Body" for treatment off of the face. A similar technique with multiple passes should be used.



Forever Young BBL™ Base Parameters - FACE

Skin Type	Filter (nm)	Fluence (J/cm ²)	Pulse Width (ms)	Cooling (°C)	Spot adapter (mm)	Passes	Pulses
I-II	560	8-10	10-15	15	Full 15 x 45 crystal for cheeks 15x15 square for forehead, nose, under eyes	2*	200-240
III	560	8-9	10-15	15	Full 15 x 45 crystal for cheeks 15x15 square for forehead, nose, under eyes	2*	200-240
IV	590 or 640	7-9	20	15	Full 15 x 45 crystal for cheeks 15x15 square for forehead, nose, under eyes	2*	200-240
V	640 or 695	6-8	40	10	Full 15 x 45 crystal for cheeks 15x15 square for forehead, nose, under eyes	2*	200-240

***Note:** Spot treatments for new or recurring pigmented and vascular lesions may be applied after 2 full passes have been administered. Choose spot treatment settings from BBL Application Screen and refer to the applicable protocol. **If significant erythema or other adverse effects are noted in the patient after the 1st pass has been administered, discontinue the treatment and execute appropriate post care intervention procedures.**



Forever Young BBL™ Base Parameters - BODY

Skin Type	Filter (nm)	Fluence (J/cm ²)	Pulse Width (ms)	Cooling (°C)	Spot adapter (mm)	Passes	Pulses
I-II	560	8-9	15	15	Full 15 x 45 or 15 x 15 square	2*	neck & chest ~150 hands~40
III	560	7-8	20	15	Full 15 x 45 or 15 x 15 square	2*	neck & chest ~150 hands~40
IV	590 or 640	6-7	30	15	Full 15 x 45 or 15 x 15 square	2*	neck & chest ~150 hands~40
V	640 or 695	5-6	40	10	Full 15 x 45 or 15 x 15 square	2*	neck & chest ~150 hands~40

***Note:** Spot treatments for new or recurring pigmented and vascular lesions may be applied after 2 full passes have been administered. Choose spot treatment settings from BBL Application Screen and refer to the applicable protocol. **If significant erythema or other adverse effects are noted in the patient after the 1st pass has been administered, discontinue the treatment and execute appropriate post care intervention procedures.**

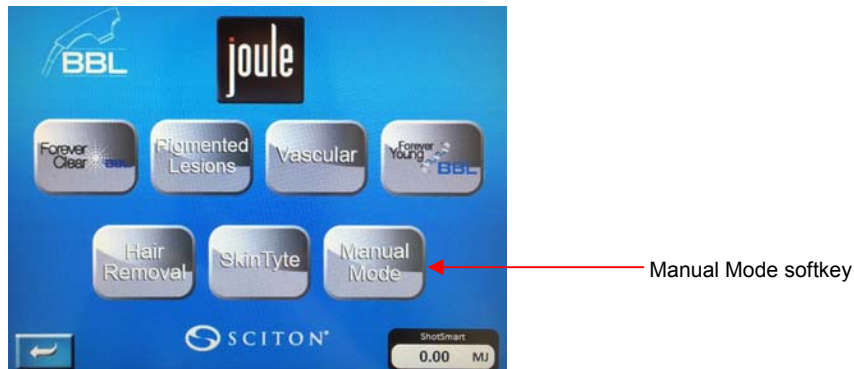
Add-on SkinTyteII™ Parameters							
Skin Type	Filter (nm)	Irradiance (Watts/cm ²)	Pulse Width (sec)	Cooling (°C)	Spot adapter (mm)	Target Temp (°C)	Total Energy (J)
I-II	590ST	10-15	12	30	Full 15 x 45 crystal for cheeks and neck 15x15 square for forehead	38-42	Neck 40,000-50,000 Cheeks 30,000
III	590ST or 695ST	10-15	12	30	Full 15 x 45 crystal for cheeks and neck 15x15 square for forehead	38-42	Neck 40,000-50,000 Cheeks 30,000
IV	695ST or 800ST	8-15	12	30	Full 15 x 45 crystal for cheeks and neck 15x15 square for forehead	38-42	Neck 40,000-50,000 Cheeks 30,000
V	800ST	8-15	12	30	Full 15 x 45 crystal for cheeks and neck 15x15 square for forehead	38-42	Neck 40,000-50,000 Cheeks 30,000
*Note: Spot treatments for new or recurring pigmented and vascular lesions may be applied after 2 full passes have been administered. Choose spot treatment settings from BBL Application Screen and refer to the applicable protocol. If significant erythema or other adverse effects are noted in the patient after the 1st pass has been administered, discontinue the treatment and execute appropriate post care intervention procedures.							

Post Treatment

- Observation – Erythema for several hours post treatment.
- Intervention – Cool compresses or ice packs can provide some comfort after treatment. If blistering occurs, aggressive wound healing measures should be implemented.
- If performing a Forever Young BBL treatment in conjunction with other procedures such as Micro Laser Peel, HALO or ProFractional, perform the BBL treatment first.
- Check with manufacturer for guidelines on using injectables in conjunction with Forever Young BBL treatments.

9.11.16 Manual Mode

Touching the following softkey permits the user to enter the Manual Mode.

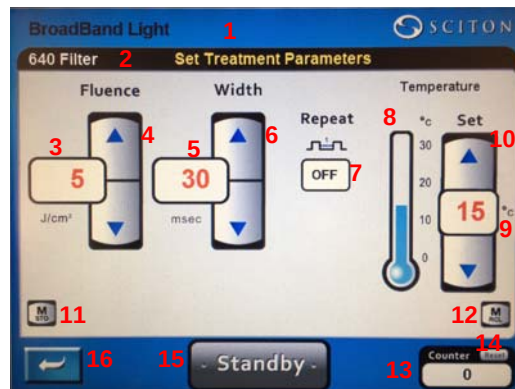


Note: All filters except 800ST are available for use, however, SkinTyte™ and Forever Bare BBL™ applications are not available.

The manual mode allows the user to bypass the preset parameter screens reference above.

BBL User Screen

BBL User screen allows the user to adjust a wide range of treatment settings. The available functions are described below, using the 640 filter screen as an example. Settings for all treatments performed with the BBL will be set using the screen below with the exception of SkinTyte™ and Forever Bare BBL™.



1. Application indicator
Application indicator shows which application is being used for treatment.
2. Filter wavelength indicator
Filter wavelength indicator shows which wavelength is being used for the treatment.
3. Fluence indicator
Fluence indicator shows the amount of fluence or energy being delivered per pulse of BBL light. The fluence is measured in joules per centimeter squared (J/cm^2).
Note: The factory default is displayed in red and will turn black as the setting is altered.
4. Fluence adjustment softkeys
Fluence adjustment softkeys allows the user to increase or decrease fluence by $1 \text{ J}/\text{cm}^2$ by tapping or holding down the up ▲ or down ▼ arrow softkeys.
5. Pulse width indicator
Pulse width indicator shows the length of time the energy is being delivered per pulse of BBL light. Pulse width is measured in milliseconds (ms).
Note: The factory default is displayed in red and will turn black as the setting is altered.

6. Pulse width adjustment softkeys
Pulse width adjustment softkeys allows the user to increase or decrease pulse width by tapping or holding down the up ▲ or down ▼ arrow softkeys.
7. Pulse repeat softkey
Pulse repeat softkey allows the user to set an amount of time between consecutive pulses of 1, 2, 3, 4 or 5 seconds by tapping the Repeat softkey. Repeat can also be turned off so that each pulse is delivered by lifting and depressing the footswitch.
8. Cooling thermometer indicator
Cooling thermometer provides a pictorial representation of the cooling temperature of the BBL crystal.
9. Cooling numerical temperature indicator
Cooling numerical temperature shows the degree of cooling selected by numerical value. The temperature is measured in degrees Celsius (°C).
Note: The factory default is displayed in red and will turn black as the setting is altered.
10. Cooling adjustment softkeys
Cooling adjustment softkeys allows the user to increase or decrease the temperature of the BBL crystal by 1 °C by tapping or holding down the up ▲ or down ▼ arrow softkeys. Temperature can be set from 0 to 30 °C depending on the target and area being treated.
11. Memory Store
Permits the storage of up to 3 preset settings.
12. Memory Recall
Permits recall of up to 3 preset settings
13. Number of accumulated pulses indicator
Number of accumulated pulses indicator shows how many pulses have been delivered since the system was turned on or since the last time the reset softkey for accumulated pulses was reset.
14. Accumulated pulses reset softkey
Accumulated pulses reset softkey allows the user to reset the number of accumulated pulses to 0 by touching the reset softkey.
15. System status softkey
System status softkey allows the user to put the system in Standby or Ready.
16. Return to Broadband Light Applications screen softkey
Return to Broadband Light Applications softkey will return the system to the previous screen.

Appendix I: Chiller Operating Instructions

Chiller Start-up and Operation

1. Remove chiller from the corrugated box along with the power cord and the operator manual.
2. Remove cap on top of the chiller.
3. Fill with chiller mixture (20% methanol and 80% deionized water) supplied by Sciton.
4. Replace cap.
5. Connect the two lines from one end of the hose assembly to the chiller by simply pushing the disconnect fittings together as shown. A clicking sound will confirm proper engagement.



6. Remove hose jumper from the other end by depressing the metal tab and gently pulling the hose.



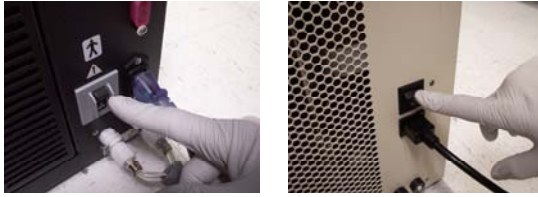
7. Route the hose along the side of the articulated arm, using hose clips to hold the hose in place as shown.



Hose Clips

8. Connect the two lines at this end of the hose to the contact cooling handpiece.
9. Install power cord into the chiller and connect the other end to the wall outlet.

10. Turn on power to the chiller and allow temperature to reach the set temperature.



11. Press "MENU" or "P" key to display set temperature.



12. Adjust to desired set temperature by using up or down arrow keys and allow time for system to reach the set temperature.



13. Proceed with laser treatment once the temperature reaches the desired cooling temperature.



Ensure that the chiller mixture flowing through the contact cooling handpiece is always clear and free of air bubbles. If you notice contamination in chiller mixture, stop treatment and contact Sciton Service . If you notice air bubbles in the contact cooling handpiece, stop the treatment and add chiller mixture as described above before proceeding.

14. Upon completion of laser treatment, turn off power to the chiller.

Note: Replace filter at least once a year if your chiller is installed with a filter. Loosen the hand- screw on the side of the chiller to remove the cover and access the filter.

Appendix II: TempASSURE™ Temperature Measurement Accessory



TempAssure is an accessory to the JOULE laser platform when utilizing the ProLipo module. It is used to monitor the temperature of tissue in close proximity to the ProLipo fiber tip during laser assisted lipolysis treatment. This allows the physician an objective method to identify endpoints and increase patient safety.

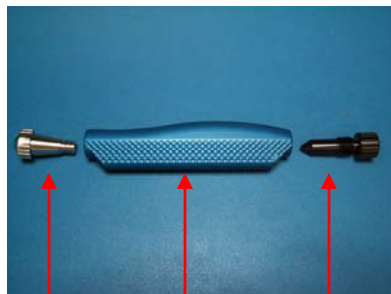


The temperature measured is at the junction of the two thermocouple wires at a point 6 millimeters (1/4 inch) from the end of the cannula. Since the laser energy is delivered to a zone forward of the fiber tip, if the thermocouple is not in motion it will not be in the region being heated and the temperature reading will be lower than the elevated temperature of the treatment zone.

Assembling the TempASSURE Cannula

1. Before assembly, the following parts should be sterilized.
 - Handpiece parts - collet, handle and optical fiber nut
 - Thermocouple cannula

Reference "Cleaning & Sterilization Requirements Prior to Reuse of Devices" section of this operator manual.
2. Assemble the ProLipo Handpiece as shown below.



Cannula
collet

Handle

Optical fiber nut



Loosely screw collet and fiber nut
into the handle

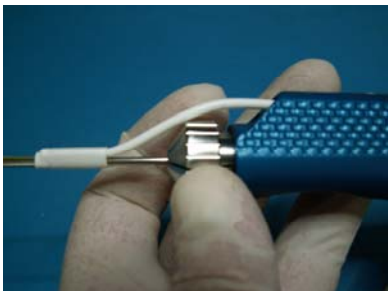
3. Thread the cannula and thermocouple wire through the hole in the handle.



4. Slide the cannula into the collet until it stops.



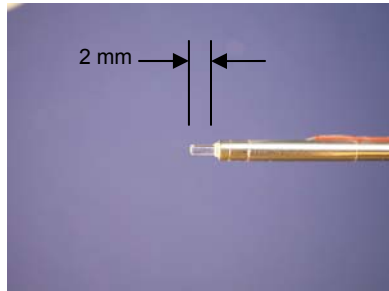
5. Twist the collet clockwise to firmly grip the cannula.



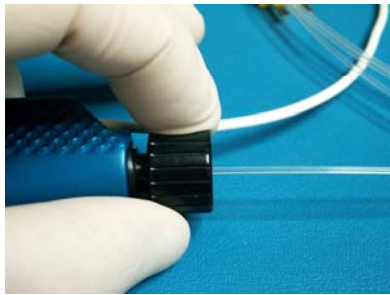
6. Insert the fiber into the fiber nut.



7. Position the fiber by sliding it forward until the tip emerges approximately 2 mm from the distal end of the cannula and a small portion of the buffer is exposed.



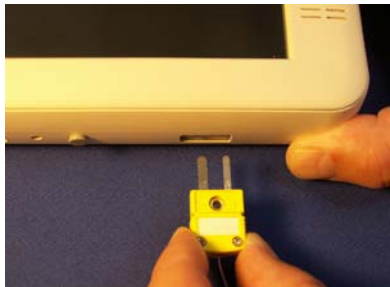
8. Tighten the fiber nut to secure the fiber so that it does not slip. Hand tighten only; do not over-tighten.



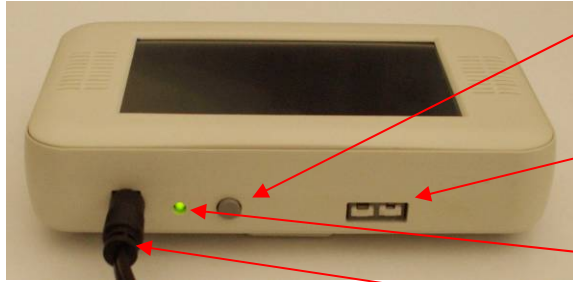
9. Fully assembled handpiece with cannula, fiber and thermocouple.



10. Plug the male thermocouple wire plug into the display receptacle. Push until fully seated.
Note that the plug has different width prongs. The wider prong must be on the side closer to the On/Off button – as shown below.



11. Features on TempASSURE console are illustrated below.



On/Off

Press for On; press again for Off
TempASSURE automatically turns off if the thermocouple temperature has not changed for 10 minutes.

Thermocouple receptacle

Note that the holes are of different widths.

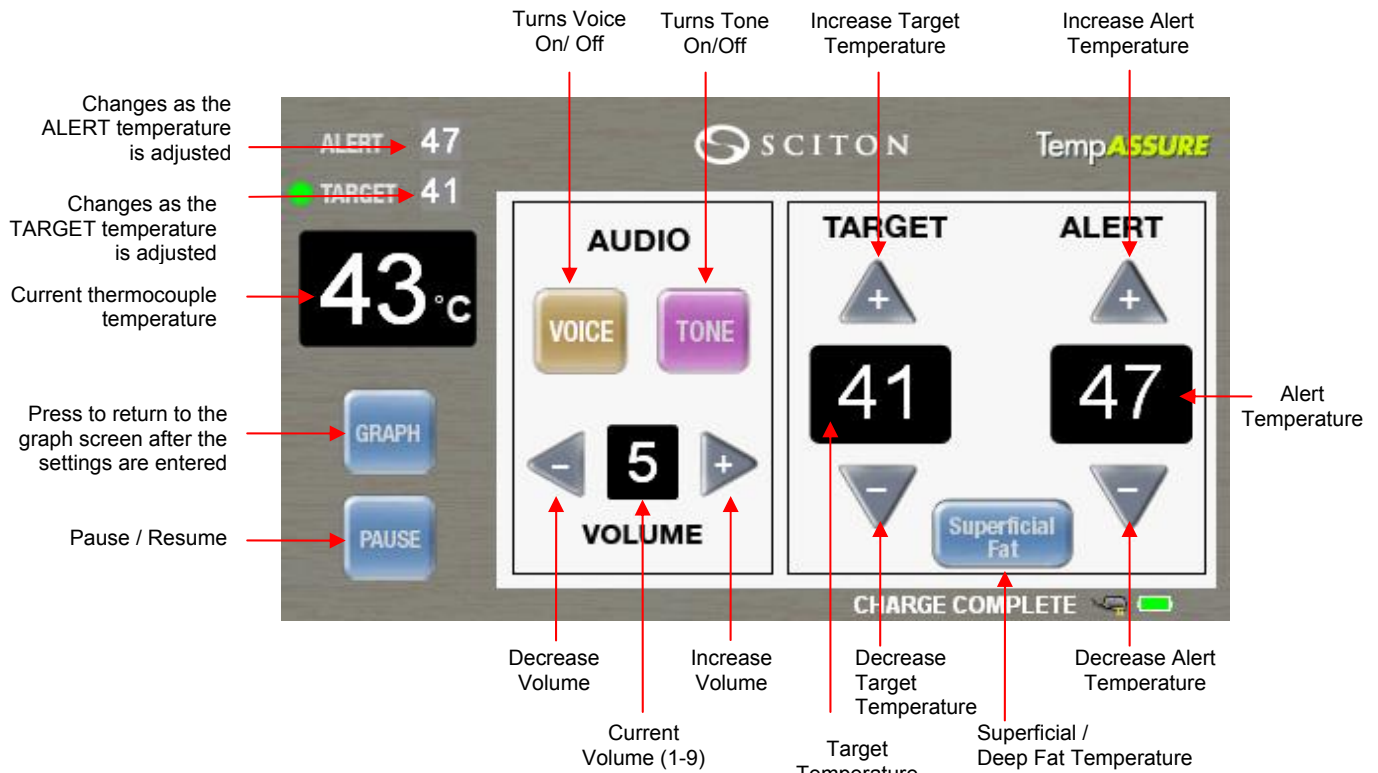
Charging indicator

Illuminates green when charging. Not illuminated when fully charged.

Battery charger plug

Charging time from full discharge: less than 3 hours
Plug in charger when not in use. The Internal circuitry prevents overcharging.

12. The controls on TempASSURE touch screen are identified below.



Audio Volume Control

Adjust the volume with + / - VOLUME keys.

Audible Tones

Toggle the tone on or off by pressing the TONE key.

Voice

Toggle the voice On or Off with the VOICE key. When On, the voice reports the temperature every 2.5 seconds.

Alert Temperature Setting

Use the + /- ALERT keys to adjust the ALERT temperature. When the thermocouple temperature exceeds the ALERT setting an audio cue sounds.

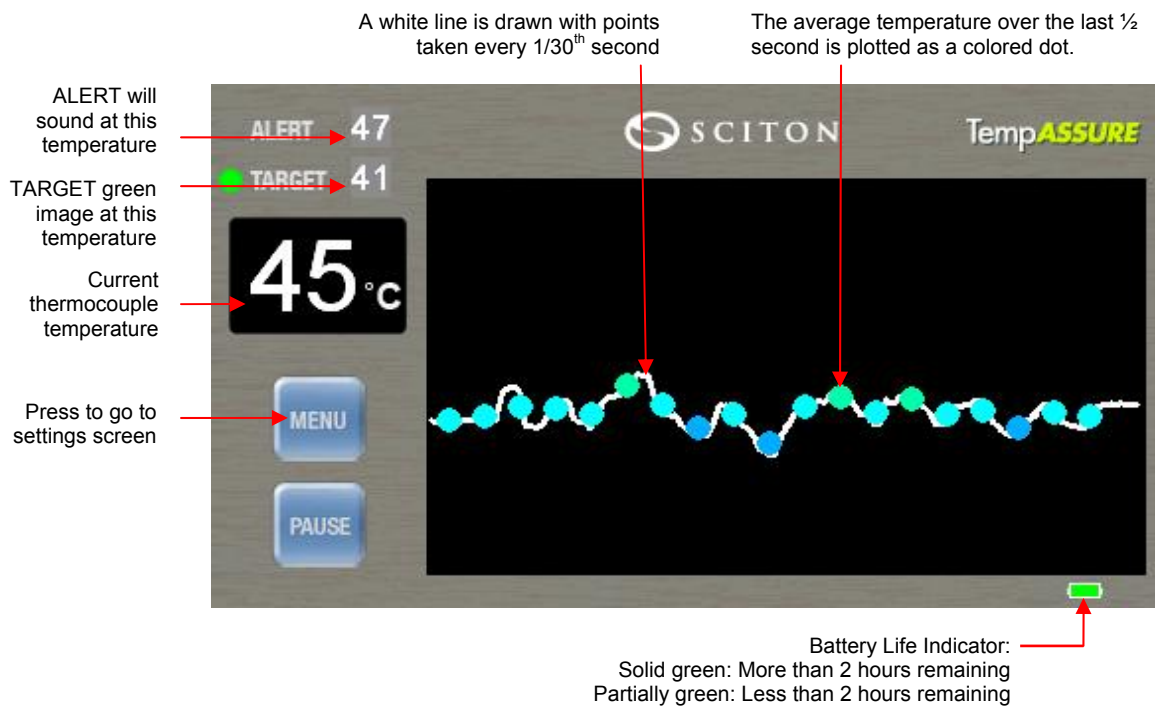
Target Temperature Setting

The TARGET temperature is the temperature you wish to reach in a particular area. Use the + /- TARGET keys to adjust this temperature. When the thermocouple temperature exceeds the TARGET setting an audio cue sounds.

Superficial / Deep Fat Temperature Setting

Toggle between superficial and deep fat settings for the TARGET and ALERT temperatures.

- To display graph, press the GRAPH key. The following screen will appear.



Appendix III: Sample Informed Consent

Informed Consent for Laser Treatment of Skin (Sample)

INSTRUCTIONS

This is an informed consent document which has been prepared to help inform you about laser treatment procedures of skin, risks, and alternative treatments.

It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page and sign the consent for the procedure as proposed by your physician.

INTRODUCTION

Lasers have been used by physicians for many years. There are many different methods for the surgical use of lasers. Laser energy can be used to cut, vaporize, or selectively remove skin and deeper tissues.

Conditions such as wrinkles, sun damaged skin, scars and some types of skin lesions/disorders may be treated with the laser. Certain surgical procedures may use the laser as a cutting instrument. In some situations, laser treatments may be performed in combination with other surgical procedures.

Skin treatment programs may be used both before and after laser skin treatments in order to enhance the results.

Alternative Treatment - Alternative forms of treatment include not undergoing the proposed laser skin treatment procedure. Other forms of skin treatment (chemical peel) or surgical procedures (dermabrasion or excisional surgery) may be substituted. In certain situations, the laser may offer a specific therapeutic advantage over other forms of treatment. Alternate laser treatment procedures, in some situations, may not represent a better alternative to other forms of surgery or skin treatment when indicated. Risks and potential complications are associated with alternate forms of treatment that involve skin treatments or surgical procedures.

Risks of Laser Treatment of Skin - There are both risks and complications associated with all laser treatment procedures of the skin. Risks involve both items that specifically relate to the use of laser energy as a form of surgical therapy and to the specific procedure performed. An individual's choice to undergo a procedure is based on the comparison of risk to potential benefits. Although the majority of patients do not experience these complications, you should discuss each of them with your physician to make sure you understand the risks, potential complications and consequences of laser skin treatment.

Infection - Although infection following laser skin treatment is unusual, bacterial, fungal, and viral infections can occur. Herpes simplex virus infections around the mouth or other areas of the face can occur following a laser treatment. This applies to both individuals with a past history of Herpes simplex virus infections and individuals with no known history of Herpes simplex virus infections in the mouth area. Specific medications may be prescribed and taken both prior to and following the laser treatment procedure in order to suppress an infection from this virus. Should any type of skin infection occur, additional treatment including antibiotics may be necessary.

Scarring - Although normal healing after the procedure is expected, abnormal scars may occur both in the skin and deeper tissues. In rare cases, keloid scars may result. Scars may be unattractive and of different color than the surrounding skin. Additional treatments may be needed to treat scarring.

Burns - Laser energy can produce burns. Adjacent structures including the eyes may be injured or permanently damaged by the laser beam. Burns are rare yet represent the effect of heat produced within the tissues by laser energy. Additional treatment may be necessary to treat laser burns.

Color Change - Laser treatments may potentially change the natural color of your skin. Skin redness usually lasts 2 weeks-3 months and occasionally up to 6 months following laser skin treatment. There is the possibility of irregular color variations within the skin including areas that are both lighter and darker. A line of demarcation between normal skin and skin treated with lasers can occur.

Accutane (Isotretinoin) - Accutane is a prescription medication used to treat certain skin diseases. This medication may impair the ability of skin to heal following treatments or surgery for a variable amount of time even after the patient has ceased taking it. Individuals who have taken the medication are advised to allow their skin adequate time to recover from Accutane before undergoing laser skin treatment procedures.

Fire - Inflammable agents, surgical drapes and tubing, hair, and clothing may be ignited by laser energy. Laser energy used in the presence of supplemental oxygen increases the potential hazard of fire. Some anesthetic gases may support combustion.

Laser Smoke (plume) - Laser smoke is noxious to those who come in contact with it. This smoke may represent a possible bio-hazard.

Skin Tissue Pathology - Laser energy directed at skin lesions may potentially vaporize the lesion. Laboratory examination of the tissue specimen may not be possible.

Visible Skin Patterns - Laser treatment procedures may produce visible patterns within the skin. The occurrence of this is not predictable.

Patient Failure to Follow Through - Patient follow through following a laser skin treatment procedure is important. Post operative instructions concerning appropriate restriction of activity, use of dressings, and use of sun protection need to be followed in order to avoid potential complications, increased pain, and unsatisfactory result. Your physician may recommend that you utilize a long-term skin care program to enhance healing following a laser skin treatment.

Damaged Skin - Skin that has been previously treated with chemical peels or dermabrasion, or damaged by burns, electrolysis (hair removal treatments), or radiation therapy may heal abnormally or more slowly following treatment by lasers or other surgical techniques. The occurrence of this is not predictable. Additional treatment may be necessary.

Distortion of Anatomic Features - Laser skin treatments can produce distortion of the appearance of the eyelids, mouth and other visible anatomic landmarks. The occurrence of this is not predictable. Should this occur, additional treatment including surgery may be necessary.

Unsatisfactory Result - There is the possibility of an unsatisfactory result from these procedures. Laser procedures may result in unacceptable visible deformities, skin slough, loss of function, and permanent color changes in the skin. You may be disappointed with the final result from laser treatments.

Pain - Very infrequently, chronic pain may occur after laser skin treatment procedures.

Allergic Reactions - In rare cases, local allergies to tape, preservatives used in cosmetics or topical preparations have been reported. Systemic reactions which are more serious may result from drugs used during medical procedures and prescription medicines. Allergic reactions may require additional treatment.

Lack of Permanent Results - Laser or other treatments may not completely improve or prevent future skin disorders, lesions, or wrinkles. Additional procedures or surgery may be necessary to further tighten loose skin.

Delayed Healing - It may take longer than anticipated for healing to occur after laser treatments. Slower than normal skin healing may result in thin, easily injured skin. This is different from the normal redness in skin after a laser treatment.

Unknown Risks - There is the possibility that additional risk factors of laser skin treatments may be discovered.

Surgical Anesthesia - Both local and general anesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anesthesia and sedation.

Additional Treatment or Surgery Necessary - There are many variable conditions which influence the long-term result of laser skin treatments. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with these procedures. Other complications and risks can occur but are even more uncommon. Should complications occur, procedures, surgery or other treatments may be necessary. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied on the results that may be obtained.

FINANCIAL RESPONSIBILITIES - The cost of laser skin treatment involves several charges for the services provided. This includes fees charged by your doctor, the cost of pre and post-operative skin care medications, surgical supplies, laser equipment and personnel, laboratory tests, and possible outpatient hospital charges, depending on where the procedure is performed. It is unlikely that cosmetic surgery costs would be covered by an insurance plan. Even if there is some insurance coverage, you will be responsible for necessary co-payments, deductibles and charges not covered. Additional costs may occur should complications develop from the treatment.

Disclaimer: Informed consent documents are used to communicate information about the proposed treatment of a disease or condition along with disclosure of risks and alternative forms of treatment. The informed consent process

attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances. However, informed consent documents should not be considered all inclusive in defining other methods of care and risks encountered. Your physician may provide you with additional or different information which is based on all the facts in your particular case and the state of medical knowledge.

Informed consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

It is important that you read the above information carefully and have all of your questions answered before signing the consent.

1. I hereby authorize Dr. _____ and such assistants as may be selected, to perform the following procedure or treatment:
2. I recognize that during the course of the procedure and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants, or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
3. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
4. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
5. I consent to the photographing or televising of the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the picture.
6. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
7. I consent to the disposal of any tissue, medical devices or body parts which may be removed.
8. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.
9. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
 - a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
 - b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
 - c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-9). I AM SATISFIED WITH THE EXPLANATION.

Patient or Person Authorized to sign for Patient:

Witness: _____

Date: _____

Patient Initials: _____

Date: _____

Appendix IV: Richards-Merhag Chart

Richards-Merhag Chart

Anatomical Region	Telogen (%)	Anagen (%)	Telogen (duration)	Anagen (duration)	Density of Hair (hair/cm ²)	Depth of Follicle (mm)
Scalp	13	85	3 - 4 months	2 - 6 years	350	3 - 5
Eyebrow	90	10	3 months	4 - 8 weeks	-	2 - 2.5
Ear	85	15	3 months	4 - 8 weeks	-	-
Cheek	30 - 35	50 - 70	1 year	-	880	2 - 4
Beard/Chin	20	70	10 weeks	1 year	500	2 - 4
Upper Lip	35	65	6 weeks	16 weeks	500	1 - 2.5
Axillae	70	30	3 months	4 months	65	3.5 - 4.5
Trunk	NA	NA	-	-	70	2 - 4.5
Bikini	70	30	3 months	4 months	70	3 - 5.5
Arm	80	20	18 weeks	13 weeks	80	2 - 4.5
Leg	80	20	24 weeks	16 weeks	60	2.5 - 4
Breast	70	30	-	-	65	3 - 4.5

Appendix V: EMC Statements

It has been determined that the JOULE will meet the following essential requirements if compliance is maintained as noted in the EMC statements listed below.

2. Output power and energy is maintained within specifications.
3. Touch screen display operates as designed.
4. CPU timing and controls are maintained as designed, including power up, initialization, calibration, operation and power down.

Warning:

- The JOULE system needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
- Portable and mobile RF communications equipment can affect the JOULE.
- External chiller and the temperature measurement accessory have not been assessed and may result in increased EMISSIONS or decreased IMMUNITY of the system.
- The use of accessories, transducers and cables other than those specified by Sciton, may result in increased EMISSIONS or decreased IMMUNITY of the system.
- The JOULE should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the JOULE should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration – electromagnetic emissions		
The JOULE is intended for use in the electromagnetic environment specified below. The customer or the user of the JOULE should assure that it is used in such an environment.		
Emissions Test	Compliance	
RF emissions CISPR 11	Group 1	The JOULE uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The JOULE is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage Fluctuations/ Flicker emissions	Not Applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The JOULE is intended for use in the electromagnetic environment specified below. The customer or the user of the JOULE should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance Level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast	±2 kV for power supply	±2 kV for power supply	Mains power quality should

transient/burst IEC 61000-4-4	lines ±1 kV for input/output lines	lines Not Applicable	be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV 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 IEC 61000-4-11	<5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles 70 % <i>UT</i> (30 % dip in <i>UT</i>) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 5 sec	<5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles 70 % <i>UT</i> (30 % dip in <i>UT</i>) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the JOULE requires continued operation during power mains interruptions, it is recommended that the JOULE be powered from an uninterruptible power supply or a battery.
(50/60 Hz) 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 <i>UT</i> is the a.c. mains voltage prior to application of the test level.			

Recommended separation distance between portable and mobile RF communications equipment and the JOULE system			
The JOULE is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the JOULE can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the JOULE as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = [3.5/3]\sqrt{P}$	80 MHz to 800 Mhz $d = [3.5/3]\sqrt{P}$	800 MHz to 2.5 GHz $d = [7/3]\sqrt{P}$
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 maximum output power not listed above, the recommended separation distance <i>d</i> in meters(m) can be estimated using equation applicable to the frequency of the transmitter, where <i>P</i> 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.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The JOULE is intended for use in an electromagnetic environment specified below. The customer or the user of the JOULE should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the JOULE, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [3.5/3]\sqrt{P}$ $d = [3.5/3]\sqrt{P}$ 80 MHz to 800 MHz $d = [7/3]\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b. Interference may occur in the vicinity of equipment marked with the following symbol. 
^a Field strengths from fixed transmitters, such as base stations or 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 JOULE is used exceeds the applicable RF compliance level above, the JOULE should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the JOULE. ^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			