



GentleLASE with 18mm upgrade and GentleLASE PLUS Treatment Guidelines

These guidelines were developed from clinical experience and are subject to change as additional experience is gained. Be sure to inquire with your Candela Sales Representative, Clinical Consultant or visit MyCandela.com regularly for the latest updates and a comprehensive bibliography list of references/published articles. Treatment Guidelines do not take the place of the procedures and instructions found in the Operator's Manual. **FAILURE TO USE THE LASER IN ACCORDANCE WITH SUCH PROCEDURES AND INSTRUCTIONS COULD RESULT IN SERIOUS INJURY TO THE OPERATOR, THE PATIENT AND OTHERS, AS WELL AS DAMAGE TO THE LASER SYSTEM.** Follow OSHA and ANSI standards for laser safety. Protective eyewear must be worn by all persons in the treatment room during laser operation. Perform User Verification tests as outlined in Section 6 of the Operators Manual at the start of each treatment day and when the hand piece is changed. Check the delivery system for any damage (i.e.: dropped). **Discontinue use of your laser delivery system if you suspect a problem.**

Hair Removal Treatment Guidelines

Lesion/ Skin type	Spot size (mm)	Fluence J/cm2	**DCD Spray/delay (ms)	Retreat	Comments
I-II Red hair, Freckles, Fair skin, Blue eyes (Caucasian)	8	30-40	Skin Types 1-III Most commonly selected settings: 40/40;50/30; 50/40	Facial: 4-6 weeks Trunk: 6-8 weeks Leg: 10-12 weeks	Skin types I-III Test small area and wait several minutes to evaluate response prior to treating entire area.
	12	25-35			
	15	20-30			
III (Darker Caucasian, light Asian)	8	25-40	**If using the Serenity PSF, DCD must be turned off and add a thin layer of lubricant	Leg: 10-12 weeks	**Serenity PSF vacuum should be set at a starting point of 450 mbars and adjusted according to patient comfort
	12	18-30			
	15	16-25			
IV (Mediterranean Asian, Latin)	8	20-30	Skin types IV-VI Most commonly selected settings: 40/30; 50/30;50/40		Skin types IV-VI and tanned skin Pretreat with prescription strength hydroquinone for at least 2 weeks prior to treatment. Test small area and wait 1-2 weeks prior to treating entire area to evaluate tissue response Assess need to adjust DCD when altering fluence. Do not treat recently tanned skin. Allow tan to fade prior to treatment.
	12	16-20			
	15	10-20			
V (Middle Eastern, Latin, Asian light skinned Black, Indian, Native American)	8	20-25	**The Serenity PSF SHOULD NOT BE USED ON SKIN TYPES V & VI		
	12	14-20			
	15	10-20			
VI (Dark skinned Black)	8	20-25	Use if above settings are ineffective:50/30, 60/40,60/50,60/60 **The Serenity PSF SHOULD NOT BE USED ON SKIN TYPES V & VI		**VERY IMPORTANT** Please see additional Serenity PSF notes found on page 7
	12	10-20			
	15	6-20			
	18	6-16			

Wrinkles Treatment Guidelines					
Lesion/ Skin type	Spot size (mm)	Fluence J/cm2	**DCD Spray/delay (ms)	Retreat	Comments
1-5	12	25-40	40/40 50/30 60/40	1-8 treatments 2-4 weeks apart	May apply cold compress or cold gel packs immediately after treatment to cool skin and remove heat.
Vascular Lesions Treatment Guidelines					
Lesion/ Skin type	Spot size (mm)	Fluence J/cm2	**DCD Spray/delay (ms)	Retreat	Comments
Telangiectasia Skin Types I-III	8	50-80 (leg) 40-50(face)	50/30 60/40	3-4 weeks depending on response	Pulse each area once. Endpoint is perivascular erythema, subtle edema of vessel, or no vessel re-fill.
	3x10	60-80 (leg) 45-55(face)			
Hemangioma	8	60-70	90/80		
Benign Pigmented Lesions Treatment Guidelines					
Lesion/ Skin type	Spot size (mm)	Fluence J/cm2	DCD Spray/delay (ms)	Retreat	Comments
Solar lentigines, benign melanoctytic nevi Skin Types I-IV	8 12	30-40	0	1-2 treatments 4 weeks apart	Treatment of skin types V or VI is not recommended. The dynamic cooling device is generally not used for the treatment of benign pigmented lesions. For some patients, some cryogen may be beneficial. Candela recommends use of a cooling method such as cool gel pack or cold compress for brief pre and post laser epidermal cooling. Start at lowest fluence for treatment one and observe tissue response. Start by treating darkest lesions, which require lower fluences. Lighter spots may require higher fluence.
Seborrheic keratoses Skin Types I-IV		80-100			

Pre-Treatment Preparation

Pre-treatment visit

Patient selection should be based upon the physician's assessment of the individual patient including a detailed medical history. The treatment protocol should be discussed in detail including risks & benefits, side effects and expected results, alternative or concurrent therapies and follow up care. The physician should set proper expectations based upon their clinical experience. Informed consent and photographs should be obtained. Individual patient characteristics such as skin condition and type, sex, age and medications may influence the response to and efficacy associated with treatment. The response to treatment may vary on subsequent visits and the skin reaction must be carefully assessed on each visit. These guidelines are intended for use by providers who are knowledgeable in laser tissue interactions.

Contraindications and Precautions

DO NOT TREAT RECENTLY TANNED SKIN.

BLISTERING AND HYPOPIGMENTATION MAY OCCUR.

ALLOW TAN TO FADE PRIOR TO TREATMENT.

- Accutane: Wait 6 months after the completion of Accutane therapy
- Tattoos: Do not treat tattooed skin, including decorative, permanent makeup and radiation port tattoos.
- History of photosensitivity to 755 nm light.
- Pregnancy: Refer to Candela Corporation policy # 0920-23-0814.
- Seizure disorders: Do not treat patients with a history of light-triggered seizures.
- Medications and Supplements: Daily anticoagulation therapy, iron supplements, herbal supplements such as ginkgo, ginseng or garlic and fish oil supplements may bruise more readily.
- Photosensitizing Medications: Medications that induce photosensitivity or medications within or above the 755nm wavelength range. Refer to Candela Corporation Drugs That May Cause Photosensitivity. Stop the medication if possible for 3-5 days prior to treatment.
- Topical Medications and skin care products: stop 72 hours pre and post
- HSV 1 & 2: Do not treat if active lesion(s) are present within the intended treatment area. Patients with a known history of frequent HSV 1&2 lesions should begin prophylaxis prior to treatment as prescribed by their physician.
- Poorly controlled Medical Conditions: These patients should be carefully evaluated by their physician for medical clearance.
- Active skin infection: Avoid treatment of open wounds and skin that is actively infected.
- Cold sensitivity: Use caution when treating patients with Raynaud's phenomenon.
- Keloid scarring: Perform test spots prior to treating larger areas.
- Implanted medical devices: Pacemakers, cardioverters and other implantable devices or fillers: consult MD.
- Sunburn: Although the device may safely treat darker skin types, postpone treatment for 10-14 days after acute unprotected sun exposure.

Skin Preparation for Treatment

- Topical anesthetics may be used prior to LHR per manufacturers' directions. HOWEVER, the topical anesthetics should be removed from the skin prior to treatment.

- Skin must be clean and dry; remove all lotions, perfumes, make-up, deodorant, self tanners etc. These products may contain flammable ingredients which may induce epidermal damage.
- When cleaning the skin with alcohol, make sure the alcohol is completely removed and the area rinsed prior to treatment.
- Shave area to be treated immediately before treatment, Do NOT leave any stubble on skin.
- Do NOT treat long hair, as the external hair acts as a heat sink and may burn the skin.
- Patients should not tweeze, wax, or have electrolysis 6 weeks before treatment.

Test Areas

- Perform test areas when a concern exists regarding the potential response to treatment.
- Select a small area in the anticipated treatment site.
- Apply a series of pulses with several fluences.
- Evaluate the sites in 2 weeks
- Treatment may proceed when perifollicular erythema and edema is noted.

Laser Treatment Considerations

- Perform User Verification Tests prior to each treatment session. This test procedure is outlined in the Operator's Manual.
- Position patient comfortably and confirm that the patient and everyone in the treatment room are wearing the correct protective eyewear.
- Always hold the laser handpiece perpendicular to the skin to apply laser energy, otherwise an uneven application of cryogen and energy may occur and an untoward skin reaction may occur.
- The aiming beam and laser beam are dimensionally identical, so the aiming beam can be used to accurately define the treatment area. The spot should be absolutely circular if the handpiece is held at the appropriate 90 degree angle.
- Follow the procedures outlined in the Candela **Cleaning GentleLASE and GentleYAG Distance Gauges Protocol 8502-00-0847** to prevent debris build up on the inside of the distance gauge and maintain good visibility. The Cleaning and Disinfecting Policy is outlined in the Operator's Manual. Always start with the lowest fluence for the patient's skin type, perform several test spots with 2 J/cm² fluence increments, and evaluate the epidermal and hair response before continuing with treatment.
- Select progressively smaller spot sizes as treatments progress and surviving hair becomes thinner and less deeply pigmented. Choose an appropriate fluence which induces perifollicular erythema and edema each time the patient is treated.
- Maintain patient comfort and skin protection by adjusting DCD settings based upon the skin reaction and tolerance. The spray should be sufficient to cover the treatment area to provide epidermal cooling in opposition to the heat generated by laser light absorption. Darker skin types do not tolerate excessive amounts of DCD spray.

Measures to prevent untoward effects and decrease discomfort

- Cool compress or cold gel packs may be applied immediately before, during and after treatment to decrease discomfort

- Large areas that are divided into sections need to be cooled just prior to treatment.
- After each laser pulse, a gentle rub of the area with a dry gauze pad or gentle rub with a gloved hand may minimize discomfort.
- Complaints of significant discomfort during treatment should be investigated immediately. Discomfort is frequently related to use of an excessive fluence or treating recently tanned skin.

Treating Specific Body Areas

- **CANDELA DOES NOT RECOMMEND treating the area within the orbital rim as ocular damage may occur.**
- Insert moistened white gauze cotton in nose or ears during treatment to prevent laser absorption by unintended targets..
- Patients with dental work may experience sensitivity when the laser pulse is administered in the perioral area; place moistened dental roll or moistened white gauze between the teeth and the inside of the lip during treatment to prevent damage to the teeth or oral mucosa.
- Cover any area requiring shielding with moistened white gauze or a moistened white card to prevent absorption of light.
- Before treating a full beard or scalp, be sure the patient wants this area to remain free of hair, and has signed an informed consent.
- Use a white makeup pencil for drawing in a treatment area grid.
- When treating anal area, place wet gauze over the anus first. Methane gas is flammable.

Post-Treatment Care

- Cool compresses or cold gel packs or chilled aloe vera gel may be applied after treatment.
- A moisturizing SPF 30+sunblock should be applied prior to the next treatment.
- Avoid irritation.
- Resume use of usual topical agents when irritation resolves.

Expected Responses

Laser Hair Removal:

- Perifollicular edema/erythema, urticaria. Mild to moderate epidermal erythema often occurs as well.
- The appearance of perifollicular edema and erythema may be altered if a topical anesthetic is used, as the topical may cause vasoconstriction or erythema.
- After laser hair reduction (LHR), the treated hair may not shed for several weeks. Patient should be reassured that the hair will eventually exfoliate.
- Approximately 20% reduction of hair growth noted 4-8 weeks following each procedure.

Wrinkles

- Immediate erythema and edema which subside within several hours
- Improvement noted following a series of 4-5 treatments performed one month apart

Vascular lesions:

- Vasoconstriction of facial and leg veins, transient urticaria.
- Gradual fading over several weeks to months.

Benign Pigmented Lesions

- Immediate(tan to brown) darkening of the lesion
- Slight peri-lesional erythema and urticaria
- Formation of superficial red-brown scale which resolves within 7-14 days
- Gradual fading over 4-6 weeks

Untoward Responses

- Burning, blistering, scabbing, crusting, hyperpigmentation, hypopigmentation, purpura, lymphadenopathy-pain and swelling and/or herpes simplex activation—in rare cases, scarring may result.
- Hypo- or hyperpigmentation may not appear for 1-2 weeks and in rare cases may last for months or longer.
- If hypo- or hyperpigmentation occurs treatment should not be performed until pigmentation returns to normal.

Determining the end of treatment

- Multiple treatments over a period of several months may be required.
- The provider's judgement will determine the end of treatment.
- Treatment should cease when the desired clinical endpoint has been achieved.
- Maintenance treatments may be required to maintain the desired response .

Reduction of Plume and Hair Odor in Treatment Room

- Use a smoke evacuator during treatment especially for treatment of larger areas.
- Wear a laser mask to reduce breathing plume.
- Keep room well ventilated to disperse hair odor.

Warnings and precautions

Warning

When using the GentleLASE and GentleLASE PLUS with the Dynamic Cooling Device (DCD) in use in conjunction with an ECG monitoring device interference with the ECG monitoring device may result.

Warning

Refer to Candela Policy for Pregnancy and the Use of Lasers (Document No. 0920-23-0814).

Warning

Candela does not recommend treating the eyebrow or within the orbital rim as ocular damage may occur.

Caution

If crescent shaped marks, wheals, or welts are noted during treatment, the fluence or DCD settings should be adjusted immediately. Not making such an adjustment can result in subsequent crusting, blistering, and other adverse reactions.

Caution

Hot spots or burns may result if the hand piece windows are dirty or burned, as the amount of energy passing through the window and delivered to the patient may be affected.. Failure to calibrate the device after changing a dirty window

may result in burns .Fluence levels should be adjusted down after changing a dirty window and calibrating the device, to compensate for the difference between the dirty window and clean window.

Caution

A buildup of frost may occur on the distance gauges during extended treatments. It is important to as ensure that frost does not block the opening of the distance gauge Wipe the distance gauge with a warm moist cloth to prevent extensive accumulation of frost.

Caution

Do not use flammable products on the skin or in the vicinity of the laser.

Additional considerations

The cap covering the DCD canister must stay on to allow the system to operate at the proper temperature

SPECIAL CONSIDERATIONS WHEN USING THE SERENITY PSF

****The Serenity PSF should not be used on skin types V & VI while using the GentleLASE as DCD must be used to protect the epidermis.**

****Remember to turn the DCD to the OFF position. This can be done by adjusting the spray setting to "Zero".**

****A thin layer of lubricant should be used for adequate vacuum.**

****Recommended vacuum setting should start at 450 mbars and adjusted according to patient comfort. Too high of a vacuum pressure may increase the likelihood of bruising or excessive redness. If skin redness is excessive reduce vacuum by 10 mbars.**

****The GentleLASE Plus only accommodates the Standard Handpiece and PCS (pneumatic chamber set).**

For vacuum setting instructions, please refer to the Serenity Pro User Guide

<p>CRYOGEN REORDER - Replacement canisters of cryogen are ordered by the part number listed on the GentleCool™ canisters shipped with laser. Use only 1000-gram size canisters for this product.</p>
