LimeLight
Treatment Guidelines
The Cutera, Inc. LimeLight handpiece is indicated for the treatment of:

- Benign pigmented lesions
- Vascular lesions including telangiectasia, rosacea, port wine stains and angiomas
- Dyschromia
- Poikiloderma
- Mild to moderate inflammatory acne vulgaris

PREREQUISITE
The LimeLight handpiece should only be operated by qualified practitioners who have received appropriate training and have thoroughly reviewed the Operator Manual prior to operating the LimeLight handpiece.

LIMELIGHT DEVICE

- Wavelength range is 520nm to 1100nm
- There are multiple wavelengths of light absorbed by the chromophores Melanin and Hemoglobin
  - Benign Pigmented Lesions / Melanin
    - Laser light is absorbed by melanin
    - Pigmented cells are denatured and darken, rise to the surface
    - Epidermal melanin will darken and may leave a “coffee-ground” appearance
    - This usually exfoliates in an average of 7-14 days
  - Vascular / Hemoglobin
    - Laser light is absorbed by hemoglobin in the veins and the heat produced causes photocoagulation
    - Heat is transferred to the vessel wall which ultimately destroys the vessel
    - New veins may appear over time
    - Endpoints may include the following:
      - Immediately disappearance
      - Change of color (dusky or purpura)
      - Develop diffused appearance (looks “hazy”)
PATIENT ASSESSMENT

Contraindications: Pregnancy and Skin Cancer

This is a medical device. It is important to obtain a complete medical history and signed informed consent.

Determine ethnicity and skin type by using the attached Fitzpatrick Skin Type scale.

Patient Considerations including but not limited to are below:

- 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
  - Anticoagulants – may increase risk of purpura or bruising
- Vitiligo – may cause de-pigmentation
- Herpes – pre-treatment with an antiviral may be indicated
- Open wounds
- History of keloid or hypertrophic scarring
- Only treat over known benign lesions
- Do not treat over dysplastic nevi or questionable pigmented lesions
  - Online Melanoma resources include [www.aad.org], [www.cancer.org]

Avoiding Complications:

- 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 should be always be used.
  - The treatment window should be pointed away from the eye and applied to the skin outside of the orbital rim.
  - Skin at the edge of the orbital rim can be treated by pulling it away from the eye while simultaneously holding the goggles in place, so treatment is kept outside of the orbital rim.
- Do not treat over or close to tattoos or permanent make-up
- Sun exposure, tanning beds or artificial tanning may increase risk of side effects and adverse events
- No self-tanners for at least 2-4 weeks prior to treatment
- All traces of make-up must be removed
- Be aware of implants and threads
- Stay at least 6 inches away when treating near a Pacemaker
- Reaction to fillers unknown
- Ensure the entire sapphire crystal is in full contact with the skin during the treatment.
- Ice should NEVER be applied to a suspected burn as it may cause unwanted side effects. Cold gel packs or cool compresses can be used post-treatment.
- Although this wavelength is not optimal for hair reduction, patients should be advised that hair reduction may occur as a result of this treatment.
- Consider shaving treatment area if excessive or dark hair is present to prevent unwanted adverse events.
TREATMENT PARAMETERS
The following parameters are provided as a guide only. Observe laser-tissue interaction and clinical endpoints to determine appropriate settings.

Fluence is the energy measured in J/cm²
- The lighter the chromophore, the more energy (fluence) is needed

Repetition Rate is the number of pulses per second measured in Hz
- Repetition Rate should only be used by advanced users

Pulse Duration is the length of each pulse measured in milliseconds (ms)
- Automatically selected by program – see chart below

Sun Mode and Gel
- Sun Mode - Increases the treatment window from the standard settings of 5°C-10°C to 20°C in all programs. Fluence may need to be lowered when using Sun Mode.
  - Do not use Sun Mode when treating any vascular indication
  - Sun Mode is optional when treating benign pigmented lesions
    - Lighter pigment may require additional heat to target the melanin and this can be reached by using Sun Mode with no gel.
- Ultrasound gel (clear, no color) – Cools the epidermis and allows tracking of crystal placement
  - Vascular / Hemoglobin
    - Ultrasound gel is recommended when treating all vascular indications
  - Benign Pigmented Lesions / Melanin
    - Ultrasound gel is optional when treating benign pigmented lesions

Program Description
- **Program A** is most aggressive program
  - Shortest pulse duration
    - Pulse Duration equals approximately half of the fluence selected
    - Best program for vascular treatments for lighter skin types
  - Window temperature 5° C
- **Program B** is mid-range program
  - Mid-range pulse duration settings
    - Pulse Duration equals approximately the fluence selected
  - Window temperature 5° C
- **Program C** is least aggressive program
  - Longest pulse duration settings
    - Pulse Duration equals approximately 2X the fluence selected
  - Window temperature 10° C

<table>
<thead>
<tr>
<th>Program</th>
<th>Wavelength</th>
<th>Pulse Duration Range</th>
<th>Cooling Temperature Sun Mode Off</th>
<th>Cooling Temperature Sun Mode On</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Shortest 520 nm peak</td>
<td>2-12 ms</td>
<td>5° C</td>
<td>20° C</td>
</tr>
<tr>
<td>B</td>
<td>Mid-range 560 nm peak</td>
<td>5-29 ms</td>
<td>5° C</td>
<td>20° C</td>
</tr>
<tr>
<td>C</td>
<td>Longest 580 nm peak</td>
<td>10-60 ms</td>
<td>10° C</td>
<td>20° C</td>
</tr>
</tbody>
</table>
The following guidelines are based on physician feedback from treatments primarily on patients with Fitzpatrick skin types I-IV. Treatment parameters have not been developed for skin types V & VI. The increased melanin in darker skin will also absorb the light and increase the risk of hypopigmentation / hyperpigmentation and/or an adverse event.

Skin typing can be subjective. These parameters are based on the Fitzpatrick Skin Type Chart contained in this guideline. Use the chart to determine the skin type for each patient prior to selecting parameters below. Re-evaluation may be necessary prior to each treatment.

**Treatment Progression**

- If treating a variety of lighter and darker pigment, parameters should be chosen for the darker pigment to avoid over-treatment. Lighter pigment should be treated on subsequent visits.
  - You may have to increase fluence at subsequent visits to target the lighter pigment
- If there are equal amounts of browns (benign pigmented lesions) and reds (vascular), treat the browns first and then the reds on subsequent visits.
  - You may have to increase fluence at subsequent visits to target the lighter vascular component

**Treating Off the Face**

- Reduce Fluence when treating off the face
- Highly sun exposed areas (chest & arms) should be treated less aggressively

<table>
<thead>
<tr>
<th>Indication</th>
<th>Skin Type</th>
<th>Program</th>
<th>Fluence Face Treatments</th>
<th>Sun Mode</th>
<th>Gel</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Benign Pigmented Lesions / Browns</strong> <em>actinic bronzing should be treated with less aggressive settings</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate to Dark Brown</td>
<td>I-II</td>
<td>B</td>
<td>12 – 20 J/cm²</td>
<td>OPTIONAL</td>
<td>YES</td>
</tr>
<tr>
<td>(high contrast) with or without reds</td>
<td>C</td>
<td></td>
<td>14 – 22 J/cm²</td>
<td>OPTIONAL</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>III</td>
<td>B</td>
<td>10 – 18 J/cm²</td>
<td>OPTIONAL</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C</td>
<td>12 – 22 J/cm²</td>
<td>OPTIONAL</td>
<td>YES</td>
</tr>
<tr>
<td>Lighter IV</td>
<td>B</td>
<td></td>
<td>8 – 16 J/cm²</td>
<td>OPTIONAL</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td></td>
<td>10 – 20 J/cm²</td>
<td>OPTIONAL</td>
<td>YES</td>
</tr>
<tr>
<td>Darker IV</td>
<td>C</td>
<td></td>
<td>5 – 14 J/cm²</td>
<td>OPTIONAL</td>
<td>YES</td>
</tr>
<tr>
<td>Light Brown</td>
<td>I-II</td>
<td>A</td>
<td>14 – 24 J/cm²</td>
<td>OPTIONAL</td>
<td>YES</td>
</tr>
<tr>
<td>(low contrast) with or without reds</td>
<td>B</td>
<td></td>
<td>16 – 26 J/cm²</td>
<td>OPTIONAL</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>III</td>
<td>A</td>
<td>12 – 20 J/cm²</td>
<td>OPTIONAL</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td></td>
<td>B</td>
<td>14 – 22 J/cm²</td>
<td>OPTIONAL</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>Lighter IV</td>
<td>B</td>
<td>8 – 14 J/cm²</td>
<td>OPTIONAL</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C</td>
<td>10 – 16 J/cm²</td>
<td>OPTIONAL</td>
<td>YES</td>
</tr>
<tr>
<td>Darker IV</td>
<td>C</td>
<td></td>
<td>8 – 12 J/cm²</td>
<td>OPTIONAL</td>
<td>YES</td>
</tr>
<tr>
<td><strong>Vascular / Redness (Do not treat leg veins)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minimal pigment</td>
<td>I-II</td>
<td>A</td>
<td>16 – 24 J/cm²</td>
<td>OFF</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td></td>
<td>B</td>
<td>18 – 26 J/cm²</td>
<td>OFF</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>III</td>
<td>A</td>
<td>14 – 22 J/cm²</td>
<td>OFF</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td></td>
<td>B</td>
<td>18 – 26 J/cm²</td>
<td>OFF</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>Lighter IV</td>
<td>A</td>
<td>10 – 18 J/cm²</td>
<td>OFF</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td></td>
<td>B</td>
<td>12 – 20 J/cm²</td>
<td>OFF</td>
<td>YES</td>
</tr>
<tr>
<td>Darker IV</td>
<td>Not recommended</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Actinic Bronzing – chronic brown pigment due to sun damage
The laser system should only be operated by qualified practitioners who have received appropriate training and have thoroughly read the operator manual.

PREPPING THE PATIENT

- Clean skin removing all make-up and/or topical anesthetic.
- Consider shaving treatment area if excessive or dark hair is present to prevent unwanted adverse events
- Pre-operative photographs should be taken prior to the initial treatment for future reference.
- Treatment of a test area should be performed and observed prior to treatment. Potential adverse reactions may take 24-72 hours to appear.
  - Foot-printing is usually evident 24-72 hours post treatment and is not a desirable result; indicates over-treatment. If this occurs, settings should be lowered for desired results.
  - Patients with actinic bronzing have a higher risk of developing foot-printing.
  - Test spots should be done on the same area being treated (i.e. don’t test spot on arm when treating the face)
  - Tests spots are recommended prior to subsequent treatments
- Topical anesthetic is optional and must be removed before treating
  - CAUTION: Toxicity may result from overuse. Consult the manufacturer’s labeling.
- Safety eyewear must be worn by ALL people in the treatment room.
  - Use eyewear appropriate for Intense Pulsed Light devices (520-1100 nm)

Shutter Operator Goggles  Operator Goggles  Patient Goggles  Disposable Patient Eye shield
TREATMENT TECHNIQUE

- Select Program & Fluence (see Treatment Parameters section for recommendations)
  - LimeLight is not recommended for leg veins
  - Reduce fluence over bony areas to reduce the risk of adverse events
  - Reduce fluence for darker targets (both benign pigmented and vascular lesions)
  - Reduce fluence for darker skin types or actinic bronzing
  - If in doubt, it is safest to use the longer wavelength program of the two choices (i.e. B over A and C over B).
  - As targeted chromophore decreases or if treatments are not effective, change to more aggressive program (i.e. B to A or C to B) at subsequent treatments
- Patients should be reassessed prior to each treatment
  - Settings should NOT be based on settings used with other IPL devices or previous treatments.
- Ultrasound gel (see Treatment Parameters for recommendations)
  - Apply a thin layer of ultrasound gel for increased epidermal protection and easy gliding of the handpiece to determine placement of adjacent rows.
  - Gel optional when treating very low contrast (light) pigment
- Crystal must be in full contact with skin during treatment
  - Pay particular attention when treating rounded/bony areas such as the forehead, nose, around mouth, bony hands, etc.
  - Pulses should be placed adjacent to one another with no overlap
- If treating a variety of lighter and darker pigment, treat the darker pigment first and then the lighter pigment on subsequent visits.
  - You may have to increase fluence at subsequent visits to target the remaining lighter pigment
- If there are equal amounts of browns (benign pigmented lesions) and reds (vascular), treat the browns first and then the reds on subsequent visits
  - You may have to increase fluence at subsequent visits to treat the remaining lighter vascular component
- Vascular Treatment –
  - It is important to always maintain full contact of the crystal on the skin. However, excessive pressure may blanch the vessel, diminishing the target chromophore.
- Do not “double pulse” or retreat an area within a single visit
- Always observe the epidermis during the treatment, watching for signs of damage (epidermal separation or gray coloration). If damage is seen, stop the treatment and cool the skin. Evaluate area for possible complications and wound care.
End Points

- Foot-printing is not a desirable result; indicates over-treatment.
  - If this occurs, may require subsequent treatments, changing crystal placement from the previous treatment (i.e. place handpiece vertically instead of horizontally)
  - Patients with actinic bronzing have a higher risk of developing foot-printing

- Diffused Redness / Vascular
  - Immediate disappearance
  - Change of color (dusky or purpura)
  - Develop diffused appearance (looks "hazy")

- Benign Pigmented Lesions
  - Darkening of the lesion over the next 24-72 hours
    - Immediate darkening of the pigment may indicate excessive fluence

POST TREATMENT CARE

- Cool compresses, chilled gel, or hydro-gel pads may be applied post-treatment as needed for patient comfort. The treatment window can also be used as an effective post-cooling device.
- Treated lentigines usually darken slowly over the next 24-72 hours, and crusting begins to form within a few days. This crusting usually resolves in 1 to 3 weeks. It should be allowed to naturally flake off for best results.
- Localized erythema and/or edema may also be present and typically resolves within 24 to 72 hours.
- If a blister or crusting develops, treat as a wound.
- Ice may increase edema and lead to undesired outcome and/or adverse event
- Do not directly ice a suspected burn, use a cool compress
- Patients should avoid artificial tanning, or sun exposure between treatments.
- Patients should actively wear sunscreen, reapplying multiple times daily.
- The recommended treatment interval is 4 weeks or longer, depending on the rate of clearance.

SAFETY AND SYSTEM MAINTENANCE

- Log on to the Clinical & Training section of the Cutera website’s Education tab (www.cutera.com) for important information on Laser Safety and Laser Physics.
  - These presentations review light-tissue interaction and safe laser practices
- It is important to properly maintain your system. Failure to do so may affect the life of your laser. Review the Operator Manual thoroughly for detailed instructions.
## Fitzpatrick Classification Questionnaire

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

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