SCITON

PROFILE™ CLEARSCAN™ 1.064-µM LASER MODULE: HAIR REDUCTION

Introduction

The 'removal' of hair with light-based technologies has been steadily improving over the last decade. Several different laser wavelengths and methods have been used. The history of hair removal includes complications and limiting factors that put at least some portion of the patient population at risk for blistering, scarring, hyper and hypopigmentation. Darker skin type individuals have experienced the core of the complications seen to date. In order to avoid epidermal melanin while targeting hair follicles with high levels of safety many physicians are using infrared lasers such as the Nd:YAG laser at a wavelength of 1064-nm. The combination of a safe clinical wavelength with a tissue cooling system protecting the patient's skin, during, and after the laser pulse makes the Sciton Profile the laser of choice for the long-term reduction of unwanted hair in all skin types.

Hair Growth Phases

Hair revolves through three phases of growth: anagen, catagen and telogen. It is only during the growing phase, *anagen,* that hair is sensitive to laser light. The goal in hair removal is for laser light to penetrate to the depth of the hair follicle and damage it during the anagen phase to achieve long-term results.

> ***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. The hair grows in both directions, upward and downward. Early anagen is when the bulb is closest to the surface of the skin allowing for the most efficacious treatment. The time span for this phase is measured in months/years.
>
> ***catagen:*** brief intermediate phase between anagen and telogen. During this phase, the body absorbs the lower third of the follicle. The time span for this phase is measured in weeks.
>
> ***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. The time span for this phase is measured in weeks/months.

The theory of selective photothermolysis can be used to determine the wavelength, fluence, and pulse width required for the destruction of a target and the preservation of the surrounding tissue. The fluence required to damage the large target will spare a smaller structure, if the fluence is applied for a period that exceeds the time for the small structure to release its absorbed heat. Because of the unfavorable volume-to-surface area ratio, target structures of large volume (e.g., hair) are less capable of conducting the absorbed energy (heat) through their relatively small surface into surrounding tissue than small volume

structures of the same chromophore. The thermal relaxation time of hair is 40 -100 milliseconds (ms), and the thermal relaxation time of the epidermis is 3 -10 ms.

When laser light is applied to a large target, such as a hair follicle, the pulse width of the laser must be shorter than the thermal relaxation time of the larger target and yet much longer than the thermal relaxation time of the epidermis.

Some advantages of the Profile laser includes:

- ability to treat skin types I-VI with minimal epidermal damage
- suitable for dark skin types including tan skin
- non-invasive
- shorter course of treatment than electrolysis
- consistent reproducible results
- non-sequential high-speed scanning

Avoiding epidermal melanin

A problem in using laser energy that is absorbed in melanin for hair reduction is heating the melanin of the epidermis in Fitzpatrick skin types IV-VI and in tanned Fitzpatrick skin types II-III. The Profile laser resolves the problem with two methods. The first is the ability to select pulse widths that target hair follicles without while avoiding damage to melanocytes and melanin in the epidermis. The second is the Profiles ability to cool and protect the epidermis and dermis with a controlled, adjustable surface cooling system. Theses two methods, a large range fluence range and a computer-guided scanner, allow treatment of all skin types at high speed and full treatment coverage without the need for the time and mess of a topical anesthetic for the majority of patients.

Surface Cooling

Contact surface cooling clamps the skin surface at a predetermined temperature so that treatments will be consistent regardless of the patient's nominal skin temperature. The thermodynamic properties of skin are very similar for all patients and a reproducible thermal response will be achieved by setting surface cooling temperature, laser fluence, and laser pulse width. Adjusting these settings will allow you to adjust the treatment to different skin conditions with reproducible treatment temperatures. The Profile cooling plate cools the skin before, during and after treatment for maximum protection. Profile does not cool to a preselected depth since there is no preset cooling time, but instead cools with a temperature gradient determined by the surface temperature of the cooling system.

Patient Selection

Profile laser therapy is contraindicated for those patients who:

- Are hypersensitive to light.
- Take medication, which is known to increase sensitivity to sunlight, such as accutane and gold treatment therapy.
- Have suspicious pigmented lesions.
- Have <u>very recent</u> sun exposure or tanning

Classification of Skin Types

Fitzpatrick Scale

The following table offers a broad guidance to identifying skin types based on hair, skin and eye color as well as sun reaction.

Type	Hair Color	Skin Color	Eye Color	Sun Reaction
I	Red	Light	Blue-green	Burn, never tan
II	Blonde	Light	Blue	Burn, may tan
III	Brown	Medium	Brown	Burn, then tan
IV	Brown-black	Moderate brown	Brown-black	Tan
V	Black	Dark brown	Dark	Tan
VI	Black	Black (African)	Dark	Tan

Consultation / Treatment

The consultation or initial visit allows an exchange of views between case provider and patient in an attempt to reach a decision regarding treatment. The patient must understand the procedure, pre and post care instructions, and expectations before the procedure is performed.

Patient Education (Expectations)

The Profile laser is used to reduce or eliminate unwanted hair. Patients must understand that results vary with each individual.

Duration of hair growth cycles varies as to the body location being treated. The laser can only eliminate the hair that is currently in an anagen growth cycle (table 2). Multiple treatments are necessary over a time span (6-8 week intervals) to remove hair from most areas. Final results may not be apparent for several months post treatment. Suggested treatments and treatment intervals are:

Body Part	**Number of Treatments**	**Treatment Interval**
Lip	3 - 4	6 – 8 weeks
Face	3 - 4	6 – 8 weeks
Bikini Line	4 - 5	6 – 8 weeks
Arms	6 -7	6 – 8 weeks
Under arm	4 - 5	6 – 8 weeks
Back	4 - 5	6 – 8 weeks
Legs	5 - 6	6 – 8 weeks

The laser pulse is often described as a wave of heat with the sensation of a pinprick. A topical anesthetic may be applied if necessary. Sciton's cooling device is found to be effective in pain reduction during the laser treatment.

Erythema/follicular edema may be seen for 4 – 6 hours following the laser treatment. The treated hairs can take 7 – 14 days to exfoliate and may appear to be "growing" during this time.

Patient History

A thorough history of previous treatment methods, current medications, allergies and pigmentary problems should be discussed. Exclusion criteria may include but not be confined to: photosensitivity, keloid formation, immunosuppression, and/or history of poor wound healing.

Patient Documentation Forms

- 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 consultation and acknowledges that the patient understands the procedure and that all questions have been answered.

- Review post care instructions and confirm that the patient will adhere to such instructions throughout the course of their laser treatment. (Sample post care instruction sheets are included.)

- Upon patient's assessment, the case provider must determine the need of medications or creams. These can be given before the procedure and used throughout the treatment.

- Post-treatment appointments are scheduled for: treatment assessment, patient evaluation and routine therapy.

Photographs

Before and after photographs should be taken throughout the course of the treatment to monitor patient response to therapy. Photographs should be taken prior to treatment, immediate post operatively and during follow-up visits. Results must be similar in quality and camera parameters (settings) should be the same to maintain photographs of similar quality. Obtaining a photo release form the patient will enable you to develop of catalog of results for education of your patients.

Pre Treatment Procedure

- For better results, patients are to avoid sun exposure, tanning beds and tanning creams for 2-3 weeks prior to treatment and throughout the course of their laser treatment. Sunless tanning lotions must also be avoided for 2-3 weeks prior to treatment. However, if sun exposure is not avoidable a reduced fluence may be used. In this case treatment sessions

need to be increased. Instruct the patient that recent sun exposure may result in cancellation of the treatment.

- Instruct the patient to shave the treatment areas 24 hours prior to treatment. This is to remove the overlying hair from the treatment site. Thick overlying hair (if not shaved) will absorb the laser energy and superficial thermal injury can occur as well as reducing the amount of energy absorbed by the hair follicle.

Post Testing Evaluation

Treatment energies for each patient will vary according to patient skin type, location and color of hair. Test spots using a variety of energies are recommended. These will ensure that the energy delivered to the patient is within a safe parameter range.

- Evaluation of the tested area(s) usually occurs 1-2 weeks post treatment.

- Verify that any hypo/hyperpigmentation has been transient (to date). If the patient is concerned about the pigmentary changes, further treatments may be delayed. Once the area returns to normal skin tone, treatments may be resumed.

- If the treated area appears hypopigmented (blanched or white) this is an indication that the energy density was too high and should be decreased accordingly.

- Further testing may be indicated depending on the results seen from the first tested area(s).

Determination of Clinical Endpoint

Warning: Treating with excess energy levels can result in adverse effects such as abnormal pigmentation and scarring.

- Sparking – the visible hair shaft should flash when instantly heated by the laser pulse.

- Smell of success – hair has a unique and very noticeable odor when it burns.

- Mild discomfort – thermal damage to hair follicles will be noticed by the patient during the laser pulse.

- A slight erythema should be noted in the skin around the hair follicles. Increased erythema during the treatment can indicate the energy is too high or the patient has had recent sun exposure.

- Peri-follicular edema – in some cases edema will show up around the treated hair follicles.

- If the treatment area has even the slightest tan, the erythema response is greater and can lead to a purpuric response (blue-gray discoloration). If blistering occurs,

treatment should be stopped immediately. Treatment can resume when the tan has faded.

Treatment Procedures

- The highest energy density determined through test spots should be utilized. An increase in fluence should be tolerated after 2-3 consecutive treatments.

- A white or yellow washable marker can be used to outline the area to be treated. **Caution!** The use of blue, black or brown markers may absorb the laser energy and result in epidermal injury.

- The system allows the continuous cooling on the treatment area to ease the pain sensation from the laser pulse. A coating of gel, KY, surgilube or water may be used in conjunction with the system as a conduit for the laser energy.

- A decrease in fluence may be necessary in sensitive areas and high hair density areas such as the upper lip, shin, ankle area and bikini areas.

- Topical anesthetics such as EMLA may be applied to the treatment area 90 minutes prior to treatment. Cover the area with a liberal amount of EMLA and provide an occlusive covering (e.g. saran wrap with edges taped). Eutectic LA ointment may be applied only 20 - 30 minutes prior to treatment.

- Double pulsing at the same spot is not recommended and can increase the chances of post treatment complications.

- Following the treatment, the cooling system or an ice pack can be applied to the treated area to ease the sensation from the laser pulses. Post treatment cooling is highly recommended for darker skin types.

- Treatments can be scheduled at 6 to 8 week intervals for most body areas or when hair is actively regrowing. It is not recommended to re-treat any sooner than 6 weeks.

Sun Protection

- A broad spectrum (UVA/UVB) sun block with an SPF of 30 must be applied 15 minutes prior to casual sun exposure.

- Prolonged sun exposure requires repeated applications of sun block every 2 hours (e.g. yard work, beach activities, etc.).

- Sun block must be reapplied after swimming.

Adverse Effects

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 probability of complications.

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

Post Treatment Skin Care

Patients should receive post skin care instruction following each laser treatment. Sample post care instruction sheets are included.

Application of an ointment or aloe vera:

Ointment is applied to the area to prevent drying and crusting. If crusting develops it should be allowed to fall off naturally (no picking). Ointment applied following the laser treatment can have a soothing effect and should be utilized if there is any blistering or break in the skin.

The patient should be instructed to contact the office if there is an indication of infection (redness, tenderness or pus).

Shaving:

No shaving of treated area for 1 to 3 days post treatment.

Bathing:

If treated area is irritated the area should not be rubbed with a face cloth or towel. The area should be patted dry.

Makeup:

If the area blisters, extreme caution should be used when applying or removing makeup. The treated area is very delicate and should be treated with care.

Rough removal of makeup can increase the incidence of post treatment complications.

SCITON

PROFILE™ CLEARSCAN™ 1.064-µM LASER MODULE: HAIR REDUCTION SAFE START PROTOCOL

The following protocol is a safe start guide based upon the clinical observations of experienced physicians.

IMPORTANT: **Treating with dirty lenses, high fluence or overlapping laser pulses may lead to undesirable outcomes, including blisters, depressions and transient hyperpigmentation, all due to overheating of tissue. Although the LAPG™ computer guided scanner and the flat top beam profile are designed to alleviate these issues, attention to technique and conservative treatment are recommended. This guide is not intended as a replacement for clinical training, preceptorship or supervised experience. Please follow the instructions in the Operator's Manual for the system you will be using.**

1. PRE-TREATMENT CONSIDERATIONS

1.1. CLEAN SKIN

Use a mild cleanser to remove any dirt, makeup, or moisture from the treatment area. Follow with an alcohol wipe. Allow alcohol to evaporate before treatment. Use special care around the eyes.

1.2. ANESTHESIA

Use a topical preparation, as needed, to alleviate discomfort for sensitive patients or sensitive areas prior to treatment. Remove before treatment with mild soap and water or an alcohol swab, then plain water. Dry the area thoroughly before treatment.

1.3. SHAVING OR THE REMOVAL OF SURFACE HAIR

Removal of surface hair prior to laser treatment assures a safe treatment without the risk of epidermal irritation or burn from the presence of dark surface hair. The site should present at treatment with only short stubble, no longer than 0.5 mm long, in order to clearly identify the treatment area. Shaving immediately before treatment is safe as long as the nicking of skin is avoided and short stubble remains.

1.4. SCANNER CLEANING

Prior to each treatment, clean the cooling plate with an alcohol swab. Check the lenses and cooling plate during long procedures and clean as necessary.

CAUTION: Water condensation on the upper surface of the cooling plate may result in laser beam scattering and an incorrect setting for fluence. Treating the top of the plate with a surfactant will reduce scattering due to condensation.

1.5. EYE PROTECTION

Always use eye protection for the patient, the operator, and anyone in the laser treatment room during the treatment.

1.6. TREATING AREAS WHERE ARTIFICAL MAKE-UP, TATTOOS, or DARKENED MOLES ARE PRESENT:

TATTOO or MAKE-UP
Areas with tattoos or artificial make-up must be avoided. Tattoos with red or frosty white appearance commonly have iron or titanium in their composition. The red or white pigment will often oxidize and turn black from laser exposure. If one must treat those areas, a test spot with close monitoring for one to four days is recommended.

DARKENED MOLES
Darkened moles often have unwanted dark hair present in their core. It is important to remember that the removal of that hair and the subsequent potential bleaching of the mole prevent monitoring of the mole. Cancerous lesion assessment is based on the ABCD method (Asymmetry, Borders, Color, and Diameter).

CAUTION: Tattooed areas should not be treated. Tattoo ink may absorb laser energy resulting in a color change in tattoo ink or a risk of epidermal damage.

CAUTION: Darkened moles should not be treated. Moles may absorb laser energy resulting in a color change creating a risk of epidermal damage and the inability to monitor the lesion under ABCD guidelines.

2. SETTING TREATMENT PARAMETERS

2.1. COOLING TEMPERATURE

5°C is recommended for maximum patient comfort. Treating with higher COOLING temperatures will require treating with lower FLUENCE settings. The inverse also applies. The cooling temperature is set on the separate chilling device and not on the laser panel. Most treatment can be performed at the 5°C setting. A coating of colorless gel or surgilube should be used in conjunction with the system for better heat removal, improved optical coupling, filling void and irregularities in the skin, and lubrication for sliding the plate over skin. The gel simulates contact with the skin while reducing the risk of damage to the plate.

CAUTION: Check the cooling plate temperature prior to every treatment. The risk of epidermal injury such as blistering increases with decreased cooling.

CAUTION: Clean the cooling plate with a soft cotton gauze moistened with alcohol before every treatment. A dirty cooling plate may lead to an incorrect setting for fluence.

2.1 FLUENCE

The FLUENCE required depends on the starting surface temperature of the area being treated. Reduce fluence by as much as 20% over bony areas such as shin and the face.

Patient response can vary, so fluences should begin low, 50 to 70 J/cm^2. After assessing the individual patient response the fluence may need to be increased in 5 to 10 J/cm^2 increments to get the desired immediate clinical result. In some cases you may need to treat in excess of 100 J/cm^2 for effective results.

At the correct fluence there should be noticeable sparking of the hair during treatment, and the patient may report immediate discomfort in the area being treated. The desired response is spontaneous erythema converting within a few minutes of laser application to perifollicular edema (similar in appearance to razor burn or rash). Fluence and pulse width settings will need to change for a patient during the series of treatments. Perifollicular edema may last approximately 4-6 hours after treatment. Be sure to properly evaluate the treatment parameters before each treatment based on previous successes, or complications, and the response of the patient to questions about the first 24 hours after the previous treatment. Those who respond with no irritation, blistering, or complication for the first 24 hours after treatment are within a safe, and possibly low, fluence range.

2.2. PULSE WIDTH

Set the starting pulse width according to the onscreen guidelines, previous fluences, or personal experience. Understand that pulse width is partially determined by the size of the hair shaft and follicle. As hair reduces in size during the treatment series it will be necessary to reduce the appropriate pulse width. ClearScan uses a train of pulses to achieve the desired fluence.

Area	Skin Type	Typical starting fluence	Pulse Width
face	I-IV V-VI	50 J/cm^2 35 J/cm^2	10 to 35 ms 25 to 50 ms
elsewhere	I-IV V-VI	70 J/cm^2 50 J/cm^2	10 to 35 ms 25 to 50 ms
PFB	I-IV V-VI	40 J/cm^2 25 J/cm^2	10 to 35 ms 25 to 50 ms

3. TECHNIQUE

3.1. PATIENT POSITION

Position is based on the area to be treated. Patient should be in a comfortable position. The treatment area should be presented to the laser user at a convenient height and position.

In areas where hair bearing skin is adjacent to mucous membrane (mouth or genital areas) care should be taken to avoid non-hair-bearing skin.

3.2. TEST AREA

Treating a test area before a patient's first treatment can establish their response threshold and help establish safe starting parameters. The test area should be monitored for response for a period of five to ten minutes. Blistering or the immediate grey or white presentation of the skin is the immediate concern.

Set the scanner to single spot or a small 2 by 2 array. TEST AREA should reach the desired response of erythema and perifollicular edema within a few minutes.

Increase fluence in small increments until the desired response is achieved.

CAUTION: Use only enough fluence to achieve the desired endpoint of erythema. At the correct fluence there should be noticeable sparking of the hair during treatment, and the patient may report immediate discomfort in the area being treated. Excessive fluence, immediate retreatment, pulse stacking, or poor contact with skin can lead to dermal injury or blisters. Use gel to create good cooling contact without having to apply pressure to the skin.

IMPORTANT: Keep fluence conservative for the first treatment session, and monitor the patient for any evidence of prolonged erythema, swelling, urticaria or blistering.

3.3. SCANNER POSITION

Position the SCANNER so the cooling plate is in full contact with the skin. For highly curved regions, a smaller scan pattern or using OFFSET to place the scan pattern near the edge of the cooling plate while pushing the skin upward with your other hand will insure proper cooling. Use the OFFSET function to place the scan pattern near the edge of the cooling plate near the boundary of cosmetic regions.

The SCANNER must remain in contact with the gel on skin long enough before and after the laser scan to cool the surface of the skin and reduce the heat sensation. It will take several seconds for the deeper heat to propagate to the surface after the scan. A coating of colorless gel, KY, surgilube or water must be used in conjunction with the system for

better heat removal, improved optical coupling, filling voids and irregularities in skin, and lubrication for sliding the plate over skin.

IMPORTANT: Make sure that the cooling plate is in good contact with the gel on skin for the area to be scanned by the laser. A very thin layer of colorless gel will avoid the need to apply pressure to skin which can change blood flow to follicles reducing the absorbtion by the target. A thin layer of gel between the skin and the cooling plate will also avoid damage to the plate by contact with burning hairs.

3.4. TREATMENT METHOD

Match the "trailing edge" of the next scan to the "leading edge" of the previous scan. The computer-guided scanner will give a uniform treatment with selected beam placement within the scan.

Make certain to maintain complete skin contact below the scanned area before, during and after the scan. Adjust the scan size or shape to fit only the area where chill plate is in good skin contact. A coating of colorless gel or surgilube must be used in conjunction with the system for better heat removal, improved optical coupling, filling voids and irregularities in skin, and lubrication for sliding the plate over skin.

Use the 6 mm single-spot handpiece with small chiller window accessory if unable to get complete contact with the scanner. Do not overlap or immediately repeat laser pulses.

CAUTION: Do not stack pulses or overlap consecutive scans. Repeated pulses in the same location, improper cooling plate placement, repeated scans, improper cooling temperatures, or excessive fluence may lead to a build up of subsurface heat and a subsequent blister or burn.

Presentation of a blister or immediate graying or whitening of tissue indicates immediate complication. Treatment methods and parameters should immediately be reevaluated. The blisters or skin discoloration will commonly resolve without complication.

A thin layer of gel between the cooling plate and the skin surface will avoid needing pressure on skin and will protect the cooling plate from damage due to burning hairs.

4. TREATMENT GOALS

- The ideal fluence will often present as small light flashes on tissue (sparks) as the scan occurs.
- The light smell of denatured proteins (rotten egg or sulphuric smell), and the voluntary shed of a few hairs at the treatment site when wiped immediately after the scan.
- Patients should feel mild discomfort from the laser during treatment.

- Patients will typically report feeling tighter skin or the sensation of mild sunburn following treatment.
- The immediate goal is light, uniform erythema converting to perifollicular edema (similar to razor burn or rash in appearance) a few minutes after treatment.

5. POST-TREATMENT CONSIDERATIONS

5.1. OBSERVATIONS

- Erythema, perifollicular edema, and a mild sunburn sensation should be noticed in the treatment area for up to two hours after treatment.
- Patients should not feel any significant discomfort after treatment.
- Hair should appear to grow for several days post treatment as the hair is extruded.
- Hair should spontaneously fall out about day 4 -14.
- Shaving of the area is allowed between laser treatments as necessary.

5.2. INTERVENTION

Cold compress can provide some comfort after treatment. If blistering occurs, aggressive wound treatment should be administered, i.e. Vigilon, Second Skin, silastic sheeting or other intervention.

Caution: When treating the bikini area, panty elastic at the leg should be avoided for several days after treatment. The irritation of the elastic over the treatment area can lead to rash or blistering.

5.3. INTERVAL

Recommended time interval between treatments is 6 - 8 weeks. Physicians report that a fixed retreatment time may shorten the series period and increase efficacies. The number of treatments necessary may be roughly estimated from the Richards-Merhag chart by dividing the percentage of Anagen hair present in an area into 100% and adding one additional treatment. (example: Legs, 20% anagen divided into 100% equal five cycles plus one additional treatment to equal six total)

Richards-Merhag Chart

	Telogen (%)	Anagen (%)	Telogen duration	Anagen duration	Density Hair/cm^2	Depth (mm)
Scalp	13	85	3-4 months	2-6 years	350	3-5
Eyebrow	90	10	3 months	4-8 weeks		2-2.5
Ear	85	15	3 months			
Cheeks	30-50	50-70		1 year	880	2-4
Beard-chin	20	70	10 weeks	16 weeks	500	2-4
Upper lip	35	65	6 weeks	6 weeks	500	1-2.5
Axillae	70	30	3 months	4 months	65	3.5-4.5
Trunk	NA	NA			70	2-4.5
Bikini	70	30	3 months	4 months	70	3.5-5
Arm	80	20	18 weeks	13 weeks	80	2-4.5
Leg	80	20	24 weeks	16 weeks	60	2.5-4

Breast	70	30			65	3-4.5

6. CONCURRENT PROCEDURES

COMBINATIONS –Hair reduction treatments may be given in combination with other minimally invasive therapies. If a patient is to receive another treatment (light chemical peel, microdermabrasion, Botox, collagen injection), it is advisable to perform the hair removal treatment first. There may be increased sensitivity in the treated areas for an hour or two.

7. PSEUDO-FOLLICULITIS BARBAE

PFB can be successfully treated with the parameters shown above. Treatment may produce permanent change preventing hair regrowth in the treatment area. This can have long term effect in areas where beard growth is desired.

8. CONCLUSIONS

Do not be overly aggressive. Begin conservatively and be patient. Results are determined by the physiology of the patient's skin. This is not a surgical process; hair reduction takes time. You should help your patient understand that the results are long term.

SCITON

PROFILE™ CLEARSCAN™ 1.064-µM LASER: HAIR REDUCTION SAFE START PROTOCOL SUMMARY

1. Pre-Treatment:

- Clean area to be treated.
- Anesthesia - Use a topical preparation if necessary. Remove before treatment.
- Clean hand piece prior to each treatment.
- Eye Protection - Always use eye protection for the patient, the operator and anyone in the laser treatment room.
- Set Cooling Plate Temperature to 5°C.
- Hair length should be no more than 0.5 mm long at the treatment site.
- Apply a very thin layer of colorless gel.
- Test fire at moderate fluence.

2. Treatment:

- Set Fluence for TEST AREA, according to table or previous experience.
- Adjust Fluence - to achieve uniform erythema converting to perifollicular edema
- Check Cooling Temperature before each area to be treated

Area	Skin Type	Starting fluence	Pulse Width
face	I-IV V-VI	50 J/cm^2 35 J/cm^2	10 to 35 ms 25 to 50 ms
elsewhere	I-IV V-VI	70 J/cm^2 50 J/cm^2	10 to 35 ms 25 to 50 ms
PFB	I-IV V-VI	40 J/cm^2 25 J/cm^2	10 to 35 ms 25 to 50 ms

- Set to DESIRED SCAN PATTERN. Treat with non-overlapping scans.
- POSITION SCANNER COOLING PLATE in full contact with treated area.
- Use colorless gel or surgilube between the cooling plate and skin for better heat removal, improved optical coupling, and lubrication for sliding the plate over skin.
- Avoid applying pressure to the skin or direct contact with the cooling plate by using gel.
- ALLOW COOLING before and after depressing laser foot switch.

3. Clinical Observations

- Small light flashes on tissue (sparks) as the scan occurs.
- The light smell of denatured proteins (rotten egg or sulphuric smell), and the voluntary shed of a few hairs at the treatment site when wiped immediately after the scan.
- Patients should feel mild discomfort from the laser during treatment.

- Patients will typically report feeling tighter skin or the sensation of mild sunburn following treatment.
- The immediate goal is light, uniform erythema converting to perifollicular edema (similar to razor burn or rash in appearance) a few minutes after treatment.

4. **Post-Treatment:**

- OBSERVATIONS - Erythema and perifollicular edema for up to six hours after treatment.
- INTERVENTION - Cool compresses or ice packs can provide some comfort after
- treatment. If blistering occurs, aggressive wound treatment should be administered.
- INTERVAL - between PROFILE treatments is approximately 6 - 8 weeks.

5. **Perform treatment before Concurrent Procedures**

IMPORTANT: The scanner must remain in contact with skin long enough to cool the surface of the skin before and after the scan. It may take several seconds for the deeper heat to propagate to the surface. Make sure that the cooling plate is in good contact with skin for the area to be scanned by the laser.

CAUTION

Water condensation on the upper surface of the cooling plate may result in laser beam scattering and an incorrect setting for fluence. Treating the top of the plate with a surfactant will reduce scattering due to condensation.

A dirty cooling plate may lead to an incorrect setting for fluence. Clean the cooling plate with a soft cotton gauze moistened with alcohol before every treatment and during extended treatments.

Check the cooling plate temperature prior to every treatment. The risk of epidermal injury such as blistering increases with decreased cooling.

Tattooed areas should not be treated. Tattoo ink may absorb laser energy resulting in a color change in tattoo ink or a risk of epidermal damage.

Darkened moles should not be treated. Moles may absorb laser energy resulting in a color change creating a risk of epidermal damage and the inability to monitor the lesion under ABCD guidelines.

Do not stack pulses or overlap consecutive scans. Repeated pulses in the same location, improper cooling plate placement, repeated scans, improper cooling temperatures, or excessive fluence may lead to a build up of subsurface heat and a subsequent blister or burn.

Presentation of a blister or immediate graying or whitening of tissue indicates immediate complication. Treatment methods and parameters should immediately

be reevaluated. The blisters or skin discoloration will commonly resolve without complication.