

xeo[®]

TREATMENT GUIDELINES



Nd:YAG

The following information is supplemental to the xeo Operator Manual. Refer to the Operator Manual for detailed information, including important cautions and warnings, prior to using the laser system.

USING THESE TREATMENT GUIDELINES

These treatment guidelines are based on physician feedback and are provided as a guide only. They are not designed to be a substitute for clinical training. The xeo should only be operated by qualified practitioners who have received appropriate training and have thoroughly reviewed the Operator Manual that shipped with the system. When using the laser, always observe laser-tissue interaction and clinical endpoints to determine appropriate settings.

The parameter recommendations in these guidelines are for patients with Fitzpatrick skin types I-VI with the 1064 nm wavelength (unless otherwise indicated). In general, longer pulse durations and lower fluence are recommended for darker skin types and tanned skin. The increased melanin content in darker skin increases the risk for side effects.

Test pulses are always advised. Start conservatively, fire a test pulse, and evaluate tissue response before continuing or adjusting parameters. Be advised, however, that potential adverse reactions may take 24-48 hours or longer to appear.



INDICATIONS FOR USE

Refer to the Operator Manual for a complete list of indications for use.

The Cutera xeo laser systems includes the Nd:YAG and optional attachment handpieces. These guidelines are for the Nd:YAG handpiece that is included with the XEO system.

The Cutera, Inc. Nd:YAG 1064nm Laser is intended for:

- Temporary and permanent hair reduction. Permanent hair reduction is defined as long-term, stable reduction in hair counts observed at 6, 9, and 12 months after the end of a treatment regimen. As well as for the treatment for pseudofolliculitis barbae (PFB).
- Coagulation and hemostasis of benign vascular lesions, such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasias, rosacea, venus lake, leg veins, spider veins, and poikiloderma of civatte; and treatment of benign cutaneous lesions, such as, but not limited to, warts, scars.
- Treatment of mild to moderate inflammatory acne vulgaris.
- Treatment of wrinkles, such as, but not limited to, periocular and perioral wrinkles.



PATIENT ASSESSMENT

- Obtain a medical history and signed consent prior to treatment.
 - Consent Form templates are available on MyCutera.com
- Determine skin type to help guide treatment parameter selection.
 - Re-evaluate patient prior to each treatment.
 - Sun exposure may increase melanin content of the skin; treatment settings may need to be adjusted.



EXPECTED TRANSIENT EVENTS & POSSIBLE ADVERSE EVENTS

Medical treatment of any adverse events is at the discretion and medical judgment of the treating clinician.
See xeo Operator Manual for a complete list of expected Transient Events and possible Adverse Effects.

Patient consent template provided on www.MyCuterax.com

The patient informed consent template is provided “as is” and is intended for informational purposes only. The template may not meet all state and federal legal or regulatory requirements for use with patients. Physicians using the template are responsible for ensuring the informed consent form used with patients meets all applicable state and federal legal and regulatory requirements, and are encouraged to consult with their attorney.

The procedure may result in the following adverse experiences or risks:

DISCOMFORT/ PAIN - Some discomfort may be experienced during treatment. Pain may include the feeling of burning, stinging, and radiating pain.

REDNESS/SWELLING - Short term redness (erythema) is common and swelling (edema) of the treated area may occur. An urticarial (hive-like) reaction may occur with smaller vessels .

PURPURA / BRUISING - Purpura (bruising) is a transient phenomenon that usually resolves with time.

HEMOSIDERIN STAINING (iron leaking into tissue from blood breakdown) - May occur and usually resolves over time, but it may be permanent.

HYPOPIGMENTATION / HYPERPIGMENTATION (Changes in skin Color) - During the healing process, there is a slight possibility that the treated area may become either lighter (hypopigmentation) or darker (hyperpigmentation) in color compared to the surrounding skin. This is usually temporary, but, on a rare occasion, it may be permanent.

EPIDERMAL CRUSTING - Pigmented lesions may crust as part of the healing process. Epidermal crusting may develop over vascular lesions. It is important not to disturb the crusts. May require medication if sensitivity or redness occurs. Crusts will typically slough 7 to 14 days after treatment.

WOUNDS - Treatment can result in burning, blistering, or bleeding of the treated areas. If any of these occur, please call our office.

INFECTION - Infection is a rare possibility whenever the skin surface is disrupted, though proper wound care should prevent this. If signs of infection develop, such as pain, heat or surrounding redness, patient should be advised to contact their treatment provider.

SCARRING - Scarring is a rare occurrence, but it is a possibility if the skin’s surface is disrupted. To minimize the chances of scarring, it is IMPORTANT that the patient follows all post-treatment instructions provided by their treatment provider.

TEXTURAL CHANGES/CUTANEOUS INDENTATIONS - May occur as a result of heat diffusion and thermal injury to tissue surrounding vessels.

ITCHING/DRY SKIN - Treatment may results in itching and/or dry skin.

RED RASH/BUMPS - Red rash/bumps may appear after treatment. This resolves with time.

UNDESIRABLE HAIR REDUCTION - Hair reduction may occur at treatment sites not intended for hair reduction such as vascular or laser genesis treatments. This is usually temporary but may be permanent.

PARADOXICAL HAIR GROWTH - Stimulation of terminal hair growth following photo-epilation. Can occur within or adjacent to treated area.

LEUKOTRICHIA - Temporary or permanent gray hair

SUN EXPOSURE / TANNING BEDS / ARTIFICIAL TANNING - May increase risk of side effects and adverse events.

EYE EXPOSURE – Appropriate protective eyewear should be provided to everyone in the treatment room during the treatment. Failure to wear proper protective eyewear during the entire treatment may cause severe and permanent eye damage.

Refer to the Operator Manual for a complete list of contraindications, warnings, and precautions.

CONTRAINDICATIONS

- Pregnant patients
- Patients undergoing treatment for skin cancer

WARNINGS

- Do not treat over dysplastic nevi or questionable pigmented lesions.
 - Online Melanoma resources include www.aad.org and www.cancer.org.
- Do not treat over or close to:
 - tattoos or permanent make-up
 - metal or electronic implants
- Hair removal by lasers or intense pulse light sources can cause increased hair growth in some individuals. Based upon currently available data, the highest risk groups for this response are females of Mediterranean, Middle Eastern and South Asian heritage treated on the face and neck.

PRECAUTIONS

- Do not treat patients who have taken Accutane in the past 6 months.
- Anticoagulants may increase the risk of purpura or bruising.
- Gold therapy may cause blue-gray discoloration.
- Vitiligo may cause de-pigmentation.
- Pre-treatment with an antiviral may be indicated for patients with herpes.
- Use caution when treating patients with a history of keloids or hypertrophic scarring.
- Do not treat over open wounds.
- Only treat over known benign lesions.
- Use caution when treating over hair bearing areas, as the laser energy may affect hair growth.
- The Nd:YAG may affect a tooth if exposed.
 - Moist gauze may be placed between the lips and teeth.
- Implants:
 - Reaction to metal or electronic implants is unknown.
 - Treat at least at least 6 inches away from Pacemakers/Defibrillators.

AVOIDING COMPLICATIONS

- Use extreme caution when treating near the eye.
 - Always use patient eye protection.
 - Always treat outside the orbital rim of the eye.
 - Point the sapphire window away from the eye and apply to the skin outside of the orbital rim.
- Sun exposure, tanning beds, and artificial tanning may increase the risk of side effects and adverse events.
 - Patients should avoid sun exposure, including tanning beds, and artificial tanning (spray tans, tanning lotions, etc.) for at least 4 weeks prior to treatment.
 - Patients with any residual suntan in the treatment area have a higher risk of adverse events.
- Remove all traces of make-up prior to treatment.
- Darker skin types have an increased risk of complications and/or pigmentary issues.
- Pre and post cooling helps reduce the risk of complications.
- Reaction to treating over fillers and toxins is unknown.
- Reaction to treating over superficial cosmetic implants or threads is unknown.

PRE-TREATMENT PREPARATION

- Topical anesthetic is optional with Hair Removal or Vascular treatments. If used, thoroughly remove before treating.
 - CAUTION: Toxicity may result from overuse. Consult the manufacturer's labeling.
- Do not use topical anesthetic with Laser Genesis treatments. Patient feedback is very important for non-ablative skin therapy.
- Clean patient's skin, removing all make-up and/or topical anesthetic.
- Shave the treatment site if there is excessive hair.
- Take photographs prior to the initial treatment for future reference.

SAFETY EYEWEAR

ALL people in treatment room must wear safety eyewear appropriate for 1064 nm.

- The laser ships with opaque stainless-steel patient goggles as well as operator goggles.
- Check the wavelength and optical density (OD ≥ 6.1 @ 1064 nm) marked on all operator goggles.
- Apply wet gauze over the eyelids when using metal eye shields.
 - CAUTION: Metal eye shields may increase in heat and burn the patient if a protective layer of gauze is not used.

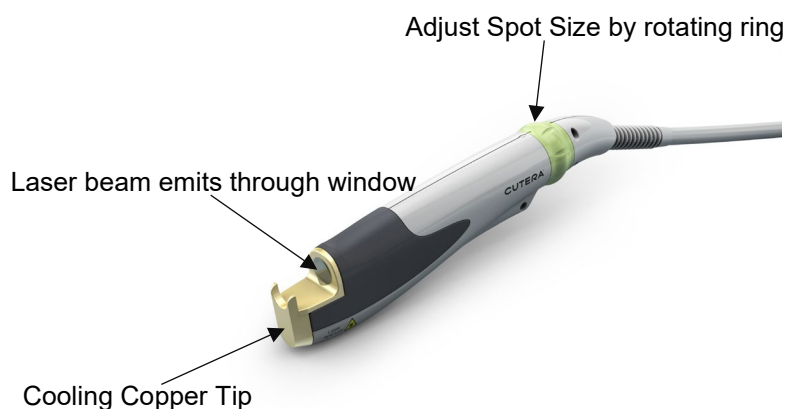


Operator Goggles



Patient Goggles

ND:YAG HANDPIECE



XEO USER INTERFACE

STANDBY MODE



READY MODE



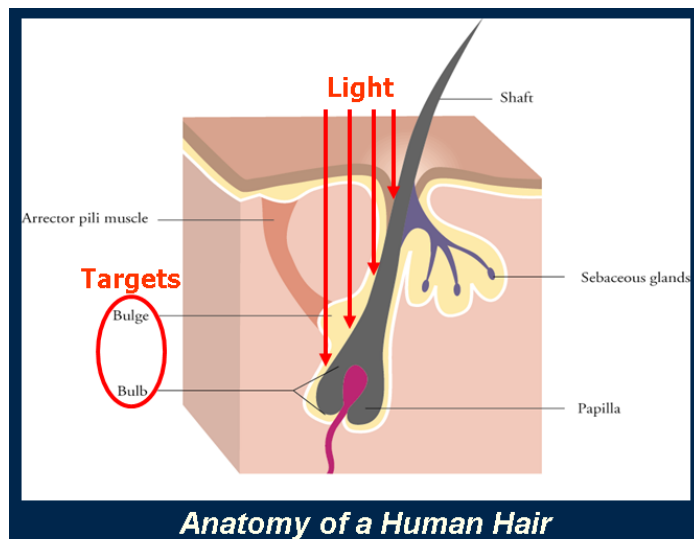
1. **Fluence** is the energy measured in J/cm^2 . Press the Up/Down arrows to adjust.
2. **Pulse Duration** is the length of each pulse measured in milliseconds (msec). Press the Up/Down arrows to adjust.
3. **Repetition Rate** is the number of pulses per second measured in Hz with foot pedal depressed. Press the Up/Down arrows to adjust.
4. **Standby Button** – Select to enable Standby Mode. The handpiece cannot be fired when in Standby Mode. The system automatically goes into Standby Mode when handpiece is placed into the holster or if not in use for more than 3 minutes.
5. **Ready Button** – Select to enable Ready Mode. The system will not go into ready mode unless the handpiece is out of the holster. Press the foot pedal to start the pulse after the “flute” sound indicates system is ready.
6. **Aiming Beam** – Press button to adjust the aiming beam brightness and blinking/solid options.
7. **Memory Button** saves 2 different settings per spot size for common indications.
8. **Number of Pulses** is displayed. Press the button to reset.
9. **Spot Size** is displayed. The spot size is the diameter of the aiming beam at the skin measured in mm. Adjust the spot size by turning the knob on the base of handpiece. Available in 3mm, 5mm, 7mm and 10mm.

NOTE: Treatment parameters are interrelated. Therefore, not all parameter combinations are simultaneously available. If you attempt to select a treatment setting that is not available, the system emits a distinct audible tone. Changing one or more of the other parameters may enable you to select the desired treatment setting.

HAIR REMOVAL

HAIR REMOVAL PROCESS

- The purpose of the treatment is to selectively treat the hair follicle without causing thermal damage to the surrounding tissue.
 - The cooling copper tips provides epidermal cooling and protection.
- Permanent hair reduction is achieved by using heat to disable the hair follicle and prevent re-growth.
 - The bulb and bulge of the hair follicle, which are responsible for hair re-growth, are targeted by the Nd:YAG laser.
 - Because the bulb and bulge of the hair follicle must be present, do not pluck or wax targeted hair in between treatment sessions.
- The Nd:YAG laser targets the melanin in the hair bulb and bulge; therefore, hair must be brown or black.
 - The Nd:YAG laser does not target and cannot be absorbed by white, gray, or red hair.



HAIR REMOVAL TREATMENT INTERVALS

- Only the hair follicle in the anagen growth phase can be effectively targeted and disabled.
- Each hair goes through the 3 growth phases independently of the neighboring hairs, so not all hairs will be in the same phase at the same time. Therefore, multiple treatments are required to achieve sufficient reduction in hair growth.
- Treatment Interval recommendations are a general guideline only and are a compilation of intervals used by successful operators.
 - Facial hair: 6 - 8 week intervals between treatments
 - Body hair: 8 - 10 week intervals between treatments
 - Back or Leg hair: 10 - 12 week intervals between treatments
- Hormones, diseases, medication, and other factors can affect the treatment outcome.
- Treatments that are spaced too closely together may appear to be more successful within the first few treatments. However, more treatment sessions may be required for the desired final outcome, because a smaller percentage of regrown hairs may be available as targets.
- Patients should be assessed before each treatment to determine treatment intervals and settings.
 - Hair may grow back lighter and finer, and settings may need to be adjusted to target this new hair.
- If the patient returns for treatment and there is minimal hair, it may be in a transitional or resting phase.
 - Wait until hair is actively growing to resume treatment cycle.
- Facial skin has significantly more hair follicles per cm² than the body, which is why you can see results within the first three to four treatments with shorter interval times.
- When in doubt, it is better to space the treatments farther apart than closer together.

PREPARING THE PATIENT FOR HAIR REMOVAL TREATMENT

- Clean the skin by removing all make-up and/or topical anesthetic.
- Ensure that the treatment area is clean shaven.
- Take photographs prior to the initial treatment for future reference.
- Topical anesthetic is optional and must be removed before treatment.
 - CAUTION: Toxicity may result from overuse. Consult the product labeling for any anesthetic used.
- Ensure that ALL people in the treatment room are wearing safety eyewear.

HAIR REMOVAL TREATMENT PRECAUTIONS

- Avoid treating surrounding skin with actinic bronzing or chronic tan.
- Reduce fluence when treating:
 - darker skin types
 - sun exposed areas (such as chest and arms) or actinic bronzing
 - over bony areas
 - on the body
- Extreme caution should be used when treating near the eye.
 - Always treat outside the orbital rim of the eye aiming the beam away from the orbit.
 - Patient eye protection is required to avoid ocular damage.
 - The laser beam should ALWAYS be pointed away from the eye and only applied to the skin outside of the orbital rim.
 - Distance from the orbit can often be increased by pulling the skin away from the eye for treatment.
- Do not treat over or close to tattoos or permanent make-up.
- Implants:
 - Reaction to metal implants is unknown.
 - Pacemaker - stay at least 6 inches away from implant.
 - Reaction to fillers is unknown.

SELECTING TREATMENT PARAMETERS FOR HAIR REMOVAL TREATMENT

- The following parameters are provided as a guide only.
- Perform and observe test spots prior to treatment. Potential adverse reactions may take 24-72 hours to appear. Pigmentation changes for darker skin type patients may develop up to several weeks following treatment.
 - Test spot fluence settings are determined by evaluating skin type and, for hair removal procedures, hair color, thickness, and density.
 - Treatment settings should be selected based on test spot clinical response.
 - Perform test spots on the same area as being treated.
 - Deliver single pulses to assess clinical response and potential adverse reactions.
 - Deliver 3 to 4 adjacent pulses to assess skin's reaction to bulk heating.
- Start with conservative settings and observe laser-tissue interaction and clinical endpoints to determine appropriate settings for each patient.
- Fluence and/or pulse duration adjustments should be performed gradually.
 - Adjust by 5 J/cm² or 5 ms at a time, while watching for epidermal response.
 - Adjust only one parameter (fluence OR pulse duration) at a time.
 - Shortening the pulse duration by 5 ms is more aggressive than increasing the fluence.
- Patients should be re-assessed prior to each treatment to determine sun exposure and hair density and coarseness.
 - Parameters may need to be adjusted.
- Mild to moderate erythema and/or perifollicular edema are desired endpoints.
 - IMPORTANT: Clinical endpoints are not always required for an effective treatment. It is possible for a treatment to be effective without seeing these reactions.
- If treated area darkens or develops significant erythema or edema, the fluence should be decreased or the pulse duration should be increased.
- Repetition rate should be adjusted according to patient comfort, skin type, hair density, and user experience.
 - Single pulses or low repetition rate are recommended on areas where additional cooling is desired (such as higher energy settings, sun exposed areas, coarse/dense hair, darker skin types, curved or bony areas, etc.).
 - Higher repetition rates are only recommended for experienced practitioners and only when treating lighter skin types on larger treatment areas that allow for easy handpiece motion.
 - If using a higher repetition rate, the fluence may need to be lowered.
- CAUTION: When treating darker skin types, additional pre-cooling and lower repetition rates or single pulse modes are recommended to maximize epidermal protection.
- Re-evaluate the patient prior to each treatment to determine sun exposure and treatment target.
 - Parameters may need to be decreased if increased melanin content due to sun exposure is observed.
- Treatment ranges are wide due to significant variations in patient response.
- CAUTION: Sun-exposed areas have a higher risk of adverse events.

HAIR REMOVAL TREATMENT PARAMETERS

The following parameters are provided as a guide only and are based on practitioner feedback. Start at the lowest fluence and observe laser-tissue interaction and clinical endpoints to determine appropriate settings.

Hair Removal			
Skin Type	Spot Size	Fluence	Pulse Duration
I - II	10 mm	50 - 65 J/cm ²	10 - 20 ms
III	10 mm	45 - 60 J/cm ²	15 - 25 ms
IV	10 mm	40 - 55 J/cm ²	15 - 30 ms
V	10 mm	35 - 50 J/cm ²	25 - 35 ms
VI	10 mm	20 - 45 J/cm ²	30 - 60 ms

SELECTING HAIR REMOVAL TREATMENT PARAMETERS

Skin Type

- Use Fitzpatrick Skin typing chart provided to determine appropriate settings
- Caution - when treating darker skin types or with aggressive settings, additional pre-cooling, and slow repetition rate (Hz) are required to protect the epidermis.

Hair Color

- Darker Hair Color = Lower Fluence, Longer Pulse Duration
- Lighter Hair Color = Higher Fluence, Shorter Pulse Duration

Hair Thickness

- Coarse Hair = Lower Fluence, Longer Pulse Duration
- Finer Hair = Higher Fluence, Shorter Pulse Duration

Hair Density

- Dense Hair = Lower Fluence, Longer Pulse Duration.
- Dense hair requires longer pre-cooling and slower repetition rate
- Hair density should decrease with subsequent treatments
- Parameters may need to be adjusted as density decreases, skin type permitting.
- Use caution when transitioning from lower density areas to higher density areas such as men's necks approaching the hairline and the bikini line.

Actinic Bronzing

- Actinic bronzing is chronic "tan-like" pigmentation damage resulting from long-term sun exposure.
- Patients with actinic bronzing are at higher risk for crusting and other adverse events.
- Patients with actinic bronzing should be treated as though they are one skin type darker than their underlying ethnicity would suggest.
 - For example, treat a skin type II patient with skin type III settings.

HAIR REMOVAL TREATMENT STEPS

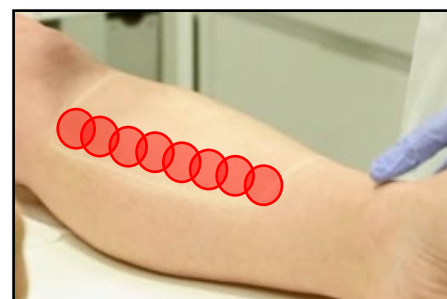
- Perform and observe test spots prior to treatment. Potential adverse reactions may take 24-72 hours to appear. Pigmentation changes for darker skin type patients may develop up to several weeks following treatment.
- Large areas may be easier to treat if divided into smaller grids.
 - Mark with a white eyeliner pencil.
 - Use only WHITE pencil as it will not be absorbed by laser light.
 - Because eyeliner pencil components are not standardized, test the pencil before using on patients.
- Apply a thin layer of clear gel (such as ultrasound or aloe vera gel) for increased epidermal protection, for easy gliding of the handpiece, and to determine placement of adjacent rows.
 - Using cool (refrigerated) gel can help with patient comfort.
- Place the copper cooling portion of handpiece on the treatment area to pre-cool the skin. The epidermis must be pre-cooled with the back of the handpiece to prevent epidermal damage.
- Pull the handpiece back at least 1 full spot size to deliver the laser pulse.
- Glide the handpiece in the same direction to deliver subsequent laser pulses.
- Ensure that the cooling portion of the handpiece always remains in contact with the skin, especially over curves.
 - Laser pulses should only be delivered to areas that have been pre-cooled.
- Darker skin or areas of dense hair will require longer pre-cooling.
- Pulses should be spaced with a 10-20% overlap between adjacent pulses.
 - Avoid overlap on darker skin.
 - Do not stack pulses ("double-pulse") or retreat an area within a single visit.
- Repetition Rate should be adjusted according to patient comfort, skin type, hair density and user experience.
 - Low or no Repetition Rate is recommended for dark skin and on curved areas (jaw).
- Be extra cautious when treating delicate or highly sensitive areas (knuckles, genitalia, ears, upper lip, etc.).
 - Provide extra cooling with handpiece and/or frozen gel pack.
 - Thinner skin is more easily damaged.
 - Insert damp cotton ball inside ear canal when treating the ear.
 - Pull skin away from testes to treat.
 - When treating near the mouth, a moist gauze can be placed between the lips and teeth to protect teeth from discomfort.



Mark treatment area with white eyeliner pencil



Ensure handpiece has full contact with skin



Typical 10% - 20% overlap of pulses

- Common endpoints are mild to moderate erythema and/or peri-follicular edema, which may be delayed. However, these endpoints are not required for a successful treatment.
 - If desired clinical endpoint is not achieved, consider increasing fluence or shortening the pulse duration.
- Always observe the epidermis during the treatment, watching for signs of damage (blanching or gray coloration).
 - If damage is seen, stop the treatment and apply a cool compress and evaluate the area for possible complications and wound care.



Perifollicular edema is a common endpoint

VERY LIGHT OR VERY FINE HAIR

- If very light or very fine hair is not diminishing with the 10mm settings, the 7mm spot size settings below can be used during subsequent sessions on skin types I-III only.
- Do not retreat same area with 7mm after 10mm in the same treatment session.
 - Use 7mm settings at subsequent treatments only.
- The 7mm spot size settings are more aggressive and should only be used on very light or very fine hair.
- Treat only patients who are skin types I-III with no tan or actinic bronzing.
- Do not place pulses with any overlap, leave space in between each pulse.
- Do not use a Repetition Rate.
- Must pre-cool prior to each pulse and post-cool after each pulse.

Very Light and/or Very Fine Hair			
Skin Type	Spot Size	Fluence	Pulse Duration
I – III	7 mm	100 – 120 J/cm ²	10 – 20 ms



HAIR REMOVAL POST-TREATMENT CARE

- Avoid sun exposure and use a broad spectrum (UVA/UVB) sunscreen.
- Avoid heat (hot tubs, saunas, etc.) for 1-2 days.
- Avoid skin irritants (products containing tretinoin, retinol, benzoyl peroxide, glycolic/salicylic acids, astringents, etc.) for a few days post-treatment.
- Do not wax or pluck between treatments.
- Redness and perifollicular edema are common and will resolve with time.
- Bruising and swelling are uncommon but may occur and will resolve with time.
- Hair may take up to two weeks to fall out.

VASCULAR TREATMENTS

VASCULAR TREATMENT PROCESS

- The purpose of the treatment is to selectively treat the target of hemoglobin (chromophore) without causing thermal damage to the surrounding tissue.
- Laser light is absorbed by hemoglobin in the veins and the heat produced causes photocoagulation.
- This heat is transferred to the vessel wall which affects the collagen and ultimately helps to destroy the vessel and prevent recanalization.
- The laser treats individual veins, but new veins may appear due to an underlying disorder.

TYPES OF VEINS



Telangiectasia or spider veins

- Up to 1 mm in diameter
- Superficial, small veins; pink to purple in color



Reticular veins or "feeder veins"

- 1 – 3 mm in diameter
- Superficial collecting veins that are blue green



Varicose veins

Usually requires surgery, not appropriate for laser therapy

- Vary in diameter
- Bulging and twisting veins of the lower extremity caused by increased venous pressure because of venous incompetence.
- A vascular surgeon should evaluate bulging varicose veins.

REFLUXING OR INCOMPETENT VEINS

- Venous reflux or incompetence is a diseased or abnormal valve that is no longer able to close when subjected to pressure. This failure to close prevents the valve from stopping the backward flow of blood. In response to gravity, blood pours backward (like a waterfall), overloading the vein with volume and pressure which leads to the development of varicose veins.
- Duplex ultrasound may be ordered to diagnose possible reflux of the Greater or Lesser Saphenous Vein which is usually treated surgically.

SELECTING VASCULAR TREATMENTS TREATMENT PARAMETERS

Select parameters in the order listed below. Always start with the least aggressive settings for a specific vessel. Observe laser-tissue interaction and clinical response to determine appropriate settings for each patient.

Spot Size is measured in millimeters (mm). Selection is based on treatment type & vessel depth.

- Depth of Penetration is controlled by spot size
 - Larger spot sizes penetrate deeper with the 1064 nm wavelength
 - Smaller spot sizes treat more shallow targets



The depth of penetration is based on spot size. Use smallest effective spot size for safest result and greatest patient comfort.

- Smaller, superficial vessels = smaller spot size
 - Smaller spot sizes (such as 3mm) penetrate red telangiectasia more superficially as shown and do not heat beyond the spot size. Pulses can be placed adjacently.
- Larger, deeper vessels = larger spot size
 - Larger spot sizes such as the 7mm, heat the vessels beyond the spot size. Pulses should be spaced apart (at least one spot size) to help prevent over treating the vessel. Extra cooling is also recommended to avoid overheating the vessel.

Fluence is the energy, measured in J/cm². Selection is based on vessel size, depth, and skin type.

- Smaller vessels = higher fluence; Larger vessels = lower fluence
- Darker skin types or tan skin = lower fluence

Pulse Duration is the length of each pulse, measured in milliseconds (ms). Selection is based on vessel size and color.

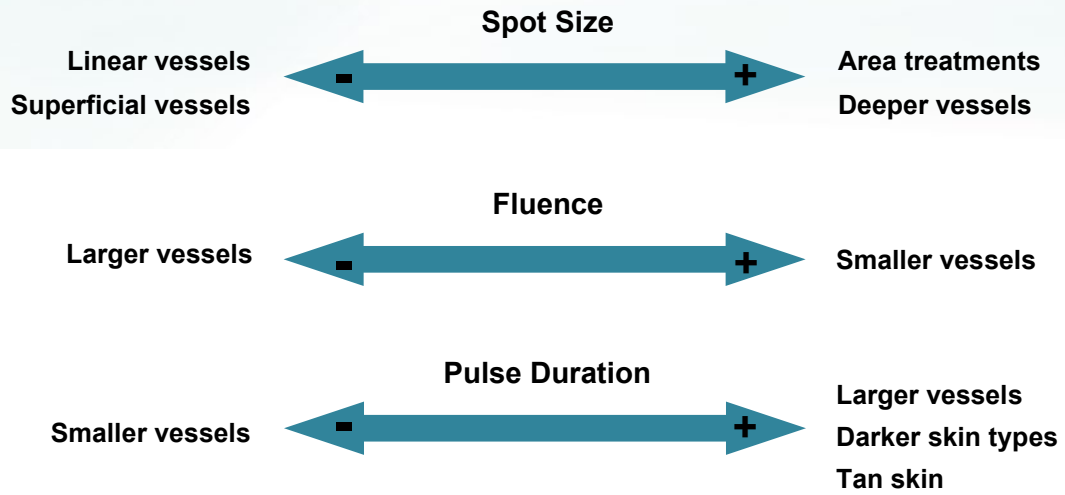
- Smaller diameter, lighter vessel = shorter pulse duration
- Larger diameter, darker vessel = longer pulse duration
- Darker skin types or tan skin = longer pulse duration
- Pulse durations shorter than 10 ms increase the likelihood of purpura when treating vascular lesions.

Repetition Rate is the number of pulses per second, measured in Hz, with foot pedal depressed.

- For increased epidermal safety, use single pulses (0.0 Hz) with pre and post cooling.
- Repetition Rate should only be used with the 3mm spot size as described in following Treatment Parameters.

Contact Cooling – Copper tip on handpiece provides pre and post cooling.

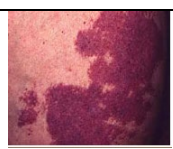
- Pre-cooling protects the epidermis by reducing initial skin temperature.
- Post-cooling extracts heat from tissue to help prevent epidermal injury.
- Longer pre and post cooling is recommended when treating larger, darker vessels, darker skin types and tan skin.



VASCULAR TREATMENT PARAMETERS

These parameters are provided as a guide only. Observe laser-tissue interaction and clinical endpoints to determine appropriate settings. The following guidelines are based on physician feedback from vascular treatments primarily on patients with Fitzpatrick skin types I–IV. Treatment Parameters have not been developed for skin types V & VI. The increased melanin in darker skin is a competing chromophore with the vessels increasing the risk of an adverse event.

Indication	Example Picture	Skin Type	Spot Size	Fluence	Pulse Width
**Facial Telangiectasia		I - IV	3 mm	120 – 160 J/cm ²	10 – 25 ms
			5 mm*	110 – 160 J/cm ²	15 – 35 ms
**Fine Leg Telangiectasia < 0.5 mm diameter		I - IV	3 mm	140 – 180 J/cm ²	10 – 20 ms
			5 mm	130 – 170 J/cm ²	15 – 25 ms
Purple/Blue Facial Telangiectasia		I - IV	5 mm	90 – 130 J/cm ²	15 – 50 ms
Periorbital Blue Veins		I - IV	5 mm	90 – 130 J/cm ²	25 – 50 ms
Red Spider Leg Veins 1 - 2 mm		I - IV	3 mm	130 – 170 J/cm ²	10 – 30 ms
			5mm	110 – 150 J/cm ²	20 – 40 ms
Purple Spider Leg Veins 1 – 2 mm		I - IV	5 mm	120 – 160 J/cm ²	15 – 40 ms
			7 mm	110 – 160 J/cm ²	20 – 45 ms
Reticular Leg Veins 2 - 4 mm		I - IV	7 mm	110 – 160 J/cm ²	35 – 60 ms
	* Use caution when using a 5mm spot size on facial telangiectasia. Gain experience with the 3mm spot size before advancing to the 5mm. ** The 3mm spot size can be used to treat 3-4 directly adjacent consecutive pulses at 0.0 – 1.0 Hz using lower fluences without cooling in between each pulse. Cooling MUST be done before and after each sequence.				

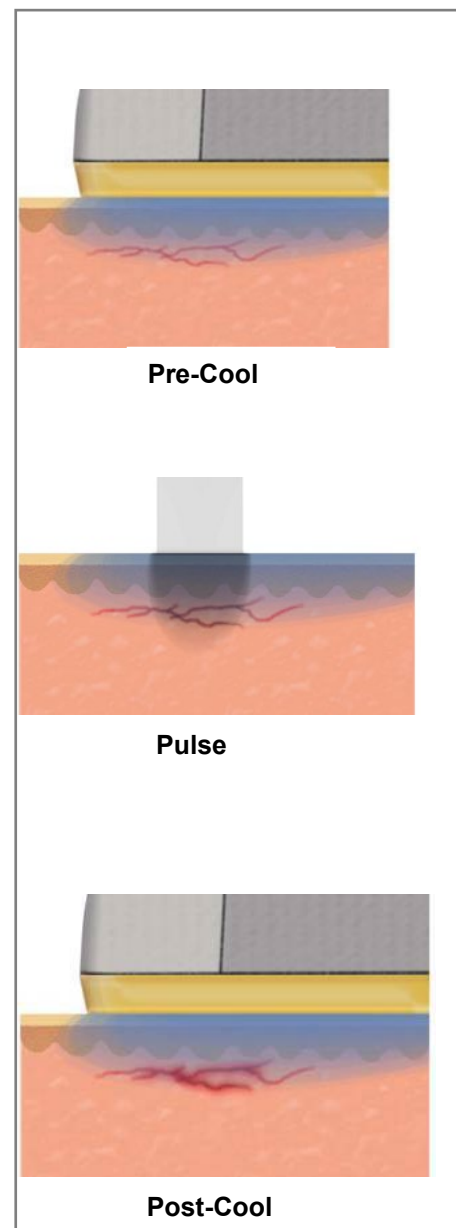
Indication	Example Picture	Skin Type	Spot Size	Fluence	Pulse Width
Cherry or Spider Angioma		I - IV	3 mm (<2 mm)	130 – 170 J/cm ²	8 – 30 ms
			5 mm (>2mm)	90 – 150 J/cm ²	15 – 40 ms
Venous Lake		I - IV	5 mm (Target <4 mm)	70 – 120 J/cm ²	20 – 50 ms
			7 mm (Target >4 mm)	70 – 120 J/cm ²	30 – 50 ms
Skin Tag		I - IV	3 mm (Small / non-pigmented)	180 – 190 J/cm ²	8 – 10 ms
			5 mm (Large / pigmented)	155 - 170 J/cm ²	10- 15 ms
***Large Dark/Raised Angiomas or Port Wine Stains		I - IV	5 or 7 mm	110 – 120 J/cm ²	30 – 40 ms
*** Large Dark/Raised Angiomas or Port Wine Stains should only be treated by experienced practitioners. Extreme caution should be used.					

VASCULAR TREATMENT PRECAUTIONS

- **WARNING:** Use caution when treating skin type IV.
 - Do not treat patients who are skin types V or VI.
 - Patients with darker skin types have a higher risk of adverse reactions.
 - Use a lower fluence, longer pulse duration and additional pre-cooling.
- **WARNING:** The handpiece should be in full contact with the skin during each laser pulse.
 - Pay close attention when treating over the nose or curved areas to ensure all creases are pre-cooled with cooling copper tip prior to each pulse.
 - Consider using smaller spot size if you cannot ensure full contact with the sapphire window.
- Test pulses are always advised. Observe laser-tissue interaction before proceeding.
- Use extreme caution when treating near the eye.
 - Patient eye protection is required to avoid ocular damage.
 - Always treat outside the orbital rim.
 - The laser beam should ALWAYS be pointed away from the eye and only applied to the skin outside of the orbital rim.
 - Distance from the orbit can often be increased by pulling the skin away from the eye for treatment.
- Do not treat over or close to tattoos or permanent make-up.
- Possible hair loss may occur.

VASCULAR TREATMENT TECHNIQUE

- Pre-cool and start with “test” pulse
 - Treatment of a test area is recommended observing tissue reaction.
- Potential adverse reactions may take 24-48 hours to appear. Apply a thin layer of clear gel (such as ultrasound gel) for increased epidermal protection and easy gliding of the handpiece.
- Pre-cooling the skin is required to prevent epidermal damage.
 - **Pre-cooling is the most important step of the procedure**
 - Place the copper cooling tip of handpiece on the treatment area ensuring FULL CONTACT with the skin
 - When treating the nose or any curved area, ensure all portions of skin (example: ala) are in full contact with the copper tip
 - Length of pre-cooling time required will vary according to size, color, and depth of vessel.
 - Larger, darker vessels require longer pre-cooling.
- Gradually decrease pulse duration or increase fluence to reach desired endpoint
 - Do not stack pulses
- Pull the handpiece back at least 1 full spot size to deliver the laser pulse.
 - For smaller vessels, place pulses adjacent to one another.
 - For larger vessels, leave at least one spot size untreated between pulses.
- Post-cool by placing the copper tip of the handpiece back onto the treated area.
- Do not stack or “double pulse”.
- Always observe the epidermis during the treatment, watching for signs of damage (blanching or frosting or gray coloration).
 - If damage is seen, stop the treatment and apply a cool compress and evaluate the area for possible complications and wound care.
- Tissue response
 - Start with a test pulse, pre-cooling well.
 - Gradually shorten the pulse duration until desired pulse duration is reached, then increase the fluence.
 - Experienced practitioners may treat an area with more than one pulse after cooling but be aware of stacking the energy/heat and the increased likelihood of tissue injury.
 - Consider returning to the area in 10 minutes to re-evaluate tissue response.
- “Popping” and extravasation may occur when a vessel is ruptured.
 - Cool and compress the area; purpura may develop.
 - Lengthen the pulse duration and/or reduce the fluence or leave space on subsequent pulses.
 - Common endpoints for skin tags are a dusky or slightly frosty look.



- Endpoints will vary based on type, size, color, volume, pressure, and location of vein.
 - Common endpoints are color change, vein disappearance, or constriction.
 - If the clinical endpoint is not reached, shorten the pulse duration. If clinical endpoint still not reached, then increase the fluence.
 - The endpoint may not be evident or may be very subtle when treating larger reticular leg veins.
- Re-assess the treatment area prior to subsequent treatments and adjust the parameters accordingly.
- Expectations
 - 2-3 treatments are typically required for up to 70% resolution on patients with no underlying conditions.
 - Redness surrounding vessels is expected.
 - Urticarial reaction (hive-like/bug-bite look) is common with superficial veins.
 - Bruising may occur and usually resolves in a few weeks.
 - Small mild blisters are undesirable but may occur.
 - Thrombosis (hardening and darkening of vessels) is expected for larger veins and will be absorbed over time.
 - Hemosiderin (hyperpigmentation from iron leaking into skin due to vein breakdown) can occur and will usually slowly fade over many months.



SPECIFIC VASCULAR TREATMENT INSTRUCTIONS

Venous Lake

- Treat only the lesion and not the surrounding tissue.
- Common endpoints for a venous lake are a dusky or deflated look, it should not turn black.
- Do not double-pulse.
- The venous lake may feel firm a few minutes after treating, this firmness should dissipate within a few days.

Skin Tag

- Do not use gel
- Pulse 2-3 times, pre and post cooling in between each pulse, until endpoint is reached.
- Additional cooling can be applied post-treatment for patient comfort.
- Treat only the lesion and not the surrounding tissue.

Periorbital Vein

- Only experienced practitioners should treat periorbital veins.
- Always use patient eye protection.
- Always point the laser beam away from the eye, and never treat near or within the orbital rim.
- Distance from the orbit can often be increased by pulling the skin away from the eye for treatment.

Port Wine Stain

- The treatment of Port Wine Stains (PWS) should only be performed by experienced practitioners.
- Extreme caution should be used as PWS vary greatly in size and depth
- Test pulses are always advised. Observe laser-tissue interaction before proceeding.
 - Ask the patient to return in 6 weeks to fully assess test pulse results.
 - Several treatments may be necessary
- Start with a test pulse, pre-cooling well and gradually shorten the pulse duration or increase the fluence over a few pulses on different spots.
 - Return to the area in 10 minutes to re-evaluate tissue response.
- PWS require significant pre-cooling and post-cooling. Always use gel and pre and post cool the treatment area
 - 2-3 seconds of precooling per pulse recommended. Larger/darker PWS require longer pre and post cooling.
 - Additional post-cooling with Zimmer, ice packs, etc. is also recommended
- Leave at least one full spot size gap in between each pulse. Never place pulses adjacent or with overlap.
- Endpoint should be darker color or purple, without any grey or white areas with minimal purpura.
 - If you do not reach proper end point, you need to first shorten the pulse duration by 5ms at a time, cool, then try again on an adjacent area.
- Cold Compresses or chilled gel packs are recommended post-treatment

VASCULAR POST TREATMENT CARE

- Cold compresses or chilled gel packs may be applied post treatment.
- If a blister develops, treat as a wound.
- Normal Reactions:
 - Erythema – usually resolves within 2-4 hours
 - Edema – usually resolves within 24 hours
 - Bruising – usually resolves within 7-10 days
 - Urticarial (hive-like) reaction (smaller vessels) – usually resolves within 1-2 days
 - Hemosiderin staining is uncommon but may occur (more commonly in leg veins) and usually resolves
- Retreatment of vessels is not recommended prior to 4-6 weeks.
 - Larger reticular vessels may take longer to resolve and should not be re-treated prior to 2-3 months.
- Avoid sun exposure and use a broad spectrum (UVA/UVB) sunscreen to minimize the risk of PIH (Post Inflammatory Hyperpigmentation).
- Avoid heat (hot tubs, saunas, etc.) for 1-2 days post-treatment.
- Avoid skin irritants (i.e., products containing tretinoin, retinol, benzoyl peroxide, glycolic/salicylic acids, astringents, etc.) a few days post-treatment.
- Request that the patient contact your office with any concerns, such as blistering, excessive redness/swelling, etc.
- Leg vein treatments only:
 - Linear crusting may occur when treating leg veins and should be allowed to slough off naturally.
 - Compression stockings (20-30 mm/hg) are optional.
 - Avoid high impact activity for 3-5 days.
 - Large leg veins may take many months to resolve and should not be re-treated before then.

WART TREATMENTS

WART TREATMENT PARAMETERS

These parameters are provided as a guide only for skin types I-VI. Observe laser-tissue interaction and clinical endpoints to determine appropriate settings. Warts (or verrucae) can be treated with vascular lasers – typically at higher energy settings and shorter pulse durations than veins or telangiectasia.

Example Picture	Skin Type	Spot Size	Fluence	Pulse Duration
	I - VI	3 mm	170 – 190 J/cm ²	6 – 15 ms
		5 mm	140 – 190 J/cm ²	6 – 15 ms

WART TREATMENT TECHNIQUE

- Smoke evacuator and laser plume masks (filters to 0.1 µm) are recommended when treating.
- Warts may need to be debrided (pared down) prior to treatment.
- Do not use gel.
- Handpiece should be flush with skin.
- Cool treatment area prior to treatment.
- Treat within the wart border.
- The wart may spark when treated.
- Cool with ice/frozen gel pack in between each pulse.
- Some warts may require more than one pulse.
 - Do NOT stack pulses (i.e., place one pulse directly on top of another with no cooling time).
 - Pause for a few seconds and cool the treatment area between pulses.
 - Do not use a Repetition Rate.

Individual Warts

- Pulse over the wart.
- Do not treat outside the wart border.
- Cool the treatment area in between pulses.
- If the wart is smaller than the laser beam, assess the surrounding tissue before placing additional pulses to avoid over-treatment of normal tissue.
- If the wart is larger than the laser beam:
 - Use less aggressive parameters.
 - Multiple treatments may be required (treat small sections over multiple visits).
 - Place pulses with approximately 10%-50% overlap.
 - lighter/smaller warts = more overlap
 - larger/darker warts = less overlap



Mosaic Warts

- Mosaic warts typically require multiple treatments and less aggressive parameters.
- Do NOT treat the entire mosaic wart area in one session.
 - Only treat the darker/thicker area, usually near the center of the wart.
 - Do NOT overlap pulses. Place pulses adjacent to one another or spaced out.
 - Cool the treatment area in between pulses.
- At each subsequent visit, repeat the treatment steps.



Endpoint

- Check for the endpoint after the first pulse.
- The desired endpoint is a slight ashen color that should occur immediately after the pulse.
 - The color change may be subtle.
 - If the surrounding area becomes white or edematous, it was probably over-treated and should be treated as a wound.
- If the endpoint is not reached:
 - Increase the fluence by 5 J/cm² and shorten the pulse duration by the minimum amount until you reach the endpoint.
 - Cool the treatment area in between pulses.
 - Repeat the treatment steps detailed above.
- Immediate post cooling with a cold gel pack, Zimmer, etc. may be used for patient comfort.



WART POST-TREATMENT CARE

- Warts usually have a black or crusty appearance within 24 hours after treatment.
- You may apply an ointment of choice and non-stick dressing for patient comfort.
- If a blister develops, treat it as a wound.
- Treated tissue usually sloughs within 1-4 weeks.
- Deep tissue injury and prolonged wound healing may occur.
- More than 1 treatment may be required (4-6 weeks apart).



ACNE TREATMENTS

ACNE TREATMENT PARAMETERS

The following parameters are for the treatment of mild to moderate inflammatory acne. These parameters are provided as a guide only for skin type I-III on the face. Treatment protocols have not been developed for skin types IV-VI or off the face treatments. Observe laser-tissue interaction and clinical endpoints to determine appropriate settings.

Treatment Location	Skin Type	Spot Size	Fluence	Pulse Duration	Repetition Rate
Face	I - III	10 mm	45 – 65 J/cm ²	40 – 60 ms	0 – 1 Hz

ACNE TREATMENT TECHNIQUE

- **WARNING:** Do not treat patients who have taken Accutane (isotretinoin capsule) in the past 6 months.
- **Technique:**
 - Apply a thin layer of clear gel (such as ultrasound gel) for increased epidermal protection and patient comfort.
 - Do not apply too much pressure on the skin.
 - Pre-cool area with copper cooling tip, pull handpiece back, depress the foot pedal to fire a pulse, then post-cool area with copper cooling tip of handpiece.
 - Glide handpiece to next treatment area and repeat.
 - Ensure that handpiece has complete contact with skin during each pulse.
- Always observe the epidermis during the treatment, watching for signs of damage (blanching or gray coloration).
 - If damage is seen, stop the treatment and apply a cool compress and evaluate the area for possible complications and wound care.
- Treat the individual lesions and surrounding area. This is not a full face treatment so surrounding area should be limited to affected areas only.
 - Overlap pulses by no more than 10 – 20%.
 - Only 1 pass recommended.
- Treat to endpoint of mild erythema.
- Treating off the face is not recommended.
- As with other 1064nm treatments, hair reduction in treatment area is a possible reaction to treatment.
- Common treatment intervals are every 2-4 weeks. Number of treatments varies by patient.

ACNE POST TREATMENT CARE

- Cold compresses or chilled gel packs may be applied post treatment.
- If a blister develops, treat as a wound.
- Avoid sun exposure and use a broad spectrum (UVA/UVB) sunscreen to minimize the risk of PIH (Post Inflammatory Hyperpigmentation).
- Bruising, redness, and swelling are common and resolve with time.
- Avoid heat (hot tubs, saunas, etc.) for 1-2 days post-treatment.
- Avoid skin irritants (i.e., products containing tretinoin, retinol, benzoyl peroxide, glycolic/salicylic acids, astringents, etc.) a few days post-treatment.
- Request that the patient contact your office with any concerns, such as blistering, excessive



LASER GENESIS TREATMENTS

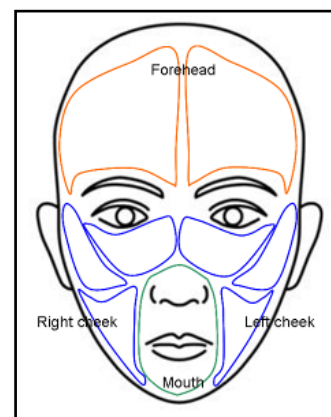
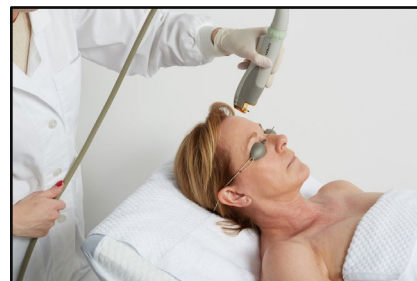
LASER GENESIS TREATMENT PARAMETERS

These parameters are provided as a guide only for skin types I-VI. Observe laser-tissue interaction and clinical endpoints to determine appropriate settings. Laser Genesis is recommended for scar revision, diffuse redness, fine lines, and wrinkles.

Treatment Area	Skin Type	Spot Size	Fluence	Pulse Duration	Rep Rate	# Tx	# of Pulses
Large Area (face, neck, or chest)	I-IV	5 mm	12-18 J/cm ²	0.3 ms	7 – 10 Hz	4-6	8,000 – 12,000
	V-VI	5 mm	8-14 J/cm ²	0.3 ms	5 – 8 Hz	4-6	
Small Area (including scars)	I-IV	5 mm	12-16 J/cm ²	0.3 ms	4 – 8 Hz	1-6	500 – 1,000 Depending on the size of the area
	V-VI	5 mm	8-12 J/cm ²	0.3 ms	4 – 8 Hz	1-6	

LASER GENESIS TREATMENT TECHNIQUE

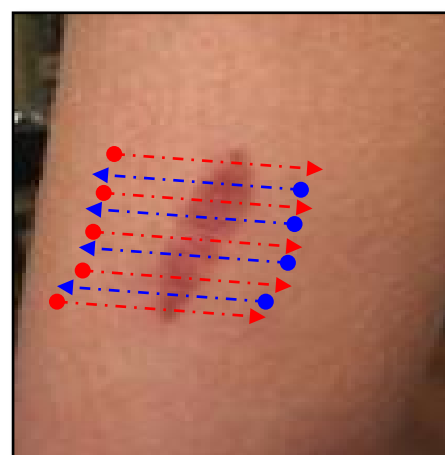
- Do NOT use topical anesthetic.
 - Patient feedback is important.
- Start with low fluence and slow repetition rate to observe laser-tissue interaction.
 - Adjust fluence and/or repetition rate to patient tolerance.
- Sensitive areas, darker skin types, and areas of dense hair or recent sun exposure may require lower fluences or lower repetition rates.
- To create heat to target the microvasculature, divide the face into multiple regions (see example on right).
 - Divide the forehead in half.
 - Do NOT treat upper lids.
 - Divide the cheeks into 2-3 sections.
 - The vermillion border may be treated but ensure that there is no tattoo or permanent makeup in the area.
 - Place moist gauze between lips and teeth to protect enamel.
- Hold the handpiece 1-2 cm from the skin's surface.
 - Handpiece should not be touching the skin during treatment.
 - Move handpiece continuously in an even zig-zag motion.
 - Adjust speed according to the patient's tolerance.
 - Treat each region to point of discomfort and erythema
 - Then move to adjacent regions using multiple passes.



- Darker skin types, scars or hot spots may need short break during treatment.
 - Pause treatment or use a frozen gel pack or wet 4x4 between passes to cool the skin.
- Use extreme caution when treating near the eye.
 - Always use patient eye protection.
 - Always point the laser beam away from the eye, and never treat near or within the orbital rim.



- **Treating a Scar**
 - Check with surgeon before starting treatment on fresh scars.
 - Always include the tissue surrounding the scar observing for erythema of the scar as endpoint.
 - Scar will absorb more energy than surrounding skin.
 - Do not rely on heat in surrounding skin as an endpoint.
 - Decreased or no sensation of the scar tissue increases the risk of a burn.
 - Treat in a zig-zag movement across the scar.
 - Do not treat linearly.
 - Pause and use cooling copper tip or a frozen gel pack to cool the treatment area between passes.
 - Several treatments may be required.



LASER GENESIS POST TREATMENT CARE

- Avoid sun exposure and use a broad-spectrum (UVA/UVB) sunscreen to prevent further sun damage.
- If a blister develops, treat as a wound.
- Bruising, redness, and swelling may occur and resolve with time.
- Urticarial reaction (hive-like/bug-bite look) may occur and usually resolves in 1-2 days.
- Avoid heat (hot tubs, saunas, etc.) for 1-2 days.
- Avoid skin irritants (products containing tretinoin, retinol, benzoyl peroxide, glycolic/salicylic acids, astringents, etc.) for a few days post-treatment

SKIN TYPE QUESTIONNAIRE

SCORE		0	1	2	3	4
	What is the natural color of your hair?	Sandy red	Blond	Chestnut, dark blond	Dark brown	Black
	What is the eye color?	Light blue, Gray, Green	Blue, Gray, Green	Brown	Dark Brown	Brownish Black
	What is the color of sun unexposed skin areas?	Reddish	Very pale	Pale with beige tint	Light brown	Dark brown
	How many freckles on unexposed skin areas?	Many	Several	Few	Incidental	None
	What happens when you are in the sun TOO long without sunblock?	Painful redness, blistering, peeling	Blistering followed by peeling	Burns, sometimes followed by peeling	Rarely burns	Never had a problem
	How well do you turn brown?	Hardly or not at all	Light color tan	Reasonable tan	Tan very easily	Turn dark very quickly
	Do you turn brown within one day of sun exposure?	Never	Seldom	Sometimes	Often	Always
	How does your face respond to the sun?	Very sensitive	Sensitive	Normal	Very resistant	Never had a problem
	When did you last expose yourself to the sun or artificial sun treatments?	More than 3 months ago	2-3 month ago	1-2 months ago	Less than 1 month ago	Less than 2 weeks ago
	Do you expose the area to be treated to the sun?	Never	Hardly ever	Sometimes	Often	Always
	TOTAL					

- 00-07 points = Skin type I
- 08-16 points = Skin type II
- 17-25 points = Skin type III
- 25-30 points = Skin type IV
- 30-40 points = Skin types V and VI

ADDITIONAL INFORMATION

PATIENT FORMS

Downloadable and customizable patient forms (Consent Forms, Health History Form, Pre & Post Treatment Instructions, Treatment Records, etc.) are available to download from www.MyCutera.com

CLINICAL RESOURCES

Clinical resources such as tutorial videos, treatment guidelines, and operator manuals area available to download from www.MyCutera.com. Check the website regularly for updates.

CLINICAL SUPPORT

Cutera provides complimentary phone and email clinical support for Cutera customers. Cutera clinical staff cannot dispense medical advice or diagnose, but can provide guidance on appropriate patient selection, parameter choices and treatment technique.

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TECHNICAL SUPPORT & SYSTEM CARE

It is owner's responsibility to ensure that their Cutera system is properly maintained. See Operator Manual or contact Technical Support for detailed instructions on system care and proper maintenance.

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