

Clinical Applications - BBL™



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 visible tissue particulates.

1.1 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 qualified user.
- An accredited training course within the practitioner’s specialty.

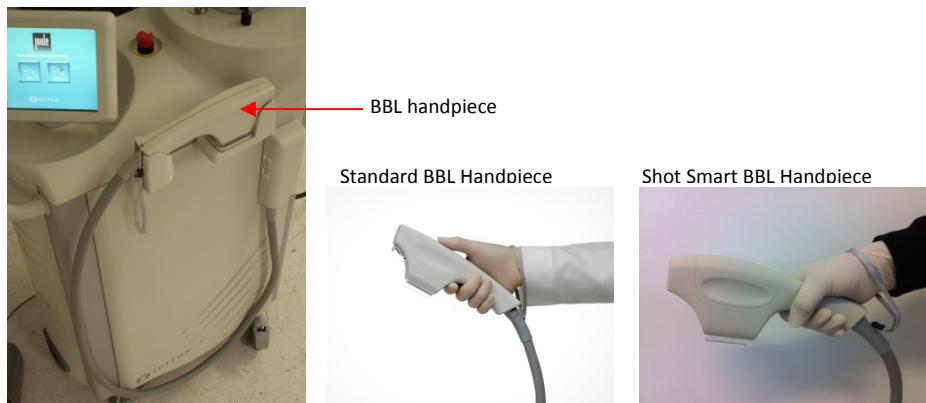
1.2 Broadband Light (BBL)

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.

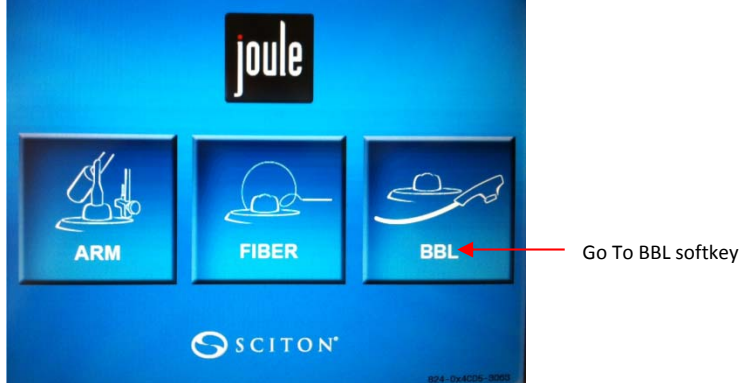


User Interface

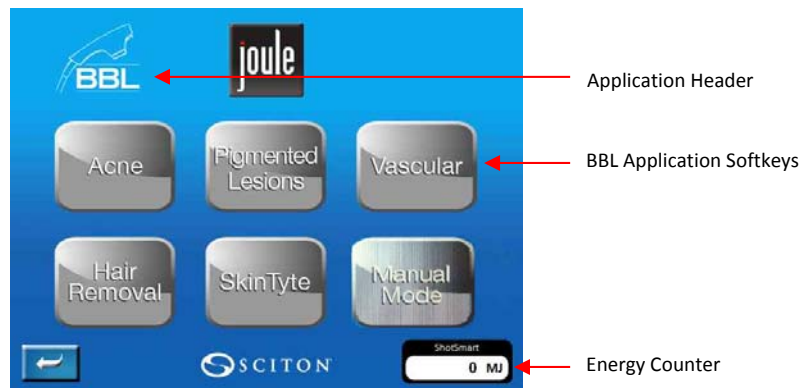
BBL has multiple user interface screens for different uses. The application screens are accessed via the Arm Application menu screen. Access to user screens also requires the appropriate filter to be inserted in the handpiece. Each screen and its functions are outlined as follows.

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

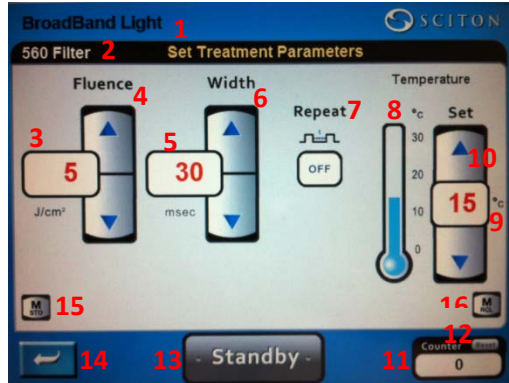
Insert appropriate filter into the BBL handpiece to enter the desired application.

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 590 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/cm²).
4. Fluence adjustment softkeys
Fluence adjustment softkeys allows 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 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 5 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 (°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

1.2.1 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)
- 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)

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).

1.2.2 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

1.2.3 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

1.2.4 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.

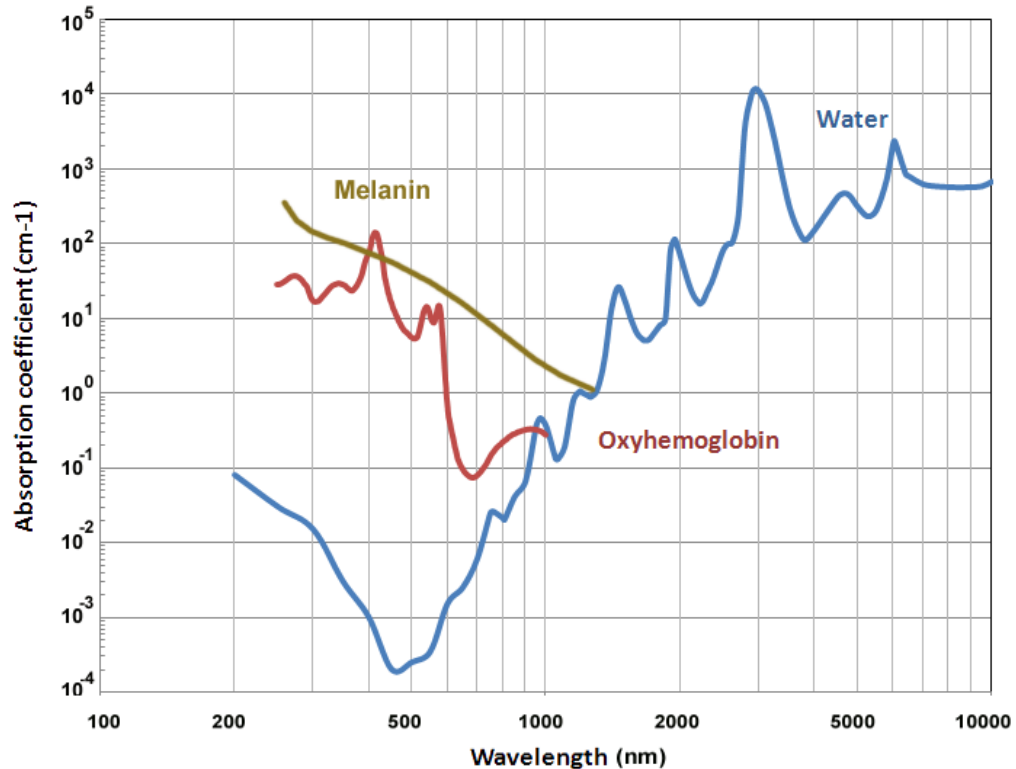
1.2.5 Warnings

- 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.

1.2.6 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

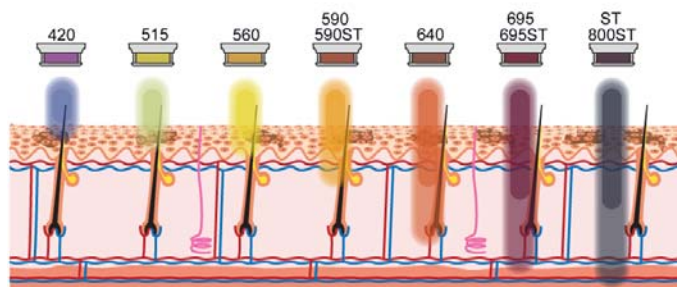


Care should be taken not to touch or scratch the BBL filters. If the filters become dirty or covered with fingerprints, an alcohol gauze may be used to clean the filter. DO NOT soak or submerge BBL filters in water or any other liquid.

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.

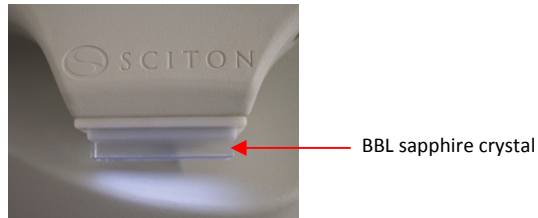
Depth of Penetration

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.

1.2.7 Getting Started

1.2.7.1 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.

1.2.7.2 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.

1.2.7.3 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.

1.2.7.4 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.

1.2.7.5 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.

1.2.7.6 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.

1.2.7.7 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.

1.2.7.8 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.

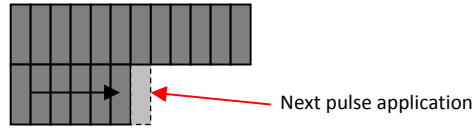


Snap On Adapters



- **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.

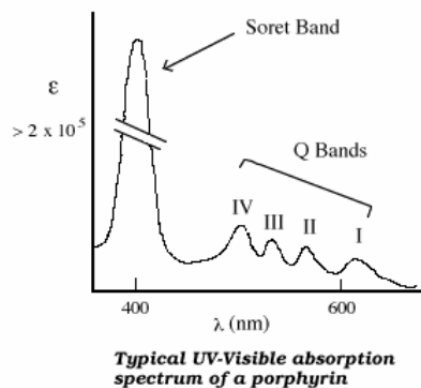
1.2.8 Safe Start Protocol for Forever Clear BBL™ Acne Treatment

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 II 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.

1.2.8.1 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 softkey permits the user to enter the Acne Application.



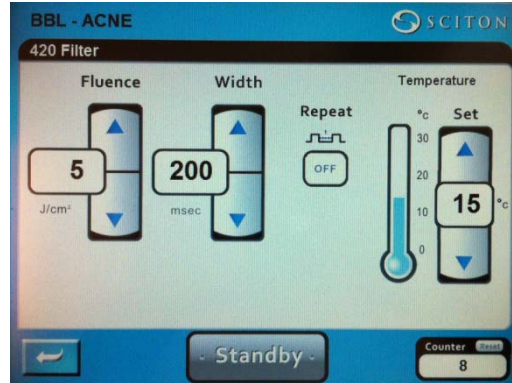
Acne softkey
(Allowed filters: 420nm, 560nm and 590nm, 640nm, 590ST and 800ST)

Step 1 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:

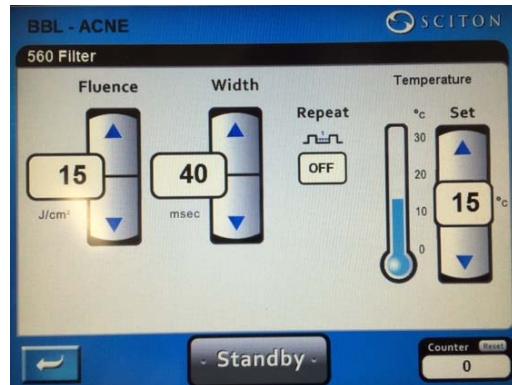
On sensitive patients and patients with more severe acne, the use of a small snap on adaptor focused on individual acne lesions may help to minimize discomfort and allow for all passes to be completed.


Step 2 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.

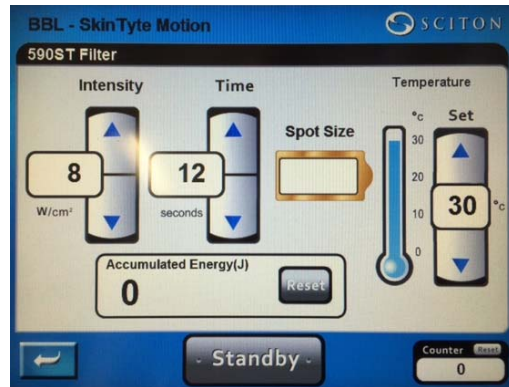


Step 3 Parameters:

(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

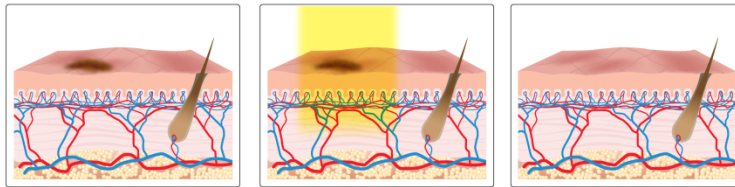
- Observation – Possible slight erythema for several hours after treatment.
- Intervention – Cool compresses or ice packs, though rarely needed, can provide some comfort after treatment. If blistering occurs, aggressive wound healing measures should be implemented.
- Interval – Treatments are performed 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.

1.2.9 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


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

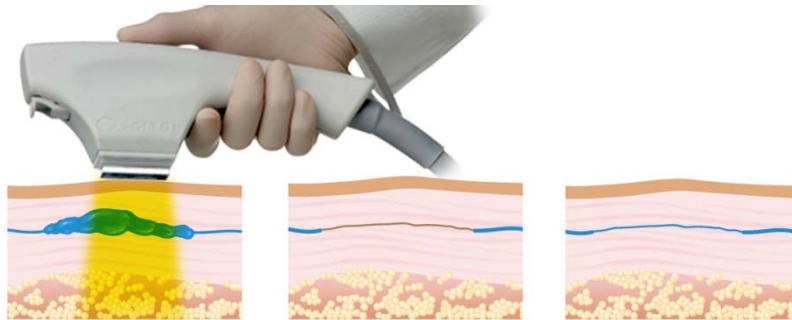
- Observation – Erythema for several hours after treatment
- Intervention – Cool compresses or ice packs can provide some comfort after treatment. If blistering occurs, aggressive wound healing measures should be implemented.
- Interval – Treatments are performed 3 - 4 weeks apart. 3 - 5 treatments may 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.

1.2.10 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.

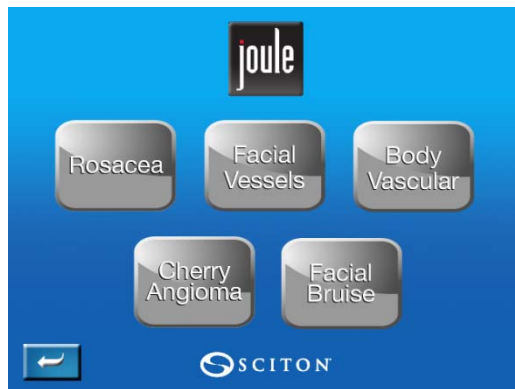
Although absorption of the BBL light in vascular lesions is desirable, some epidermal cooling is essential to protect the skin. The amount of cooling required will vary with skin type, amount of target present, and area treated.

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.

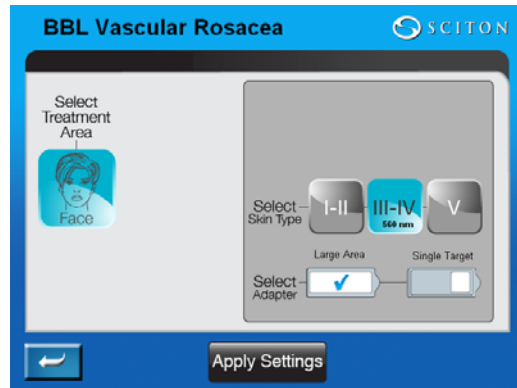
Air chillers, such as a Zimmer, should not be used during BBL vascular treatments. Prolonged cold air on skin can cause vasoconstriction of the targeted vessels resulting in an ineffective treatment.

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.



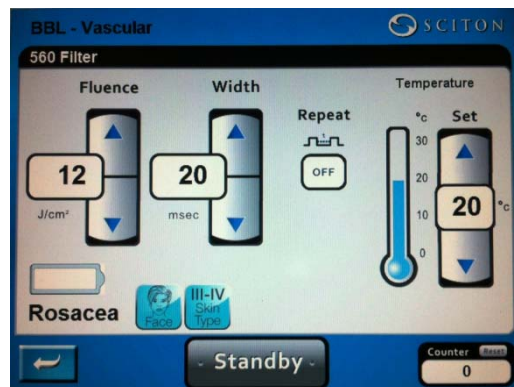
Vascular Rosacea Treatment



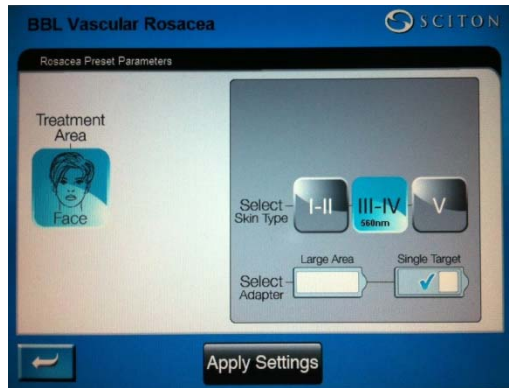
BBL Vascular Rosacea Treatment Starting Parameters – FACIAL Tissue with Large Area Spot



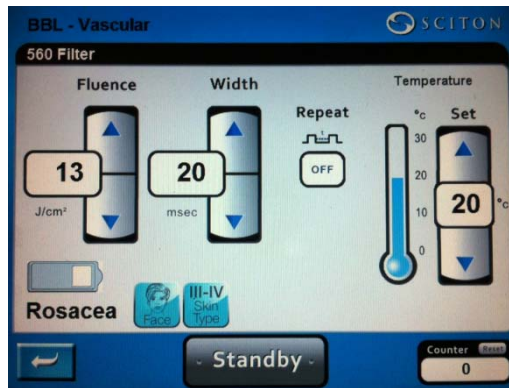
Skin Type	Fluence (J/cm ²)	Pulse Width (ms)	Temperature (°C)
I-II 560nm	14	20	20
III-IV 560nm	12	20	20
V 590nm	10	30	15



BBL Vascular Rosacea Treatment Starting Parameters – FACIAL Tissue with Small Area Spot

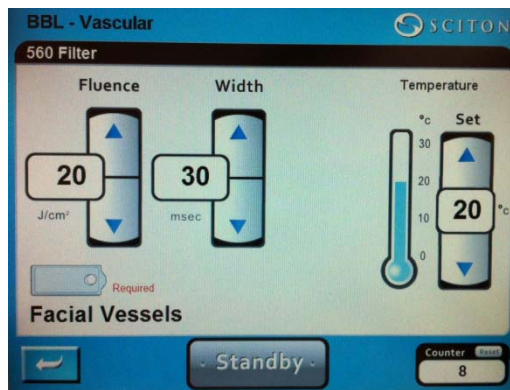


Skin Type	Fluence (J/cm ²)	Pulse Width (ms)	Temperature (°C)
I-II 560nm	15	20	20
III-IV 560nm	13	20	20
V 590nm	11	30	15



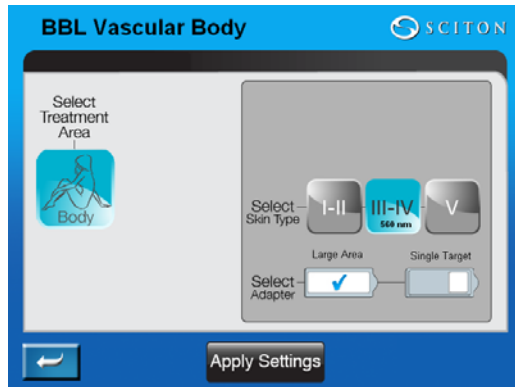
BBL Vascular Facial Vessels Treatment Starting Parameters – Round Spot

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.

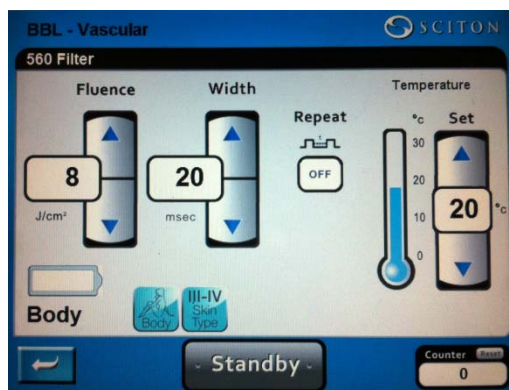


Body Vascular Treatment

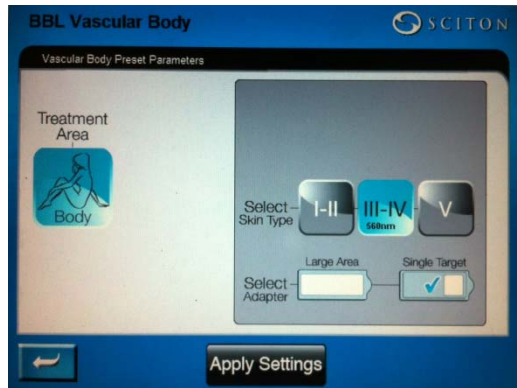
BBL Vascular Body Treatment Starting Parameters – BODY Tissue with Large Area Spot



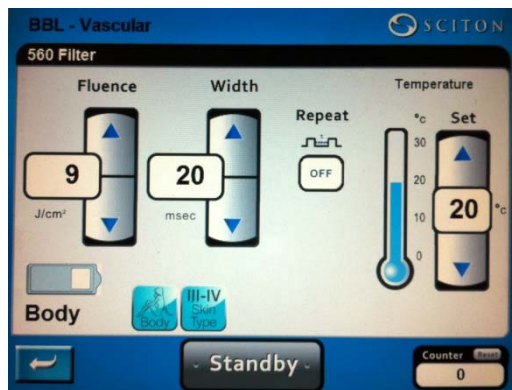
Skin Type	Fluence (J/cm ²)	Pulse Width (ms)	Temperature (°C)
I-II 560nm	10	20	20
III-IV 560nm	8	20	20
V 590nm	8	30	15



BBL Vascular Body Treatment Starting Parameters – BODY Tissue with Small Area Spot

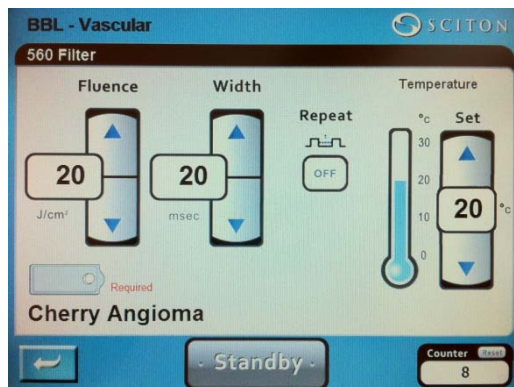


Skin Type	Fluence (J/cm ²)	Pulse Width (ms)	Temperature (°C)
I-II 560nm	11	20	20
III-IV 560nm	9	20	20
V 590nm	9	30	15



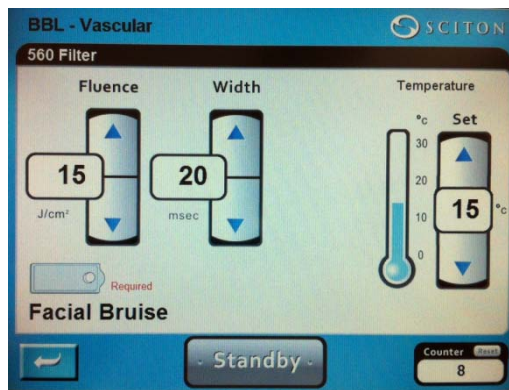
BBL Vascular Cherry Angioma Treatment Starting Parameters – Round Spot

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.

1.2.11 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.

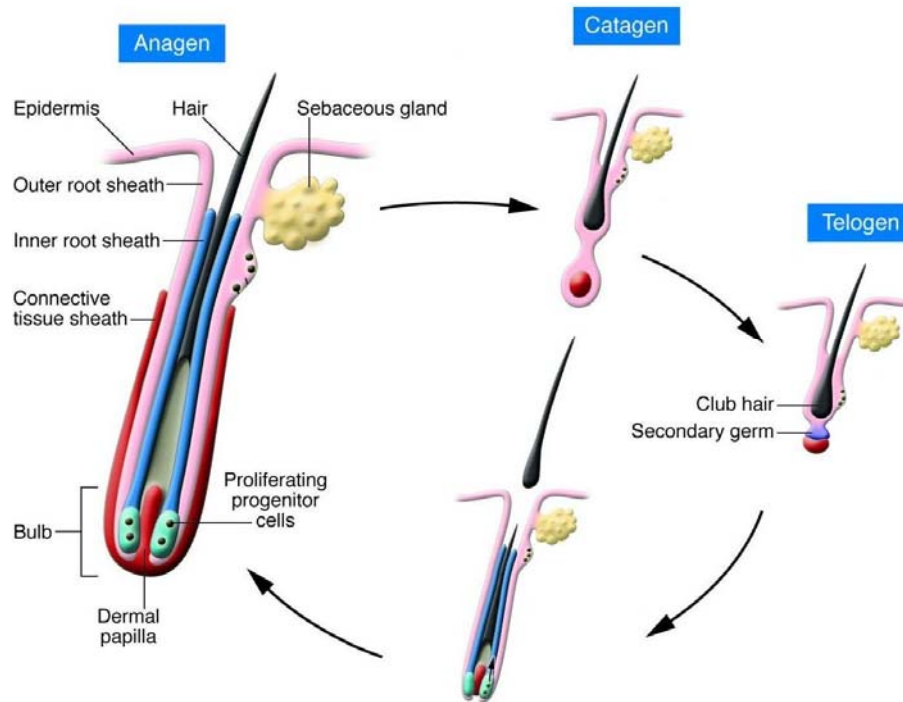
Hair revolves through three phases of growth: anagen, catagen and telogen. It is only during the growing phase, anagen, that hair reacts to BBL light. Not all hair present in an area is in the anagen phase at the same time. Duration of hair growth cycles depends on the body location being treated. Multiple 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

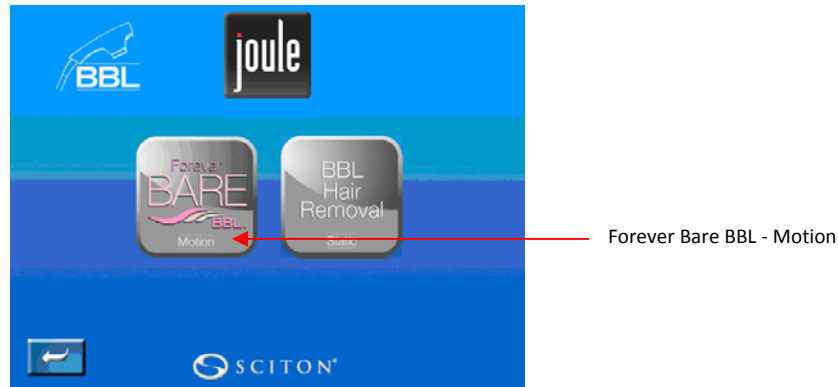
Refer to Treatment Starting Parameters for appropriate temperature selection.

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.

1.2.11.1 Treatment Basics – Forever Bare BBL - MOTION



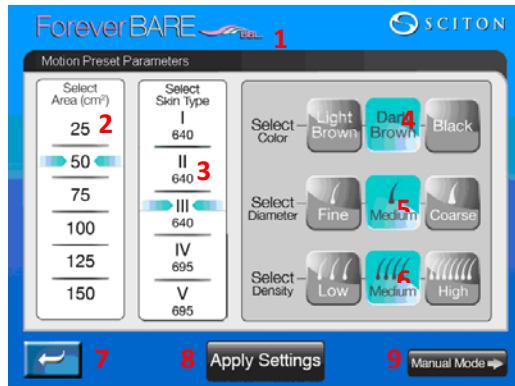
- Hair to be treated should be shaved 0 - 24 hours prior to treatment. Hair should not be waxed or plucked for 4 weeks prior to treatment.
- Measure treatment area using the template as a guide. The template below has 6 squares that are each 25 cm² (size of a 2" x 2" sticky note). The template sizes 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

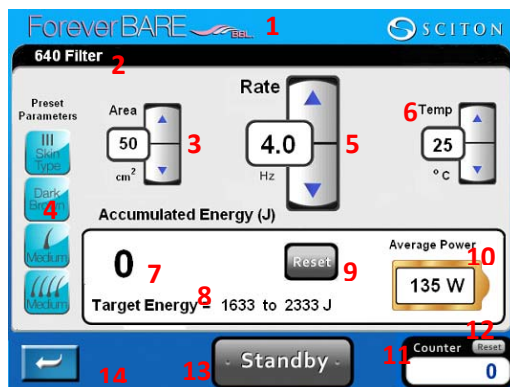


Each square is 25 sq cm.
Use 1-6 squares depending on size of treatment area. 3 crystal widths fit in 1 square.

- 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.

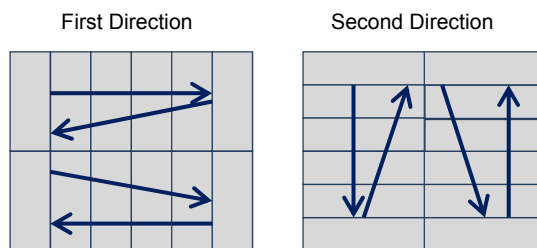


1. Forever Bare BBL Selection Screen
This indicates that hair (motion) application has been selected.
 2. Treatment Selection Area
The treatment area may be selected from 25 - 150 sq cm.
 3. Skin Type Selection
Skin types I – V may be selected. Skin types I – III require 640 nm filter whereas IV – V require 695 nm filter.
 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. Return to Previous Screen
Touching this softkey permits the user to return to the previous screen.
 8. Apply Settings
Touching this softkey will permit the user to apply the selected preset parameters and advance to the next screen.
 9. 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.



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.

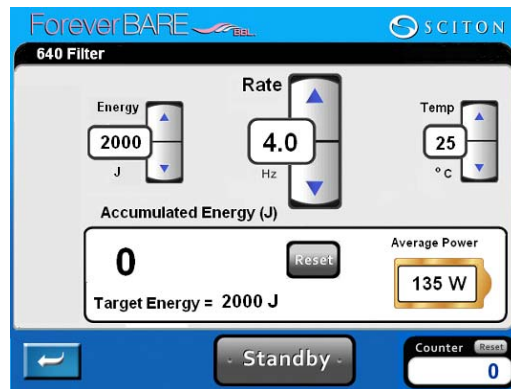
Post Treatment

- 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

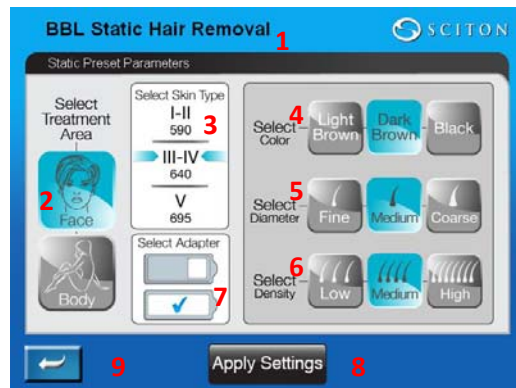
The preset parameters can be bypassed by the user. Touching the Manual Mode softkey allows the user to set the energy, rate and temperature as desired.



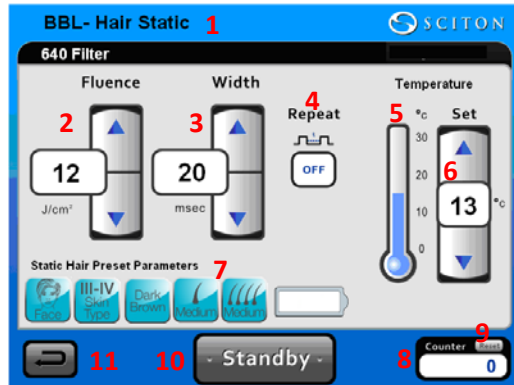
1.2.11.2 Treatment Basics – BBL Hair Removal - STATIC




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.
 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.

1.2.12 Safe Start Protocol for BBL SkinTyte //™

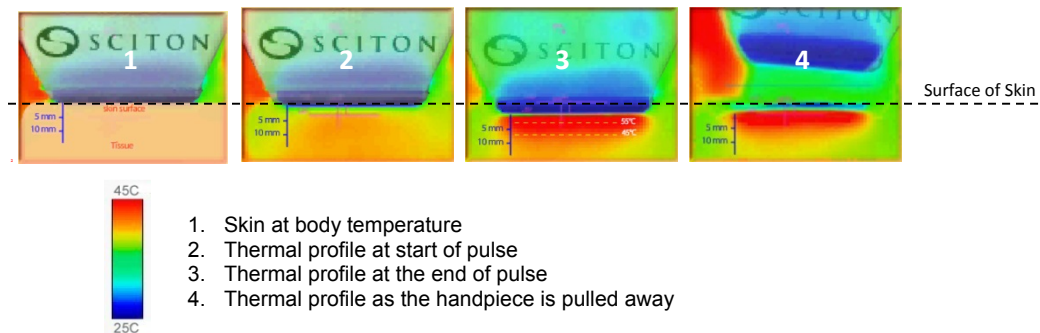
Protocol Introduction

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.

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 average power with the 800ST so it can be used in the “Static” technique and on all skin types.

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.

1.2.13 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 II 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 II 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 II 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.



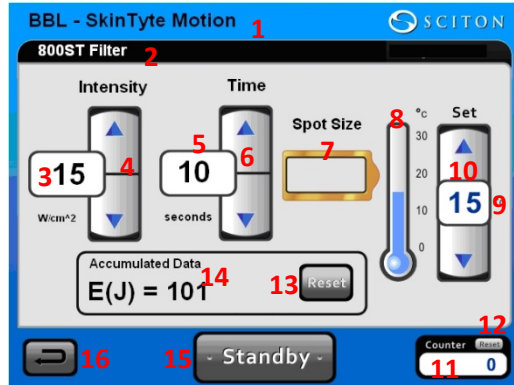
The higher the intensity selected, the higher the temperature of the target, the surrounding tissue and the epidermis. Treating with excess energy can result in adverse effects such as abnormal pigmentation, blistering and scarring. Patient response can vary, so the intensity setting should begin low and be increased gradually after assessing the individual patient response and observation of endpoints desired. Reference treatment endpoints at the end of this section.

SkinTyte II User Screen – Motion Technique

Insert the appropriate filter into the BBL handpiece. Press the Motion SkinTyte II softkey on the Broadband Light Application screen and the system will enter the SkinTyte II 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/cm^2 .
4. Intensity adjustment softkeys
Intensity adjustment softkeys allow the user to increase or decrease intensity by $1W/cm^2$ 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 ($^{\circ}C$).
10. Cooling adjustment softkeys
Cooling adjustment softkeys allow the user to increase or decrease the temperature of the BBL crystal by $1^{\circ}C$ by tapping or holding down the up ▲ or down ▼ arrow softkeys. Temperature can be set from 0 to $30^{\circ}C$ 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



SkinTyte II treatment may be performed on all skin types. 590ST is used for treating skin types I-III, 695ST is for skin types IV-VI 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.

- 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 on to 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.



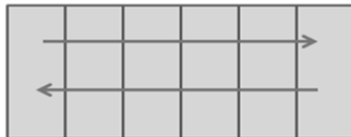
Snap On Smoothie Adapters

- Keep the BBL handpiece in constant, steady motion in a 6 x 1 sized pattern during the entire duration of the pulse.



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 6 crystal widths in one continuous direction, then reverse the direction 6 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 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 38-42 °C is reached.

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)	Post Cooling (sec)	Passes	Target Temperature (°C)
I – VI	800ST	9 - 12	10	30	none	2 - 5	38 - 42
IV - VI	695ST	10 - 13	10	30	none	2 - 5	38 - 42
I - III	590ST	11 - 14	10	30	none	2 - 5	38 - 42

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)	Post Cooling (sec)	Passes	Target Temperature (°C)
I – VI	800ST	7 - 10	10	20	none	2 - 5	38 - 42
IV - VI	695ST	7 - 10	10	20	none	2 - 5	38 - 42
I - III	590ST	7 - 10	10	20	none	2 - 5	38 - 42

Original ST Filter Safe Start Parameters - practitioners with original SkinTyte who upgrade to SkinTyte // - Refer to conversion table below for settings.

Skin Type	Filter	Adapter Size	Fluence (J/cm ²)	Pulse Width (sec)	Cooling (°C)	Post Cooling (sec)	Passes	Intensity Per Pass (W/cm ²)
I – VI	800ST	15 x 45 mm	150	15	30	none	2 - 5	10
I – VI	800ST	15 x 15	120	11 - 15	20	none	2 - 5	8-11

		mm						
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To convert from Fluence (J/cm^2) to Watts (W/cm^2) – divide the fluence by the pulse width. (i.e. $150 J/cm^2$ at 15 seconds pulse width is $150/15$, or equal to $10 W/cm^2$).

Endpoints

- The temperature of the epidermis should read between 38 -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 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.
- Maintain external temperature: To ensure a reproducible treatment, after reaching the target temperature of 38-42 °C treat the adjacent tissue to maintain the target temperature. Area treated should be warm to the touch for 1-3 minutes after treatment.

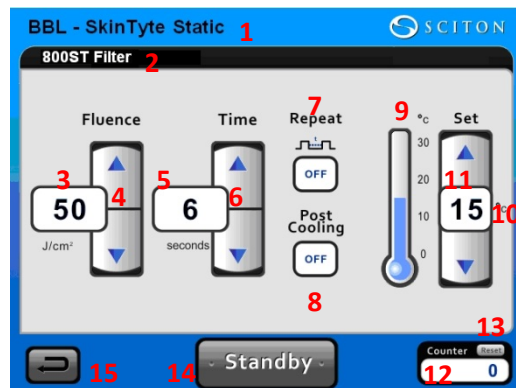
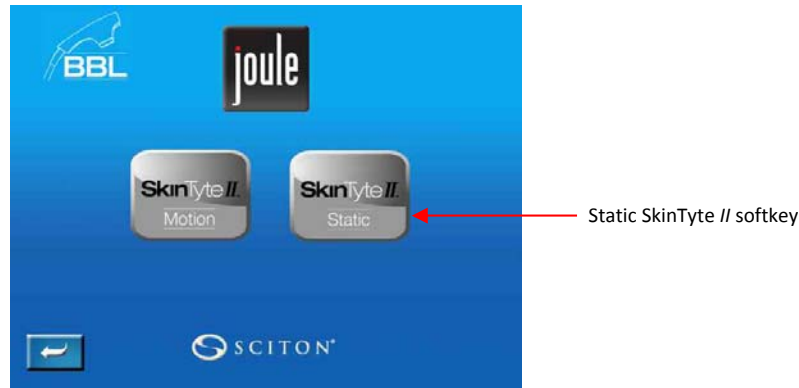
Post Treatment

- 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 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.

1.2.14 Safe Start Protocol for BBL SkinTyte II™ – Static Technique (800ST)

Insert the 800ST filter into the BBL handpiece. Press the Static SkinTyte II softkey on the Broadband Light Application screen and the system will enter the Static SkinTyte II application screen.

SkinTyte II 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 II 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.

1.2.15 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 II™ 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/cm²) 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.

1.2.15.1 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.

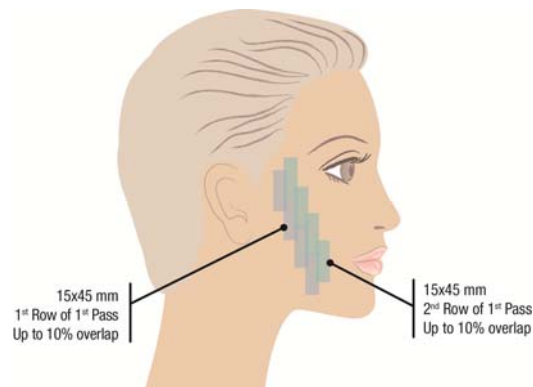


Figure 1

- 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 nonbeard 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).

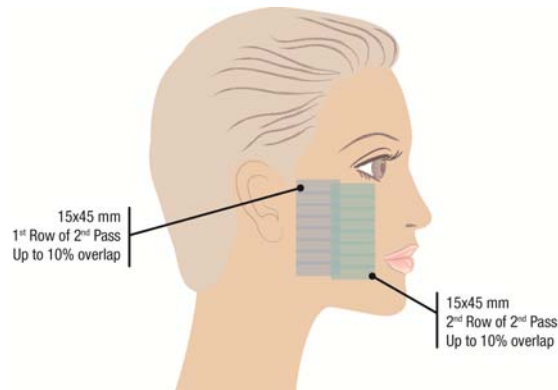


Figure 2

- 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).

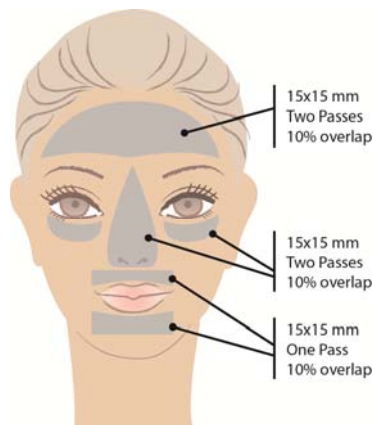



Figure 3

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 II™ 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™ 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™ 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.**

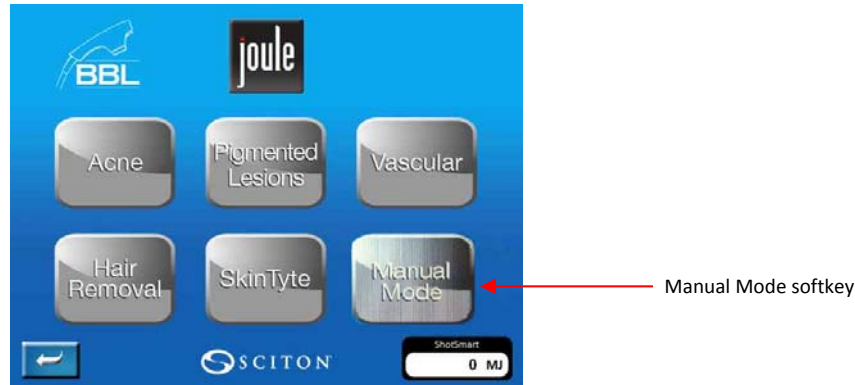
Add-on SkinTyteII™ Parameters							
Skin Type	Filter (nm)	Irradiance (Watts/cm ²)	Pulse Width (sec)	Cooling (°C)	Spot adapter (mm)	Target Temp (°C)	Total Energy (J)
I-II	590ST	10-15	12	30	Full 15 x 45 crystal for cheeks and neck 15x15 square for forehead	38-42	Neck 40,000-50,000 Cheeks 30,000
III	590ST 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
<p>*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.</p>							

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.

1.2.16 Manual Mode

Touching the following softkey permits the user to enter the Manual Mode.

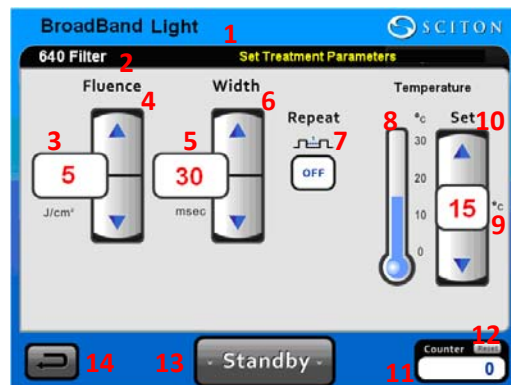


Note: All filters except 800ST are available for use, however, SkinTyte™ and Forever Bare BBL™ applications are not available.

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™.



- Application indicator
Application indicator shows which application is being used for treatment.
- Filter wavelength indicator
Filter wavelength indicator shows which wavelength is being used for the treatment.
- 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/cm²).
Note: The factory default is displayed in red and will turn black as the setting is altered.
- Fluence adjustment softkeys
Fluence adjustment softkeys allows the user to increase or decrease fluence by 1 J/cm² by tapping or holding down the up▲ or down ▼ arrow softkeys.
- 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 5 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 (°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. 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.