



# **PROFILE™ THERMASCAN™ 1.319-μM LASER MODULE: ACNE TREATMENT SAFE START PROTOCOL**

## **Introduction**

The proper combination of cooling with laser treatment can create a beneficial rise in temperature at a desirable point below the skin surface. Cooling the surface of skin will alter its subsurface temperature gradient. The temperature of the PROFILE cooling plate and the fluence delivered from the laser will determine the temperature profile beneath the surface of treated skin. The following guide is a safe starting protocol for the use of the PROFILE ThermaScan Module for the treatment of active acne.

The treatment works by heating the sebaceous glands in the dermis of the skin leading to a reduction of oil production. Repeated treatments lead to an observable reduction in active acne in 2 to 4 weeks. Results of acne treatment by sebaceous gland heating have been reported to last up to 6 months.

The PROFILE has a computer guided scanning device that allows the user to provide a very uniform treatment at high speeds. The scanner is a significant advance, providing treatment consistency and reproducibility unachievable by hand placed laser treatments.

## **Laser Skin Heating**

The epidermis is a robust and resilient structure at the surface. It functions as a physical barrier to protect the deeper dermis, and retain the skin's hydration. It is less hydrated than the dermis resulting in less absorption of energy at 1319 nm than in the dermis, since energy at a wavelength of 1319 nm is preferentially absorbed in water and collagen. The highest absorption, and thus the highest temperature, will occur below the epidermis in the more hydrated papillary dermis. In addition, a high degree of scattering prevents photons at 1319 nm from penetrating deep into tissue. Instead, they are absorbed before penetrating deeper into the dermis. The result is a peak temperature near the region of the papillary dermis. By clamping the outer skin surface at a fixed temperature with the PROFILE cooling plate, the peak temperature from laser treatment can be biased toward shallower or deeper regions of the skin.

## **Surface Cooling**

The thermal profile in the skin will have a maximum temperature below the epidermis at a depth determined by the surface temperature and the absorption characteristics of the 1319 nm laser energy in tissue. It is thought that brief heating of sebaceous glands heated to above 60°C causes a reduction in the production of oil.

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 areas and different patients with reproducible treatment temperatures.

**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 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. HANDPIECE 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. Operation at a temperature above the dew point or treating the top of the plate with a surfactant will reduce scattering due to condensation.***

### 1.4. EYE PROTECTION

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

### 1.5. TREATING AREAS WHERE SCARS ARE PRESENT:

#### 1.5.1. FIBROTIC SCARS

**Dense fibrotic tissue has been seen to blister at a lower temperature than normal tissue.**

#### 1.5.2. ATROPHIC SCARS

**Depressions can be treated less aggressively and possibly more frequently. Using a lower FLUENCE may help avoid injury to the thinner epidermis of atrophic tissue.**

***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.***

## 2. SETTING TREATMENT PARAMETERS

### 2.1. COOLING

#### 2.1.1. COOLING TEMPERATURE

12°C is recommended for maximum patient comfort. Treating with higher COOLING temperatures will require treating with lower FLUENCE settings. The cooling temperature is set on the separate chilling device and not on the laser panel. A coating of colorless gel, KY, surgilube or water may be used in conjunction with the system for better heat removal, improved optical coupling, and lubrication for sliding the plate over skin. The gel should be used as a very thin film on the bottom surface of the cooling 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.***

### 2.2. FLUENCE

The FLUENCE required depends on the starting surface temperature of the area being treated. Reduce fluence by 20% over bony areas.

Patient response can vary, so fluences should begin low and be increased gradually after assessing the individual patient response. The desired response is erythema within a few minutes of laser application.

Excessive fluence or poor contact with skin can lead to dermal injury or blisters.

***Caution: In a patient with an infection, overtreatment that results in devitalized subcutaneous tissue may set up conditions for aneorbic cellulitis.***

### 2.3. PULSE WIDTH

Set the starting pulse width to 50 milliseconds.

Cooling Temperature	Typical Starting Fluence	Pulse Width
5-12°C	12 J/cm <sup>2</sup>	50 - 200 ms

## 3. TECHNIQUE

### 3.1. TEST AREA

Treating a test area before a patient's first treatment can establish their response threshold and help establish safe starting parameters. For example: Begin by testing a small area; treatment requires lower fluence when treating over bony prominences.

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

A coating of colorless gel, KY, surgilube or water may be used in conjunction with the system for better heat removal, improved optical coupling, and lubrication for sliding the plate over skin. The gel should be used as a very thin film on the bottom surface of the cooling plate. Gel will insure contact in highly areas with highly irregular surfaces.

Increase fluence in 2 J/cm<sup>2</sup> increments until the desired response is achieved.

***CAUTION: Use only enough fluence to achieve the desired endpoint of erythema.***

**IMPORTANT: Keep fluence below 18 J/cm<sup>2</sup> for the first treatment session, and monitor the patient for any evidence of prolonged erythema, swelling, urticaria or blistering.**

**IMPORTANT: Make sure that the cooling plate is in good contact with skin for the area to be scanned by the laser.**

### **3.2. HANDPIECE POSITION**

Position the patient so the HANDPIECE can be held perpendicular to the skin surface. Move the patient if necessary so that the treatment area is easy to reach.

Position the HANDPIECE 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.

The HANDPIECE must remain in contact with skin long enough (several seconds) to cool the surface of the skin. It will take several seconds for the deeper heat to propagate to the surface. A coating of colorless gel, KY, surgilube or water should be used in conjunction with the system for better heat removal, improved optical coupling, and lubrication for sliding the plate over skin. The gel should be used as a very thin film on the bottom surface of the cooling plate.

### **3.3. 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.

Use the offset function for the scanner to place the scan pattern near the edge of the cooling plate for convenience in treating small areas or near the boundary of cosmetic regions.

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, KY, surgilube or water may be used in conjunction with the system for better heat removal, improved optical coupling, and lubrication for sliding the plate over skin. The gel should be used as a very thin film on the bottom surface of the cooling plate. Gel will insure contact in areas with highly irregular surfaces.

Use a slower rep rate (1.5 Hz) if a scan pattern is 2x2 or 2x3.

Treating with higher COOLING temperatures will require treating with lower FLUENCE settings.

Two passes are recommended. Wait at least five minutes between passes to observe the immediate response from the first pass.

***CAUTION: Do not stack pulses or overlap consecutive scans. Repeated pulses in the same location may lead to a build up of subsurface heat and a subsequent blister or burn.***

IMPORTANT: Blistering is an indication of over treatment due to excessive temperatures, which can be caused by improper handpiece placement, overlapping pulses, repeated scans, improper cooling temperatures, or excessive fluence.

#### **4. TREATMENT GOALS**

The immediate goal is light, uniform erythema developing a few minutes after treatment. The longer-term treatment goal, after a series of treatments, is reduction of active acne for periods of 6 months or more. Patients will typically report feeling tighter skin in the days following treatment.

More aggressive treatment may lead to slight bumps that may take an hour to a couple of days to resolve. Often red, raised and palpable, these are not blisters and usually will resolve spontaneously.

#### **5. POST-TREATMENT CONSIDERATIONS**

##### **5.1. OBSERVATIONS**

Erythema and a moderate sunburn sensation should be noticed in the treatment area for up to two hours after treatment. Patients should not feel any significant discomfort after PROFILE Rejuvenation treatment.

##### **5.2. INTERVENTION**

While not often used, 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.

##### **5.3. INTERVAL**

Recommended treatment interval is 3 to 4 weeks. Results should become noticeable within 2 or 3 treatments. Dermal changes from fibroblast activity leading to improved skin texture may also begin to be observed between 3 to 6 months after treatment. Incremental improvement may progress for six months or longer along with the reduction in active acne. Tightness of the treated area may be noticed immediately after treatment.

#### **6. CONCURRENT PROCEDURES**

COMBINATIONS – PROFILE Rejuvenation 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) in conjunction with the PROFILE, it is advisable to perform the PROFILE treatment first. There may be increased sensitivity in the treated areas for an hour or two.

## **7. 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; collagen remodeling takes time. You should help your patient understand that the results are long term.



# PROFILE™ THERMASCAN™ 1.319-µm LASER MODULE: ACNE TREATMENT 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**
- **Use Lower Fluence and Temperature on Fibrotic and Atrophic scars**
- Set Cooling Plate Temperature
- Test fire at moderate fluence and treatment temperature.

## 2. Treatment:

- Set Cooling Temperature: 12°C is recommended.
- Set Fluence for TEST AREA, 12 J/cm<sup>2</sup>
- Adjust Fluence - to achieve uniform erythema in 1 J/cm<sup>2</sup> increments.
- Check Cooling Temperature before each area to be treated.

Cooling Temperature	Typical Starting Fluence	Pulse Width
5-12°C	12 J/cm <sup>2</sup>	50 ms

- TREAT- Set to DESIRED SCAN PATTERN. Treat with non-overlapping scans.
- POSITION HANDPIECE COOLING PLATE in full contact with treated area. Use a thin film of colorless gel, KY, surgilube or water with the system for better heat removal, improved optical coupling, and lubrication for sliding the plate over skin. Gel will insure contact in areas with highly irregular surfaces.
- ALLOW SEVERAL SECONDS OF COOLING before depressing laser foot switch.
- Wait at least 5 minutes before second pass.

## 3. Post-Treatment:

- OBSERVATIONS - Erythema for up to two 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 3 to 4 weeks.

#### 4. Perform treatment before Concurrent Procedures

**IMPORTANT:** The handpiece must remain in contact with skin long enough (several seconds) to cool the surface of the skin. 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. Operation above the dew point or treating the top of the plate with a surfactant will reduce scattering due to condensation.*

*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.*

*The risk of epidermal injury such as blistering increases with decreased cooling. Use only enough fluence to achieve the desired endpoint of erythema. Check the cooling plate temperature prior to every treatment.*

*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.*

*Overlapping pulses may lead to excessive temperature resulting in blisters or denatured collagen. Proper pulse spacing will avoid this. The computer-guided scanner accomplishes this by correct placement of the beam and by a non-sequential pattern not achievable by hand placement.*

*Do not stack pulses or overlap consecutive scans. Repeated pulses in the same location may lead to a build up of heat and a subsequent blister or burn.*

*Caution: In a patient with an infection, overtreatment that results in devitalized subcutaneous tissue may set up conditions for anaerobic cellulites. Patients experiencing swelling or inflammation within 2 to 3 days following treatment should be examined for cellulites.*