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Chapter 1

Introduction

About the Guide

The purpose of the *PicoSure Clinical Reference Guide* is to provide a summary of treatments and techniques when using the PicoSure laser system. The clinical suggestions contained within this guide are based on current clinical use. However, they do not substitute for the clinical judgment of the practitioner and the individual patient’s needs.

Please refer to *PicoSure Operator Manual*, P/N 850-7012-000, for instructions on operating the PicoSure laser. Operators of the PicoSure laser should read the operator manual before using the laser system.

About the Laser

The PicoSure laser delivers energy in the 755-nm and 532-nm regions of the electromagnetic spectrum.

![Electromagnetic Spectrum](image)

*Figure 1–Electromagnetic Spectrum*
About the Technology

PicoSure technology combines a dual approach when treating: a modest photothermal process and a strong photomechanical impact based on ultra-short pulse duration. This combination of photothermolysis and intense photomechanical impact, known as PressureWave™, breaks up the intended target, e.g., ink or pigment, into particles that are easily eliminated from the body.

Selective Photothermolysis

Selective photothermolysis refers to the precise targeting of a structure or tissue using a specific wavelength of light with the intention of absorbing light into that target area alone. The energy directed into the target area produces sufficient heat to damage the target while allowing the surrounding area to remain undamaged.

The curve representing laser wavelengths vs. absorption coefficient for each of the target chromophores is referred to as an absorption spectrum, as shown in Figure 2. Specific absorption criteria for the various target chromophores will be discussed in more detail below.

Photomechanical Impact

With its ultra-short pulse durations, laser pulses enable significant photomechanical stresses to targets. The system delivers very high peak powers so quickly that the target is disrupted. Optimum efficacy can be achieved for a laser pulse duration shorter than the acoustic transit time. Clinically useful efficacy is achieved for laser fluence and pulse duration that satisfy a Photomechanical index condition (PMi) >1.
Targeting Tattoos
The basis of laser treatment for the removal of tattoos is the destruction of ink particles by absorption of laser energy without damaging surrounding tissue. Tattoo ink particles may be located in dermal fibroblasts. These fibroblasts are predominantly in a perivascular location beneath a layer of fibrosis.

Targeting Pigmented Lesions
The basis of laser treatment for benign pigmented lesions is the destruction of abnormal amounts of melanin in the skin without damaging surrounding tissue.
In benign pigmented lesions, melanin is the chromophore that absorbs the intense laser energy causing the target to be destroyed. Melanin is present in the superficial layers of the skin, the dermis and the intra-epidermal layer.

Wavelength
When considering a wavelength to treat benign pigmented lesions, a wavelength that is well absorbed by melanin is desirable.

The absorption curve for melanin absorbs broadly across the electromagnetic spectrum with a gradual drop through the visible to the near-infrared spectra. Melanocytes can be destroyed at a wavelength of 755 nm. The longer wavelength of the PicoSure alexandrite at 755 nm is more effective than shorter wavelengths in causing fragmentation to melanin and melanocytes because of deeper dermal penetration. Although wavelengths in the 351–532-nm range may effectively treat epidermal pigmented lesions, they do not penetrate deep enough to reach dermal lesions. The PicoSure laser at 755 nm, however, will effectively treat both epidermal and dermal lesions.

Pulse Duration
The pulse duration or exposure time is critical because it must be less than the thermal relaxation time of the target.

Melanosomes have an estimated thermal relaxation time of 10-100 nanoseconds. Therefore, a short pulse of 750 picoseconds (0.75 nanoseconds) is ideal for selective treatment of benign pigmented lesions. When the pulse width is less than one microsecond, melanosome fragmentation is thought to occur from shock waves or cavitation and expansion.
Chapter 2  Clinical Application

This section of the guide discusses the clinical application of the PicoSure laser in general terms. The section covers contraindications, possible adverse effects and patient selection.

NOTE: For the reader’s convenience the contraindications, warnings and precautions listed in the PicoSure Operator Manual have been reprinted in this guide.

Skin Types

Before treating with the PicoSure laser, consider skin type and pigmentation of the patient. Understanding the ethnicity of the patient can influence skin type and treatment consideration. Pigment in the skin may compete with the intended target for absorption of laser energy. The Fitzpatrick Scale is a generally accepted means of determining skin type. Tanned skin may also compete with the intended target and must be considered before treating.

Table 1 offers a broad guide to identify skin types based on hair, skin and eye color as well as sun reaction.

<table>
<thead>
<tr>
<th>Type</th>
<th>Hair Color</th>
<th>Skin Color</th>
<th>Eye Color</th>
<th>Sun Reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Red</td>
<td>White</td>
<td>Blue-green</td>
<td>Always burns, never tans</td>
</tr>
<tr>
<td>II</td>
<td>Blonde</td>
<td>White</td>
<td>Blue</td>
<td>Usually burn, tans with difficulty</td>
</tr>
<tr>
<td>III</td>
<td>Brown</td>
<td>White to Light Brown</td>
<td>Brown</td>
<td>Sometimes burns, average tanning</td>
</tr>
<tr>
<td>IV</td>
<td>Brown-black</td>
<td>Moderate Brown</td>
<td>Brown-black</td>
<td>Rarely burns, tans with ease</td>
</tr>
<tr>
<td>V</td>
<td>Black</td>
<td>Dark brown</td>
<td>Dark</td>
<td>Very rarely burns, tans very easily</td>
</tr>
<tr>
<td>VI</td>
<td>Black</td>
<td>Black</td>
<td>Dark</td>
<td>Never burns, tans very easily</td>
</tr>
</tbody>
</table>

1 The Fitzpatrick Skin Type Classification Scale Posted: October 24, 2007, from the November 2007 issue of Skin Inc. magazine.
Contraindications
Therapy using the PicoSure laser is contraindicated for those patients who:

- Are hypersensitive to light in the near infrared wavelength region
- Take medication which is known to increase sensitivity to sunlight
- Have seizure disorders triggered by light
- Take or have taken oral isotretinoin, such as Accutane®, within the last six months
- Have an active localized or systemic infection, or an open wound in area being treated
- Have a significant systemic illness such as lupus or an illness localized in area being treated
- Have common acquired nevi that are predisposed to the development of malignant melanoma
- Have herpes simplex in the area being treated
- Are receiving or have received gold therapy
- Are pregnant or breastfeeding (lactating)

Warnings/Precautions
Practitioner discretion is required to determine feasibility of treatment administration.

- Unprotected sun exposure within four weeks of treatment, including the use of tanning beds or self-tanning products, such as creams, lotions and sprays
- History of immunosuppression/immune deficiency or an auto-immune disorder
- Coagulation disorder or currently using anticoagulation medication, including heavy use of aspirin
- Medications that alter the wound-healing response or evidence of compromised wound healing
- If patient is known to have a history of keloid formation
- If patient has a history of skin cancer or suspicious lesions in the treatment area
- Patient with red ink tattoos who present with non-healed, itching, irritated, swollen or other suspect symptoms on or around the tattoo should be assessed for ink allergy and potentially excluded from treatment
Adverse Effects

Adverse effects can include discomfort, redness, swelling, pinpoint bleeding, blistering, scabbing, crusting and bruising, which are usually transient and resolve without intervention. Possible adverse effects include pustules, skin burns, hypopigmentation, hyperpigmentation, scarring, infection and allergic reaction. Most of these are transient and resolve over time.

Patient Consultation

Patient selection criteria are individuals presenting with unwanted benign pigmented lesions, acne scars, wrinkles and/or unwanted tattoos.

Determine Suitability

As with all medical procedures determining suitability, practitioners should consider the following factors for each individual case:

- Patient’s age
- Patient’s skin type
- Family history
- Current medications
- Reason patient is seeking treatment
- Patient’s expectations

Inform Patient About the Treatment

After determining suitability, the physician should inform the patient of the following:

- The expected outcome of the treatment versus other possible outcomes
- The probable number of treatments needed to achieve the desired outcome
- Possible side effects resulting from laser treatment
General Treatment Guidelines

The operator should determine the appropriate energy level of the laser, approximate number of treatment sessions, size of treatment area, and when no further treatment is warranted.

Minimizing Adverse Effects
Adverse effects may be reduced by air cooling prior to treatment, and removal of all make up, lotions or creams from the area to be treated.

Setting Energy Level
Energy levels used during treatment should be based on the patient’s skin type.
Administering test spots prior to treating and starting treatment at the lowest suggested energy setting is recommended.

Number and Intervals of Treatment Sessions
The number and interval of treatment sessions depends on the various factors including: size of the treatment area, the success rate of the treatment, and the patient’s tolerance of the treatment. For more specific guidance please refer to the tattoo section of this guide.

Determining End of Treatment
The practitioner should determine the end of treatment by the complete success of treatment, non-compliance on the part of the patient, or adverse effects of the treatment.
Pretreatment Procedures

Test Spots

Test spots are recommended prior to treating pigmented lesions and tattoos. The tissue response following the test spot and healing phase (approximately 6 weeks) will help determine the fluence parameters necessary to effectively treat the lesion.

Patients who present with freckles or other types of lentigines and tattoos are usually treated at the initial session using a safe energy range for that specific lesion.

Test spots should be administered in an inconspicuous location if possible. However, the test spot site should be in the same general area of the bulk of the lesion.

The test spots may be performed with different spot sizes that consist of single or multiple pulses. Multiple pulses should be delivered in a non-overlapping, but adjacent fashion.

When evaluating test spot sites, the spot size utilized to produce clearing should be used in subsequent treatments. Test sites that show evidence of hyperpigmentation may indicate stimulation of melanogenesis by the administration of sub-threshold fluences. This effect is more pronounced in skin that is not tanned. If desired, test spots may be tried once the hyperpigmentation fades.

If no tissue response is noted, test spots should be repeated with different spot sizes.

Documenting test sites either with photos or anatomic forms is helpful during the evaluation phase. Use anatomic forms to both clarify the location of the test sites, and to make note of the spot size and fluence used during treatment. Photos are very helpful in determining incremental fading between treatment sessions.

Photographs

Cynosure recommends taking photographs to document all procedures done using the PicoSure laser. This allows assessment of treatment efficacy and assists in development of a clinical plan for subsequent treatments of persistent lesions, as is often the case in tattoo treatment.

Skin Cleaning

Prior to actual treatment, remove all makeup, lotions, deodorant or oil from the area to be treated. Clean area to be treated thoroughly using a facial cleanser or mild soap and water, and alcohol to remove skin oils. Allow the skin to dry before treating.
Posttreatment Recommendations

After each treatment session, practitioners should advise their patients about the proper care of the treated area:

- Wash the treatment area gently with soap and water. Do not soak.
- Do not shave the treated area if crusting is evident.
- Avoid contact sports or any other activity that could cause injury to the treated area.
- Avoid sun exposure between treatments. If sun exposure is unavoidable, use a SPF 30+ sunblock to cover exposed, treated areas.

Practitioners should advise patients that failure to follow posttreatment instructions could increase the risk of adverse effects.

Patient Documentation Forms

Patient documentation is important to track the progression of any laser treatment. Samples of Consent Forms, Treatment Records and Pretreatment and Posttreatment Instructions are provided for your convenience in the “Documentation” section starting on page 33.

Informed Consent forms document the process of accepting and confirming treatment and must be reviewed, understood and signed by the patient prior to treatment. These forms must review the topics discussed during consultation and acknowledge that the patient understands the procedure and that all questions have been answered.

Always review the Pretreatment and Posttreatment Instructions and confirm that the patient will adhere to such instructions throughout their treatment course. Determine the need for medications or creams to be used pretreatment and/or throughout the treatment.

Treatment Records track treatment information throughout the treatment course, such as fluence, as well as number of pulses used.
First Tabbed Page--Century Gothic Font

Pigmented Lesions
Chapter 3  Treatment Guidelines—Lesions

Types of Treatable Lesions

Pigmented lesions can be treated with 755 nm and the zoom handpiece, or the fixed handpieces (6, 8 and 10 mm) both with and without the Focus™ lens array. For treatment information on pigmented lesions using the Focus Lens Array see section starting on page 15 of this clinical guide.

The following type of lesions may be treated with 755 nm: benign epidermal and dermal pigmented lesions, i.e., lentigines, ephelides, Nevus of Ito, Nevus of Ota, melasma and Café au Lait macules.

Treatment Guidelines—Lesions with Zoom Handpiece

- Each area should be treated only once with tight interlocking, but not overlapping pulses.
- The handpiece should be held as perpendicular to the skin as possible touching the surface of the skin with distance gauge lightly to optimize laser beam focus and energy delivery.
- Examine the handpiece optic between each treatment session with the laser turned off. Debris on the lens optic may cause a decrease in fluence. Refer to the PicoSure Operator Manual for complete instructions on cleaning the handpiece.
- The anticipated tissue response is an immediate slight whitening of the treatment area upon laser impact. Histologically, the tissue whitening represents vacuolization (gas bubble formation) of the pigmented cells throughout the epidermis primarily at the dermal-epidermal junction. The tissue whitening usually persists for several hours posttreatment. Other observable clinical endpoints include peri-lesional erythema and lesional edema.
- Most lesions can be treated without anesthesia. However, if the lesion is large, in a sensitive area, or the patient has a low pain threshold, consideration should be given to make the patient comfortable.
- Spot size used to treat a lesion should be determined before treatment through test spot sites. Fluences will vary according to spot size depending on the type of lesion and skin type treated.
- Most lentigines will clear in one or two sessions. The second session is usually a “touch up” visit to treat lesions or partial lesions that were not treated initially.
- Post-inflammatory hyperpigmentation and/or hypopigmentation may occur with any laser treatment. Typically both resolve spontaneously without intervention in 6-12 months.
- If pinpoint bleeding or epidermal exfoliation is noted during laser treatment, it is likely the fluence is too high.
Suggested Treatment Guidelines—Benign Pigmented Lesions

Suggested treatment parameters for treating lesions are based on information provided by practitioners using the PicoSure laser, published articles and results of clinical studies. Each patient is unique and should be evaluated prior to treatment for skin type. When in doubt about what parameters to use, it is recommended that a test spot be administered to determine the appropriate treatment parameters. Using lower energy settings for darker skin types may decrease the likelihood of side effects.

Tables 2 and 3 below are for guideline purposes only, and should not take the place of your professional knowledge and training.

### Table 2—Treatment Parameters, Pigmented Lesions, 755 nm
(For lesions, such as ephelides and solar and senile lentigines using Zoom/Fixed handpieces)

<table>
<thead>
<tr>
<th>Skin Type</th>
<th>Spot Size</th>
<th>Rep Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>I–III</td>
<td>3.0–3.5 mm</td>
<td>1–5 Hz</td>
</tr>
<tr>
<td>IV</td>
<td>4.0–6.0 mm</td>
<td>1–5 Hz</td>
</tr>
<tr>
<td>V–VI</td>
<td>6.0–10.0 mm*</td>
<td>1–5 Hz</td>
</tr>
</tbody>
</table>

*Larger spot sizes; fixed handpiece 6, 8 or 10 mm may be selected for darker skin types to decrease the likelihood of side effects.*

### Table 3—Treatment Parameters, Pigmented Lesions, 755 nm
(For Lesions, such as Nevus of Ito, Nevus of Ota, ABNOM/Hori’s nevus, or Café au Lait macules using Zoom handpiece)

<table>
<thead>
<tr>
<th>Skin Type</th>
<th>Spot Size</th>
<th>Rep Rate</th>
<th>Treatment interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>I–VI</td>
<td>2.5–4.0 mm</td>
<td>2.5 Hz</td>
<td>4 weeks</td>
</tr>
</tbody>
</table>

The parameters suggested above are the most commonly used. Fluence is dependent on spot size; the larger the spot the lower the fluence. Select a spot size according to the size of the lesion and the color, for darker lesions larger spot sizes can be used, for lighter lesions a smaller spot can be used.
Focus Lens Array
Wrinkles, pigment and acne scarring can be treated with the Focus™ Lens Array that attaches to the PicoSure 755-nm fixed handpieces. Fixed handpieces are available in 6 mm, 8 mm, and 10 mm spot sizes. Refer to the *PicoSure Operator Manual* for information on attaching the lens array. The following type of lesions may be treated: benign epidermal and dermal pigmented lesions, i.e., lentigines, ephelides, Nevus of Ito, Nevus of Ota, melasma and Café au Lait macules.
General Guidelines

- Divide larger treatment areas into quadrants. Then divide each quadrant into smaller areas, this allows laser energy to be distributed effectively and efficiently.
- Deliver passes, using a “feathering” (painting) technique in a multidirectional pattern.
- Use a 10-25% overlap for mild to moderate and up to a 50% overlap for severe acne scars and pigmentation.
- Hold the handpiece as perpendicular as possible to the treatment surface, lightly touching the surface of the skin. Doing so ensures optimal laser beam focus.
- A slight snapping sound will be heard during the treatment.
- Use of a skin cooling method is recommended during treatment, e.g., cold air, or a cold gel pack. Care must be taken to insure the cooling method does not interfere with the laser beam.
- Treat the area until you reach the desired clinical endpoints of overall mild to moderate erythema, light frosting or ashy/dusky coloration of unwanted pigmentation.
- Move on to the next area and continue this technique until the entire area of concern is treated.
- Examine the handpiece optic between each treatment session with the laser turned off. Debris on the lens may cause a decrease in fluence. Refer to the PicoSure Operator Manual for complete instructions on cleaning the handpiece.
- Most adults can be treated without anesthesia. However, if the area is large, in a sensitive area, or the patient has a low pain threshold, consideration should be given to make the patient comfortable.
Posttreatment Expectations

- Erythema typically resolves in less than an hour but in some cases may linger for 24 hours.
- Frosting usually fades in 30 minutes.
- Unwanted pigment will continue to darken and may turn 2-3 shades darker than original color and shed over time.
- Most unwanted pigment will significantly lighten or clear in 2-3 sessions.
- Hypopigmentation may occur when treating epidermal pigmented lesions. It is usually transient and resolves over a period of 4-6 months.
- Post-inflammatory hyperpigmentation and/or hypopigmentation may occur with any laser treatment. Typically both resolve spontaneously without intervention in 6-12 months.

Posttreatment Recommendations

After each treatment session, practitioners should advise their patients about the proper care of the treated area and that following posttreatment instructions could decrease the risk of adverse effects.

- Warmth or heat sensation is expected and will last for about 1 hour.
- Slight swelling (edema) and erythema (redness) of the treated area may occur after treatment.
- Cool the skin posttreatment as needed with cold gel packs, cool gel, or cool air.
- Wash the treatment area gently with soap and water.
- Do not soak the treated areas.
- There may be a slight darkening (bronzing) of the skin noticeable 3-10 days posttreatment which resolves without intervention.
- Do not shave the treated area if crusting is evident.
- Avoid sun exposure between treatments. If sun exposure is unavoidable, apply SPF 30+ to protect exposed, treated areas.
- Apply moisturizers for sensitive skin as needed
- For patients who are prone to break outs or have sebaceous skin, consider waiting 24 hours before applying any topical products
Diffuse Pigmentation Treatment Guidelines

NOTE: Includes benign epidermal pigmented lesions, i.e., Café au Lait macules, lentigines and ephelides.

- Treat until the desired clinical endpoints are reached: overall mild to moderate erythema and light frosting or ashy/dusky coloration of lentigines.
- Some lesions/areas may require more than six (6) passes to achieve clinical endpoint.

<table>
<thead>
<tr>
<th>Skin types</th>
<th>Fixed spot size HP</th>
<th>Number of passes</th>
<th>Treatment Intervals</th>
<th>Number of treatments</th>
</tr>
</thead>
<tbody>
<tr>
<td>I-IV</td>
<td>6, or 8 mm</td>
<td>3-6</td>
<td>2-4 weeks</td>
<td>2-4</td>
</tr>
<tr>
<td>V-VI</td>
<td>6, 8, 10 mm</td>
<td>2-6</td>
<td>Up to 8 weeks</td>
<td></td>
</tr>
</tbody>
</table>
NOTE: Includes combination Benign Epidermal/Dermal Pigmented Lesions, i.e., Melasma

- Treat only the affected area.
- Treat the area only until there is a trace to mild erythema which in some cases may result from a single pass.
- When managing melasma with the Focus Lens Array, a continuation of your routine melasma topical regimen including a skin-whitening agent or skin-lightening agent is recommended.
- Sun protection is crucial.
- Multiple treatments (7-10) may be needed.
- If condition worsens at any treatment or no improvement is noticed after several treatments, discontinue treatments.

### Table 5–Treatment Guidelines, Combination Benign Epidermal/Dermal Pigmented Lesions
(For Combination Benign Epidermal/Dermal Pigmented Lesions, i.e., Melasma using the Focus Lens Array, 755 nm)

<table>
<thead>
<tr>
<th>Skin Type</th>
<th>Spot Size (mm)</th>
<th>Rep Rate (Hz)</th>
<th>Number of Passes per Treatment Area*</th>
<th>Treatment Interval (weeks)</th>
<th>Number of Treatments</th>
</tr>
</thead>
<tbody>
<tr>
<td>I-III</td>
<td>6, 8</td>
<td>5</td>
<td>1-2</td>
<td>4</td>
<td>Variable</td>
</tr>
<tr>
<td>IV</td>
<td>6, 8</td>
<td>5</td>
<td>1-2</td>
<td>4</td>
<td>Variable</td>
</tr>
<tr>
<td>V*</td>
<td>6, 8, 10</td>
<td>5</td>
<td>1-2</td>
<td>4</td>
<td>Variable</td>
</tr>
</tbody>
</table>

* Evaluate test spots in 48-72 hours, use caution when treating Skin Type V.

### Table 6–Treatment Guidelines, Benign Dermal Pigmented Lesions
(For ABNOM Hori’s nevus* using the Focus Lens Array, 755 nm)

<table>
<thead>
<tr>
<th>Skin Type</th>
<th>Spot Size (mm)</th>
<th>Number of passes</th>
<th>Treatment Intervals</th>
<th>Number of treatments</th>
</tr>
</thead>
<tbody>
<tr>
<td>III-VI</td>
<td>6, 8</td>
<td>3-4</td>
<td>2 weeks</td>
<td>5-6</td>
</tr>
</tbody>
</table>

* Treatment can be done in combination with Zoom handpiece using 3-4 mm spot size for the first 1-2 treatments every 3-4 weeks.
Treatment Guidelines—Overall Skin Treatment

NOTE: Overall skin area includes full face, hands or chest areas
Table 7 and Table 8 should be used only as guidelines, and should not replace professional knowledge and training.

### Table 7—Pulses per Treatment Area, Overall Skin Treatment
(Treatment using the Focus Lens Array, 755 nm)

<table>
<thead>
<tr>
<th>Area</th>
<th>Pulse Range*</th>
<th>Average Total Number of Pulses*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Face</td>
<td>4000-7000</td>
<td>5500</td>
</tr>
<tr>
<td>Hands (both)</td>
<td>3000-5000</td>
<td>4000</td>
</tr>
<tr>
<td>Décolleté (chest)</td>
<td>7000-9000</td>
<td>8000</td>
</tr>
<tr>
<td>Arms (both)</td>
<td>7000-9000</td>
<td>8000</td>
</tr>
</tbody>
</table>

*The pulse range and average total number of pulses will vary depending on the surface area treated and the number and size of solar lentigines, as well as the severity of general dyschromia.

The following suggested parameters are the most commonly used. Fluence is dependent on spot size; the larger the spot the lower the fluence, for example, 6 mm= 0.71 J/cm², 8 mm=0.4 J/cm² and 10 mm= 0.25 J/cm². Larger spot sizes may reduce the likelihood of side effects for darker skin types.

### Table 8—Treatment Guidelines—Overall Skin Treatment
(Overall skin area includes full face, hands or chest areas, treatment using the Focus Lens Array, 755 nm)

<table>
<thead>
<tr>
<th>Skin Type</th>
<th>Spot Size (mm)</th>
<th>Rep Rate (Hz)</th>
<th>Number of Passes per Treatment Area*</th>
<th>Treatment Interval (weeks)</th>
<th>Number of Treatments**</th>
</tr>
</thead>
<tbody>
<tr>
<td>I-III</td>
<td>6</td>
<td>10</td>
<td>3-6</td>
<td>2-4</td>
<td>2-4</td>
</tr>
<tr>
<td>IV</td>
<td>6, 8</td>
<td>10</td>
<td>3-6</td>
<td>2-4</td>
<td>2-4</td>
</tr>
<tr>
<td>V, VI***</td>
<td>6, 8, 10</td>
<td>10</td>
<td>2-6</td>
<td>2-8</td>
<td>2-4</td>
</tr>
</tbody>
</table>

**Melasma may require additional treatments.
***Evaluate test spots in 48-72 hours, use caution when treating Skin Type V and VI.
Treatment—Acne Scarring

- Physician discretion is required to determine feasibility of treatment administration.
- Acne scars will begin to show improvement in 2 treatments but a series of 4 to 6 treatments is recommended.
- Treatment intervals are 4-6 weeks.

Suggested Treatment Guidelines

Suggested treatment parameters for using the Focus Lens Array are based on information provided by practitioners using the PicoSure laser, published articles and results of clinical studies.

To determine the appropriate treatment parameters, test spots are recommended. Each patient is unique and should be evaluated prior to treatment for skin type. Use lower energy settings or passes/total pulses for darker skin types. The following tables should be used as a guideline only, and should not replace professional knowledge and training.

<table>
<thead>
<tr>
<th>Area</th>
<th>Pulse Range*</th>
<th>Average Total Number of Pulses*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forehead (~100cm²)</td>
<td>1000-2000</td>
<td>1500</td>
</tr>
<tr>
<td>Both cheeks (~200cm²)</td>
<td>2000-4000</td>
<td>3000</td>
</tr>
</tbody>
</table>

* Pulse range and total number of pulses will vary depending on the size of affected area, severity of acne scarring and Fitzpatrick Skin Type.

For other anatomical areas (shoulders, back) base the treatment on a 10 x 10 cm area and deliver about 1500 pulses per area. Consider using fewer pulses when treating the chest, based on skin reaction in this area.

Consider 4-6 passes over the affected area allowing time between passes; treating until the desired endpoint is observed (mild to moderate erythema, light frosting or ashy/dusky coloration of epidermal pigmentation).

Unwanted pigmentation including the post-inflammatory hyperpigmentation (PIH) associated with the acne scarring should slightly frost (whiten) during treatment, darken over the next 24 hours, and then shed over time.

### Table 10—Treatment Guidelines, Acne Scarring
*(Treatment using the Focus Lens Array, 755 nm)*

<table>
<thead>
<tr>
<th>Condition</th>
<th>Skin Type</th>
<th>Spot Size (mm)</th>
<th>Rep Rate (Hz)</th>
<th>No. of pulses per 10x10 cm area (approx.)</th>
<th>Number of passes</th>
<th>Treatment Interval</th>
<th>Number of Treatments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>I-III</td>
<td>6</td>
<td>5-10</td>
<td>1500</td>
<td>4-6</td>
<td>4-6 weeks</td>
<td>4-6</td>
</tr>
<tr>
<td></td>
<td>IV</td>
<td>6-8</td>
<td>5-10</td>
<td>1250</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>I-III</td>
<td>6</td>
<td>5-10</td>
<td>1750</td>
<td>4-6</td>
<td>4-6 weeks</td>
<td>4-6</td>
</tr>
<tr>
<td></td>
<td>IV</td>
<td>6-8</td>
<td>5-10</td>
<td>1500</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>I-III</td>
<td>6</td>
<td>5-10</td>
<td>2000</td>
<td>4-6</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>IV</td>
<td>6-8</td>
<td>5-10</td>
<td>1750</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Selection of repetition rate (Hz) should be based on the clinician’s experience level and ability to administer passes as recommended.

For darker skin types consider starting with the larger of the recommended spot size (lower fluence) and gauge the skin response before using the small spot (higher fluence).

The suggested parameters are the most commonly used. Fluence is dependent on spot size; the larger the spot the lower the fluence, for example, 6 mm=0.71 J/cm², 8 mm=0.4 J/cm² and 10 mm=0.25 J/cm².

It is important to monitor tissue response rather than solely depend on the number of pulses administered.
Treatment—Wrinkles

- A series of up to 4 treatments is recommended.
- Treatment intervals are 4 weeks.
- Deliver several passes in a multidirectional pattern until clinical endpoint of mild to moderate erythema is reached.
- Gently stretch the skin in target areas while treating to improve treatment coverage.

Suggested Treatment Guidelines

Suggested treatment parameters are based on information provided by practitioners using the PicoSure laser, published articles and results of clinical studies. Each patient is unique and should be evaluated prior to treatment for skin type.

The table below should be used for guidelines only, and should not replace professional knowledge and training.

<table>
<thead>
<tr>
<th>Skin Type</th>
<th>Spot Size (mm)</th>
<th>Rep Rate (Hz)</th>
<th>Fluence (J/cm²)</th>
<th>Treatment Interval (weeks)</th>
<th>Number of Treatments</th>
</tr>
</thead>
<tbody>
<tr>
<td>I-IV</td>
<td>6</td>
<td>5</td>
<td>0.71</td>
<td>4</td>
<td>Up to 4</td>
</tr>
</tbody>
</table>
Tattoos
Chapter 5 Treatment Guidelines—Tattoos

Tattoo colors are of great significance to overall treatment success. Most tattoo colors/inks respond very well to laser treatment; they absorb the laser light and are fragmented by both photothermal and photoacoustic effects. Some inks are not consistently destroyed photothermally and therefore, fragmentation of these chromophores occurs by photoacoustic destruction only.

<table>
<thead>
<tr>
<th>Color</th>
<th>Tattoo Composition(^4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black</td>
<td>Carbon, Iron Oxide, Logwood</td>
</tr>
<tr>
<td>Brown</td>
<td>Ochre</td>
</tr>
<tr>
<td>Blue</td>
<td>Cobaltic</td>
</tr>
<tr>
<td>Green</td>
<td>Chrome Oxide, Hydrated Chromium Sesquioxide, Malachite Green, Lead Chromate, Ferro-Ferric Cyanide, Curcumin Green, Phthalocyanine Dyes</td>
</tr>
<tr>
<td>Red</td>
<td>Mercury Sulfide, Cadmium Selenide, Sienna</td>
</tr>
<tr>
<td>Yellow</td>
<td>Cadmium Sulfide, Ochre, Curcumin</td>
</tr>
<tr>
<td>Violet</td>
<td>Manganese Violet</td>
</tr>
<tr>
<td>White</td>
<td>Titanium Dioxide, Zinc Oxide</td>
</tr>
<tr>
<td>Flesh</td>
<td>Iron Oxides</td>
</tr>
</tbody>
</table>

\(^4\) Information in table from Cutaneous Laser Surgery: The Art and Science of Selective Photothermolysis by Dr. Mitchel P. Goldman and Dr. Richard E. Fitzpatrick.

Types of Treatable Tattoos

Amateur: In most cases, amateur tattoos respond more readily than professional tattoos. Removal can be accomplished in approximately three fewer treatments than professional tattoos. Exceptions are those cases in which the ink has been deposited in the subcutaneous tissue.

Professional: Professional tattoos usually have an even distribution of ink with an even depth of placement. Most of the ink is in the dermis with little in the subcutaneous tissue. Since more ink is used in professional tattoos; more treatments are needed to remove them. Professional tattoos may also include a greater number of colors.

Cosmetic: Cosmetic tattoos, such as lip and eyeliner, are usually made of iron-based inks. These inks may oxidize or blacken upon laser impact.

Traumatic: Traumatic tattoos occur when substances, such as carbon or gunpowder are accidentally introduced into the skin. They can usually be removed in one or two treatment sessions. Use caution when treating gunpowder tattoos because the heat dispersion from micro ignitions of the gunpowder may be released into the surrounding tissues.
Treatment Considerations—Tattoos

Mechanism

• Upon laser impact, the ink particles fragment, followed by macrophage engulfment and gradual clearing of the tattoo. Some tattoo ink may be stored in the regional lymph nodes, some ink is cleared and excreted through the lymphatic system and some ink may be removed through transdermal transport. Factors impacting incremental tattoo fading include tattoo size, depth of pigment, pigment density, patient’s age, location of tattoo on body, pretreatment condition of the skin and macrophage mobility.

• Cosmetic inks may oxidize or blacken upon laser impact. Test sites should always be performed on cosmetic tattoos prior to treating.

Technique

• You will notice that the aiming beam is round and the actual laser pulse is square and this can help you plan your treatment approach.

• Each area should be treated with one pass only with tight interlocking, but not overlapping pulses.

• The handpiece should be held as perpendicular as possible and be lightly touching the surface of the skin. This distance guide maintains the laser beam focus.

• Examine the handpiece optic between each treatment session with the laser turned off. Debris on the lens optic may cause a decrease in fluence. Refer to the PicoSure Operator Manual for complete instruction on cleaning the handpiece.

• Protective metal eye shields must be used in the eyes and must be fully occlusive. It is important to use extreme caution when treating near the eyes.

Tattoo Characteristics

• Old tattoos will appear dull, blue, indistinct and blurred with time. These visual changes correlate with the ink particles moving deeper into the dermis, as well as out of the dermis through phagocytic activity. New tattoos are more superficial and have sharp, distinct lines, and in many cases, bright colors.

• Superficial tattoos may require fewer numbers of treatments for clearance; however increased density and thickness may require more treatments for clearance.

• Do not treat newly implanted tattoos for a minimum of six (6) weeks. A longer wait interval such as three (3) months is preferable.

Patient History

• It is highly recommended to consider skin type and history of scarring prior to any treatment session. Test spots will help determine the most efficacious and safe treatment for each patient.

• Evaluate and document baseline condition of skin under and around tattoo pigment. Make note of pre-existing scarring and other skin abnormalities, and discuss with patient before treating.
Clinical Endpoints and Side Effects

- The ideal clinical endpoint of tattoo treatment is slight epidermal whitening (frosting). Whitening of the tissue is related to vacuoles forming in the dermis secondary to gaseous products released on laser interaction with tattoo pigment.

- Whitening may not be as evident on tattoos that have had multiple treatments. Whitening should not be considered the sole clinical endpoint. Frosting may also appear as yellow, grey, beige or other shades.

- Other observable clinical endpoints include peri-lesional (tattoo) erythema and lesional (tattoo) edema.

- If purpura (bruising) or pinpoint bleeding occurs during treatment, the treatment fluence may be too high. Lower the fluence by increasing the spot size until purpura no longer occurs. Fluences used for treatment should not cause bleeding or epidermal exfoliation.

- Hypopigmentation may be a side effect caused by any laser treatment. It is more prevalent in darker skin types. It is usually transient and resolves within 1–12 months.

- Posttreatment blisters are mechanically induced by the PicoSure PressureWave and are a possible side effect. Blisters usually heal without intervention in 5-7 days. These blisters are not heat induced burns.

- Very large blisters may be punctured using a sterile needle and drained using gentle massage. Do not remove the blister skin but instead gently pat the skin into place to provide a natural barrier and apply dressing until the area is healed. To lower the risk of infection, keep the area clean and protected with a bandage until healed.

- It may take more than one treatment to see a visible change in dark, dense black ink tattoos. Laser energy targets tattoo ink layer by layer, starting at superficial layers. Once the superficial target is removed the laser energy can penetrate to the residual deeper ink.

- When there is only a light shadow of tattoo ink visible you may consider using a larger spot size to reach the deeper layers of ink.

- Tattoo ink darkening may occur with any picosecond laser and is most commonly seen in flesh tone, cosmetic tattoos, but may occur in other colors as well. The mechanism of ink darkening is unknown; however, ferric oxide tends to convert to ferrous oxide or iron. This chemical conversion can occur at picosecond laser impact. Ferric oxide may produce a rust color, whereas ferrous oxide may produce black color.

- Cosmetic tattoos may oxidize (change color) and may require a number of treatments before improvement can be seen.
Treatment Intervals

- Tattoo treatment interval is not solely dependent on skin recovery but also on the physiological processes that eliminate ink from the tissue.
- The longer treatment interval (e.g. 8 weeks or more) generally leads to increased ink clearance which may result in fewer treatments.
- For tattoo removal the treatment intervals are generally every 6-8 weeks but this may be extended for patients with darker skin types, or if the skin has not returned to baseline condition and side effects including erythema have not resolved.
- To determine if redness is residual ink or lingering erythema, firmly press and release the skin and observe for blanching. If the skin blanches this is an indicator that erythema persists and the treatment should be postponed.
Suggested Treatment Guidelines—Tattoos

Suggested treatment parameters for treating tattoos are based on information provided by practitioners using the PicoSure laser, published articles\(^3\)\(^-\)\(^6\) and results of clinical studies. Each patient is unique and should be evaluated prior to treatment for skin type. Test spots are recommended to help determine treatment settings.

Larger spot sizes with lower fluence should be used in highly pigmented tattoos, as well as with tattoos on lower extremities. Use larger spot size settings for darker skin types, which may include 6, 8 and 10 mm fixed spot sizes.

Start treatment with larger spot size; slowly decrease spot size in following treatments when clinical endpoint is not evident.

The following tables should be used only as guidelines, and should not replace professional knowledge and training.

<table>
<thead>
<tr>
<th>Table 13–Treatment Parameters, Tattoos, 755 nm, Zoom HP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Skin Type</strong></td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>I-III</td>
</tr>
<tr>
<td>IV-VI*</td>
</tr>
</tbody>
</table>

For Black Dense Tattoos and Extremity Tattoos

<table>
<thead>
<tr>
<th><strong>Skin Type</strong></th>
<th><strong>Spot Size (mm)</strong></th>
<th><strong>Treatment Interval</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>I-III</td>
<td>4.5-4.0</td>
<td>6 to 8 weeks</td>
</tr>
<tr>
<td>IV-VI*</td>
<td>6.0-5.5**</td>
<td>6 to 8 weeks</td>
</tr>
</tbody>
</table>

*Test spots are strongly recommended for skin type IV-VI. Evaluate test spots at follow up visits for pigmentary changes.

**Use larger spot size settings for darker skin types if needed, which may include use of 6, 8 or 10 mm fixed handpieces.

---


### Table 14–Treatment Parameters, Tattoos, 532 nm

<table>
<thead>
<tr>
<th>Skin Type</th>
<th>Spot Size (mm)</th>
<th>Treatment Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>I-III</td>
<td>2.0-1.5 mm</td>
<td>6 to 8 weeks</td>
</tr>
</tbody>
</table>

### Table 15–Treatment Parameters, Tattoos

<table>
<thead>
<tr>
<th>Skin type</th>
<th>Tattoo Ink Colors</th>
<th>Wavelength</th>
<th>Spot size</th>
</tr>
</thead>
<tbody>
<tr>
<td>I-III</td>
<td>All colors</td>
<td>755 nm</td>
<td>3.5-3.0 mm</td>
</tr>
<tr>
<td></td>
<td>Red, Orange, Yellow</td>
<td>532 nm*</td>
<td>2.0-1.5 mm</td>
</tr>
<tr>
<td>IV**</td>
<td>All colors</td>
<td>755 nm</td>
<td>5.5-4.0 mm</td>
</tr>
<tr>
<td>V-VI**</td>
<td>All colors</td>
<td>755 nm</td>
<td>6 mm, 8 mm, 10 mm</td>
</tr>
</tbody>
</table>

* 532-nm delivery system is an optional PicoSure upgrade for use on skin type I-III.
** Pigmentary changes are possible side effects after tattoo treatments on skin types IV-VI. It is important to discuss potential risks with the patient.
Combination Treatment (755 nm and 532 nm)

Several approaches can be used to implement the combination of 755 nm and 532 nm treatment.

Option 1

During each treatment session, first treat entire tattoo with 755 nm, and then retreat any colors that did not respond with 532 nm. Continue treatment method until inks clear.

NOTE: Non-response = lack of frosting/peri-lesional erythema and/or edema.

<table>
<thead>
<tr>
<th>Predominant tattoo colors</th>
<th>Skin Type</th>
<th>Tx 1</th>
<th>Tx 2</th>
<th>Tx 3</th>
<th>Tx 4</th>
<th>Tx 5*</th>
</tr>
</thead>
<tbody>
<tr>
<td>All colors</td>
<td>I-III</td>
<td>755 nm</td>
<td>755 nm</td>
<td>755 nm</td>
<td>755 nm</td>
<td>755 nm</td>
</tr>
<tr>
<td>Only colors that didn’t respond</td>
<td>532 nm</td>
<td>532 nm</td>
<td>532 nm</td>
<td>532 nm</td>
<td>532 nm</td>
<td></td>
</tr>
</tbody>
</table>

*Less or more than 5 treatments may be needed to achieve full resolution of tattoo depending on the amount and type of the ink, location and age of tattoo, and several other factors.

Option 2

During each treatment session, first treat red/orange/yellow inks with 532 nm, and then treat the rest of the colors with 755 nm.

<table>
<thead>
<tr>
<th>Predominant tattoo colors</th>
<th>Skin Type</th>
<th>Tx 1</th>
<th>Tx 2</th>
<th>Tx 3</th>
<th>Tx 4</th>
<th>Tx 5*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red/orange/yellow</td>
<td>I-III</td>
<td>532 nm</td>
<td>532 nm</td>
<td>532 nm</td>
<td>532 nm</td>
<td>532 nm</td>
</tr>
<tr>
<td>Blue/green/black</td>
<td>755 nm</td>
<td>755 nm</td>
<td>755 nm</td>
<td>755 nm</td>
<td>755 nm</td>
<td></td>
</tr>
</tbody>
</table>

*Less or more than 5 treatments may be needed to achieve full resolution of tattoo depending on the amount and type of the ink, location and age of tattoo, and several other factors.
Option 3
During initial treatment sessions (Tx 1-3), treat all colors with 755 nm. During subsequent treatments, treat red/orange/yellow inks with 532 nm and continue treating the rest of the tattoo with 755 nm.

<table>
<thead>
<tr>
<th>Predominant tattoo colors</th>
<th>Skin Type</th>
<th>Tx 1</th>
<th>Tx 2</th>
<th>Tx 3</th>
<th>Tx 4</th>
<th>Tx 5*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blue/green/black</td>
<td>I-III</td>
<td>755 nm</td>
<td>755 nm</td>
<td>755 nm</td>
<td>755 nm</td>
<td>755 nm</td>
</tr>
<tr>
<td>Red/orange/yellow</td>
<td></td>
<td>532 nm</td>
<td>532 nm</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Less or more than 5 treatments may be needed to achieve full resolution of tattoo depending on the amount and type of the ink, location and age of tattoo, and several other factors.
Boost Adjustable Pressure Treatment Guidelines

Boost™ Adjustable Pressure is an advanced option for the treatment of tattoos using 755 nm. The use of Boost Adjustable Pressure is recommended for the treatment of:

- Recalcitrant tattoos; tattoos with plateaued response
- Tattoos that have been previously treated with other technology and have plateaued
- Tattoos that are responding slower than expected
- Tattoos on lower extremities
- Tattoos on older clients

The ideal clinical endpoint for tattoo treatment is an immediate slight whitening of the skin. Whitening may not be as evident on tattoos that have had multiple treatments. Other observable clinical endpoints include peri-lesional (tattoo) erythema and lesional (tattoo) edema.

Begin treatment using Boost Adjustable Pressure Level 1 and adjust the spot size to correspond with either

- The recommended starting spot size in Table 13, or
- The same fluence that was used in the last treatment (please see examples of closely matched fluence in Table 19).

Administer test pulses to a small area of the tattoo. Evaluate skin effect looking for one of the above mentioned clinical endpoints. Continue to advance the Boost Level and re-adjust the fluence until one or more clinical endpoints is observed or you have adjusted to Full Boost.

Table 19 identifies comparable spot sizes/fluences settings with Boost Off and Full Boost Power.

<table>
<thead>
<tr>
<th>Spot Size (mm)</th>
<th>Boost Off</th>
<th>Full Boost Power</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.0</td>
<td>0.71 J/cm²</td>
<td>5.5 mm 0.72 J/cm²</td>
</tr>
<tr>
<td>5.5</td>
<td>0.84 J/cm²</td>
<td>5.0 mm 0.84 J/cm²</td>
</tr>
<tr>
<td>5.0</td>
<td>1.02 J/cm²</td>
<td>4.5 mm 1.04 J/cm²</td>
</tr>
<tr>
<td>4.5</td>
<td>1.26 J/cm²</td>
<td>4.0 mm 1.31 J/cm²</td>
</tr>
<tr>
<td>4.0</td>
<td>1.59 J/cm²</td>
<td>3.6 mm 1.62 J/cm²</td>
</tr>
<tr>
<td>3.5</td>
<td>2.08 J/cm²</td>
<td>3.2 mm 2.04 J/cm²</td>
</tr>
<tr>
<td>3.0</td>
<td>2.83 J/cm²</td>
<td>2.7 mm 2.88 J/cm²</td>
</tr>
<tr>
<td>2.5</td>
<td>4.07 J/cm²</td>
<td>2.3 mm 3.97 J/cm²</td>
</tr>
</tbody>
</table>
Treatment Summary

It is important to monitor tissue response rather than solely depend on the fluence and spot size setting of the laser. Punctuate or pinpoint bleeding or epidermal exfoliation at the site of laser impact indicates too high a fluence setting, so the spot size may be too small. Conversely, if the site does not develop immediate whitening, a fluence setting that is too low means too large a spot size may have been selected. Changing spot size to adjust the fluence is what is recommended when these observations occur. Larger spot sizes should be selected for darker skin types.
Chapter 6 Documentation

Following are samples of treatment forms that can be used to document PicoSure laser treatments, number of pulses, patient reaction, and to record any complications or comments. Also provided are samples of forms, such as informed consent and pretreatment and posttreatment instructions. These are provided for your convenience.
The PicoSure laser produces an intense burst of light that is absorbed by the pigmented lesion or tattoo ink. All personnel in the treatment room, including me, will wear protective eyewear to prevent eye damage from this intense light.

The sensation of the laser light on skin is uncomfortable and may feel like a slight pinprick or the sensation of heat. These sensations may last for a few hours.

Prior to the treatment, test spots may be performed. Test spots help to determine effective treatment settings.

Tattoos may blister and have pinpoint bleeding for a few days after treatment.

Following a pigment treatment, the treated areas may be red, slightly swollen; pigment may darken and slough off in 7-10 days.

The area should be treated delicately following treatment. Do not pick on scabbing/blistering.

Multiple treatments may be necessary.

I have been informed that hyperpigmentation (darkening of the skin), and hypopigmentation (lightening of the skin) are possible complications of the procedure and incidence of this occurring are higher for darker skin types □ Yes □ No

I understand that sun exposure, as well as not adhering to the posttreatment instructions provided to me may increase my chance of complications.

I agree to have before and after pictures taken of the area to be treated: Yes □ No □

I have read and understood all information presented to me, and I have been given an opportunity to ask questions before signing this consent.

Consent for treatment of ________________________________________________

Patient: ________________________________ Date ________________________________

(or legal guardian)

Witness: ________________________________ Date ________________________________
Sample Form  Focus Lens Treatment—Informed Consent

The PicoSure laser Focus Lens Array produces an intense burst of light. All personnel in the treatment room, including myself, will wear protective eyewear to prevent eye damage from this intense light.

Prior to the treatment, test spots may be performed. Test spots help to determine effective treatment settings.

The sensation of the laser light on the skin may feel like a slight pinprick or the sensation of heat. Sensation of the heat may last for an hour or longer after the treatment. Cold air or a cool gel pack may be used during treatment or posttreatment to cool the skin and to minimize warmth. You will also hear a slight snapping sound during the treatment and feel the touch of the laser distance gauge (part of the device) in the treated area.

Following the procedure, you may have redness or slight swelling in the treated area; this may last for 24 hours. You may also develop an acne-like breakout or slight darkening of the pigment; it should resolve without intervention in 3-7 days.

The area should be treated delicately following treatment. Multiple treatments may be necessary.

Posttreatment:
- Cool the skin posttreatment as needed with cold gel packs, aloe vera gel, or cool air.
- Wash the treatment area gently with soap and water; do not soak the treated areas.
- Apply moisturizer for sensitive skin.
- Do not shave the treated area if crusting is evident
- Avoid sun exposure between treatments. If sun exposure is unavoidable, use a 30+ sunblock to protect exposed, treated areas.

I have been informed that hyperpigmentation (darkening of the skin), and hypopigmentation (lightening of the skin) are possible complications of the procedure and incidence of this occurring are higher for darker skin types: Yes ☐ No ☐

I understand that sun exposure, as well as not adhering to the posttreatment instructions provided to me may increase my chance of complications.

I agree to have before and after pictures taken of the area to be treated: Yes ☐ No ☐

I have read and understood all information presented to me, and I have been giving an opportunity to ask questions before signing this consent.

Consent for treatment of ________________________________________________

Patient: ___________________________________  Date: ______________

(or legal guardian)

Witness: ________________________________  Date: ______________
Sample Form  Pretreatment/Posttreatment Instructions

Precautions to take before your light-based treatment:

- No sun exposure, tanning beds and sunless tanning cream for 4 weeks prior to treatment. Sun exposure decreases the effectiveness of the laser treatment and can increase the chance of posttreatment complications.
- Use a broad spectrum UVA/UVB sunscreen with an SPF of 30 or higher. Apply to the treated area every 2 hours when exposed to the sun and it is recommended to make this a part of your skin care routine.
- Remove all makeup, creams or oils prior to treatment.

Instructions following your laser treatment:

General (Pigment and Tattoo):

- Cleanse the treated area at least daily with water and mild soap, and then pat the area dry.
- Do not rub or scratch the treated area.
- If crusting/scabbing occurs, do not shave or pick area. Apply Aquaphor ointment (tattoo) or other moisturizer (face) to the area 2-3 times a day. Keep the area moist, and let the crusting/scabbing resolve on its own.
- Discomfort may be relieved by cold gel packs and/or an over the counter pain reliever, such as acetaminophen.
- Avoid contact sports or any other activity that could cause injury of the treated area.
- Avoid swimming, soaking or using hot tubs/whirlpools until the skin heals.
- Contact physician if there is any indication of infection (redness, tenderness or pus).

(continued)
Tattoo:

- After cleansing and while skin is still moist, apply a thin layer of Aquaphor® ointment to the treated tattoo.
- Apply a non-stick pad over the tattoo until it is healed.
- Avoid sun exposure to the treated area. Use a broad spectrum UVA/UVB sunscreen with an SPF of 30 or higher. Apply to the treated area every 2 hours when exposed to the sun and it is recommended to make this a part of your skin care routine.
- Clean area daily with mild soap and water and pat dry.
- Do not rub or scratch the area.
- Discomfort may be relieved by using cool gel packs or acetaminophen.
- If blistering occurs, keep the area moist by applying Aquaphor 3 times per day or antibiotic ointment per recommendation of the physician. Do not enter swimming pools or hot tubs until treated areas are healed.
- No swimming or using hot tubs for 48 hours posttreatment.
Sample Form — Treatment Record—Laser Flow Sheet

Patient Name: ___________________________ Age: __________

Diagnosis: ___________________________ Location: ___________________________

Comments: ____________________________________________________________________

Laser Wavelength: □ 755 nm □ 532 nm

□ Test Spot  □ Treatment

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Date</th>
<th>Spot Size (mm)</th>
<th>Fluence (J/cm²)</th>
<th>Rep Rate (Hz)</th>
<th>No of Pulses</th>
<th>Area Treated</th>
<th>Anesthetic</th>
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Sample Form Consultation Record—Tattoo

Patient: ____________________________  Date: ____________

Skin Type: I ☐ II ☐ III ☐ IV ☐ V ☐ VI ☐

Location of the tattoo: ___________________________________________________________

Area to be treated: __________________________________________________________________

Age of tattoo: ____________________________________________________________________

Ink colors: ____________________________________________________________________

Description of the tattoo: _________________________________________________________

Size of tattoo: __________________________________________________________________

Patient has history of red ink or other allergies? Yes ☐ No ☐

If yes, please list allergies: __________________________________________________________________

Presence of scarring in tattoo area: Yes ☐ No ☐

Discussed with patient:

• Process and procedure ☐

• Discomfort ☐

• Optional use of topical numbing cream ☐

• Aftercare instructions ☐

• Realistic expectations ☐

Possible complications discussed with the patient:

• Risk of hyper or hypopigmentation ☐

• Risk of scarring ☐

Notes: __________________________________________________________________________

______________________________________________________________________________

______________________________________________________________________________

______________________________________________________________________________

Clinician signature: _____________________________
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