



Vbeam Perfecta, Platinum, Aesthetica 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 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.**

Lesion	Spot size (mm)	Pulse Duration (ms)	Fluence (J/cm ²)	DCD Spray / Delay (ms)	Retreat (weeks)	Comments
Telangiectasia	Facial 5 7 10 3x10	6, 10 ,20 6, 10 ,20 6, 10 ,20 10	7.5-12 7-12 5.5-7.5 11-14	medium 30/20	4-6	Double or triple pulse depending on the refill of the vessel. Use 3x10 on linear vessels. For vessels which do not clear immediately: treat first with the round spot followed by the 3x10 spot. Use of shorter pulse durations will induce purpura but may clear vessels faster.
Leg	3x10	10,20,30, ----- 40	11-18 ----- 15-25	medium 30/20 ----- high 40/20	8-12	Select longer pulse durations to decrease purpura.
Telangectatic Matting	7 10	10,20,30	11-15 6-7	medium 30/20	6-10	Larger spot size may improve results. Expect erythema.



Photo-Rejuvenation Wrinkles	7 10	10 6	7 6	medium 30/20	4 – 6	<p>Treat full face with one pass using dyschromia parameters followed by an additional pass using wrinkles/diffuse redness parameters.</p> <p>Diffuse vessels/background blush: may treat the entire cosmetic unit w/ 50% overlap using a larger spot. Shorter pulse durations and higher fluences may induce purpura.</p> <p>Vessels may be pulsed 2-3 times to obtain transient intravascular purpura, which will disappear and become bluish pink" dusky erythema."</p> <p>May use 10-12mm spot then retreat larger vessels immediately with smaller spot size.</p>
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	Diffuse Facial Telangiectasia Rosacea	7 10	6, 10 ,20			
	12	40	5-7			
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Dyschromia Benign Epidermal Pigmented Lesions	7	10	7-8	OFF		<p>Press the lens firmly onto the skin until the skin turns pale.</p> <p>Clinical endpoint = darkening or color change at the treatment site-observe tissue response. Always start with the lowest fluence and observe the lesion for several minutes before adjusting fluence. Darker lesions may require lower fluences.</p> <p>Peri-lesional erythema may occur.</p>
	10		5-7			
	-----	-----	-----			
	7PL 10PL	1.5	7-10 5.5-8			
Poikiloderma of Civatte	10	10	5-6.5	medium 30/20	4-6	<p>Always perform test spots laterally. Apply pulses close to one another to minimize uneven pattern. Feather edge (decrease fluence by 1-2 J/cm² @ periphery) to minimize sharp line of demarcation.</p> <p>Expect erythema</p>
Cherry Angioma; Spider Angioma	3 5 7 10	1.5	12 10 8-11.5 5-10	medium 30/20	4-6	<p>Use white, moist template to isolate lesion. Double pulse center of angioma first, then treat peripheral vessels. Clinical endpoint=purpura.</p>

Hemangiomas	5 7 10	1.5	8-10 6-10 5-6	medium 30/20 high 40/20 for larger, thicker lesions	2 weeks (neonate and Infant) 8-12 weeks (Adult)	Use caution and lower fluences for neonates and infants. Treat proliferative hemangiomas every two weeks. Improper treatment may cause scars. Refer to specialist if not within your typical practice. Clinical endpoint=purpura.
Venous Lake	7	1.5	7-10	medium 30/20	4-6	Two treatments may be required. Clinical endpoint=purpura.
Port Wine Stains	5 7	0.45	10-15	medium 30/20	8-12	Use caution lower fluences and DCD for neonates and infants. Clinical endpoint=purpura Use lower fluences on neck and extremities. Ectatic vessels associated with hypertrophic PWS may be double pulsed.
Facial	7	1.5	8-12			
Neck, Head	10		4-7.5			
Trunk, Extremities	5 7 10	1.5	6-12 6-7.5 5-7	medium 30/20		
Hypertrophic PWS	5 7 10	1.5	10-15 10-15 10	high 40/20		
Warts						Non-Facial Warts: Pare thick warts before treatment. <i>Cryogen may be sprayed pre and post laser to cool area.</i> Topical or injected anesthetic may be utilized. Pulse stack (1-3 pulses) if tolerated. Clinical endpoint=purpura. Treat a 1-2 mm margin of uninvolved skin with single pulses at the periphery of the wart. Use of home topical therapy may increase efficacy.
Non- Facial	5 7	1.5	12-15	0	2-3	
Facial	5	1.5	9-9.5	medium 30/20		
						Facial Warts: CAUTION: Single pulses only Observe tissue response Use DCD
Inflammatory Acne Vulgaris	10	3	4.5	medium 30/20	4	Slight redness and light purpura may be experienced, observe closely.
Scars	7 ----- 10	.45, 1.5	7-8 ----- 4-5	medium 30/20	4-6	Treatment may begin after suture removal. Newer more vascular scars may respond better than older, atrophic scars. Clinical endpoint=erythema-purpura.



Striae	10	0 .45	3-7	medium 30/20	4-6	Newer more vascular striae may respond better than older, atrophic striae. Clinical endpoint=erythema-purpura
Benign Cutaneous Vascular Gynecological Lesions including Vulvodynia	7	0.45	5-6	medium 30/20	8	Clinical endpoint is light purpura,
Psoriasis	5 7 10	0.45, 1.5	6-8 4-8 3-8	optional, may use 30/20 for patient comfort	2-4	May require several treatments. Remove scale prior to treatment. Clinical response =purpura.

BOLD SETTINGS ARE DISPLAY SCREEN DEFAULT PARAMETERS FOR:
Vbeam Perfecta, Platinum, Aesthetica

SPECIAL CONSIDERATIONS WHEN USING DCD CRYOGEN SPRAY:

- ♦SELECT MEDIUM (30/20) DEFAULT SETTING
- ♦ADJUST BASED UPON EPIDERMAL RESPONSE AND PATIENT COMFORT

Note: The use of epidermal cooling is strongly recommended. Cooling reduces the rise in temperature in the epidermis, allows for higher tolerated fluences, and provides partial anesthesia.

Do NOT Spray Cryogen into the eyes or into an open wound.

The DCD spray should be sufficient to cover the treatment area and provide epidermal cooling in opposition to the heat generated from the laser. It is important to maintain both skin protection and patient comfort.

Begin with suggested guidelines and increase or decrease settings based on the skin reaction and the patient's tolerance.

Darker skin types do not tolerate excessive amounts of DCD spray. Use caution when increasing DCD spray time on darker skin types. Pre and post cooling with a cold compress may be beneficial.

SPECIAL CONSIDERATIONS WHEN DCD CRYOGEN SPRAY IS OMITTED:

If the Dynamic Cooling Device Option is not utilized **and cooling is desired**, another method of cooling (air cooling or contact cooling, etc.) should be utilized.

Several applications including non-facial warts and benign epidermal pigmented lesions are treated **without** DCD cryogen spray. Application of a cool compress following the treatment may enhance patient comfort post treatment.

A. Pre Treatment Preparation

1. Pretreatment Visit

Patient selection should be based upon the physician's assessment of the individual patient, including a detailed medical and medication history. The treatment protocol should be discussed in detail including risks & benefits, possible 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 practitioners who are knowledgeable in laser tissue interactions.

2. Contraindications and Precautions

- a. Accutane: Wait 6 months after the completion of Accutane therapy
- b. Tattoos: Do not treat tattooed skin, including decorative, permanent makeup and radiation port tattoos.
- c. History of photosensitivity to 595 nm light
- d. Pregnancy: Refer to Candela Corporation policy # 0920-23-0814.
- e. Seizure disorders: Do not treat patients with a history of light-triggered seizures.
- f. Medications: Daily anticoagulation therapy, iron supplements, herbal supplements such as ginkgo, ginseng or garlic may bruise more readily.
- g. Photosensitizing Medications: Medications that induce photosensitivity or medications within or above the 595 wavelengths. Refer to Candela Corporation Drugs That May Cause Photosensitivity. Stop the medication if possible for 3-5 days prior to treatment.
- h. Topical Medications and skin care products: Stop 72 hours pre and post. Self-tanning products must be removed.
- i. Herpes Simplex Virus (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.
- j. Active skin infection: Avoid treatment of open wounds and skin that is actively infected.
- k. Cold sensitivity: Use caution when treating patients with Raynaud's phenomenon.
- l. Keloid scarring: Perform test spots prior to treating larger areas.
- m. Implanted medical devices: Pacemakers, cardioverters and other implantable devices or fillers: consult MD.
- n. Use caution when treating recently tanned skin. Blisters and hyper/hypopigmentation may occur, allow tan to fade prior to treatment to reduce this risk. When in doubt, perform test spot on tanned treated area and un-tanned area for comparison before proceeding.
- o. Treatment of warts may result in hypopigmentation or a scar.

3. Skin Preparation for Treatment

- a. Topical anesthetics may be used prior to laser treatment per manufacturers' directions. **HOWEVER**, the topical anesthetics should be removed from the skin prior to treatment.
- b. Skin must be clean and dry; remove all lotions, perfumes, make-up, deodorant, self tanners, etc.
- c. Candela does not recommend the use of alcohol to clean the skin prior to treatment. Rinse the treatment area thoroughly with water after cleaning with soap (or similar mild cleanser) and water.
- d. Shave hair-bearing areas prior to treatment.

4. Test Areas

- a. 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 1-3 pulses with several incremental increased fluences.
- b. Evaluate the sites in 2 weeks
- c. Treatment may proceed when the expected treatment response is noted.

B. Procedure for establishing the Purpura – Free Threshold

1. Select spot size, pulse duration, fluence and DCD settings.
2. Apply escalating fluences until purpura appears, then reduce the energy by 0.25-0.50 J/cm².
3. Optimum parameters may be achieved by matching pulse duration to vessel size.

Note: Treatment at sub-purpuric fluences may necessitate additional treatments for complete clearance of vessels on the face.

C. Laser Treatment Considerations

1. Perform User Verification Tests prior to each treatment session. This test procedure is outlined in the Operator's Manual.
2. Position patient comfortably and confirm that the patient and everyone in the treatment room are wearing the corrective protective eyewear.
3. Always hold the laser handpiece perpendicular to the skin to apply laser energy, otherwise an uneven application of cryogen and energy may occur, resulting in an adverse skin reaction.
4. The aiming beam and laser beam are dimensionally identical, so the aiming beam can be used to accurately define the treatment area. The spot will be absolutely circular if the handpiece is held at the appropriate 90 degree angle.
5. Always observe the epidermal response throughout the treatment and adjust the fluence and DCD as needed.



6. Measures to prevent untoward effects and decrease discomfort
 - ◆Cool compress or cold gel packs may be applied immediately after treatment to increase patient comfort.
 - ◆After each laser pulse, a gentle rub of the area with a gloved hand may minimize discomfort.

7. Treating Specific Body Areas
 - ◆Upper and lower eyelids may only be treated following the insertion of intraocular corneal eye shields.
 - ◆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; a moistened dental roll or moistened white gauze between the teeth during treatment to prevent unintentional treatment of adjacent tissue.
 - ◆Cover any area requiring shielding with moistened white gauze or a moistened white card to prevent absorption of light. Refer to the Laser Accessory Vendor sheet for additional product information.
 - ◆If desired, a white makeup pencil may be used to draw a treatment area grid.
 - ◆When treating anal area, place wet gauze over the anus first. Methane gas is flammable.

8. The Cleaning and Disinfecting Policy is outlined in Section 6 of the Operator's Manual. Follow the procedures outlined in the distance gauge cleaning protocol to prevent buildup of debris on the distance gauge and to maintain good visibility. The Compression Handpiece Distance Gauge Cleaning and Disinfecting Policy is located in Section 6.

D. Post-treatment care

1. Cool compresses or cold gel packs or chilled aloe Vera gel may be applied after treatment
2. Prolonged exposure to the sun should be avoided; a moisturizing sunblock of at least SPF30+ should be applied per manufacturer's instructions at all times throughout the course of treatment.
3. Clean the area gently and avoid irritation from friction or rubbing.
4. Resume use of usual topical agents when any irritation resolves.

E. Expected Responses

1. Purpuric Treatment: purpura, edema, minimal to moderate discomfort relieved by cold compress or cool gel pack.
2. Non-Purpuric treatment: edema, slight to moderate erythema, and a tight sensation with minimal discomfort.

F. Untoward Effects

- ◆Itching (hive-like response)
- ◆Burning, blistering, scabbing, crusting, color and/or texture changes
- ◆Herpes simplex activation
- ◆Hyperpigmentation (darkening of the skin, transient or long term)
- ◆Hypopigmentation (lightening of the skin; transient, long term or possibly permanent)



- ◆If hypo or hyperpigmentation occurs treatment should not be performed until pigmentation returns to normal.
- ◆Scarring (rare, possibly permanent)

G. Determining the end of treatment

1. Multiple treatments over a period of several months may be required.
2. The provider’s judgment will determine the end of treatment. Treatment should cease when the desired clinical endpoint and patient result has been achieved.
3. Maintenance treatments may be required to maintain the desired result.

H. Additional Warnings and Precautions

CAUTION

A buildup of frost may occur on the distance gauge during extended treatments. Wipe the distance gauge with a warm moist cloth to prevent accumulation of frost

CAUTION

If crescent shaped marks, welts or wheals are noted during treatment, the fluence and or DCD settings should be adjusted immediately. Failure to adjust these parameters can result in subsequent crusting, blistering, or other adverse reactions. Crescents may result from not holding the distance gauge properly. If problem persists, discontinue treatment and refer to user verification test section of the Operator’s Manual.

CAUTION

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

WARNING

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

WARNING

Oxygen will accelerate combustion of any flammable material. Oxygen should never be directed towards or over the laser field, extreme caution should be used. When oxygen is in use, gauze, sponges, and hair near the treatment area should be moistened with water. Be aware that hairspray, gel, deodorants, and other grooming products may contain flammable substances.

CAUTION

Treatment to areas bearing hair may cause the hair to be singe and may cause it to ignite. A fire extinguisher should be available.

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.