

enLIGHTen® III

TREATMENT GUIDELINES



FOR USE OUTSIDE OF THE UNITED STATES AND CANADA

CUTERA®
FACE + BODY AESTHETIC SOLUTIONS

The following information is supplemental to the *enlighten 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 post-market release physician feedback and pre-market release clinical experience gained in IRB-approved studies conducted to gather clinical data to support FDA submissions. The information is provided as a guide only and is not prescriptive for any patient, lesion or treatment.

The guidelines are not designed to be a substitute for clinical training. The *enlighten*[™] system 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.

INDICATIONS FOR USE

The *enlighten III* laser system is intended for use in aesthetic and cosmetic applications in the medical specialties of dermatology and plastic surgery.

- The 1064 nm wavelength of the *enlighten III* laser system is indicated for:
 - Tattoo removal for dark colored tattoo inks and for multicolored tattoos containing dark colored tattoo inks.
 - Treatment of benign pigmented lesions.
 - Treatment of acne scars and wrinkles when used with the Micro Lens Array handpiece attachment.
- The 670 nm wavelength of the *enlighten III* laser system is indicated for:
 - Tattoo removal for lighter colored tattoo inks, including green, blue, and purple inks.
 - Treatment of benign pigmented lesions.
- The 532 nm wavelength of the *enlighten III* laser system is indicated for:
 - Tattoo removal for lighter colored tattoo inks, including red and yellow inks.
 - Treatment of benign pigmented lesions.
 - Treatment of acne scars and wrinkles when used with the Micro Lens Array handpiece attachment.

MECHANISM OF ACTION

- The *enlighten* laser uses a 660 or 750 picosecond or 2 nanosecond pulse to photo-acoustically break up tattoo ink particles or melanin for the body to re-absorb through the lymphatic system.

CONTRAINDICATIONS

- Patients who are pregnant
- Patients who are undergoing treatment for skin cancer

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

WARNINGS

- Do not treat over dysplastic nevi or questionable pigmented lesions. Only benign pigmented lesions are treatable. Accurate pre-operative diagnosis is very important to prevent treatments on malignant lesions.
 - Online melanoma resources include www.aad.org and www.cancer.org.

PRECAUTIONS

- Current medications (both routine and occasional use).
- Accutane - do not treat if taken in the last 6 months.
- Gold Therapy - may cause blue-gray discoloration.
- Photosensitizing drugs (Tetracycline, etc.) - perform test spots and adjust parameters accordingly.
- Anticoagulants - may increase the risk of purpura or bruising.
- Bleeding disorders.
- Vitiligo or history of pigmentary disorders, particularly tendency for hyper- or hypopigmentation.
- Herpes - heat from the treatment could induce a flare-up; pretreatment with an antiviral may be indicated.
- Wound infections.
- Open lesions - treatments should only be performed on intact, healthy skin.
- History of coagulopathies.
- History of keloid or hypertrophic scarring.
- Diabetes - may impede wound healing.
- History of seizure disorders due to light.

PATIENT ASSESSMENT

- Obtain a complete medical history and signed informed consent prior to treatment.
- Determine skin type to help guide treatment parameter selection.

EXPECTED TRANSIENT EVENTS AND POSSIBLE ADVERSE EFFECTS

- Discomfort
- Purpura
- Blisters/scabs/crusting
- Petechiae/pinpoint bleeding
- Hyper/hypopigmentation
- Texture changes
- Edema and erythema
- Allergic reaction
- Infection
- Scarring
- Persistence of pigmented lesion
- Incomplete tattoo removal
- Darkening of lesions
- Paradoxical darkening or color change
- “Bleeding” of ink into surrounding skin



AVOIDING COMPLICATIONS

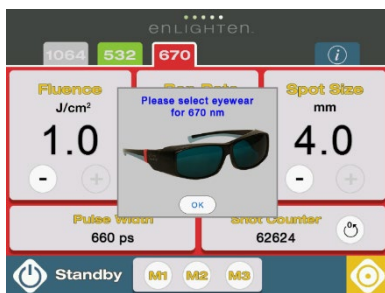
- Sun exposure, tanning beds, and artificial tanning may increase the risk of side effects and adverse events.
 - Patients should avoid sun exposure, including tanning beds, and artificial tanning (spray tans, tanning lotions, etc.) for at least 4 weeks prior to treatment.
 - Patients with any residual sun tan in the treatment area have a higher risk of adverse events.
- Pre and post cooling can help reduce the risk of complications.
- Reaction to treating over fillers and toxins is unknown.
- Patients should avoid treatments that may irritate the skin (depilatories, harsh chemicals, etc.) for 1-2 weeks prior to treatment.
- Pigmented lesions may darken. Allow these to slough off naturally.

SAFETY EYEWEAR

Safety eyewear appropriate for 532 nm, 670 nm or 1064 nm must be worn by ALL people in treatment room. The Enlighten III system will prompt user when to change safety eyewear based on the wavelength selected.

- It is Important to ensure that the correct safety eyewear is worn by everyone in the treatment room when the laser fires. There are two sets of safety eyewear for the operators:
 - 532 nm & 1064 nm treatments
 - Check the wavelength and optical density (OD 7+ @ 532 nm and 1064 nm) marked on the amber 532 nm/1064 nm operator goggles.
 - 670 nm & 1064 nm treatments
 - Check the wavelength and optical density (OD 8+ @ 670 nm) marked on the blue 670 nm operator goggles.
- The laser ships with opaque stainless steel patient goggles as well as operator goggles.
 - Apply wet gauze over the eye lid 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.

User Interface Prompt



Operator Goggles



Patient Goggles



LASER PLUME

- Surgical masks (filtered to 0.1 μ) are recommended for tattoo removal treatments. Use of a smoke evacuator is optional.



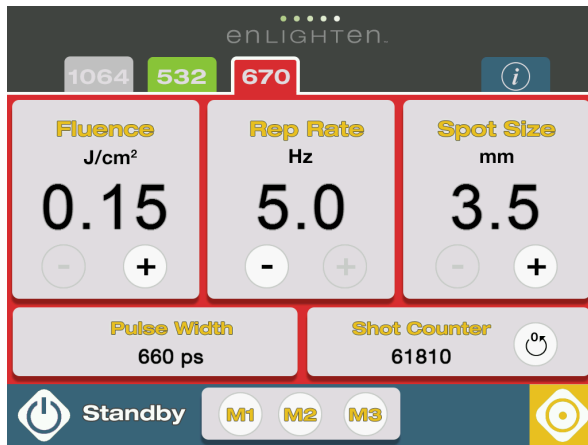
**Laser Plume Mask
Filtered to 0.1 μ**

MINIMUM / MAXIMUM FLUENCE CHART

- The following chart lists the minimum and maximum fluence allowed for each spot size. If the desired fluence setting is unavailable, it is recommended to change the spot size until the desired fluence setting is available.

Spot Size	532 nm		670 nm		1064 nm	
	Minimum Fluence	Maximum Fluence	Maximum Fluence	Minimum Fluence	Minimum Fluence	Maximum Fluence
2 mm	0.45 J/cm ²	2.5 cm ²	0.45 cm ²	4.0 cm ²	1.6 J/cm ²	10 J/cm ²
2.5 mm	0.3 J/cm ²	2.5 cm ²	0.30 cm ²	2.6 cm ²	1.1 J/cm ²	10 J/cm ²
3 mm	0.2 J/cm ²	2.5 cm ²	0.20 cm ²	1.8 cm ²	0.8 J/cm ²	10 J/cm ²
3.5 mm	0.15 J/cm ²	2.5 cm ²	0.15 cm ²	1.3 cm ²	0.6 J/cm ²	8.4 J/cm ²
4 mm	0.15 J/cm ²	2.5 cm ²	0.15 cm ²	1.0 cm ²	0.4 J/cm ²	6.4 J/cm ²
5 mm	0.1 J/cm ²	2 cm ²	0.10 cm ²	0.6 cm ²	0.3 J/cm ²	4.1 J/cm ²
6 mm	0.1 J/cm ²	1.4 cm ²	0.10 cm ²	0.45 cm ²	0.2 J/cm ²	2.8 J/cm ²
7 mm	0.1 J/cm ²	1 cm ²	N/A	N/A	0.15 J/cm ²	2.1 J/cm ²
8 mm	0.1 J/cm ²	0.8 cm ²	N/A	N/A	0.1 J/cm ²	1.6 J/cm ²
9 mm	0.1 J/cm ²	0.6 cm ²	N/A	N/A	0.1 J/cm ²	1.2 J/cm ²
10 mm	0.1 J/cm ²	0.5 cm ²	N/A	N/A	0.1 J/cm ²	1.0 J/cm ²

USER INTERFACE



Wavelength can be adjusted to either 532 nm, 670 nm or 1064 nm. Select the tab corresponding to intended treatment wavelength.

Fluence is the energy density, measured in J/cm². Press the +/- buttons to adjust. The following chart lists the minimum and maximum fluence allowed for each spot size. If the desired fluence setting is unavailable, it is recommended to change the spot size until the desired fluence setting is available.

Repetition (Rep) Rate is the number of pulses delivered per second, measured in Hz, with foot pedal depressed. Press the +/- buttons to adjust.

- Available repetition rates are: Single Shot (---) to 5 Hz for 670 nm wavelength
- Available repetition rates are: Single Shot (---) to 10 Hz for 532 nm & 1064 nm wavelength

Spot Size is the diameter of the beam at the skin. Press the +/- buttons to adjust.

- Available spot sizes are: 2, 2.5, 3, 3.5, 4, 5, 6 mm for 670 nm wavelength
- Available spot sizes are: 2, 2.5, 3, 3.5, 4, 5, 6, 8, 9, 10 mm for 532 nm & 1064 nm wavelength

Pulse Width/Duration is the length of each pulse. Press white button to change.

- Pulse width/duration is set at 660 ps (picoseconds) for the 670 nm wavelength.
- Pulse width/duration available can be adjusted to either 750 ps (picoseconds) or 2 ns (nanoseconds) for the 532 nm & 1064nm wavelength.

Shot Counter is the number of pulses fired. Press the reset button to reset to 0.

Standby Button icon is selected to go into Standby Mode. The system cannot fire when in Standby Mode. The bottom of user interface is blue and “Standby” is displayed when in Standby Mode.

Memory Buttons saves 3 different settings per wavelength for common indications. Press and hold memory button M1, M2 or M3 for more than three seconds to program new settings.

Ready Button icon is selected to go into Ready Mode to allow treatment. Press the foot pedal to start delivering treatment pulses. The bottom of user interface is yellow and “Ready” is displayed when in Ready Mode. The system will automatically go into Standby Mode after 3 minutes of inactivity.

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.

TATTOO REMOVAL



Photo Courtesy of CUTERA CRC

SELECTING TREATMENT PARAMETERS FOR TATTOO REMOVAL

The following parameters are provided as a guide only and are based upon clinical study data and published peer-reviewed literature used in development of clinical protocols for clinical studies for this device.

Wavelength is measured in nanometers (nm).

- The 1064 nm wavelength is typically used for dark colored tattoo inks and for initial treatments of multicolored tattoos containing dark colored tattoo inks.
- The 670 nm wavelength is typically used for lighter colored tattoo inks, including blue, green and purple inks, in the absence of darker colored inks, or for following sessions when darker inks have been removed from the tattoo.
- The 532 nm wavelength is typically used for lighter colored tattoo inks, including red and yellow inks, in the absence of darker colored inks, or for following sessions when darker inks have been removed from the tattoo.

Fluence is the energy density, measured in J/cm².

- Selection is based on tattoo response.
- The appropriate setting is often the lowest fluence for which correct clinical endpoint is observed.
 - For subsequent treatments, higher fluence settings may be required.

Pulse Width/Duration is the length of each pulse. Selection is based on tattoo characteristics, treatment sequence, tattoo response, and patient skin type.

- Dark, dense areas of a patient's tattoo, including heavy line work, are often more responsive to 2 ns pulse duration treatment.
- Lighter tattoo areas, including areas of diffuse shading, are typically more responsive to 750 ps pulse duration treatment.
- As treated tattoos lighten over a series of sessions and become less responsive to 2 ns pulse duration exposures, 750 ps pulse duration treatments become more appropriate.
- If using the 670nm wavelength, only the 660 ps pulse duration is available.

Spot Size

- Larger spot sizes typically allow faster and more uniform treatment and potentially allow clearing of tattoo ink residing deeper in the skin.
- Smaller spot sizes allow the selection of higher treatment fluence.
- The spot size should be chosen based on an assessment of the patient's tattoo size, shape, line work, expected ink depth, and anticipated range of treatment fluence required.
 - Larger spot sizes are recommended for initial tattoo treatments.
 - Smaller spot sizes are recommended for subsequent treatments if higher fluence settings are required.

Test Spots and Selecting Treatment Fluence

- Perform and observe test spots prior to every treatment before treating larger tattoo areas.
 - Start with conservative settings, and observe laser-tissue interaction and clinical endpoints to determine appropriate settings for each tattoo.
 - Settings from previous sessions should be used as a guide for subsequent sessions.
 - Deliver single pulses and assess clinical endpoint and possible paradoxical darkening.

- Optimal treatment settings are often the lowest settings for which brisk frosting of the treatment spot is observed.
- Lower settings are recommended for initial treatments.
- For later treatments, as the density of tattoo ink diminishes, higher settings and shorter pulse durations may be required to achieve the desired clinical endpoint.
- 1 Hz repetition rate is recommended.
- Treatment ranges are wide due to significant variations in patient and tattoo response.
- CAUTION: Sun exposed areas have a higher risk of adverse events.

TATTOO REMOVAL TREATMENT GUIDELINES

The following parameters are provided as a guide only. Start at the low fluence values or prior session values and observe laser-tissue interaction and clinical endpoints to determine appropriate settings. Adjust settings based on tissue response.

Treat with largest possible spot size and lowest fluence first. If no endpoint reached, increase the fluence. You may need to use a smaller spot size to achieve higher fluences.

High Density Dark Ink Black or Blue Ink					
Skin Type	Tattoo Characteristics	Wavelength	Pulse Duration	Spot Size	Fluence
Skin Type I-III	Initial treatments or non-treated tattoos	1064 nm	2 ns	10 to 8 mm	0.8 – 1.2 J/cm ²
Skin Type I-III	Initial treatments or non-treated tattoos <i>if no clinical endpoint with larger spot sizes</i>	1064 nm	2 ns	7 to 5 mm	0.8 – 2.0 J/cm ²
Skin Type I-III	Subsequent treatments or previously treated tattoos	1064 nm	2 ns or 750 ps	5 to 4 mm	1.5 – 3.2 J/cm ²
Skin Type IV-VI	Initial treatments or non-treated tattoos	1064 nm	2 ns	10 to 8 mm	0.8 – 1.0 J/cm ²
Skin Type IV-VI	Initial treatments or non-treated tattoos <i>if no clinical endpoint with larger spot sizes</i>	1064 nm	2 ns	7 to 5 mm	0.8 – 1.8 J/cm ²
Skin Type IV-VI	Subsequent treatments or previously treated tattoos	1064 nm	2 ns or 750 ps	5 to 4 mm	1.5 – 2.8 J/cm ²

The following parameters are provided as a guide only. Start at the low fluence values or prior session values and observe laser-tissue interaction and clinical endpoints to determine appropriate settings. Adjust settings based on tissue response.

Treat with largest possible spot size and lowest fluence first. If no endpoint reached, increase the fluence. You may need to use a smaller spot size to achieve higher fluences.

Low Density Dark Ink Black or Blue Ink					
Skin Type	Tattoo Characteristics	Wavelength	Pulse Duration	Spot Size	Fluence
Skin Type I-III	Initial treatments or non-treated tattoos	1064 nm	2 ns or 750 ps	10 to 8 mm	1.0 – 1.6 J/cm ²
Skin Type I-III	Initial treatments or non-treated tattoos <i>if no clinical endpoint with larger spot sizes</i>	1064 nm	2 ns or 750 ps	7 to 5 mm	1.4 – 3.8 J/cm ²
Skin Type I-III	Subsequent treatments or previously treated tattoos	1064 nm	750 ps or 2 ns	5 to 4 mm	2.0 – 4.6 J/cm ²
Skin Type IV-VI	Initial treatments or non-treated tattoos	1064 nm	2 ns or 750 ps	10 to 8 mm	1.0 – 1.5 J/cm ²
Skin Type IV-VI	Initial treatments or non-treated tattoos <i>if no clinical endpoint with larger spot sizes</i>	1064 nm	2 ns or 750 ps	7 to 5 mm	1.4 – 2.8 J/cm ²
Skin Type IV-VI	Subsequent treatments or previously treated tattoos	1064 nm	750 ps or 2 ns	5 to 4 mm	2.0 – 3.8 J/cm ²

The following parameters are provided as a guide only. Start at the low fluence values or prior session values and observe laser-tissue interaction and clinical endpoints to determine appropriate settings. Adjust settings based on tissue response.

Treat with largest possible spot size and lowest fluence first. If no endpoint reached, increase the fluence. You may need to use a smaller spot size to achieve higher fluences.

Light Ink Blue, Green, Purple, Ink					
Skin Type	Tattoo Characteristics	Wavelength	Pulse Duration	Spot Size	Fluence
Skin Types II-IV	Initial treatments or non-treated tattoos	670 nm	660 ps	5 to 4 mm	0.5 – 0.9 J/cm ²
Skin Types II-IV	Subsequent treatments or previously treated tattoos	670 nm	660 ps	5 to 3 mm	0.7 – 1.8 J/cm ²
Skin Type IV-VI	Initial treatments or non-treated tattoos	1064 nm	2 ns	10 to 8 mm	1.0 – 1.8 J/cm ²
Skin Type IV-VI	Initial treatments or non-treated tattoos <i>if no clinical endpoint with larger spot sizes</i>	1064 nm	2 ns or 750 ps	7 to 5 mm	1.4 – 3.4 J/cm ²
Skin Type IV-VI	Subsequent treatments or previously treated tattoos	1064 nm	2 ns or 750 ps	5 to 4 mm	2.0 – 4.0 J/cm ²

The following parameters are provided as a guide only. Start at the low fluence values or prior session values and observe laser-tissue interaction and clinical endpoints to determine appropriate settings. Adjust settings based on tissue response.

Treat with largest possible spot size and lowest fluence first. If no endpoint reached, increase the fluence. You may need to use a smaller spot size to achieve higher fluences.

Red, Yellow Ink					
Skin Type	Tattoo Characteristics	Wavelength	Pulse Duration	Spot Size	Fluence
Skin Types I-III	Initial treatments or non-treated tattoos	532 nm	2 ns	5 to 4 mm	0.5 – 0.8 J/cm ²
Skin Types I-III	Subsequent treatments or previously treated tattoos	532 nm	2ns or 750 ps	4 to 3 mm	0.7 – 1.6 J/cm ²
Skin Type IV-VI	Initial treatments or non-treated tattoos	1064 nm	2 ns	10 to 8 mm	1.0 – 1.8 J/cm ²
Skin Type IV-VI	Initial treatments or non-treated tattoos <i>if no clinical endpoint with larger spot sizes</i>	1064 nm	2ns or 750 ps	7 to 5 mm	1.4 – 3.4 J/cm ²
Skin Type IV-VI	Subsequent treatments or previously treated tattoos	1064 nm	2 ns or 750 ps	5 to 4 mm	2.0 – 4.0 J/cm ²

TREATMENT SETTINGS

Wavelength

- Use parameter guide to determine appropriate wavelength.
- For multi-color tattoos (except red, orange or yellow tattoos) treat entire area with the 1064 nm wavelength first.
 - If within 10 minutes, frosting fades or other colors are present, follow with either 532 nm or 670 nm depending on the color of any remaining ink.
 - If only dark ink is present or frosting does not fade within 10 minutes, do not treat with any other wavelength.

Spot Size

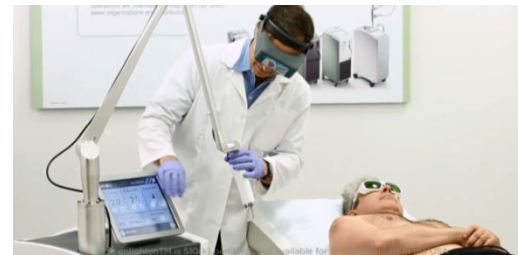
- Always use the largest spot size for which the desired fluence is available.
- Initial treatments – Start with a larger spot size and conservative fluence and increase fluence until the desired clinical endpoint is reached. You may have to decrease the spot size to achieve a higher fluence.
- Subsequent treatments – Reduce the spot size only if the desired clinical endpoint cannot be reached with the fluence settings available for the larger spot.

Pulse Width/Duration (532nm & 1064 nm wavelength treatments)

- 2 ns is recommended for initial treatments of high density tattoo ink.
- 750 ps is recommended for low density tattoo ink and for later treatments when tattoos become less responsive to 2 ns treatment.

PREPARING THE PATIENT FOR TATTOO TREATMENT

- Patient should not suntan or use self-tanners for at least 4 weeks prior to treatment.
- Patient should avoid treatments that may irritate the skin (depilatories, harsh chemicals, etc.) for 1-2 weeks prior to 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 or local infiltration of anesthetic may be used for management of treatment discomfort.
- Ensure that ALL people in the treatment room are wearing safety eyewear.
 - Use eyewear appropriate for the *enlighten* laser system.



PRIOR TO TREATMENT

- While the system is off or in Standby Mode, inspect the handpiece lens and standoff to ensure the lens and metal standoffs are free of debris.
 - If needed, clean the handpiece lens or metal standoffs.
 - Instructions are provided in the enlighten Operator Manual for cleaning the handpiece lens.
 - Metal standoffs can be cleaned with a germicidal wipe.



Inspect the handpiece prior to and during treatment

PATIENT COMFORT

- Treatment discomfort with enlighten is similar to treatment discomfort with traditional q-switched devices.
 - When treating smaller areas and/or using lower repetition rates, cold packs alone or combined with external cooling devices (such as Zimmer) can provide sufficient pain control for most patients.
 - When treating larger areas and/or using higher repetition rates, topical anesthetic or local infiltration may be required for some patients.
 - Topical anesthetic - Extended occlusion times are required to allow anesthetic penetration into the dermis to the depths where the tattoo ink resides.
 - Local infiltration - Anesthetics with epinephrine are preferred, as the resulting blanching may reduce energy absorption by oxyhemoglobin as a competing chromophore, improving efficacy and decreasing bleeding and purpura.
 - **CAUTION** - Toxicity may result from overuse. Consult the product labeling for any anesthetic used.

PERFORMING THE TREATMENT

- Precool treatment area with ice pack for ~1 minute (cooling devices, such as a Zimmer, may not provide sufficient pre-cooling).
- Select Ready Mode and position the handpiece over the treatment area, targeting the tattoo with the aiming beam.
- The metal standoffs must be in light but full contact with skin during each pulse to ensure a uniform beam profile and an accurate treatment spot size.
 - If using the handpiece with one or more standoffs removed, ensure the handpiece is both perpendicular to skin and at the correct treatment distance, particularly when treating rounded/bony areas.
 - **CAUTION** - Never pull handpiece away from the skin during treatment as this may result in excessive treatment and an adverse event.
- Ensure that the aiming beam is in sharp focus and is the correct size for the selected spot size.
- Depress the foot pedal to fire a pulse, then glide handpiece standoffs to next treatment area and repeat.
 - If using a repetition rate, keep foot pedal depressed as the laser fires each pulse. Ensure that handpiece standoffs have complete contact with skin during each pulse.
- Treat with up to 20% overlap.
- Do not stack pulses (“double-pulse”) or retreat an area until frosting resolves. Start with conservative settings, and observe laser-tissue interaction and clinical endpoints to determine appropriate settings for each tattoo.
 - Settings from previous sessions should be used as a guide for subsequent sessions.
 - Optimal treatment settings are often the lowest settings for which brisk frosting of the treatment spot is observed.
 - Darker skin is more safely treated with lower fluence, longer wavelength, and longer pulse duration.
- Assess clinical endpoint and possible paradoxical darkening.
- If more tissue effect is desired, increase the fluence in small increments until the desired tissue effect is observed.
 - 532 nm – Adjust 0.1 J/cm² at a time, while watching tissue response.
 - 1064 nm – Adjust by 0.2 J/cm² at a time, while watching tissue response.
- Watch for signs of damage, such as severe petechiae or plasma formation.
 - Plasma formation may appear as a flash observed within the skin during the laser pulse and loud audible snapping during the pulse.
 - If tissue damage is observed, stop the treatment, apply a cool compress, and evaluate area for possible complications and wound care.
- If treating inner lip tattoo
 - Place a gauze between teeth and lip.
 - Pull out the lip while treating to ensure correct handpiece placement.
 - Endpoint/frosting may be less noticeable.
- Do not treat near the eye.
 - Always treat outside the orbital rim of the eye, aiming the beam away from the orbit
 - Keep laser pulses at least 1 cm from the orbital rim.
 - Always use patient eye protection.



Ensure the handpiece remains in perpendicular contact with the skin

Photo Courtesy of Cutera Research Clinic



Initial Treatment Endpoint Example

Photo Courtesy of Dr. Michael Kaminer



Subsequent Treatment Endpoint Example

- The primary endpoint is a brisk frosting of the tattoo in response to a single laser exposure.
 - For later treatment sessions where brisk frosting is not observed, an immediate change in the hue or intensity of the tattoo at depth with each treatment pulse is a suitable treatment endpoint.
 - Erythema, edema and petechiae may develop up to 15 minutes after treatment.
- Typical treatment interval is 6-8 weeks.
 - Do not retreat until the skin is fully healed from the prior treatment session.
 - For later treatments, lengthening the time in between treatments may improve treatment response by allowing time for fragmented ink to re-aggregate.
 - Spacing treatments farther apart may decrease the total number of treatments required, but may also increase the calendar time until final clearing is achieved.

ADDITIONAL INFORMATION FOR TATTOO TREATMENTS

- The total number of treatments required varies based on ink density, ink color, professional/amateur, body location, efficiency of the patient's lymphatic system, etc.
 - Some low-density older or faded tattoos may clear in as few as two to three sessions.
 - Newer, dark, high-density tattoos may require more sessions.
 - Not all tattoos will fully clear.
 - Tattoos located on limbs and extremities will take more sessions based on distance from the heart.
- If treating tattoo ink in scar tissue (including scarring associated with the tattoo placement), higher fluences and more sessions may be required.
- Tattoos can be retreated in the same treatment session, but only after frosting has resolved.
 - If no endpoint or very limited endpoint is observed, immediate retreatment can be performed with the same wavelength at a higher fluence or with a shorter pulse duration.
 - After treating a dark color tattoo with the 1064nm wavelength, lighter color areas of tattoo can be treated with the 532 nm or 670 nm wavelength.

IMMEDIATELY POST-TREATMENT

- Post-cool the treatment area with an ice pack for increased patient comfort.
- Dress the area with Aquafor® or simple petroleum and cover with a bandage.
- Instruct the patient on proper post-treatment care.
- Advise the patient to:
 - Avoid sun exposure for 2 to 4 weeks following treatment, and use a broad spectrum (UVA/UVB) sunscreen.
 - Avoid skin irritants (products containing tretinoin, retinol, benzoyl peroxide, glycolic/salicylic acids, astringents, etc.) until the skin is fully healed and all crusting has resolved.

PATIENT POST-TREATMENT CARE INSTRUCTIONS

- Dressing should be changed once a day or after a shower in the first three days of treatment.
- Prior to removing the dressing, wash hands with soap and water.
- Carefully remove the dressing, gently cleanse the area with soap and water, and pat dry with a clean towel.

- Apply Aquafor® or simple petroleum and cover with a large bandage or non-stick gauze dressing, ensure the bandage is not too tight.
- Some patients may require help of another person to reach treatment area on back.
- Try not to bump or stretch treated tattoo.
- Scabbing over the treatment area is expected and may last 7 to 14 days.
- Do not pick scabs, and avoid scrubbing the treated area when bathing.
- Do not unroof blisters if they occur. Advise patient to contact physician if blisters are uncomfortable.
- Only non-aspirin, over-the-counter pain drugs, such as acetaminophen, should be taken for discomfort after the laser treatment.
- Advise patient to contact office if any of the following occur:
 - Bleeding that soaks the dressing, or bleeding that happens after the first 24 hours
 - Increased redness or swelling
 - Uncomfortable blisters
 - Yellowish or greenish drainage
 - Persistent pain that last more than 24 hours
 - Fever

EXPECTED REACTIONS WHEN USING 532 NM WAVELENGTH ON RED TATTOO INK

- Raised fluid-filled blisters are an expected occurrence when treating with red or similar ink colors with the 532 nm wavelength.
 - The ink is released into the closed blister due to this "superficial" wavelength and eventually is reabsorbed in the tissue within 3-5 days.
 - The ink is then flushed out through the body's lymphatic system naturally.
 - Ask the patient not to "unroof" the blisters and keep applying Vaseline or equivalent ointment until the area crust over and sloughs off naturally.
- Crusting can last longer when treating red ink and look irritated on the epidermis until healed.

BENIGN PIGMENTED LESION TREATMENTS



Photo Courtesy of CUTERA CRC

SELECTING TREATMENT PARAMETERS FOR BENIGN PIGMENTED LESION TREATMENT

Benign Pigmented Lesion Single Spot Treatment can be used for the treatment of individual benign pigmented lesions.

The following parameters are provided as a guide only and are based upon clinical study data and published peer-reviewed literature used in development of clinical protocols for clinical studies for this device.

Wavelength is measured in nanometers (nm).

- The 532 nm and 670 nm wavelengths are recommended when treating lighter skin types.
- The 1064 nm wavelength is recommended for darker skin types.

Fluence is the energy, measured in J/cm².

- Selection is based on the shade of the lesion and lesion response.

Pulse Width/Duration is the length of each pulse.

- The 670 nm wavelength has a set pulse duration of 660 ps.
- The 532 nm and 1064 nm wavelengths have a selectable pulse duration of 750 ps or 2 ns.

Spot Size

- Larger spot sizes typically may allow faster and more uniform treatment, but may result in more exposure of normal skin between isolated lesions.
- Smaller spot sizes allow targeting of smaller lesions without exposing uninvolved skin, and may allow the selection of higher treatment fluence.
- The spot size should be chosen based on an assessment of the lesion size and anticipated range of treatment fluence required.
- 3-5 mm spot size is generally preferred for isolated lesions.

Test Spots and Selecting Treatment Fluence

- Perform and observe test spots prior to every treatment.
 - Start with conservative settings, and observe laser-tissue interaction and clinical endpoints to determine appropriate settings.
 - Deliver single pulses and assess clinical endpoint.
 - Optimal treatment settings are often the lowest settings for which brisk frosting of the treatment spot is observed.
 - Treatment ranges are wide due to significant variations in patient and lesion response.
 - CAUTION: Sun exposed areas have a higher risk of adverse events.

BENIGN PIGMENTED LESION SINGLE SPOT TREATMENT GUIDELINES

Benign Pigmented Lesion Single Spot Treatment can be used for the treatment of individual benign pigmented lesions. 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.

Skin Type	Benign Pigmented Lesion Color	Wavelength	Pulse Width/Duration	Fluence
I-III	Dark	532 nm	750 ps	0.2 – 0.8 J/cm ²
I-III	Light	532 nm	750 ps	0.3 – 1.2 J/cm ²
IV	Dark	670 nm	660 ps	0.3 – 0.8 J/cm ²
IV	Light	670 nm	660 ps	0.4 – 1.4 J/cm ²
V-VI	Dark	1064 nm	750 ps	1.5 – 3.5 J/cm ²
V-VI	Light	1064 nm	750 ps	2.0 – 4.0 J/cm ²

CAUTION: *Patients with actinic bronzing and darker skin types are at higher risk for crusting and other adverse events.*

TREATMENT SETTINGS

- Spot size should be chosen based on the size of the lesion and fluence settings available for each spot size.
- Use the lowest fluence for which the desired clinical endpoint is achieved.
- If treating skin types V or VI, start at the lowest settings.

PREPARING THE PATIENT FOR BENIGN PIGMENTED LESION TREATMENT

- Patient should not sunbathe or use self-tanners for at least 4 weeks prior to treatment.
- Patient should avoid treatments that may irritate the skin (depilatories, harsh chemicals, etc.) for 1-2 weeks prior to 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.
- Benign pigmented lesion treatments are typically well tolerated. Topical anesthetic is optional and if used must be removed before treatment.
- Ensure that ALL people in the treatment room are wearing safety eyewear.
 - Use eyewear appropriate for the *enlighten* laser system.



PRIOR TO TREATMENT

- While the system is off or in Standby Mode, inspect the handpiece lens and standoff to ensure the lens and metal standoffs are free of debris.
 - If needed, clean the handpiece lens or metal standoffs.
 - Instructions are provided in the enlighten Operator Manual for cleaning the handpiece lens.
 - Metal standoffs can be cleaned with a germicidal wipe.



Inspect the handpiece prior to and during treatment

PERFORMING THE TREATMENT

- Select Ready mode and position the handpiece over the treatment area, targeting a lesion with the aiming beam.
- The metal standoffs must be in light but full contact with skin during each pulse to ensure a uniform beam profile and an accurate treatment spot size.
 - If using the handpiece with one or more standoffs removed, ensure the handpiece is both perpendicular to skin and at the correct treatment distance, particularly when treating rounded/bony areas.
 - **CAUTION** - Never pull handpiece away from the skin during treatment as this may result in excessive treatment and an adverse event.
- For the 523 nm and 1064 nm wavelengths, ensure that the aiming beam is in sharp focus and is the correct size for the selected spot size. For the 670 nm wavelength, the aiming beam is smaller than the treatment spot size and centered within the treatment spot. When treating with 670 nm, verify the displayed spot size is correct on the console, and in the first few pulses verify the frosting pattern is uniform and of the correct size for the selected spot size.
- Depress the foot pedal to fire a pulse, then glide handpiece standoffs to next treatment location and repeat.
- Treat with up to 20% overlap.
- Do not stack pulses (“double-pulse”), and do not retreat an area until frosting resolves.
- Start with conservative settings, and observe laser-tissue interaction and clinical endpoints to determine appropriate settings for each patient/lesion.
 - Optimal treatment settings are often the lowest settings for which mild frosting of the treatment spot is observed.
 - Darker skin is more safely treated with lower fluence, longer wavelength, and longer pulse duration.
- If more tissue effect is desired, increase the fluence in small increments until the desired tissue effect is observed.
 - 532 nm & 670 nm – Adjust 0.1 J/cm² at a time, while watching tissue response.
 - 1064 nm – Adjust 0.2 J/cm² at a time, while watching tissue response.
- Watch for signs of damage, such as severe petechiae or plasma formation.
 - Plasma formation may appear as a flash observed within the skin during the laser pulse.
 - If damage is observed, stop the treatment, apply a cool compress, and evaluate area for possible complications and wound care.
- Do not treat near the eye.
 - Always treat outside the orbital rim of the eye, aiming the beam away from the orbit.
 - Keep laser pulses at least 1 cm from the orbital rim.
 - Always use patient eye protection.
- It is recommended to treat only the lesion and not the surrounding skin.
- The primary endpoint for treatment is a mild frosting of the lesion in response to a single laser exposure.
 - Erythema, edema, and petechiae may develop up to 15 minutes after treatment.
- Typical treatment intervals are every 4-6 weeks, as necessary.



Ensure the handpiece remains in perpendicular contact with the skin



Endpoint Example

POST-TREATMENT CARE

- Post-cool the treatment area with an ice pack.
- Cold compresses or chilled gel packs may be applied post treatment.
- If a blister develops, treat as a wound.
- Bruising, redness, and swelling are common and resolve with time.
- Avoid direct sun exposure for 2 to 4 weeks, and use a broad spectrum (UVA/UVB) sunscreen.
- Treated pigment will turn darker (brown to black) within 24-48 hours.
 - Do not pick at treated areas.
 - Treated pigment will exfoliate off the face in approximately 1 week.
 - Treated pigment will exfoliate off the body in approximately 2-3 weeks.
- Avoid heat (hot tubs, saunas, etc.) for 1-2 days.
- Avoid skin irritants (products containing tretinoin, retinol, benzoyl peroxide, glycolic/salicylic acids, astringents, etc.) a few days post-treatment.

PICO GENESIS GLOBAL TREATMENT

The PICO Genesis global treatment technique can be used for Skin Revitalization (to make diffuse or mottled pigment more uniform) and for treatment of Melasma symptoms. 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.

Indication & Skin Type	Spot Size	Wavelength	Pulse Duration	Fluence	Repetition Rate	Number of Passes	Number of pulses
Melasma Skin Types I-VI	8 mm	1064 nm	750 ps	0.3 – 0.8 J/cm ²	5 – 10 Hz	2 +	N/A
Skin Revitalization Skin Types I-VI	8 mm	1064 nm	750 ps	0.5 – 1.0 J/cm ²	5 – 10 Hz	N/A	5,000 - 6,000

Endpoint

- If the desired clinical endpoint is not achieved, adjust the settings accordingly.
 - Melasma endpoint is mild erythema.
 - Skin Revitalization endpoint is mild to moderate erythema.

Treatment Precautions

- Reduce fluence when treating:
 - Actinic bronzing
 - 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 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.

Melasma Patient Selection

- Melasma patients should understand that the treatment is maintenance of the Melasma symptoms and is not a permanent treatment.
- Some practitioners prescribe a topical lightening cream to Melasma patients for a few weeks prior to, during and after enlighten Melasma treatment regimen.
- It is important to choose proper patients with Melasma to help ensure successful treatment outcome
 - Melasma that is stable and unchanging with the season
 - Discreet small areas of involvement [one or both partial cheeks, partial forehead, etc.]
 - Patients who are not currently undergoing hormonal treatment
 - Patients not recently post-partum
 - Patients not perimenopausal or recently started hormonal birth control

PREPARING THE PATIENT FOR SKIN REVITALIZATION & MELASMA TREATMENT

- Patient should not sun tan or use self-tanners for at least 4 weeks prior to treatment.
- Patient should avoid treatments that may irritate the skin (depilatories, harsh chemicals, etc.) for 1-2 weeks prior to 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.
- Anesthetic is not recommended as patient feedback is important.
- Ensure that ALL people in the treatment room are wearing safety eyewear.
 - Use eyewear appropriate for the *enlighten* laser system.

PRIOR TO TREATMENT

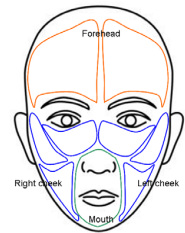
- While the system is off or in Standby Mode, inspect the handpiece lens and standoff to ensure the lens and metal standoffs are free of debris.
 - If needed, clean the handpiece lens or metal standoffs.
 - Instructions are provided in the enlighten Operator Manual for cleaning the handpiece lens.
 - Metal standoffs can be cleaned with a germicidal wipe.
- If the patient has a history of histamine flare responses, consider pretreating with antihistamines.



Inspect the handpiece prior to and during treatment

PERFORMING THE TREATMENT

- Select Ready mode and position the handpiece over the treatment area.
- Skin Revitalization Treatment Regions:
 - Divide the face into multiple regions (see example on right).
 - Divide the forehead in half.
 - Divide the cheeks into 2-3 sections.
 - Do NOT treat upper lids.
 - The vermillion border may be treated but ensure that it is completely clean of lipstick and that there is no tattoo or permanent makeup in the area.
 - Place moist gauze between lips and teeth to protect enamel.
- Melasma Treatment Regions:
 - All pigmented areas of concern must be treated.
- If treating both Melasma and Skin Revitalization:
 - Treat the Melasma regions first to the proper clinical endpoint.
 - Next treat the skin revitalization areas (taking care to NOT retreat Melasma region) to the proper clinical endpoint.
- The metal standoffs should be in light but even contact with skin during treatment to ensure a uniform beam profile and an accurate treatment spot size.
 - If holding the standoffs off the skin, hold as close to the skin without touching ensuring that the treatment beam is the correct size.
 - If using the handpiece with one or more standoffs removed, ensure the handpiece is both perpendicular to skin and at the correct treatment distance, particularly when treating rounded/bony areas.
 - **CAUTION** - Never pull handpiece away from the skin during treatment as this may result in excessive treatment and an adverse event.
- Ensure that the aiming beam is in sharp focus and is the correct size for the selected spot size.
- Keep foot pedal depressed as the laser fires each pulse.
- Move the handpiece over the treatment area in a slow and controlled back and forth painting motion until endpoint is seen or number of passes or pulses has been achieved.
 - The handpiece should be continuously moved in a zig-zag motion with even distribution of pulses.
 - Treat in a basket weave pattern, horizontally, then vertically.
 - Do not wave the handpiece around in a sloppy fashion.
- Start with conservative settings, and observe laser-tissue interaction and clinical endpoints to determine appropriate settings for each patient.
- Darker skin is more safely treated with lower fluence.



Divide face into multiple regions as shown for Skin Revitalization treatments.



Ensure the handpiece remains perpendicular with the skin and remains in contact with the skin or as close to the skin as possible.

- If more tissue effect is desired, increase the fluence in small increments until the desired tissue effect is observed.
 - Higher fluence may be more uncomfortable for patients.
- Watch for signs of damage, such as severe petechiae or plasma formation.
 - Plasma formation may appear as a flash observed within the skin during the laser pulse.
 - If damage is observed, stop the treatment, apply a cool compress, and evaluate area for possible complications and wound care.

TREATMENT INTERVALS

- Skin Revitalization:
 - Typical treatment intervals are every 4-6 weeks, as necessary.
 - Higher Skin Revitalization fluence may require fewer treatments.
- Melasma:
 - Typically requires 4+ treatments.
 - Typical treatment intervals are every 4+ weeks.
 - Can also be provided as single maintenance treatment as necessary.

POST-TREATMENT CARE

- If a blister develops, treat as a wound.
- Skin Revitalization / PICO genesis - Bruising, redness, and swelling can occur and resolve with time.
- If patient displays an urticaric response to treatment (localized rash with or without redness and/or itching), an antihistamine can be administered and/or hydrocortisone can be applied. Symptoms should resolve within a few days.
- Avoid direct sun exposure for 2 to 4 weeks, 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.) a few days post-treatment.

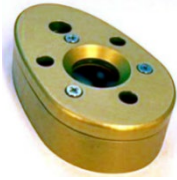
Combination Treatment

Benign Pigmented Lesion + PICO Genesis



- Benign Pigmented Lesion (BPL) Single-Spot Treatment (532 nm / 670 nm / 1064 nm) can be combined with the PICO Genesis Global Treatment technique (1064 nm)
 - Treat individual benign pigmented lesions first with Benign Pigmented Lesion Single Spot Treatment with the 532 nm, 670 nm or 1064 nm using the treatment protocol provided in this document.
 - Follow the individual Benign Pigmented Lesion Single Spot Treatment with a PICO Genesis Global Treatment for Skin Revitalization following the treatment protocol provided in this document.

PICO Genesis FX (MLA Attachment)



The PICO Genesis FX treatment requires the use of the Micro Lens Array (MLA), a reusable, all-in-one, multi-wavelength, fractionating handpiece attachment for Cutera enlighten laser systems. The MLA fits on the enlighten handpiece for convenient attachment and removal. See the enlighten Operator Manual for complete instructions on attachment, removal and cleaning of the MLA.

PICO GENESIS FX TREATMENT GUIDELINES

PICO Genesis FX treatment can be used for the treatment of acne scars and wrinkles when used with the Micro Lens Array handpiece attachment. The following parameters are provided as a guide only and are based on practitioner feedback. More aggressive treatments should be used for deeper targets with anticipation of longer downtime. Start at the lowest fluence and observe laser-tissue interaction and clinical endpoints to determine appropriate settings.

Less Aggressive Lesion Treatment (Face, Neck or Body)							
Skin Type	Spot Size	Wavelength	Pulse Duration	Fluence	Repetition Rate	Number of Passes	Endpoints
I – III	6-8 mm	532	750 ps	0.2 – 0.5 J/cm ²	0 Hz	2 Treat ONLY the lesion	Very Mild erythema
I – III	6-8 mm	1064	750 ps	0.5 – 1.0 J/cm ²	0 - 5 Hz	2 - 3	Mild erythema
IV – V	6-8 mm	1064	750 ps	0.3 – 0.5 J/cm ²	0 - 5 Hz	2	Mild erythema
More Aggressive Treatment (Including Acne Scars and Wrinkles)							
Skin Type	Spot Size	Wavelength	Pulse Duration	Fluence	Repetition Rate	Number of Passes	Endpoints
II-III Face	8 mm	1064 nm	750 ps	0.7 – 1.0 J/cm ²	5 – 10 Hz	Up to 5 passes	Mild to Moderate erythema
II-III Neck	8 mm	1064 nm	750 ps	0.7 – 0.8 J/cm ²	5 Hz	Up to 3 passes	Mild to Moderate erythema
IV Face	8 mm	1064 nm	750 ps	0.5 – 0.8 J/cm ²	5 – 10 Hz	Up to 4 passes	Mild erythema
IV Neck	8 mm	1064 nm	750 ps	0.5 – 0.7 J/cm ²	5 Hz	Up to 2 passes	Mild erythema
V Face	8 mm	1064 nm	750 ps	0.3 – 0.5 J/cm ²	5 – 10 Hz	Up to 3 passes	Very Mild erythema
V Neck	8 mm	1064 nm	750 ps	0.3 – 0.4 J/cm ²	5 Hz	Up to 2 passes	Very Mild erythema

Combining PICO Genesis & PICO Genesis FX

- Acne Scars & Skin Texture/Wrinkles
 - Skin Types I-IV: If combining PICO Genesis and PICO Genesis FX, first treat with PICO Genesis to regular endpoint. Then follow with PICO Genesis FX on areas of concern with ONLY 1 – 2 passes.
 - Skin Type V – do not combine PICO Genesis with PICO Genesis FX on same treatment.

Treatment Precautions

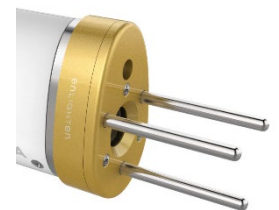
- Reduce fluence when treating:
 - Actinic bronzing
 - Darker skin types
 - Over bony areas
- Extreme caution should be used when treating near the eye.
 - Always treat outside the orbital rim of the eye aiming the beam away from the orbit.
 - Patient eye protection is required to avoid ocular damage.
 - 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.
- The vermillion border may be treated, but ensure that it is completely clean of lipstick and that there is no tattoo or permanent makeup in the area.
 - Place moist gauze between lips and teeth to protect enamel.
- Do not treat over 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.

PREPARING THE PATIENT FOR TREATMENT

- If desired, topical anesthetic can be used for PICO Genesis Fx patients.
 - CAUTION - Toxicity may result from overuse. Consult the product labeling for any anesthetic used.
 - Completely remove topical anesthetic prior to treatment.
- Patient should not sun tan or use self-tanners for at least 4 weeks prior to treatment.
- Patient should avoid treatments that may irritate the skin (depilatories, harsh chemicals, etc.) for 1-2 weeks prior to 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.
- If the patient has a history of histamine flare responses, consider pretreating with antihistamines.
- Ensure that ALL people in the treatment room are wearing safety eyewear.
 - Use eyewear appropriate for the *enlighten* laser system.

PRIOR TO TREATMENT

- While the system is off or in Standby Mode, inspect the handpiece lens and standoff(s) to ensure they are free of debris.
 - If needed, clean the handpiece lens or metal standoffs.
 - Instructions are provided in the enlighten Operator Manual for cleaning the handpiece lens.
 - Metal standoffs can be cleaned with a germicidal wipe.
 - See operator manual for complete instructions on attachment, removal and cleaning of the MLA
- Refer to the Enlighten Operator Manual for instructions on attaching MLA (Micro Lens Array) to the enlighten handpiece.
 - Ensure that the spot size is set to 6-8mm prior to attaching the MLA to the enlighten handpiece.



Inspect the handpiece and MLA prior to and during treatment

PERFORMING THE TREATMENT

- Select Ready mode and position the handpiece over the treatment area.
- The metal standoffs should be in light but even contact with skin during treatment to ensure a uniform beam profile and an accurate treatment spot size.
 - If holding the standoffs off the skin, hold as close to the skin without touching ensuring that the treatment beam is the correct size.
 - If using the handpiece with one or more standoffs removed, ensure the handpiece is both perpendicular to skin and at the correct treatment distance, particularly when treating rounded/bony areas.
 - **CAUTION** - Never pull handpiece away from the skin during treatment as this may result in excessive treatment and an adverse event.
- Ensure that the aiming beam is in sharp focus and is the correct size for the selected spot size.
- Keep foot pedal depressed as the laser fires each pulse.
- Move the handpiece over the treatment area in a slow and controlled back and forth painting motion until endpoint is seen or number of passes has been achieved.
 - The handpiece should be continuously moved in a zig-zag motion with even distribution of pulses.
 - Treat in a basket weave pattern, horizontally, then vertically.
 - Do not wave the handpiece around in a sloppy fashion.
 - Treat entire face with one pass before treating with next pass.
 - Alternate passes with vertical passes and then horizontal passes.
- Start with conservative settings, and observe laser-tissue interaction and clinical endpoints to determine appropriate settings for each patient.
- Darker skin is more safely treated with lower fluence.
- If more tissue effect is desired, increase the fluence in small increments until the desired tissue effect is observed.
 - Higher fluence may be more uncomfortable for patients.
- Watch for signs of damage, such as severe petechiae or plasma formation.
 - Plasma formation may appear as a flash observed within the skin during the laser pulse.
 - If severe petechiae or tissue damage is observed, stop the treatment, apply a cool compress, and evaluate area for possible complications and wound care.
- Treatment Interval:
 - Typical treatment intervals are every 4 weeks, as necessary.
 - Higher fluence may require less treatments.



EXPECTED EVENTS

- When applying multiple passes at higher fluences, mild to moderate petechiae, edema and erythema is a common and expected reaction.
- Erythema can take up to 3-5 days to resolve.
- Petechiae and swelling can take 3-5 days to resolve.
- Mild to moderate itching in the treatment area can occur post treatment and last up to 5 days. Advise patient not to scratch treatment area.
- More aggressive treatments typically have longer downtime.

POST-TREATMENT CARE

- If a blister develops, treat as a wound.
- Mild petechiae, redness, and swelling are common and expected
- Erythema typically takes up to 3 days to resolve.
- Petechiae and swelling typically take 3-5 days to resolve.
- If patient displays an urticaric response to treatment (localized rash with or without redness and/or itching), an antihistamine can be administered and/or topical hydrocortisone can be applied. Symptoms should resolve within a few days.
- Avoid direct sun exposure for 2 to 4 weeks, 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.) a few days post-treatment.

SKIN TYPE CLASSIFICATION QUESTIONNAIRE

SKIN TYPE	SKIN CHARACTERISTICS	SKIN COLOR
I	Burns easily, never tans	Ivory white
II	Burns easily, tans minimally with difficulty	White
III	Burns moderately, tans moderately and uniformly	White
IV	Burns minimally, tans moderately and easily	Beige-olive, lightly tanned
V	Rarely burns, tans profusely	Moderate brown or tanned
VI	Never burns, tans profusely	Dark brown or black

¹Sachdeva S. Fitzpatrick skin typing: Applications in dermatology. Indian J Dermatol Venereol Leprol 2009;75:93-6. doi:10.4103/0378-6323.45238

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 are 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.

Phone: +1-415-657-5500

Email: ClinicalSupport@Cutera.com

TECHNICAL SERVICE & SYSTEM CARE

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

Technical Service Toll-Free US/Canada: 866-258-8763

Technical Service Worldwide: +1-415-657-5500

Technical Service Email: Service@cutera.com