



PROFILE™ THERMASCAN™ 1.319-μM LASER MODULE: SKIN REJUVENATION & ACNE SCAR TREATMENT SAFE START PROTOCOL

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

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 THERMASCAN 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 THERMASCAN Module for the reduction of fine lines and wrinkles, and remodeled collagen.

The PROFILE ThermaScan has a computer guided scanning device, the LAPG™-6 Integrated Scanner, 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 just below the epidermis in the more hydrated papillary dermis. In addition, a high degree of scattering prevents photons at 1319 nm from penetrating deep into tissue. Instead, they are absorbed before penetrating deeper into the dermis. The result is a peak temperature near the region of the papillary dermis. 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

An examination of the dermal anatomy will show that the papillary dermis is in contact and protrudes into the epidermis. It is therefore impossible to cool the epidermis without some cooling of the papillary dermis. Attempts to selectively pre-cool the epidermis by pulsed cooling followed by laser are equivalent to contact surface cooling with simultaneous laser treatment at the depths and times of interest for collagen remodeling.

The thermal profile in the skin will have a maximum temperature just 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 fibroblasts are activated in an inflammatory response to a brief temperature rise above 60°C. Ideally, the peak temperature is just above the threshold for initiating collagen remodeling.

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.

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

Use the LAPG-6 Integrated Scanner or the 6-mm single-spot handpiece. The FLUENCE required depends on the starting surface temperature of the area being treated. Reduce fluence by 20% over bony areas such as forehead.

NOTE: The 8-mm single-spot handpiece may require lower fluence than the 6-mm handpiece for the same clinical response.

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.

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

2.3. PULSE WIDTH

Set the starting pulse width to 50 milliseconds.

Cooling Temperature	Typical Starting Fluence	Pulse Width
12°C	12 to 16 J/cm ² < 20% on forehead	50 ms

3. TECHNIQUE

3.1. PATIENT POSITION

It is usually easiest to lay the patient horizontally and stand directly behind the patient's head. Elevate the table so the patient's head is as high as the top of the laser console.

Position the patient's head so the treatment area faces upward. Treat the area completely with one pass. Next, position the opposite side to face upward and complete one pass. For example: Treat the right temple completely with one pass. Reposition the patient's face. Treat the left temple.

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. For example: Begin by testing the patient's forehead; then increase the fluence when progressing to the cheeks. Treatment requires lower fluence when treating over bony prominences.

Set the scanner to single spot or a small 2 by 2 array, or use the single-spot handpiece. 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/cm² 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/cm² 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.

3.3. HANDPIECE POSITION

Position the patient so the HANDPIECE can be held perpendicular to the skin surface. Move the patient's head 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; or use the single-spot handpiece.

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 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.

3.4. 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.

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.

If using the single-spot handpiece than do not overlap treatment spots. Leave a gap of at least 50% of the beam width between treatment spots.

Make certain to maintain complete skin contact below the treatment area before, during and after the treatment . 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.

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 3 to 6 months, is collagen remodeling resulting in subsequent rhytid improvement, followed by continued or maintained improvement with a maintenance program. 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 time interval between treatments is 4 - 6 weeks. Dermal changes from fibroblast activity may begin to be observed between 3 to 6 months after

treatment. Incremental improvement may progress for six months or longer. 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.



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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 – 16 j/cm²
- Adjust Fluence - to achieve uniform erythema
- Check Cooling Temperature before each area to be treated

Cooling Temperature	Typical Starting Fluence	Pulse Width
12°C	12 to 16 J/cm ² < 20% on forehead	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.

3. Post-Treatment:

- OBSERVATIONS - Erythema for up to two hours after treatment.
- INTERVENTION - Cool compresses or ice packs can provide some comfort aftertreatment. If blistering occurs, aggressive wound treatment should be administered.
- INTERVAL - between PROFILE treatments is approximately 4 - 6 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 subsurface 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 subsurface heat and a subsequent blister or burn.