Laser Genesis is a delivery mode for Nd:YAG (1064nm) lasers with a patented pulse structure designed for safe and effective treatment on all skin types and tanned skin. It can be safely used on all body parts (excluding the eye and surrounding area). Common indications include:

- Treatment of Wrinkles
- Rosacea / Diffuse Redness
- Scar Reduction: including reduction in hypertrophic and keloid scars
- Poikiloderma of Civatte

PREREQUISITE

The Laser Genesis handpiece should only be operated by qualified practitioners who have received appropriate training and have thoroughly read the laser system operator manual (shipped with laser)

PATIENT ASSESSMENT

This is a medical device. It is important to obtain a complete medical history and signed informed consent. Consult the Operator Manual for additional information, including expected transient events and possible adverse events.

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

Contraindications: Pregnancy and patients undergoing treatment for skin cancer

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
- Diabetes – may impede wound healing
- Neuropathies – decreased sensation or numbness
  - Treatment area should be evaluated for numbness or decreased sensation
- History of keloid or hypertrophic scarring
- Tan skin and darker skin types have an increased risk of complications and/or pigmentedary issues. Parameters may need to be adjusted to help prevent adverse events.
- No self-tanners, spray tans, etc. for at least 2-4 weeks prior to treatment
- Do not treat questionable skin lesions. These should be evaluated by a specialist prior to treatment.
  - Online Melanoma resources include (www.aad.org), (www.cancer.org)
Avoiding Complications

- Topical anesthetics should not be used as patient feedback is required
- Darker skin types have an increased risk of complications and/or pigmentedary issues
- Always treat outside the orbital rim of the eye aiming the beam away from the orbit
- Do not treat over or close to tattoos or permanent make-up
- All traces of make-up must be removed
- Possible hair loss may occur
- No self-tanners for at least 2-4 weeks prior to treatment.
- The Nd:YAG may harm a tooth if exposed
  - Moist gauze may be placed between the lips and teeth.
- Implants
  - Avoid metal implants in thin skinned areas; clavicle, jaw, orbit
  - Ask about surgical implants and threads
  - Do not treat over Pacemaker implant
  - Reaction to fillers unknown
- Ice should never be applied to a suspected burn as it may cause unwanted side effects. Frozen gel packs or cool compresses can be used.
SELECTING TREATMENT PARAMETERS

Always start with the least aggressive settings. Observe laser-tissue interaction and clinical response to determine appropriate settings for each patient. Adjustments should be made based on epidermal response.

<table>
<thead>
<tr>
<th>Size</th>
<th>Skin Type</th>
<th>Fluence</th>
<th>Pulse Duration</th>
<th>Repetition Rate</th>
<th># Tx</th>
<th># of Pulses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large Area (face, neck, or chest)</td>
<td>I-IV</td>
<td>12-18 J/cm²</td>
<td>0.3 ms</td>
<td>7 – 10 Hz</td>
<td>4-6</td>
<td>8,000 – 12,000</td>
</tr>
<tr>
<td></td>
<td>V-VI</td>
<td>8-14 J/cm²</td>
<td>0.3 ms</td>
<td>5 – 8 Hz</td>
<td>4-6</td>
<td></td>
</tr>
<tr>
<td>Small Area (including scars)</td>
<td>I-IV</td>
<td>12-16 J/cm²</td>
<td>0.3 ms</td>
<td>4 – 8 Hz</td>
<td>1-6</td>
<td>500 – 1,000</td>
</tr>
<tr>
<td></td>
<td>V-VI</td>
<td>8-12 J/cm²</td>
<td>0.3 ms</td>
<td>4 – 8 Hz</td>
<td>1-6</td>
<td></td>
</tr>
</tbody>
</table>

- Start with low fluence and slow repetition rate to observe laser-tissue interaction. Adjust to patient tolerance
- Darker skin types, bony areas, or areas with a higher concentration of target, dense hair or recent sun exposure may require less pulses, lower fluences and/or slower repetition rates

OPERATING THE SYSTEM

The laser system should only be operated by qualified practitioners who have received appropriate training and have thoroughly read the operator manual.

- Select 5mm spot size by rotating the ring on the handpiece
- Select appropriate parameters.
  - The last used parameters will be displayed when restarting the laser.
  - Navigation only provides the range of treatment parameters on the screen. The operator is required to choose the correct parameters. Consult operator manual for Navigation information.
- Laser should be placed in standby when not actively in use

![Display Screen for Vantage](image1)

![Display Screen for Xeo](image2)
PREPARING THE PATIENT

- Clean skin removing all make-up and/or topical anesthetic.
- Pre-treatment photographs should be taken prior to the initial treatment for future reference.
- Shave the treatment area prior to each treatment.
- A white eyeliner pencil can be used to divide the treatment area into smaller grids.
- Treatment of a test area should be performed and observed prior to the treatment.
- Topical anesthetic should not be used as patient feedback is required
- Safety eyewear must be worn by ALL people in the treatment room.
  - Check the wavelength and optical density (>=6.1 @ 1064nm) marked on all operator goggles.

TREATMENT TECHNIQUE

- Gel is not used
- Topical anesthetics should not be used as patient feedback is required
- To improve treatment uniformity and outcomes, divide the face into multiple regions (example shown).
  - Forehead – divide in half
  - Periocular – Do NOT treat upper lids
  - Cheeks divide into 2-3 sections
  - Perioral areas
- Hold the handpiece approximately 1-2 cm (about 0.5-1 inch) from the skin’s surface,
  - The handpiece should be continuously moved in a zig-zag motion with even distribution of pulses
  - Movement should be controlled and speed adjusted according to the patient’s tolerance
  - Treat each region to point of discomfort and erythema (example shown), then move to adjacent regions using multiple passes
- The laser emits a distinct “water drop” sound every 100 and 1,000 pulses. Music plays every 5,000 pulses.
- Dark skin, scars or hot spots may need cooling or a short break during treatment
- Scars
  - Check with surgeon before starting treatment on fresh scars
  - Always include the tissue surrounding the scar observing for erythema of the scar as endpoint
    - Scar will absorb more energy than surrounding skin
    - Do not rely on heat in surrounding skin as an endpoint
  - Decreased sensation of scar increases risk of burn
  - Several treatments may be necessary
- Extreme caution should be used when treating near the eye.
  - 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.

POST-TREATMENT CARE

- Erythema is common and resolves with time.
- If a blister or crusting develops, treat as a wound.
# 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