Vbeam® Perfecta
Vbeam® Platinum
Vbeam® Aesthetica

Laser Operator's Manual

PN 8501-01-1780 Rev. D - June 2014

CAUTION!

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Federal (USA) law restricts this device to sale by or on the order of a physician or other practitioner licensed by the law of the state in which he/she practices to use or order the use of the device.

Federal law and some international laws also require that this device be utilized under the direction of a physician. This device should only be used by healthcare professionals authorized under US state or international law to treat patients. All persons treating patients with this device should determine whether they are authorized healthcare professionals under the applicable US state or international law.

(EC Authorized Representative)
Scanlan Group B.V.
Aalsmeerderweg 610
1437 EJ Schiphol-Rozenburg
The Netherlands
Phone: +31(0) 20 653 0553
Fax: +31(0) 20 653 3053

Candela Corporation
530 Boston Post Road
Wayland, MA 01778-1886
Telephone (508) 358-7637
Toll Free (800) 733-8550 (Technical Assistance)
Toll Free (800) 73-LASER (Customer Service)

CE 0123

Table of Contents

Section 1: The Vbeam Laser System

Applications

This Operator's Manual provides operation instructions for the Vbeam laser system with all available spot sizes. The spot sizes included in your laser system depends on which options were purchased. The following table lists all available spot sizes for the Vbeam laser systems.

Table 1.1: Vbeam Laser System Configurations

Laser System Configuration	Spot Sizes (mm)
Vbeam Aesthetica	7 and 10 mm Smart Gauges 7 and 10 mm PL Distance Gauges
Vbeam Platinum	3, 5, 7, 10, 12 and 3x10 mm Smart Gauges
Vbeam Perfecta	3, 5, 7, 10, 12 and 3x10 mm Smart Gauges 7 and 10 mm PL Distance Gauges

The Vbeam laser system is a flashlamp-excited pulsed dye laser in the Candela Family of Pulsed Dye Laser Systems indicated for dermatological applications.

The Vbeam delivers pulses of laser energy at a wavelength of 595 nanometers (nm) that passes through the dermis and epidermis skin layers and is absorbed by the hemoglobin in the blood vessels rather than by the surrounding tissue. The absorbed laser energy is converted into heat, causing coagulation of the target vessels, which are not subsequently regenerated. The pulse duration used is long enough to produce controlled coagulation but short enough to avoid thermal damage to the surrounding tissue.

This process of targeting a specific chromophore (hemoglobin) is called selective photothermolysis. Ideally, the wavelength selected for eradiation of vascular lesions is highly absorbed by the lesion and only minimally absorbed by other competing chromophores in the skin. The laser pulse duration should be shorter than the thermal relaxation time of the target absorbing the laser radiation in order to confine the thermal damage and spare surrounding tissue. The relaxation time of a target is determined by size (milliseconds or greater for vascular lesions).

Vbeam dermatological applications include the treatment of benign cutaneous vascular lesions, benign vascular gynecological lesions and periorbital wrinkles. For instructions on the specific applications and treatment parameters for each indication, refer to the Candela Treatment Guidelines for the Vbeam Laser System (Candela Document Part Number (P/N) 8502-00-0891).

Descriptions

The Vbeam Pulsed Dye Laser System (Figure 1.1 and 1.2) is a pulsed, flashlamp-excited dye medical laser controlled by two separate processors. One processor is used to control the Graphical User Interface (GUI) and the other is used to control the laser I/O functionality. The user interface is an LCD panel with a touch screen overlay. This allows the operator to select the laser operating parameters, initiate an automatic calibration procedure and select DCD parameters.

The Laser System

The Vbeam Laser System uses a dye solution as its lasing medium, which is excited by a high intensity xenon flashlamp as it continuously circulates through the laser head. After a number of exposures to the flashlamp energy, the dye becomes degraded and the dye cartridge must be replaced. The Vbeam laser also includes the unique MegaDye Cartridge that enables the system to deliver many thousands of pulses before requiring dye replacement.

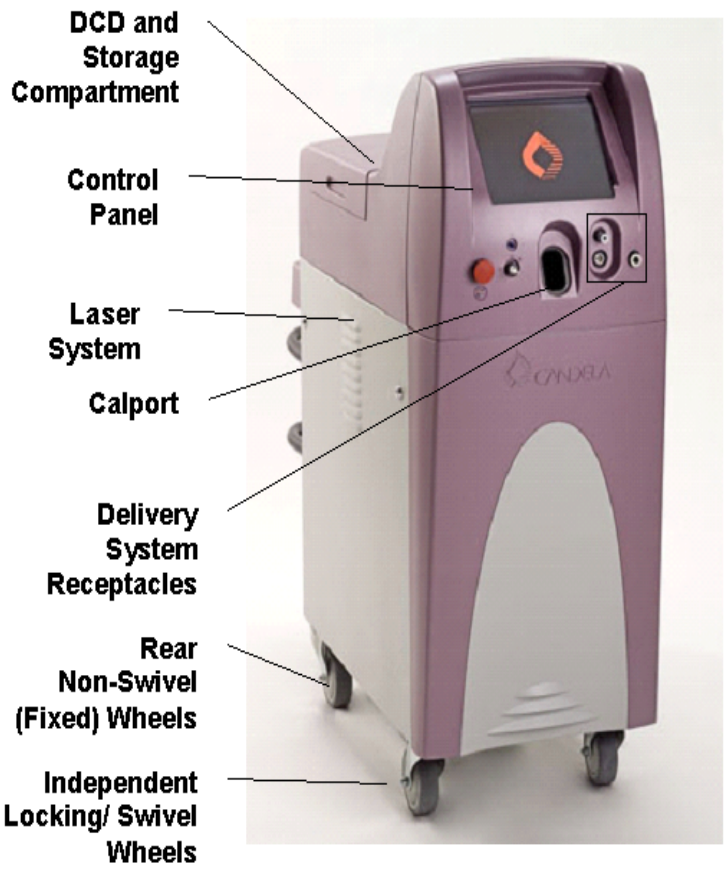


Figure 1.1: The Laser System

The laser head is cooled by the circulation of deionized (DI) water, which in turn is cooled by ambient air passing through a heat exchanger. A combination of heaters and heat exchangers maintain the temperatures of various system components within the optimum range for efficient laser operation. A calibration port is located centrally on the front of the laser. This port is used to calibrate the output of the laser through the handpiece at selected fluence levels.

To provide energy to the flashlamp, a high-voltage power supply charges a storage capacitor. Then the high voltage switch transfers a portion of the energy from the storage capacitor into the flashlamp. The resulting flash excites the dye solution causing the emission of a pulse of laser energy.

The output of the laser is delivered through an optical fiber coupled to a removable distance gauge. The distance gauge contains the internal focal lenses and a protruding distance gauge ring. The distance gauge ring is placed against the skin to ensure proper focusing and spot placement on the treatment area. A trigger-switch (finger-switch or footswitch) controls the delivery of the pulses.

The user selects the desired energy density (fluence) level and enables or disables the laser at the control panel. The laser delivers pulses at a repetition rate of up to 1.5 pulses per second depending on the fluence, pulse duration, repetition rate and spot size setting.

The laser system is equipped with interlocks that will disable the laser emissions if the remote interlock circuit is open or when the MegaDye Cartridge Top Cover or the fiber is removed.

A green aiming beam is provided to illuminate the treatment area. The aiming beam and treatment beam are dimensionally identical, so the aiming beam can be used to accurately define the treatment pulse location. The aiming beam is illuminated when the laser enters the Ready State.

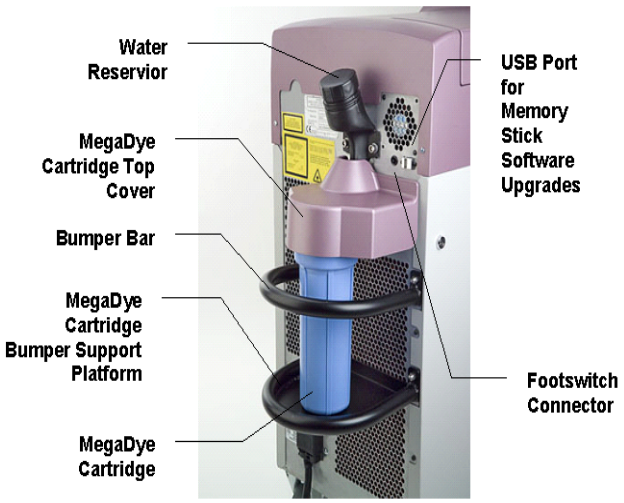


Figure 1.2: Rear of the Laser System

Dynamic Cooling Device (DCD™)

The laser system comes with a skin cooling device referred to as the Dynamic Cooling Device (DCD). This device is located inside the DCD and Storage Compartment of the laser (Figure 1.1). The DCD was FDA cleared under K001589. The DCD consists of an electrically controlled spray nozzle located at the treatment end of the handpiece, a cryogen reservoir canister and the associated electronic control circuitry located inside the system enclosure.

The cryogen, GentleCool™ is stored under pressure in the reservoir canister and brought to the solenoid valve via tubing. When the DCD system is on, depressing the trigger switch will cause a burst of cryogen spray to be applied to the skin prior to the laser pulse. Controls are provided on the laser front panel for the adjustment of the spray burst duration and for the time delay between the spray burst and the laser pulse. Refer to Section 6 of this Manual for cryogen canister installation, warm-up, removal and disposal instructions.

Handpiece Delivery System

Each laser configuration comes with its own Delivery System and Distance Gauge Kit. The Vbeam Perfecta Laser System comes with the Perfecta Delivery System and Distance Gauge Kit that includes a Perfecta delivery system and two types of distance gauges, the Smart Gauges and the Pigmented Lesion Distance Gauges. The Platinum and Aesthetica Delivery System Kits each have their own assortment of distance gauges and a matching delivery system (See Table 1.1).

Each delivery system (Figure 1.3) consists of a cable assembly and handpiece assembly. Each spot size requires a separate distance gauge to be installed in the handpiece.

The cable assembly contains the fiber optic, cryogen input line and valve control wires. The handpiece assembly contains the DCD spray nozzle, the trigger switch (fingerswitch) and the safety and detection electronics. The laser aperture is located at the distal end of the handpiece where the distance gauge is inserted. The spray nozzle is located near the distance gauge at the treatment end of the handpiece. The finger-switch is located on the top of the handpiece.

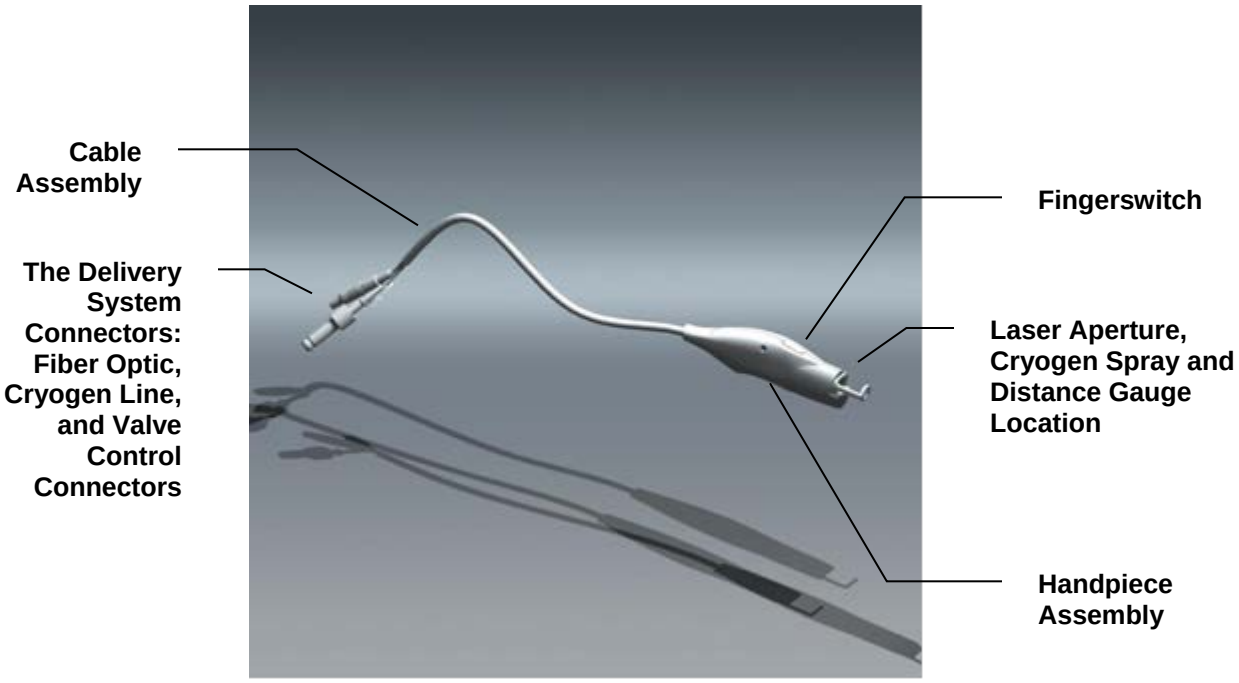


Figure 1.3: The Handpiece Delivery System

Distance Gauges: The Smart Gauges

The Smart Gauges

The Vbeam Perfecta "Delivery System and Distance Gauge Kit" includes 6 aluminum distance gauges called the Smart Gauges. The distance gauge assembly contains internal focusing lenses and input/output windows to protect the lenses from dust and debris.

The Smart Gauges come in 3, 5, 7, 10, 12 and 3x10 mm spot sizes. Removal and cleaning of the windows is explained in Section 6 of this Manual.

Figure 1.4: The Smart Gauges

The Pigmented Lesion Distance Gauge

The Pigmented Lesion Distance Gauge is designed for the treatment of benign epidermal pigmented lesions. The distance gauge (Figure 1.5) is identical to the Smart Gauges with the addition of a lens in the ring. This lens contacts the skin.

The Vbeam Aesthetica and Perfecta Laser Systems include a 7mm and 10mm distance gauge. Because this lens is in constant contact with the skin, it is important to keep this lens clean for optimum performance. Cleaning instructions are provided in Section 6 of this Manual.

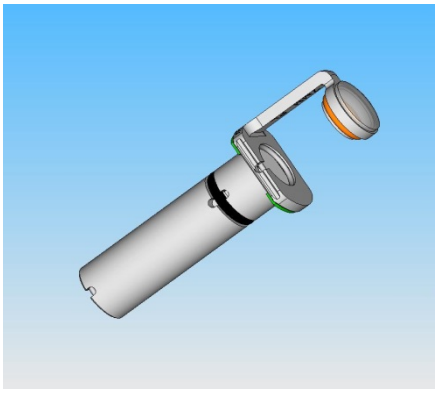


Figure 1. 5: The Pigmented Lesion Distance Gauge

Fiber Pole

The fiber pole supports the delivery system cable as shown in Figure 1.6. This device will keep the cable suspended and reduce the weight of the delivery system during use.

Figure 1.6: The Fiber Pole Assembly

The fiber pole is adjustable and can be removed from the laser system without the use of tools. The hook at the end of the fiber pole supports the fiber and helps to prevent damaging kinks or bends. The black knob located on the elbow of the fiber pole is used to lock the pivoting joints within the arm. To adjust the fiber pole, the black knob can be turned counterclockwise to loosen and move the pole to the desired position. Turn the knob clockwise to tighten and lock the fiber pole in position.

Caution!

To reduce the risk of personal injury and damage to the delivery system fiber, use the Fiber Pole to support the delivery system at all times. When not in use, insert the handpiece in the Calport. This removes excess fiber slack from the delivery system and the possibility of damage to property and/or personal injury from stepping on, tripping and/or running wheels over the fiber.

Caution!

When using the fiber pole to support the delivery system, make sure there are no sharp bends in the delivery system. The Vbeam laser system contains a fiber optic cable that can be damaged if subjected to excessive bending. Never pulse the laser system if the delivery system bend radius is less than six inches or the optical fiber will be damaged.

When not in use, the fiber pole can be folded for storage. Remove the fiber from the hook and turn the black knob counterclockwise to loosen all the joints. Fold the fiber pole and tighten the black knob clockwise to hold it in position.

To completely remove the fiber pole assembly from the laser system, firmly pull the bottom pole out of the two grommets on the side. There is a plastic cap at the base of the pole. This cap should be reinstalled with the pole.

Locking/Swivel (Front) and Fixed (Rear) Wheels

The laser is equipped with wheels. The two front wheels are capable of swiveling which makes parking in tight spaces easy. The two rear wheels are non-swiveling (fixed) wheels for direct movement of the laser (Figure 1.1).

The front swivel wheels contain levers which stop the wheels from rotating. To prevent the laser from moving, the front wheels must be locked. To lock the front wheels, depress the locking lever over each of the front wheels. To release, pull up on the lever. There are no levers in place for the rear wheels.

System Specifications

The Vbeam Laser System Specifications

Table 1.2 Specifications for the Vbeam Laser System	
Laser Type	**Flashlamp-excited, pulsed dye laser**
Wavelength	**595 nm**
Method of Optical Output	**Lens-coupled optical fiber with user selectable spot sizes.**
Maximum Delivered Energy	**8 Joules (J)**
Accuracy of Output Energy	**± 20%**
Pulse Repetition Rate	**Up to 1.5 Hz repetitive pulsing**
Pulse Duration	**0.45- 40 milliseconds**
Beam Spot Sizes	**3, 5, 7, 10, 12 millimeters and 3x10(elliptical)**
Cooling Method	**Ambient air**
Dimensions	**43” H x 16” W x 30” D (39” D with dye cartridge)**
Weight	**290 lbs.**
Aiming Device	**Class 2 Light (per EN 60825-1), 520 - 550 nm, 5.0 mW**
Cryogen	**HFC 134a**
Voltage and Power	**220 - 230 V~ , 50/60 Hz, single phase, 4,000 VA or 17.4 A at 230 V~**

Medical Electrical Equipment Standard Specifications and Classification

Electromagnetic Compatibility (EMC)

Table 1.3: Compliance per IEC / EN60601-1	
Type of protection against electric shock	**Class I equipment**
Degree of protection against electric shock offered by the applied part	**Type "B"**
Sterilization method	**None Required**
Ingress Protection	**Ordinary enclosed**
Not "AP" or "APG" equipment	

Regulatory Classifications

The laser is a Class 4 laser product with Class 1 aiming beam per EN60825-1 Laser Hazard Classification. The Candela Laser System is a Class II medical device per FDA 21 CFR 878.4810, and a Class 2b (Rule 9), non-invasive, active device according to Annex IX of Directive 93/42/EEC and Canadian Health Ministry Classification.

Candela Family of Pulsed Dye Lasers complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated July 26, 2001

Candela Family of Pulsed Dye Lasers should be installed and operated according to CAN/CSA-Z386-92: Laser safety in health care facilities.

Electrical Requirements

The Electrical Requirements for the Vbeam Laser System are listed in Table 1.4.

Caution!

IF A PLUG OR LINE CORD NEEDS TO BE CHANGED, IT MUST BE DONE BY A QUALIFIED PERSON IN ACCORDANCE WITH THIS SECTION AND THE ELECTRICAL CODE OF THE INSTALLATION SITE.

The laser is shipped with a twelve foot (3.7 meter) power cord terminated with a locking NEMA L6-30P plug for power connection in the United States. The installation site requires a mating NEMA L6-30R power receptacle located within ten feet (3 meters) of the intended laser system location. See Table 1.4 for electrical service requirements.

For International installations, the power connections should be made with a grounded 2-conductor plug and receptacle pair. The plug and receptacle must be rated for the service line voltage at a minimum and capable of handling 4,000 VA (See Table 1.4 for detailed ratings). A plug meeting these requirements must be installed onto the laser system line cord. Alternately, the entire line cord may be replaced with one which is terminated with the appropriate plug.

Installation Site Electrical Service Requirements Table 1.4 Electrical Requirements	
United States	**220 V – 230 V~, 60 Hz, center-tapped, single phase, dedicated branch circuit with earth ground conductor capable of delivering 4000 VA of power**
Worldwide	**220 V – 230 V~ (± 10%), 50/60 Hz, single phase, dedicated branch circuit with earth ground conductor capable of delivering 4000 VA of power.**

Operation of the Vbeam Laser System on a power line that is not consistently within these specifications may damage the system and will void the warranty.

Note

The system may be isolated from AC mains by unplugging the power cable from the electrical service.

Figure 1.7: Replaceable Power Cable Inlet Attachment

Ground Continuity Tests

The laser system requires a connection to earth ground to reduce the risk of electric shock. To verify that this safety feature is functioning properly, it is recommended that continuity between the laser chassis and mains plug grounding pin be checked annually at a minimum, monthly if the laser is moved frequently, or before use if the line cord and/or power plug has been altered or replaced. If unsure of which pin is "ground" on your particular power plug, consult an Electrician for help. The following procedure verifies ground continuity:

- Using the Ohms setting of a Volt-Ohm meter, set the scale to "x1". Measure the resistance between the plug's ground pin and any unpainted conductive surface on the laser chassis. This reading must fall between 0 – 0.1 Ohms.

- A battery and light, or a battery and buzzer combination maybe be alternatively used to verify a ground connection between any unpainted conductive surface and the plug's ground pin if an Ohm meter is not available. An adequate ground connection will be indicated by the illumination of the light or sounding of the buzzer.

Environmental Requirements

Before the installation of the Vbeam Laser System, the intended site must be prepared as described in this section. The site must have sufficient space to accommodate the laser system, must provide the proper electrical power configuration and receptacles, and must meet the additional environmental specifications.

Important Note

Installation of the laser must be performed by a Candela Service Representative. Following installation, a Candela Clinical Consultant must instruct designated personnel on the basic operation and care of the laser. An in-depth clinical training is required of a physician to become proficient in the use of the Vbeam Pulsed Dye Laser System.
Reference document: Vbeam Service Manual (P/N # 8501-00-1795).

Important Note

Treatment room areas associated with the use of cryogen require special precautions. Refer to the Chemical Hazards paragraphs in Section 2 of this manual and the Material Safety Data Sheet or MSDS sheet (Candela P/N 8501-00-1701) for General Treatment Area Guidelines and further information.

Space Requirements

Sufficient floor space is required for the laser system. Approximately 15 inches (40 cm) of clearance is required between the rear panel and the wall to allow room for the power cord and proper circulation of air from the cooling vents.

Humidity

Humidity of 20% to 80% (non-condensing) should be maintained in the laser room.

Air Quality

Ensure that the atmosphere is non-corrosive with no salts or acids in suspension in the air. Acids, corrosives and volatile materials are likely to attack electrical wiring and the surfaces of optical components.

Keep air-borne dust particles to a minimum. Dust particles can cause permanent damage to optical surfaces. Metallic dust can be destructive to electrical equipment.

Ambient Temperature

A temperature between 65° and 85°F (18° and 29°C) should be maintained in the laser room during operation. The laser system must be stored at a temperature between 40° and 110°F (5° and 43°C). Avoid placing the laser system near heating outlets or other sources of air currents that could cause uneven cooling in the laser system.

Relocation

Care should always be taken when moving the Vbeam Laser System. Before moving the laser, disconnect the footswitch tubing from the connector located on the rear panel of the laser and the Delivery System from the front of the laser (place the Delivery System into its original box for transportation if necessary). A handle located on the top cover behind the front panel allows easy movement of the system, but take special care when maneuvering over thresholds, elevator doors, ramps and other uneven or sloping floor surfaces. A severe physical shock could cause the alignment of the laser head or the optical fiber to be disturbed resulting in personal injury or physical damage.

Warning!

DO NOT USE THE FIBER POLE OR REAR DYE CARTRIDGE PLATFORM/BUMPER BAR (FIGURE 1.2 AND 1.6) AS HANDLES TO LIFT OR MOVE THE LASER SYSTEM. THEY WERE NOT DESIGNED TO BE USED AS HANDLES TO SUSTAIN THE WEIGHT OF THE LASER FOR RELOCATING.

If it becomes necessary to relocate the laser, contact Candela Technical Support or your distributor for details. Failure to do so may result in personal injuries or damage to the system and may void any warranty.

Mobile Use

The Vbeam laser system is not designed for mobile use.

Transport and Storage

For transport and storage of the Vbeam Laser system, the temperature must be kept between 40° and 110° F (5° and 43°C) and humidity between 20 to 80% (non-condensing). Ambient atmospheric pressure is suitable with no restrictions.

Warning!

DO NOT EXPOSE TO TEMPERATURES BELOW 5°C (40°F) OR DAMAGE MAY OCCUR. IF THE LASER IS EXPOSED TO TEMPERATURE BELOW 5°C, CONTACT CANDELA TECHNICAL SUPPORT PRIOR TO USE.

Section 2: Hazards, Precautions and Safety Features

Laser Room Precautions

- Identify the laser room clearly. Post appropriate warning signs in prominent locations at all entrances to the laser room.
- Cover all windows, portholes, etc. with opaque material to prevent unintended viewing or laser light escaping from the laser room.
- When the Vbeam Laser System is in operation, restrict entry and limit access to the laser room only to personnel that are both essential to the procedure and well trained in laser safety precautions.
- Make sure that all laser room personnel are familiar with the laser system controls and know how to shut down the laser system instantly in an emergency.

Caution!

The use of flammable anesthetics or oxidizing gases such as nitrous oxide and oxygen should be avoided. The high temperature produced during normal use of the laser equipment may ignite some materials, for example cotton or gauze pads when saturated with oxygen. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. Attention should also be drawn to the danger of ignition of endogenous gases.

Flash Fire Hazards

Hair, gauze, masks, cannula and airway materials can be ignited by laser energy in an oxygen-enriched atmosphere even if thoroughly soaked with saline. The following scenario can lead to a flash fire during laser treatment:

- Oxygen is administered via a mask, endotracheal tube, or nasal cannula. Leakage of oxygen generally occurs near the eye region where a tight seal of the mask is difficult to maintain, near the nasal area when a cannula is used, or near the mouth when an endotracheal tube is used.
- An oxygen-rich atmosphere is created and dissipates over the face. Transient local concentrations of oxygen can greatly accelerate combustion.
- During treatment, the laser beam strikes combustible material which absorbs the laser energy and heats the material above is combustion point. This may occur simply by singeing the tip of a single dry hair.
- This momentary and possible unnoticeable, ignition sets off a more significant flash fire. The fire then follows a path from the peripheral area of the oxygen enriched atmosphere to the oxygen source.
- Other combustible substances are involved as a secondary effect of the initial ignition and may be related to hair, gauze, oxygen delivery devices, anesthesia gases or byproducts of anesthesia in the oxygen enriched atmosphere. A burn may then occur where this secondary effect is present.

Caution!

THE ELECTRICAL AND LASER RADIATION HAZARDS PRESENT DURING SERVICING OF THE VBEAM LASER SYSTEM CAN BE EXTREMELY DANGEROUS AND SHOULD BE SERVICED ONLY BY THOSE QUALIFIED TECHNICIANS WHO HAVE RECEIVED APPROPRIATE TRAINING ON THE VBEAM LASER SYSTEM FROM CANDELA.

Optical Precautions

Laser Eye Hazards and Safety Eyewear

Caution!

USE ONLY SAFETY EYEWEAR WITH AN OPTICAL DENSITY OF ≥ 5.2 BETWEEN 592 AND 596 NANOMETERS (NM).

The laser beam emitted by the Vbeam Laser System is capable of causing loss of vision. The laser operates at 595 nm, which falls within the visible spectrum. The cornea and lens of the eye are transparent to visible light. Any energy emitted by the Vbeam Laser System that enters the eye will be focused directly on the retina. Direct contact of the laser beam on the retina can cause temporarily clouded vision, retinal lesions, long-term scotoma (vision absence in an isolated area), long term photophobia (sensitivity to light) and/or loss of vision.

Nominal Ocular Hazard Distance (NOHD)

The laser aperture of the Vbeam Laser System is at the distal end of the handpiece. The beam enlarges as the distance from the handpiece increases. The Nominal Ocular Hazard Distance (NOHD) is the distance at which the beam is so big it is no longer dangerous to the unprotected eye. This distance along with the full angle beam divergence for each handpiece is shown in Table 2.1.

To avoid vision hazards, everyone within the NOHD of the Vbeam Laser System must wear appropriate eye protection available from Candela.

Table 2.1: Vision Hazards Vbeam Laser NOHD Zone

Spot Diameter, mm	Beam Divergence Full Angle (radians)	NOHD, meters
3	0.064	125.3
5	0.063	184.2
7	0.100	129.7
7PL*	0.087	132.8
10	0.161	78.9
10PL*	0.141	90.5
12	0.198	65.7
3 x 10	0.095	122.6

*PL = Pigmented Lesion Distance Gauge

Caution!

THE LASER BEAM EMITTED BY THE VBEAM LASER SYSTEM SHOULD NEVER BE DIRECTED AT ANY PART OF THE BODY OTHER THAN THE INTENDED SITE OF TREATMENT OR TESTING.

Optical Safety Precautions

Follow these precautions to ensure optical safety:

- Appoint one person responsible for the laser system controls during the procedure.
- Ensure that all personnel wear appropriate safety eyewear whenever the laser system is on.
- Never look directly into the laser beam even when wearing protective eyewear.
- Never allow the laser beam to be directed at anything other than the targeted area or the calibration port.
- Never permit reflective objects such as jewelry, instruments or mirrors to intercept the laser beam.
- When the Vbeam Laser System is not in use, place it in STANDBY state to prevent accidental pulsing.
- When the Vbeam Laser System is unattended, remove the key from the key-switch or use the password protected Screen Lock Button on the Display Panel to prevent unauthorized use.

Electrical and Mechanical Hazards

High Voltage Electrical Hazard

The Vbeam Laser System converts and amplifies the AC line voltage to produce extremely high voltages inside the laser system that may be lethal. It is possible for high-voltage components to retain a charge after the power supply has been turned off and even after the Vbeam Laser System has been disconnected from the line voltage. Therefore, no part of the exterior housing should be removed except by a trained and authorized technician.

Warning!

TO AVOID RISK OF ELECTRIC SHOCK, THIS EQUIPMENT MUST ONLY BE CONNECTED TO A SUPPLY MAINS WITH PROTECTIVE EARTH.

Fiber Optics

The Vbeam Laser System laser delivery system utilizes fiber optics that can be damaged if installed or subjected to excessive bending. To avoid damage to the optical fiber, limit bends to a radius of 6 inches (15 cm) or greater. Failure to follow recommended procedures may lead to damage to the fiber or delivery system and/or harm to the patient or user. When damaged, the fiber or delivery system becomes a potential fire hazard (See Fire Hazards).

Laser Mobility Care and Wheel Locks

To prevent the laser from moving, both front wheels must be locked. To lock the wheels, step down on the tabs on the front of the wheels. To unlock, pull up on the extending tabs.

Although the Vbeam Laser System is well balanced, it weighs more than 290 pounds (almost 135 kg) and may cause injury if proper care is not used when moving it. The system should always be moved carefully and slowly.

Chemical Hazards

Laser Dye Solution and Triplet Quencher

The dye solution circulating through the system and contained within the filter housing should be treated as toxic. The system also utilizes triplet quencher contained in a clear glass jar which should be treated as toxic. Read MSDS Candela P/N 7121-90-9940 for more complete information.

The MegaDye Cartridge can be replaced by an authorized Candela Service Representative or the customer may perform this procedure. The triplet quencher is not accessible by the customer and must be changed by a Candela authorized Service Representative. The Dye Change Kit contains instructions for the dye cartridge replacement, MSDS info and dye kit return instructions. See Laser MegaDye Cartridge and Dye Change Kit in Section 6.

Use of dye or solvents not supplied by Candela voids all warranties. Candela takes no responsibility for any equipment failure, material damage, or personal injury resulting from such misuse.

In case of an accident, take the following measures:

- **Ingestion:** If the dye solution is ingested, drink 2 – 4 glasses of water, induce vomiting and call a physician.
- **Inhalation:** If the vapors of the dye solution are inhaled, move to fresh air. If symptoms are present, treat symptomatically and get medical attention.
- **Eye Contact:** If the dye solution gets into the eyes, immediately flush the eyes with water for at least 15 minutes and get medical attention if symptoms are present.
- **Skin Contact:** If the dye solution comes in contact with the skin, flush immediately with water and wash thoroughly with soap and water. Any dye residue (stain) remaining on the skin will disappear in time.

Cryogen

The laser system uses a Hydrofluorocarbon (HFC) or cryogen in the Dynamic Cooling Device (DCD).

- **Inhalation:** If high concentrations are inhaled, immediately move to fresh air. Keep person calm. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.
- **Skin Contact:** If large amounts of cryogen contact the skin due to a leak or rupture in the cryogen system, flush skin immediately with water and call a Physician to check for frostbite. Treat for frostbite if necessary by gently warming affected area.
- **Eye Contact:** In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician.
- **Ingestion:** Ingestion is not considered a potential route of exposure.

Important Note to Physicians

Because of possible disturbance of cardiac rhythm, catecholamine drugs such as epinephrine should only be used with special caution in situations, when performing emergency life support. See MSDS sheet, Candela P/N 8501-00-1701.

Guidelines for Cryogen Treatment Areas

Treatment room areas associated with the use of GentleCool™ products (cryogen) require special precautions, since there is a possibility of cardiovascular sensitivity in high concentration situations and frostbite hazards from an abnormal discharge of the product.

The objective is to maintain a cryogen concentration level in the treatment area below 1000 parts per million (ppm). This is accomplished by balancing the size of the treatment area, amount of ventilation, and duration of cryogen spraying.

General Treatment Area Guidelines

- Minimum treatment area size should be 40 sq. ft. (5 x 8 ft.) – based on an 8 ft. ceiling.
- Any treatment area smaller than 513 sq. ft. (but larger than 40 sq. ft.) should have a 130 CFM (cubic feet per minute) or higher fan in use during treatments with cryogen. It should be used in an exhaust mode. Since cryogen is heavier than air, it will settle toward the floor. If at all possible, have the exhaust fan lower rather than at ceiling height. A smoke evacuator is not a substitute.
- All treatment areas should have cross ventilation. At least one ventilation opening should be at floor level. If at all possible, one ventilation opening should be to outdoors. Both opening sizes should be approximately the same area.
- Refer to MSDS sheet (Candela Part Number 8501-00-1701) for further information.

Frostbite risks

Treatment areas should have sufficient free floor space to allow a patient or user the ability to move away from unanticipated spray of cryogen. The following table gives some exposure guidelines:

Table 2.2: Frostbite Prevention in Treatment Areas

Source of Cryogen Release	Visual outer edge of spray	Hand detection of outer edge of spray
Direct release from cryogen canister	27 inches	31 inches
Release from tip of handpiece (spray nozzle)	19 inches	23 inches

For specific customer situations, contact Candela Technical Support.

Fire Hazards

Refer to the American National Standard for Safe Use of Lasers ANSI Z136.3-2005 Section 7.

Treatment Area

Never use any flammable substance, such as alcohol or acetone in the preparation of the skin for treatment. Use soap and water if necessary.

Anesthetics

Anesthetics administered either by inhalation or topically must be approved as non-flammable.

Instruments

Since laser beams are reflected by most shiny surfaces, all instruments used in laser procedures should have brushed, burnished, or blackened, non-reflective surfaces.

Laser Fiber Fire Hazard

Vbeam Laser System fibers carry significant laser energy. If the fiber were to break during laser pulsing, a sudden flash or flame may be observed at the break point. This flash or flame with each pulse will continue until pulsing is stopped. Individuals in contact with this flash or flame could receive a burn. Ignition of combustible materials (including clothing) in the proximity of the fiber break could also occur.

- If a break or sudden flash or flame is observed in the fiber, discontinue pulsing immediately.
- Because a break could occur suddenly, always position the fiber during each use such that it is in full view. For example, do not drape the fiber over the shoulder or around the back, leaving a portion of the fiber out of view during use.
- Do not lay the fiber across combustible materials during use.
- Do not drape the fiber over the shoulder or back or place it on combustible material.

Laser Generated Air Contaminants (LGAC)

Laser Plumes

Laser Plume may contain viable tissue particulate.

Please reference the American National Standard for Safe Use of Lasers (ANSI A136.3. -2005), Section 7.3 Laser Generated Air Contaminants.

Some mechanism for decreasing LGACs should be used. Based on the type of condition being treated by the laser, there may be a higher incidence of LGAC.

NIOSH Hazard Controls

Reference the NIOSH Hazard Controls: Control of Smoke from Laser/Electrical Surgical Procedures bulletin (HC11) – US Department of Health and Human Services, Public Health Service: National Institute for Occupational Safety and Health, September 1996.

NIOSH has shown that airborne contaminants generated by laser use can be effectively controlled by proper ventilation and work practices. (The thermal destruction of tissue creates smoke byproduct, which can contain a variety of gases, vapors, dead and live cellular material, including blood fragments).

Electromagnetic Interference

The Vbeam laser system was designed to comply with IEC/EN 60601-1-2 (Group 1, Class A) "Electromagnetic Compatibility Requirements and Tests". Class A equipment is intended for use in commercial and industrial locations. A portion of IEC/EN 60601-1-2 deals with measurements of unwanted radio frequency emissions generated from a product. Both radiated emissions (radiated through the air) and conducted emissions (conducted into the AC Mains) are measured. Radiated and conducted emissions from a product have been known to interfere with the performance of other equipment in the vicinity. The emissions from the Vbeam laser system have been reduced as far as practical without compromising functionality.

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the tables below.

Table 2.3: Guidance and Manufacturer's Declaration – Emissions
All Equipment and Systems

The Vbeam system is intended for use in the electromagnetic environment specified below. The customer or user of the Vbeam system should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The Vbeam system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The Vbeam system is suitable for use in all establishments, other than domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	N/A	
Flicker IEC 61000-3-3	N/A	

Table 2.4: Guidance and Manufacturer's Declaration – Immunity All Equipment and Systems			
The Vbeam system is intended for use in the electromagnetic environment specified below. The customer or user of the Vbeam system should ensure that it is used in such an environment.			
Immunity Test	**EN/IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
ESD EN/IEC 61000-4-2	±6kV Contact ±8kV Air	±6kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%.
EFT EN/IEC 61000-4-4	±2kV Mains ±1kV I/Os	±2kV Mains ±1kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN/IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/ Dropout EN/IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Vbeam system requires continued operation during power mains interruptions, it is recommended that the Vbeam system be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz Magnetic Field EN/IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Table 2.5: Guidance and Manufacturer's Declaration – Emissions Equipment and Systems that are NOT Life-supporting			
The Vbeam system is intended for use in the electromagnetic environment specified below. The customer or user of the Vbeam system should ensure that it is used in such an environment.			
Immunity Test	**EN/IEC 60601-4-4 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
			Portable and mobile communications equipment should be separated from the Vbeam system by no less than the distances calculated/listed below: D=(3.5/V1)(Sqrt P)
Conducted RF EN/IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	
			D=(3.5/E1)(Sqrt P) 80 to 800 MHz
Radiated RF EN/IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
			D=(7/E1)(Sqrt P) 800 MHz to 2.5 GHz
			where P is the max power in watts and D is the recommended separation distance in meters.
			Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1).
			Interference may occur in the vicinity of equipment containing a transmitter.

Table 2.6: Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Vbeam System
Equipment and Systems that are NOT Life-supporting

Recommended Separations Distances for the Vbeam system

The Vbeam system is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the Vbeam system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the Vbeam system as recommended below, according to the maximum output power of the communications equipment.

Max Output Power **(Watts)**	Separation (m) 150kHz to 80MHz **D=(3.5/V1)(Sqrt P)**	Separation (m) 80MHz to 800MHz **D=(3.5/E1)(Sqrt P)**	Separation (m) 800MHz to 2.5GHz **D=(7/E1)(Sqrt P)**
0.01	.1166	.1166	.2333
0.1	.3689	.3689	.7378
1	1.1666	1.1666	2.3333
10	3.6893	3.6893	7.3786
100	11.6666	11.6666	23.3333

Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment.

If interference from the Vbeam laser system is suspected, ensure that the unit is plugged into an AC mains that is not shared by the affected equipment. If the interference still exists, move the Vbeam laser system or the affected equipment into another room.

Warning!
The Vbeam laser system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.

Warning!
When treating patients with this laser and using the Dynamic Cooling Device (DCD) feature in conjunction with an ECG monitoring device attached to the patient, interference with the ECG monitoring device may result.

Warning!
Care must be taken with patients who have an implanted pacemaker. Pacemaker operation may be affected by an electrical "plasma effect" when treating near or at the site of the implant.

Safety Features

Key-lock Switch

This key-operated switch controls electrical power to the laser system (Figure 3.1). The Candela laser system can be operated only with the key provided by Candela. The key should be removed from the key-switch when the laser is not in use.

Laser Emergency Stop Switch

When the red switch with this label 

underneath (located on the lower left side of the control panel) is pressed, the Vbeam laser is shut down immediately (Figure 3.1).

Screen Lock Button

When the screen lock button is pressed, it will query the user about locking the screen (See Section 3). If they select yes by pressing the button with the checkmark, the system will be put into Standby, all screen buttons will be locked except for the screen lock button. A Candela logo screen with a padlock and key button will be displayed indicating the display is locked. When the screen is already locked and the screen lock button is pressed, a keypad will be displayed to enter in a 4 digit code (code is “5277”). This code will be the same for all lasers and provided in the User's Manual. If the laser is locked and powered down/up, it will still be in a locked state.

PFN (Pulse Forming Network) Beep Sound Alert

An audible beep will be heard when the Pulse Forming Network (PFN) is fully charged and the laser is ready to deliver a pulse of energy.

Lasing Beep Sound Alert

An audible beep will be heard and READY indicator will change to a lasing symbol to indicate that the laser is releasing laser energy.

Ready Lamp Light Alert

The blue lamp mounted on the control panel (located above the key-lock switch) is illuminated when the laser is in the Ready state (Figure 3.1).

STANDBY and READY Operating States

The system operates in one of two states: STANDBY and READY. In the STANDBY state, laser emission is disabled. The operator must put the system into the READY state in order to enable laser emission. In the READY state, laser pulses are generated by depressing the trigger switch. As a safety precaution, there is a delay of two seconds from the time that the system enters the READY state to the time that the laser emission is enabled. When the laser system is not being used, it should be returned to the STANDBY state. The laser will automatically revert back to the STANDBY state after 2 minutes of inactivity in the READY state. The operator selects the operating state via the Display Panel. System state information is also displayed on the Display Panel. When the system is in the READY state, the blue lamp below the Display Panel is illuminated.

Note

A Software Lock Button is included to prevent unauthorized use when not in room. The laser will remain in warm-up mode when the software lock is engaged. The software lock is user initiated.

Dye Cartridge Interlock

If the MegaDye Cartridge Top Cover is accidentally removed or loosened while the laser is powered on, the dye cartridge interlock switch (Figure 6.12) will immediately shut down the dye pump to prevent unwanted dye leakages. When this occurs, reinsert the top cover and restart the laser system.

Remote Interlock

An external connector for a remote interlock switch is provided on the rear panel of the system (Figure 3.9). This interlock switch can be connected to the doors of the laser room. If the door is opened and the Candela laser is on, the laser system completely shuts down. For more information, on installation of a remote interlock, please call Candela Technical Support. .

Note

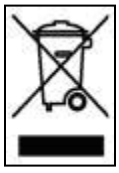
The Remote Interlock and the MegaDye Cartridge Top Cover must be in position to operate the device.

Environmental Protection: Disposal Hazards and Guidance

Used Delivery System Accessories

Residues that accumulate on the delivery system windows and distance gauge during normal use may contain infectious viable tissue particulate. Under certain conditions, contact with viable tissue particulate can put a user at risk for contracting disease. Therefore at the end of its useful life, the distance gauge, windows and cleaning materials should be disposed of in a way that minimizes risk of exposure. Such methods of disposal include, but are not limited to, disposal in a biohazard container (if available), incineration, or disposal as sealed waste in a plastic bag discarded with regular trash. Non-porous gloves should be worn during treatment and when servicing patient-contact parts to reduce risk associated with exposure. The gloves should be disposed of in the same manner as contact parts.

Laser System Components and Accessories



The Waste Electrical and Electronic Equipment (WEEE) Directive Label on the rear of the laser system indicates that the Vbeam Laser System and its components cannot be disposed of as regular trash. Contact Candela for disposal instructions.

Hazardous Material and Hazardous Waste

Several components of the Vbeam Laser System are classified as hazardous materials.

The internal dye fluid system maintains appropriate solution concentrations and circulates the solution through the laser head. Within this fluid system, there are several items that are classified as "hazardous". Refer to the MSDS (Candela P/N 7121-90-9940) and the following matrix:

Item	Hazardous Category	Comments
Triplet Quencher and Laser Dye Solution	**Flammable, Toxic**	**Must be disposed of as hazardous waste or shipped as hazardous material.**
MegaDye Cartridge	**Flammable, Toxic**	**When replaced, it is considered a hazardous material. Must be disposed of as hazardous waste or shipped as hazardous material because of its Triplet Quencher and Laser Dye solution content.**

The DCD GentleCool™ cryogen canister is classified as "hazardous". Refer to the following matrix:

Item	Hazardous Category	Comments
GentleCool™ cryogen canister	**Pressure**	**Must be disposed of as hazardous waste or shipped as hazardous material. A canister may be vented to empty and then be disposed of in the trash as "non-hazardous" waste.**

Refer to the Cryogen MSDS Candela P/N 8501-00-1701 for further information on safety, handling, first aid and disposal.

Warning!

PROPER DISPOSAL OF THE LASER SYSTEM, ITS COMPONENTS, ACCESSORIES AND HAZARDOUS MATERIALS/WASTE SPECIFIED IN THIS MANUAL AND THE REFERENCED DOCUMENTS IS REQUIRED. READ ALL LABELS, PROCEDURES AND THE REFERENCED DOCUMENTS FOR ADDITIONAL INFORMATION.

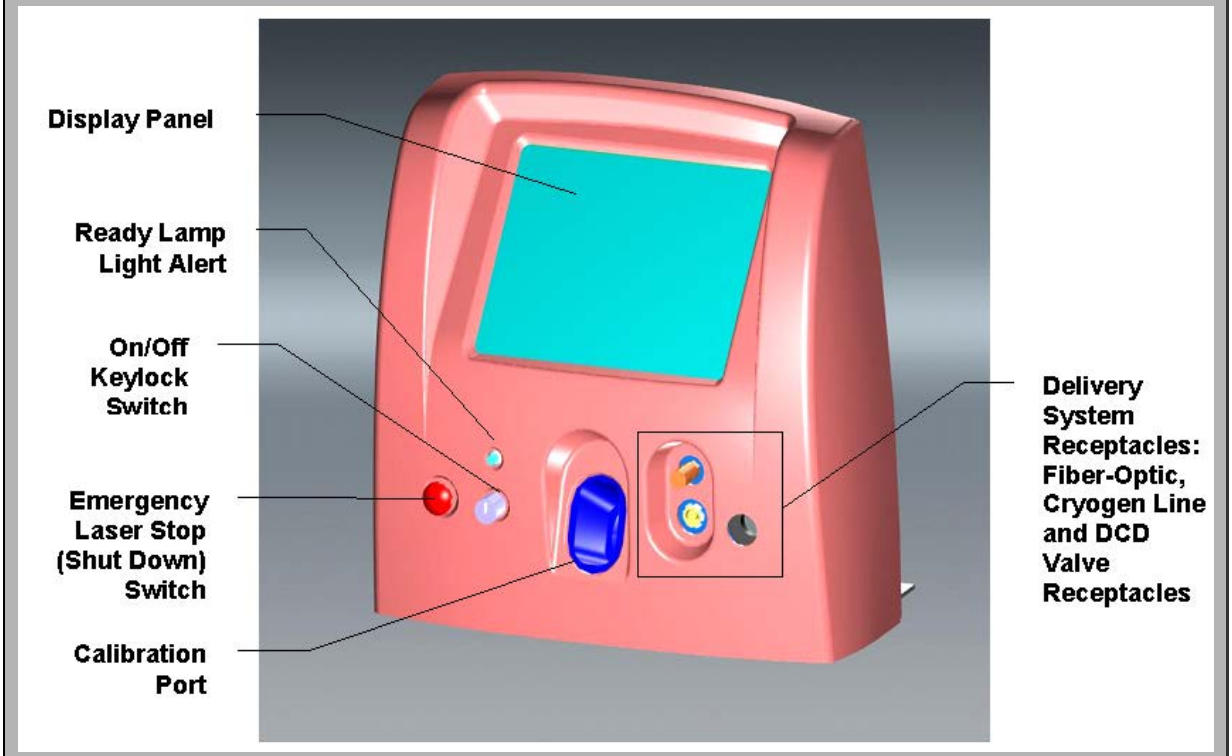
THIS PAGE LEFT BLANK INTENTIONALLY

Section 3: System Operation Features

Control Panel

The Vbeam Laser System control panel is located on the Front Display Bezel (Figure 3.1) of the laser system. It consists of an On/Off Key-lock switch, a Laser Stop (emergency off) push-button switch, Ready Lamp, Calibration Port, Handpiece Delivery System Receptacles, and a Touch Screen Display panel (Display Panel). The Display Panel provides a simple Graphical User Interface (GUI) for the operator. The operator uses this interface to select the system operating state, laser operating parameters, DCD parameters and output energy calibration.

Figure 3.1: Front Display Bezel



Key-lock Switch

This key-operated switch controls electrical power to the laser system. The Vbeam Laser System can be operated only with the key provided by Candela.

The key-lock switch has three positions with the “Off”, “On” and “Start” symbols (See Table 3.1). To start the laser, turn the key from the “Off” position to the “Start” position then release. The switch spring returns to the “On” position once the laser system starts. The laser system starts in a few seconds and four quick audible beeps will sound. Section 4 of this Manual provides step by step instructions for the Laser Start-Up Procedure.

Table 3.1: Key-lock Switch Symbols (Located on Front Display Bezel)

	**Off** The key-lock switch symbol means “Off”. When the key-lock switch is in this position, all circuits have been de-energized with the exception of the key-lock switch circuit itself.
	**On** The key-lock switch symbol means “On”. When the key-lock switch is in this position, all circuits are energized and the device will be fully functional (only after the keyswitch has been moved to the “Start” position and back to “On”)
	**Start** The key-lock switch symbol means “Start”. This is a spring-loaded key-lock switch position. It is used to initiate the system operation. This position does not initiate the release of laser energy.

Laser Stop Switch

When the red Laser Stop Switch (Figure 3.1) is pressed, the laser system shuts down immediately. To restart the system, turn the Key-lock Switch to the “Start” position and then release.

Handpiece Delivery System Receptacles

The fiber optic, cryogen line and DCD valve control receptacles are for connecting the handpiece delivery system cable assembly to the laser (Delivery System Receptacles, Figure 3.1). See Section 6 for handpiece install and removal instructions.

Calibration Port

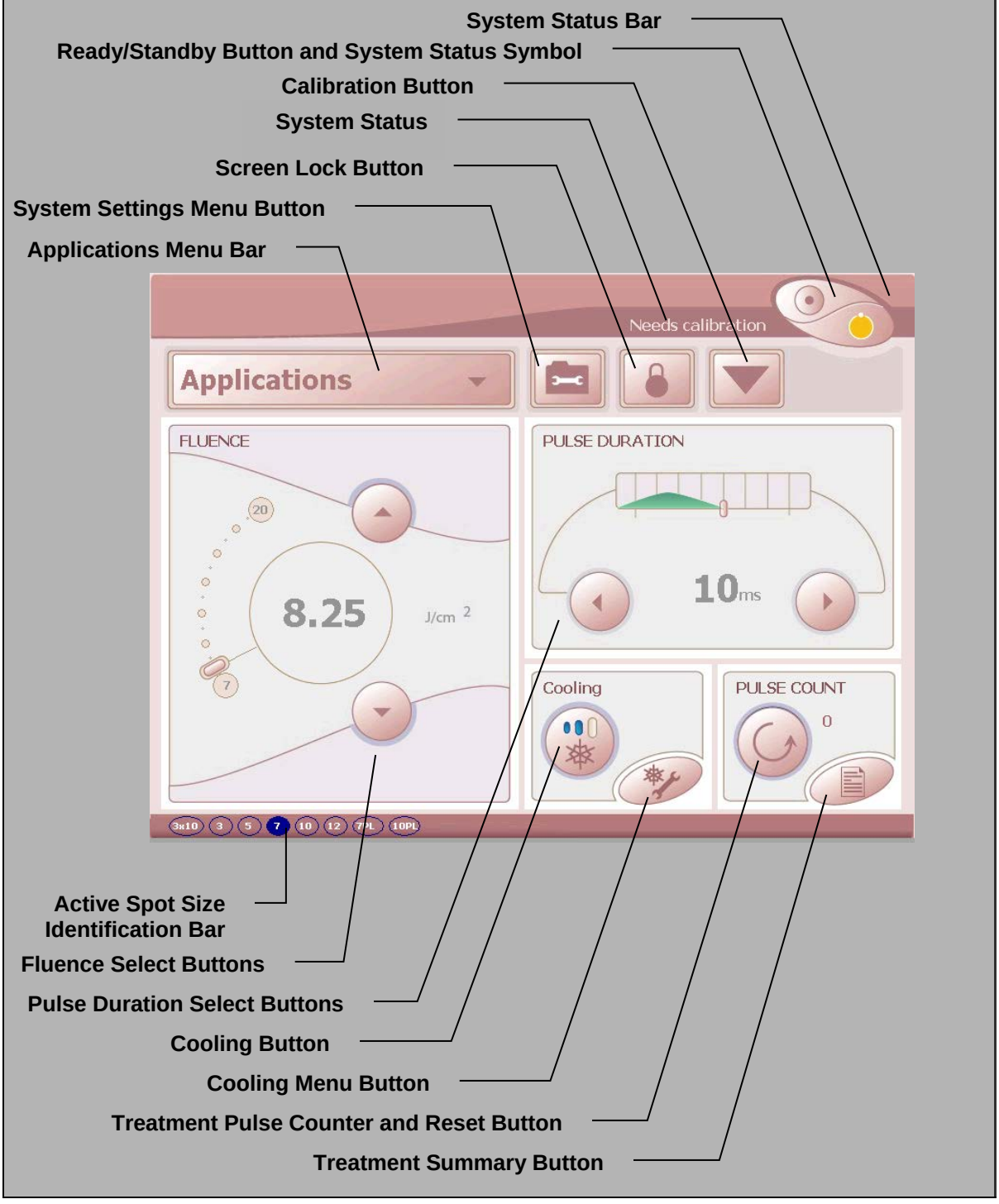
The Calibration Port (Calport) is used to measure the laser output energy (Figure 3.1). The handpiece must be inserted into the Calport in order to initiate this procedure. To perform the calibration procedure, the handpiece and the inserted distance gauge must be cleaned and dried before being placed in the Calport.

When not in use, the handpiece can be stored in the Calport with the distance gauge installed. The Calport, handpiece and distance gauge (including windows and lens) must be kept clean at all times to maintain optimal laser performance.

Touch Screen Display Panel

The Touch Screen Display Panel features a Smart User Interface, easily allowing the user to access and monitor the laser system operation functions. Figure 3.2 shows the Main Menu Interface Screen. Choosing from the Menus and Submenus, the user can set and select desired parameters to perform patient treatments.

Figure 3.2: Touch Screen Display Panel: Main Screen Menu



Screen Lock Button

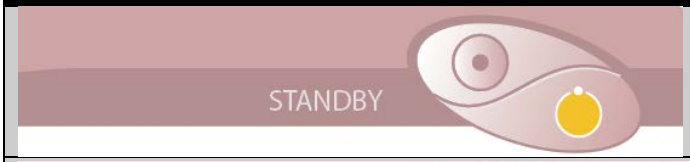
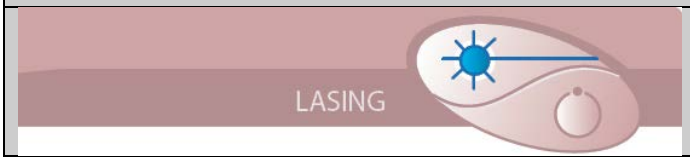
A password protected Software Lock is included to prevent unauthorized use of the laser. The laser will remain in warm-up mode when the software lock is engaged. The software lock will be initiated by the user. When the Screen Lock Button is pressed on the Main Screen Menu (Figure 3.2), it will query the user about locking the screen. If they select yes by pressing the checkmark button, the system will be put into Standby State, all screen buttons will be locked except for the screen lock button. A Candela logo screen with a padlock and a key button will be displayed indicating the display is locked.

When the screen is already locked and the Screen Lock Button is pressed, a keypad will be displayed to enter in a 4 digit code. The code will be the same for all Vbeam lasers and this code is 5277. If the laser is locked and the system power is cycled off and on, it will remain in a locked state until the code is entered.

System Status Indicator

The System Status Bar is located in the upper section of the Main Screen Menu (Figure 3.2) display and contains the READY and STANDBY Buttons. The system operates in one of two states: STANDBY or READY. When the desired state is selected, the System Status Bar will display the System Status in symbols and its operating state in words. Table 3.2 describes the meaning of the System Status Bar and Button symbols.

Table 3.2: Laser System Status Bar Symbols and Buttons

System Status Bar and Buttons	System Status Symbol	Description
		**Standby** **When the symbol is YELLOW, the system is in STANDBY.**
		**Warming Up in Standby** **Allow 15 minutes or longer for the system to complete warming up. The percentage shows the total warm-up time completed.**
	**None.**	**Needs Calibration in Standby** **Insert handpiece into calport (See Figure 1.1) and press the Calibrate Button. Follow instructions provided in the calibration message window.**
		**Ready** **Always put on protective eye wear before pressing the READY State Button. When the symbol is GREEN, the laser is in READY State. The blue light above the Calport will illuminate when in READY.**
		**Lasing Ready** **Always wear protective eye wear when lasing.**

Standby State

When in STANDBY, the laser emission is disabled.

The operator selects the STANDBY state by pressing the STANDBY button. The background for the Standby button is set to YELLOW to indicate that this state is selected. The word “STANDBY” is also displayed in the top portion of the Display Panel.

The Vbeam Laser System automatically enters STANDBY state during and following the initial warm-up period which occurs when the laser system is first powered up.

If the laser has not been pulsed for two minutes or if a fault condition is detected, the system reverts to the STANDBY state automatically.

Ready State

Caution!

DO NOT ENTER THE READY STATE WITHOUT A FIBER INSTALLED AND HAVING THE PROPER PROTECTIVE EYEWEAR ON.

When in READY, laser emission is enabled.

This state is selected by pressing the READY button. The background for the READY symbol of the READY button is set to GREEN to indicate that this state is selected. A two second delay is implemented before laser emission is enabled when the system state changes from STANDBY to READY as a safety precaution. The blue indicator light (also called the Ready Lamp) above the Key-lock Switch (Figure 3.1) is illuminated to indicate that the laser is in READY state.

Calibrate Button

The laser calibration procedure is initiated by pressing the READY or Calibrate Button (inverted triangle). When a system calibration is needed, the laser system will display the words “Needs Calibration” on the System State Status Bar. If this occurs, insert the Delivery System Handpiece into the Calport and calibrate the laser per the instructions provided in Section 5. Pop-up windows will appear on the screen to provide instructions and information about the system. **Note: The system will initiate the calibration procedure automatically if the READY state is entered and a calibration required. The laser calibration can be cancelled at any time by pressing the Cancel Button (X) on the screen.**

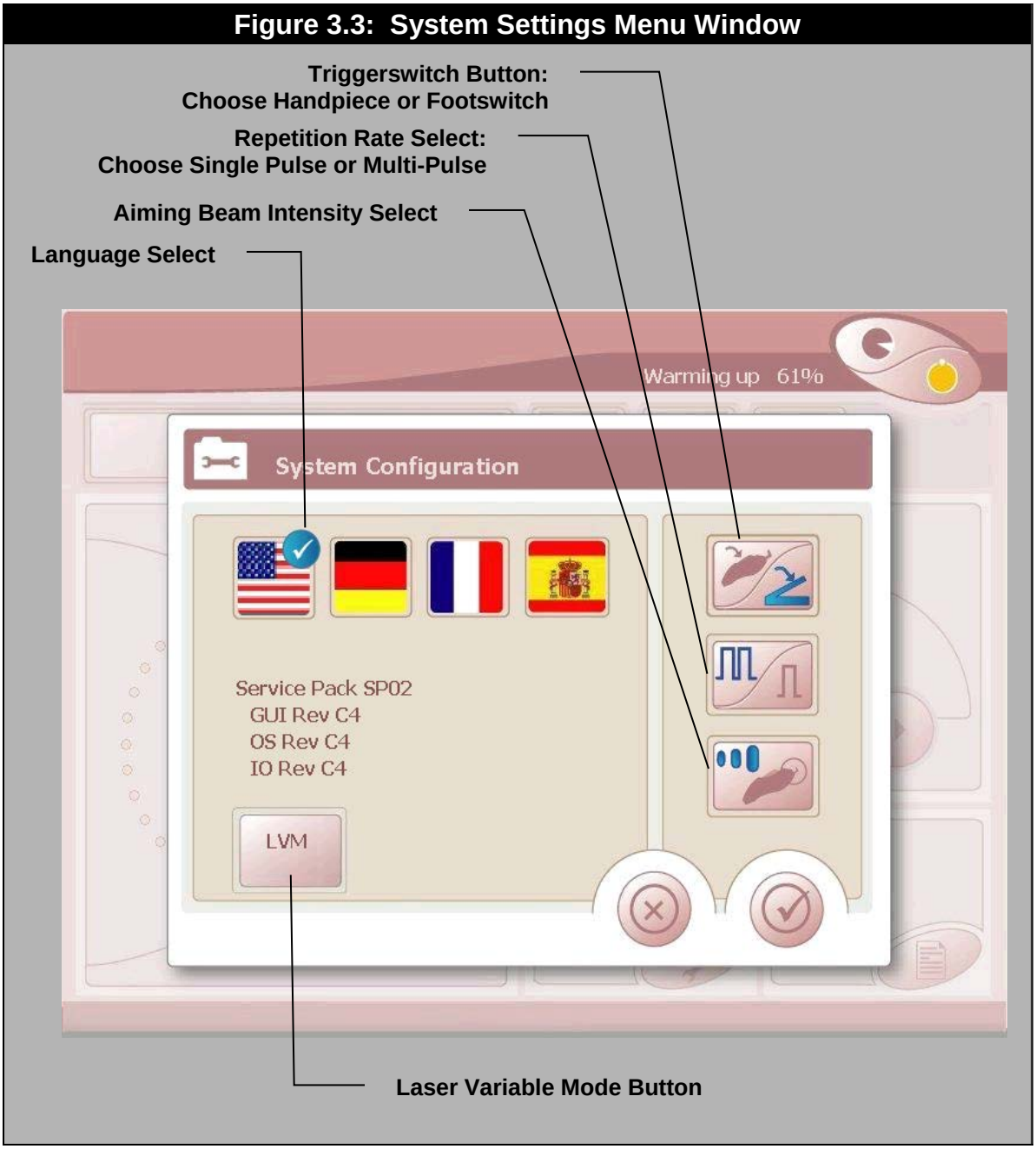
AFTER CALIBRATION, THE SYSTEM IS IN THE READY STATE AND THE TRIGGER SWITCH IS ENABLED. The operator can switch between the READY state and the STANDBY state as needed without recalibrating provided that the Fluence and Pulse Duration parameters have not been changed and no more than thirty minutes have elapsed since the last calibration.

System Settings

System Settings Menu Button

The System Settings Menu Button on the Main Screen Menu will prompt the Language, Trigger Switch, Repetition Rate, Aiming Beam Intensity and Laser Variable Mode (LVM) Buttons to appear in a System Settings Menu Window (Figure 3.3).

Figure 3.3: System Settings Menu Window



Language Select

The Language Select Button is used to select which language will be shown on the display. The selected language button will show a white check mark in a blue bubble next to it (Figure 3.3).

Trigger Switch Button: Fingerswitch or Footswitch Select

Laser emission is generated by either the finger or footswitch, as selected by the user. Pressing this button will toggle between these options. In this illustration the fingerswitch option is being used, shown by its blue color.

Repetition Rate Button

The “Repetition Rate” is a user selectable parameter in the System Settings Menu. This allows the selection of Singe Pulse mode or Multi-pulse mode. The icon to the left of this paragraph shows that Multi-pulse is selected meaning that the laser will pulse continuously and for as long as the footswitch or fingerswitch is depressed. This can be determined by the “blue” color of the 2-square waves. If the single square wave was “blue” then the system would be in Single Pulse mode meaning that the laser will pulse only once per every depression of the footswitch or fingerswitch.

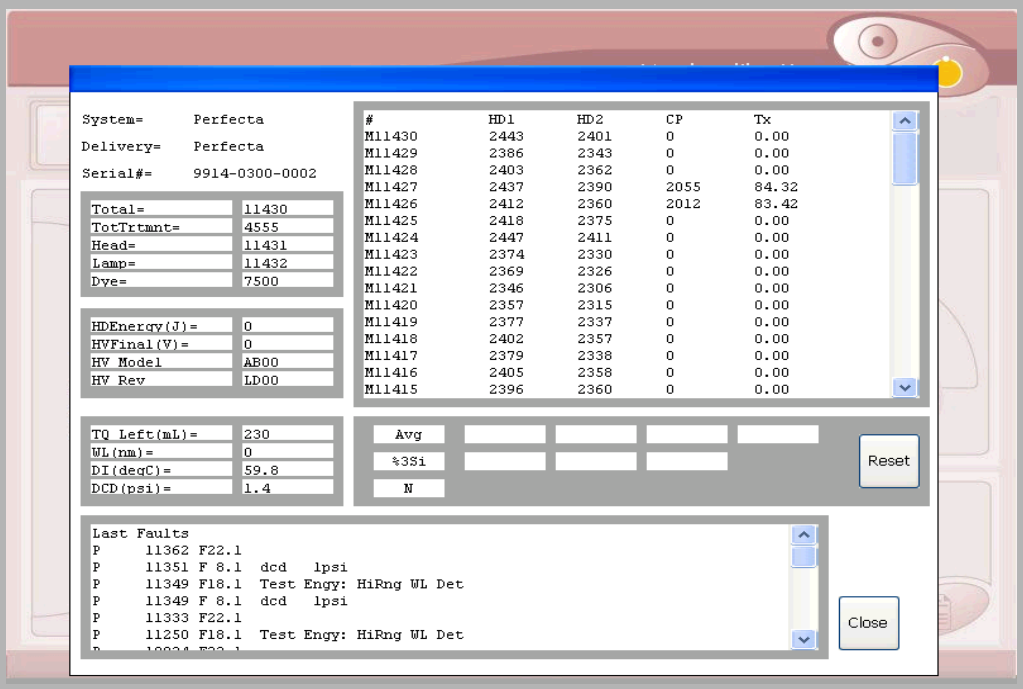
Aiming Beam Intensity Button

This button allows the user to select from three aiming beam intensity levels. The green aiming beam, which is visible only in READY state, serves as a treatment area target as well as an emissions warning indicator. The aiming beam cannot be turned off.

Laser Variable Mode Screen Button

The Laser Variable Mode Screen (Figure 3.4) contains information about the laser including system parameters. This mode is used by Candela Field Service to diagnose problems or obtain laser operating information. The Vbeam should not be used for patient treatments while Laser Variable Mode is displayed.

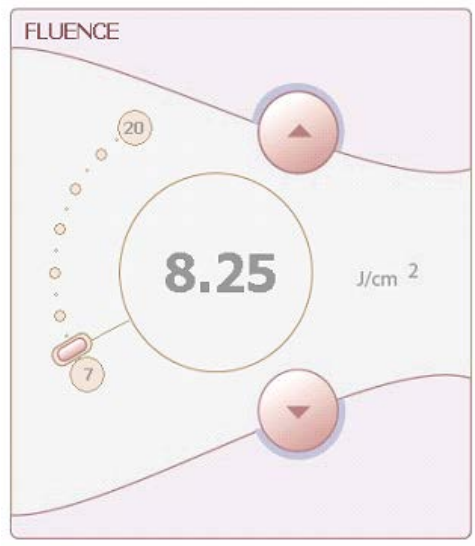
Figure 3.4: Laser Variable Mode Screen



Operating Parameters

The operating parameters that can be adjusted for laser treatments are the Fluence, Pulse Duration, Repetition Rate, DCD Spray and DCD Delay Duration settings. The parameters can each be set individually by the operator or selected from a list of Candela Preset Treatment Parameters under the Applications Menu Bar (See Figure 3.2 and Applications Menu Bar in this Section). The Laser Start-up and Calibration Procedures in Sections 4 and 5 have step-by-step instructions for setting up the operating parameters. To change a parameter, press the appropriate button or menu bar to make the selection and use the arrows to adjust the value to the desired setting.

Fluence (J/cm^2)



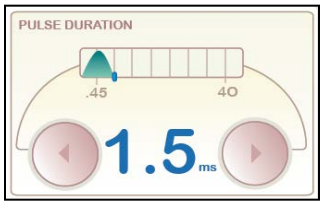
The Fluence parameter is the amount of energy (in Joules) delivered to the treatment spot size (in centimeters). The Fluence setting is adjustable in increments of 0.25 J/cm^2 between the lower and upper Fluence values for each spot size and pulse duration. Fluence Table 3.3 lists all the available fluence settings for each spot size and pulse duration. To calculate the energy from the handpiece in Joules, multiply the fluence by the area ($A = \pi r^2$) for the spot size selected. (The selected distance gauge spot size will appear in blue on the Spot Size Identification Bar on the bottom of the Main Screen in millimeters or mm).

To ensure that the selected Fluence is delivered, the laser will automatically require that a calibration procedure be performed anytime the Fluence parameter is adjusted. If the spot size is changed, the laser will automatically select the lowest possible fluence for the new spot size.

Spot Size Identification

On the bottom of the Main Screen, the Spot Size Identification Bar (Figure 3.2) will display all the spot sizes available (text in millimeters encircled by a circle or ellipse) for your laser system configuration (Table 1.1) or the treatment application selected in the Applications submenu (See Applications Menu Bar). When a distance gauge spot size is selected and installed in the handpiece, the spot size selection will be indicated by appearing in blue (as a blue-filled circle or ellipse) on the Spot Size Identification Bar. The submenus for all Treatment Applications (Figure 3.6) will also display the selection in blue to show available treatment application options for the spot size selected.

Pulse Duration Select



The Pulse Duration parameter is the duration of the pulse delivered to the patient and can be set to between 0.45 – 40 milliseconds. To ensure that the selected fluence is delivered, the laser will automatically require that a calibration procedure be performed anytime the Pulse Duration parameter is adjusted.

Repetition Rate Select

The Repetition Rate parameter was briefly introduced earlier in the System Settings Menu (press the System Settings Button located on the Main Screen Menu to prompt the System Settings Menu to pop-up to find the Repetition Rate Button). It allows the user to select the pulsing Mode. In Single Pulse mode the laser will pulse one time for each depression of the fingerswitch or footswitch (depending on which is currently active at the time). In multi-pulse mode, the laser will pulse at a steady rate as long as the triggerswitch is pressed. The Laser repetition rate is 1.0 Hz at higher fluences and 1.5 Hz at lower fluences.

Fluence Table

The following Fluence Table shows the ranges for the available fluence settings for 3, 5, 7, 10, 12, 3x10, 7PL, and 10 PL mm spot sizes.

Table 3.3: Fluence Table

Spot Size	Pulse Durations		
mm	0.45 ms	1.5 ms	3 to 40 ms
3mm	11.0 – 40.0 J/cm^2		21.0 – 40.0 J/cm^2
5mm	6.0 – 29.0 J/cm^2	6.0 – 30.0 J/cm^2	7.5 – 30.0 J/cm^2
7mm	4.0 – 19.0 J/cm^2	4.0 – 20.0 J/cm^2	7.0 – 20.0 J/cm^2
10mm	3.0 – 9.0 J/cm^2	3.0 – 10.0 J/cm^2	4.0 – 10.0 J/cm^2
12mm	2.0 – 6.5 J/cm^2	2.0 – 7.0 J/cm^2	2.75 – 7.0 J/cm^2
3mm x 10 mm	10.0 – 25.0 J/cm^2		
7 mm PL	4.0 – 15.0 J/cm^2		7.0 – 15.0 J/cm^2
10 mm PL	3.0 – 9.0 J/cm^2	3.0 – 10.0 J/cm^2	4.0 – 10.0 J/cm^2

DCD Spray and Delay Duration

The DCD Spray and Delay parameter can be set to preprogrammed settings by the laser or adjusted manually by the operator. When a treatment application is selected in the Applications Menu or the Cooling Button is used to select a DCD Spray/Delay setting, the computer will set the laser system to the preprogrammed DCD Spray and Delay duration settings. The DCD Spray and Delay parameter can be adjusted manually to non-standard settings by the operator in the Cooling Spray Menu accessed by pressing the Cooling Menu Button.

The selected DCD settings will be displayed on the Cooling Button on the Main Screen. (See Main Screen Menu, Cooling Button, Cooling Menu Button and Applications Menu in this Section).

DCD Spray Duration

The DCD Spray parameter can increase or decrease the duration of the cryogen spray applied to the patient before the laser pulse. The DCD spray can be turned off (set to 0 ms) or set to a duration between 10 and 100 milliseconds.

Caution!
Overriding the default minimum spray durations may result in localized burns to the patient.

DCD Delay Duration

The DCD Delay parameter adjusts the duration of the time between the DCD cryogen spray and the laser pulse. The delay selectable range is 10 to 100 milliseconds in increments of 10 milliseconds.

Cooling Button

The Cooling Button serves as a dual purpose button. It displays current settings for the DCD Spray and Delay parameter on the Main Screen. When pressed, the Cooling Button allows the operator to quickly adjust the DCD Spray and Delay parameter to Low, Medium, High, or off. Blue colored ovals (Low, Medium or High) or the word “Off” will be displayed on the button and the laser will set the DCD Spray and Delay durations as follows:

Table 3.4: Cooling Button DCD Spray and Delay Durations

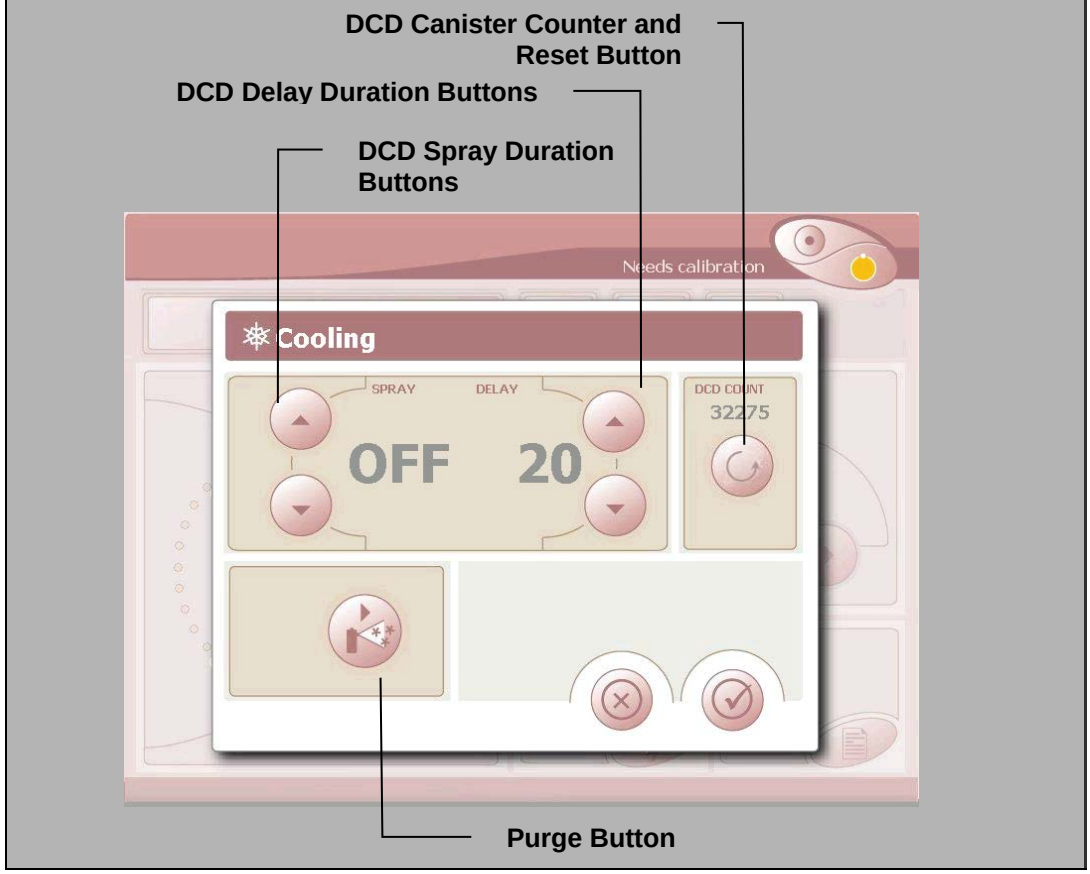
Cooling Select Setting		DCD Spray Duration (ms)	DCD Delay Duration (ms)
	Low	20 ms	20 ms
	Medium	30 ms	20 ms
	High	40 ms	20 ms
	Off	0 ms	XX ms (Delay Duration is not active when the Spray Duration is set to “0”, so it remains set to the previous selection when “off” is selected.)

If the DCD settings are manually selected, as described on the next page in the Cooling Menu Button paragraph, the Cooling button will display the Spray Duration and Delay Duration.

Cooling Menu Button

The Cooling Menu Button on the Main Screen Menu will prompt the Cooling Spray Settings Window to open (Figure 3.5). The menu offers the option to manually adjust the DCD Spray and Delay parameters; purge to remove cryogen air bubbles from the handpiece assembly; and reset the DCD Canister Counter. The manually selected DCD Spray and Delay duration values will appear as "Spray/Delay" on the Main Screen Cooling Button.

Figure 3.5: Cooling Spray Settings



Purge Button

The Purge Button is used to remove air bubbles from the DCD cryogen line when a new canister is placed in the system or a handpiece is installed. This action must be done with the handpiece removed from the calibration port and pointed in a safe direction. When pressed, the handpiece will disperse cryogen spray for the selected spray duration. If the button is held for longer than 1 second, a short spray and then a longer spray of cryogen (up to 3 seconds) will be dispersed.

DCD Canister Counter and Reset Button

The Canister Count parameter indicates the total number of DCD Spray pulses remaining in the cryogen canister for the selected spray duration. The counter accuracy depends on the user pressing the reset button with the circular arrow on it after installing a new DCD canister. It is present to give the user an indication of the canister's relative fill status.

Once the canister is replaced, the operator must reset the Canister Counter to the "full" canister value manually by pressing the Canister Count Button for approximately 2 seconds. The system will acknowledge the selection by setting the count value displayed to the number of pulses available from a full canister of cryogen. (This value depends on the value of the DCD SPRAY parameter.)

Table 3.5: DCD Pulses

Spray Duration (milliseconds)	Approximate DCD Pulses Available
10	32434
20	16217
30	10811
40	8108
50	6486
60	5405
70	4633
80	4054
90	3603
100	3243

Note

THE VBEAM LASER SYSTEM HAS BEEN CONFIGURED FOR A SPECIFIC SIZE GENTLECOOL CANISTER. ONLY INSTALL THE APPROPRIATE SIZE CANISTER AS FOLLOWS:

Vbeam Cryogen Canister		
Candela Part No.	**Laser Type**	**Canister Size**
1600-00-0210	Vbeam Laser System	GentleCool™ 1000 grams

Caution!

- **FAILURE TO INSTALL THE APPROPRIATE SIZE CANISTER FOR YOUR LASER OR FAILURE TO REPLACE IT WHEN PROMPTED BY THE LASER SYSTEM CAN LEAD TO ADVERSE PATIENT TREATMENT RESULTS INCLUDING BURNS. THESE ADVERSE RESULTS MAY OCCUR AS A RESULT OF THE FOLLOWING:**
  - **SIGNIFICANTLY REDUCED COOLING OF THE EPIDERMIS FOR A GIVEN LASER ENERGY**
  - **INADEQUATE PRESSURE TO FILL A SPOT SIZE AREA WITH CRYOGEN**
- **ALWAYS REPLACE THE CANISTER WHEN THE SYSTEM INDICATES "REPLACE CANISTER".**
- **NOTE: THE DCD PULSE COUNTER IS AN ESTIMATE OF THE AMOUNT OF CRYOGEN IN THE CANISTER ONLY! IF THE SYSTEM PROMPTS THE USER TO "REPLACE CANISTER" THEN THE CANISTER MUST BE REPLACED REGARDLESS OF THE DCD COUNT.**

Applications Menu Bar: Preset Treatment Parameters

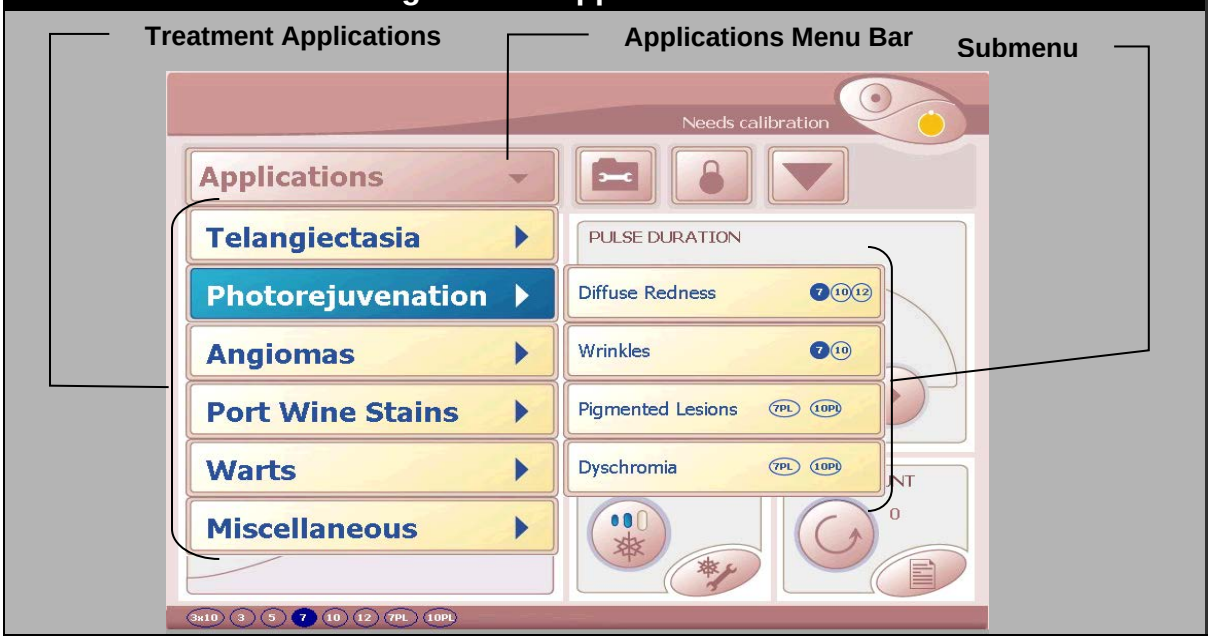
Touching the Applications Menu bar on the Main Screen will prompt a list of Preset Treatment Parameters to appear. The Preset Treatment Parameters are pre-programmed treatment applications based on the Candela Clinical Treatment Guidelines. When a treatment application is selected in the Applications Menu, the selected application bar will turn blue and a submenu will appear (Figure 3.6). The submenu offers additional treatment application options and displays all the spot size(s) available for each application. When an available treatment application is selected in the submenu with a supported distance gauge installed in the handpiece, the operating parameters will be set to the preset treatment parameters and will be indicated by showing the selected application in blue text on the Applications Menu Bar (Figure 3.7). To exit the Applications Menu or submenu, touch the Applications Menu Bar (Figure 3.6) or press the "X" button (Figure 3.7) next to Applications Menu Bar to exit a selected Application to return to the Main Screen Menu.

Treatment Application Options

The Application options are limited to the spot sizes available for the laser system configuration (See Table 1.1) and each treatment application. Unavailable treatment applications and spot sizes will appear transparent or in "ghosted" text. Selecting an available treatment application without a distance gauge installed will prompt a message to appear on the screen to install one. If an available application is selected with an unsupported distance gauge spot size installed, a message will appear on the screen that the "Application does not support Distance Gauge". The selected spot size will appear in text encircled by a blue circle or ellipse with a slash (Ø) on the Spot Size Identification Bar to show that the application does not support the spot size. The laser system will not permit users to use a treatment application with an unsupported distance gauge spot size installed. Only use distance gauge spot sizes that are supported by the desired treatment application. When a supported distance gauge is installed, the Spot Size Identification Bar will display the selected spot size as a blue-filled circle or ellipse and all other spot sizes supported by the desired treatment application. Selecting another distance gauge spot size supported by the desired application will update the screen to show the new spot size.

Refer to the Candela Clinical Treatment Guidelines (see the next page) to get the recommended pre-set treatment parameters and the supported distance gauge spot sizes for the desired treatment applications. See Sections 4 and 5 for step by step instructions for performing patient laser treatments. Read and follow all the instructions, procedures and messages provided in this Manual, on the laser screen and all referenced documents.

Figure 3.6: Applications Menu



Candela Clinical Treatment Guidelines

Warning!

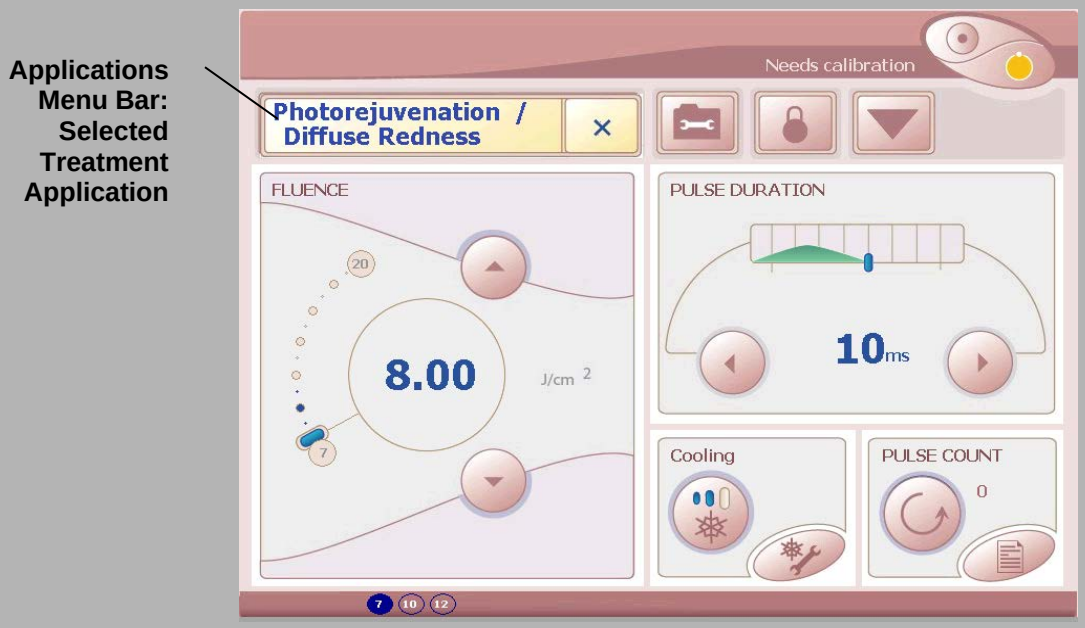
The Preset Treatment Parameters and Clinical Treatment Guidelines do not take the place of the procedures and instructions found in the Operator's Manual. FAILURE TO USE THE LASER IN ACCORDANCE WITH SUCH PROCEDURES AND INSTRUCTIONS COULD RESULT IN SERIOUS INJURY TO THE OPERATOR, THE PATIENT AND OTHERS, 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.

The Candela Clinical Treatment Guidelines were developed from clinical experience for applications specific to the Vbeam laser. Each treatment application has its own set of starting operating parameters. If needed, each operating parameter can be adjusted by pressing the up and down buttons to adjust the value to the desired setting. If questions arise or additional information about a treatment application is needed, refer to the Candela Clinical Treatment Guidelines (Candela P/N # 8502-00-0891) for laser treatment guidelines or contact Clinical Support for additional information. Refer to Sections 4 and 5 for step by step instructions for performing patient laser treatments. Read and follow all the instructions, procedures and messages provided in this Manual, on the laser screen and all referenced documents.

Note

The Candela Preset Treatment Parameters and Clinical Treatment 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, laser system software upgrades and a comprehensive bibliography list of references/published articles.

Figure 3.7: Preset Treatment Parameters

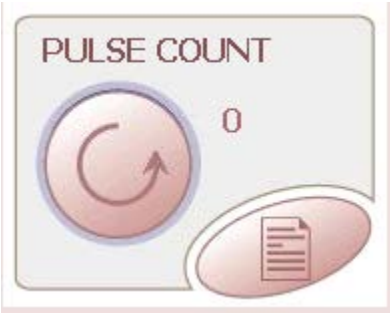


Treatment Summary Table

The Treatment Summary Button on the Main Screen Menu (Figure 3.2) will display the Treatment Summary Table (Figure 3.8). The table records the number of laser pulses and the operating parameters (Fluence, pulse duration and DCD settings) used for the last six parameter changes. Pressing the Reset button with the circular arrow on it in the Treatment Summary Table window for approximately two seconds or longer will clear all of the treatment data from the table memory.

Figure 3.8: Treatment Summary Table

Treatment Pulse Counter and Reset Button



The Treatment Pulse Counter parameter on the Main Screen (Figure 3.2) indicates the number of times the laser has been pulsed. This counter can be used to keep track of the total number of laser pulses used in a treatment session.

The Pulse Count is reset to zero by pressing the Reset button with the circular arrow on it (Figure 3.2) on the Main Screen Menu for approximately 2 seconds or longer. The system acknowledges the selection by setting the PULSE COUNT value displayed next to the Reset button to zero.

Other Controls

Remote (CDRH) Interlock

The remote interlock connector, located on the rear panel of the laser system (Figure 3.9), above to the left side of the power cord, may be connected to one or more switches on the laser room door(s). When the interlock is connected, the laser system shuts down if laser room door(s) are opened. The switch must be connected so that with the door closed, the switch contacts are closed. When the door is open, the switch contacts must open. When the remote interlock is not in use, the supplied jumper must be plugged into the interlock connector.

Footswitch Connector

The footswitch connector is located on the upper right section of the rear panel of the laser system (Figure 1.2). To enable the footswitch, press the System Menu button to go to the next screen and press the footswitch button. The fingerswitch will be disabled.

Circuit Breaker

The circuit breaker, also called the Mains Switch, is located on the rear panel of the laser system, directly above the power cord, and must be in the ON position (See Table 3.6 and Figure 3.9 for On and Off Symbols) for the laser system to operate. Always place the On/Off Mains Switch in the OFF position when the laser is not in use.

Figure 3.9: Mains Switch Circuit Breaker and Remote Interlock

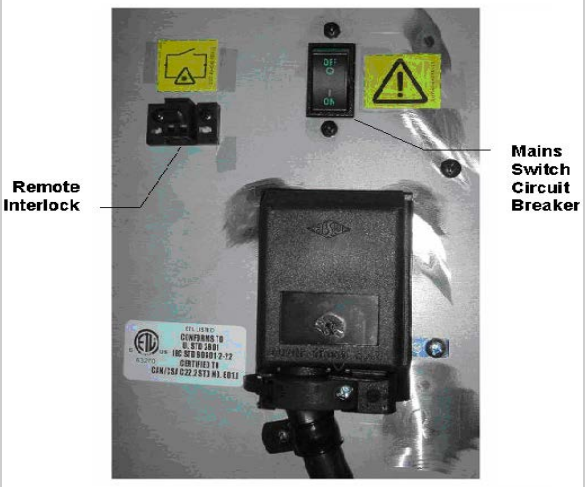


Table 3.6: Mains Switch Label/Symbols (Located on rear panel)	
 **Mains Switch Label**	The symbol label was placed next to the Mains Switch to draw the attention of the operator to the Manual for further information concerning the On/Off Mains Switch. The Mains Switch should be placed in the "O" position when the system is not being used. When the system is to be used, the Mains Switch should be moved to the "| "position.
|	**On** **Located on the Mains Switch (rear panel)** Indicates the **"ON"** switch position in which the system is connected to the mains.
O	**Off** **Located on the Mains Switch (rear panel).** Indicates the **"OFF"** switch position in which the system is disconnected from the mains.
~	**Located on the ID Label (rear panel).** Indicates that the system operates on alternating current.

THIS PAGE LEFT BLANK INTENTIONALLY

Section 4: Laser System Start-Up

Laser System Start-Up Procedure

Follow the steps given below to perform a Vbeam laser system start-up:

1. Cover treatment room windows with an opaque material to prevent unintended viewing.
2. Post laser warning sign at each entrance to the laser treatment room.
3. Ensure an adequate number of protective eyewear is available. Proper eyewear will filter light at a wavelength of 592 – 596 nm with an OD (Optical Density) of 5.2 or greater.
4. Plug the laser into the correct electrical outlet. Ensure that the Mains Switch (circuit breaker) on the rear panel is in the "ON" position (See Table 3.6 in Section 3 for more information about the Mains Switch).
5. Install the delivery system with the desired spot size distance gauge inserted. Insure that the fiber connector nut at the laser is tight and secure (See Delivery system install instructions).
6. Set up the delivery system on the fiber pole per Section 1 of this manual.
7. Inspect and verify that the handpiece, distance gauge and the windows (internal handpiece window; the input and output distance gauge windows) are clean.

WARNING!

ALWAYS PUT THE LASER SYSTEM INTO STANDBY OR "OFF" AND REMOVE THE DISTANCE GAUGE FROM THE HANDPIECE BEFORE ATTEMPTING TO CHECK, CLEAN AND/OR REPLACE THE DELIVERY SYSTEM, DISTANCE GAUGE, WINDOW(S) AND/OR PL LENS.

Warning!

Always recalibrate the laser after fixing, cleaning or replacing the delivery system, distance gauge, any window(s) and/or PL lens. Failure to initiate a calibration after cleaning/replacing the distance gauge, window(s) or delivery system may result in the delivery of excessive laser energy.

8. To start the laser system, turn the Key-lock Switch from the "OFF" to the "START" position (Refer to Section 3 for instructions on how to use the Key-lock Switch to turn on the laser and Table 3.1 for Key-lock Switch symbols and their definitions). There may be a delay of several seconds before the system initializes. This is normal. The system will enter the warm-up state (approx. 20 minutes). After the warm-up is complete, the system will enter the STANDBY state.
9. After warm-up is completed, a warning will appear on the touch screen to remind the user to perform the User Verification Tests (Section 6). The warning will read "Perform Delivery System Test."
10. Put on safety eyewear.

11. Choose the preferred System Settings:
    a. Select the preferred language
    b. Select Fingerswitch or Footswitch Mode
    c. Select Repetition Rate (Single or Multi-pulse)
    d. Select Aiming Beam Intensity Level

12. Close the System settings window (by pressing the “Checkmark” button if you wish to save the current system setting) and perform the User Verification Tests (Section 6).

Warning!

Always perform the User Verification Tests per Section 6 of this Manual to check the delivery system and distance gauge for proper operation at the beginning of each treatment day or each time it is replaced on the laser system. In addition, use the User Verification Tests to check the delivery system and/or distance gauge if there is an unexplained treatment response noted or the delivery system and/or distance gauge has been dropped. **Discontinue use of your laser delivery system or distance gauge if you suspect a problem.**

13. Select the desired spot size and install the appropriate Distance Gauge onto the handpiece. The selected spot size will appear as a blue-filled circle or ellipse on the user interface screen.

14. Select the desired laser system operating parameters (**choose a or b**):

    a. Choose a treatment application (Candela Preset Treatment Parameters):
        i. Select an available treatment application that supports the distance gauge spot size (installed in Step 13) from the Applications menu and submenu (See Applications Menu Bar in Section 3).
        ii. Verify that the Fluence, Pulse Duration and DCD Settings are within the desired treatment parameters for the current patient treatment.
        iii. If needed, adjust the operating parameter(s) by pressing the up or down arrows to adjust the value(s) to the desired setting(s).

    OR

    b. Manually select the operating parameters:
        i. Select Fluence (Spot Size dependent)
        ii. Select Pulse Duration (.45 - 40ms)
        iii. Set DCD for desired spray duration and delay parameters (Treatment dependent)

Note

If you experience difficulty setting the operating parameters, check to ensure the settings are allowed for the selected spot size and distance gauge.

15. The user will be prompted to confirm parameters prior to starting a system CALIBRATION (CAL).
    a. Fully insert the handpiece into the Calport.
    b. Press the Calibrate Button on the Main Screen Menu. Follow the instructions on the display panel. During a calibration in Fingerswitch mode, a prompt will appear instructing the User to press the Fingerswitch button to continue; at this prompt press and release the icon (button with picture of handpiece) on the screen to begin the calibration. If the Footswitch mode was selected, at this same prompt the User needs

to press and hold the footswitch until the calibration is completed. **Note: The laser calibration can be cancelled at any time by pressing the Cancel Button (X). If this occurs, refer to Section 5 to restart the Laser Calibration procedure.**

c. When the calibration is completed, remove the handpiece from the Calport.

Note

After a calibration is completed, the laser will remain in the READY STATE.

16. Press the READY button (if in STANDBY) on the Main Screen. Do not press the fingerswitch or the footswitch to pulse the laser. Aim the handpiece at a white piece of paper and inspect the aiming laser beam for circular uniformity and clarity. If the aiming beam spot is not uniform, press the STANDBY Button to put the laser in the STANDBY mode. Check for distance gauge interference. Fix or clean distance gauge per Section 6 of this manual or replace if correct results cannot be achieved. Repeat Steps 14 – 16 until satisfactory results are achieved. **Important: Always recalibrate the laser after fixing, cleaning or replacing the delivery system, distance gauge, window(s) and/or PL lens. Failure to initiate a calibration after cleaning/replacing the parts may result in delivery of excessive laser energy.**

Important!

Do not operate the laser if the aiming beam is not present! This may be an indication of a broken fiber optic. If the aiming laser is not present, replace the delivery system. If this does not correct the problem, call Technical Support.

17. Perform the laser treatment.

18. Place the laser into STANDBY after use. Insert the handpiece in the Calport. Document laser use. When in the STANDBY state, the operator can then adjust the laser output parameters as needed before restarting the Laser Calibration procedure (go to Section 5).

Notes

- To return the pulse counter to zero, press the Pulse Count Reset button on the Main Screen Menu for 2 seconds.
- The laser system will not allow treatment pulses until a calibration has been performed after any one of the following conditions:
  a. Laser is turned on
  b. Fluence or Pulse Duration parameter changed
  c. Delivery system changed
  d. The distance gauge position changed or became disconnected from the handpiece
  e. Specific faults occur
  f. In STANDBY for more than 30 minutes
- The user must remember to initiate a calibration after cleaning or replacing the window(s) in the distance gauge.

THIS PAGE LEFT BLANK INTENTIONALLY

Section 5: Calibrate Procedure

Caution!

FAILURE TO PERFORM A CALIBRATION PROCEDURE AFTER A DISTANCE GAUGE WINDOW HAS BEEN CLEANED OR REPLACED CAN RESULT IN DELIVERY OF FLUENCES GREATER THAN SPECIFIED ON THE CONTROL PANEL.

Laser Calibration Procedure

The Vbeam Laser System requires that the laser be calibrated prior to patient treatment. During calibration, the handpiece with a distance gauge must be inserted into the Calport allowing an internal energy meter to measure the laser output parameters delivered at the handpiece. The system adjusts itself until the desired output is obtained. Usually 10 – 15 laser pulses are required before calibration is complete.

1. Put on safety eyewear.

2. Select the desired distance gauge for the spot size selected and verify that the handpiece and distance gauge windows are clean (clean or replace as necessary per the Cleaning and Disinfecting Procedure in Section 6 of this Manual).

WARNING!

ALWAYS PLACE THE LASER INTO STANDBY OR "OFF" AND REMOVE THE DISTANCE GAUGE FROM THE HANDPIECE BEFORE ATTEMPTING TO CHECK, CLEAN OR REPLACE THE DELIVERY SYSTEM, DISTANCE GAUGE, WINDOW(S) AND/OR PL LENS.

Warning!

Always recalibrate the laser after fixing, cleaning or replacing the delivery system, distance gauge, window(s) and/or PL lens. Failure to initiate a calibration after cleaning/replacing the window(s), lens, distance gauge and/or delivery system may result in the delivery of excessive laser energy.

Warning!

Always perform the User Verification Tests per Section 6 of this Manual to check the delivery system and distance gauge for proper operation at the beginning of each treatment day or each time it is replaced on the laser system. In addition, use the User Verification Tests to check the delivery system and/or distance gauge if there is an unexplained treatment response noted or the delivery system and/or distance gauge has been dropped. **Discontinue use of your laser delivery system or distance gauge if you suspect a problem.**

3. Insert the desired distance gauge into the handpiece assembly.

4. Fully insert the handpiece into the Calport.

5. Select the desired laser system operating parameters (**choose a or b**):
    a. Choose a treatment application (Candela Preset Treatment Parameters):
        i. Select an available treatment application that supports the distance gauge spot size (installed in Step 3) from the Applications menu and submenu (See Applications Menu Bar in Section 3).
        ii. Verify that the Fluence, Pulse Duration and DCD Settings are within the desired treatment parameters for the current patient treatment.
        iii. If needed, adjust the operating parameter(s) by pressing the up or down arrows to adjust the value(s) to the desired setting(s).

    OR

    b. Manually select the operating parameters:
        i. Select Fluence (Spot Size dependent)
        ii. Select Pulse Duration (.45 - 40ms)
        iii. Set DCD for desired spray duration and delay parameters (Treatment dependent)

Note

If you experience difficulty setting the operating parameters, check to ensure the settings are allowed for the selected spot size and distance gauge.

6. Press the Calibrate Button on the Main Screen Menu. Follow the instructions on the display panel. During a calibration in Fingerswitch mode, a prompt will appear instructing the User to press the Fingerswitch button to continue; at this prompt press and release the icon (button with picture of handpiece) on the screen to begin the calibration. If the Footswitch mode was selected, at this same prompt the User needs to press and hold the footswitch until the calibration is completed. **Note: The laser calibration can be cancelled at any time by pressing the Cancel Button (X). If this occurs, refer to Section 5 to restart the Laser Calibration procedure.**

7. Remove handpiece from the Calport when instructed to do so.

Note

After a calibration is completed, the laser will remain in the READY STATE

8. Press the READY button (if in STANDBY) on the Main Screen. Do not press the fingerswitch or the footswitch to pulse the laser. Aim the handpiece at a white piece of paper and inspect the aiming laser beam for circular uniformity and clarity. If the aiming beam spot is not uniform, press the STANDBY Button to put the laser in the STANDBY mode. Check for distance gauge interference. Fix or clean distance gauge per Section 6 of this manual or replace if correct results cannot be achieved. Repeat Steps 3 - 8 until satisfactory results are achieved. **Important: Always recalibrate the laser after fixing, cleaning or replacing the delivery system, distance gauge, window(s) and/or PL lens. Failure to initiate a calibration after cleaning/replacing the parts may result in delivery of excessive laser energy.**

Important!

Do not operate the laser if the aiming beam is not present! This may be an indication of a broken fiber optic. If the aiming laser is not present, replace the delivery system. If this does not correct the problem, call Customer Service.

9. Perform the laser treatment.

10. Place the laser into STANDBY after use. Insert the handpiece in the Calport. Document laser use. When in the STANDBY state, the operator can then adjust the laser output parameters as needed before restarting the treatment (Repeat Steps 1 – 10).

Notes

- To return the pulse counter to zero, press the Pulse Count Reset button on the Main Screen Menu for 2 seconds.
- The laser system will not allow treatment pulses until a calibration has been performed after any one of the following conditions:
    a. Laser is turned on
    b. Fluence or Pulse Duration parameter changed
    c. Delivery system changed
    d. The distance gauge position changed or became disconnected from the handpiece
    e. Specific faults occur
    f. In STANDBY for more than 30 minutes
- The user must remember to initiate a calibration after cleaning or replacing the window(s) in the distance gauge.

Notes

If the desired Fluence cannot be reached, one of two messages will appear (Depending on Software version):

<u>Lower Fluence:</u> The Lower Fluence message simply is telling the user to go out to the main screen and manually select a lower fluence and re-calibrate.

<u>MAX FLUENCE = XX J/cm^2:</u> The Max Fluence message means that the laser automatically set itself to the highest available fluence.

This condition indicates that the system may need a new fiber, dye kit or laser head. Call Candela Customer Service. If a higher Fluence is desired immediately, reduce spot size.

THIS PAGE LEFT BLANK INTENTIONALLY

Section 6: Maintenance, Troubleshooting and Delivery System User Verification Tests

Caution!

THE ELECTRICAL AND LASER RADIATION HAZARDS PRESENT WHILE SERVICING THE VBEAM LASER SYSTEM CAN BE EXTREMELY DANGEROUS IF PROPER SAFETY PRECAUTIONS ARE NOT TAKEN.

THE VBEAM LASER SYSTEM IS TO BE INSTALLED AND SERVICED ONLY BY QUALIFIED AND AUTHORIZED TECHNICIANS WHO HAVE RECEIVED APPROPRIATE TRAINING FROM CANDELA. ANY ATTEMPT BY AN UNAUTHORIZED PERSON TO PERFORM ANY SERVICE PROCEDURE MAY RESULT IN A PERSONAL INJURY AND WILL VOID ANY WARRANTY ON THE LASER SYSTEM.
REFERENCE DOCUMENT: VBEAM SERVICE MANUAL (P/N # 8501-00-1795).

Warning!

NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED.

User maintenance should take place daily (when system is used continuously) unless otherwise specified.

Laser Software and System Upgrades

Be sure to inquire with your Candela Sales Representative, Customer Service or visit MyCandela.com regularly to check for the latest updates on Vbeam laser software and system upgrades.

The Laser System Software Upgrade USB Port and Memory Stick

Minor laser system software upgrades can be performed at the convenience of the authorized user(s) without the presence of a Candela Service Representative. The laser system software upgrades will be shipped in USB Memory Sticks with instructions. The instructions will provide simple steps and procedures to verify that the upgrade is completed successfully. The USB Port is located on the rear of the laser system (Figure 6.1). Follow the instructions and procedures provided with each software upgrade.

Figure 6.1: Laser System Software Upgrade USB Port and Memory Stick

Warning!

Always follow all instructions and perform all procedures provided with each USB Memory Stick software upgrade kit to insure the full and complete installation of each laser system software upgrade.

Laser System Upgrades

Vbeam laser system upgrade options are available to customers who wish to upgrade their laser system to add a wider range of laser treatment parameters and spot sizes. Contact Candela Customer Service for additional information. Major laser system upgrades can only be performed by a Candela Service Representative.

Fiber-Optic Delivery System

Warning!
ALWAYS PUT THE LASER SYSTEM INTO "STANDBY" OR "OFF" AND REMOVE THE DISTANCE GAUGE FROM THE HANDPIECE WHEN CHECKING, CLEANING AND/OR REPLACING THE DELIVERY SYSTEM, DISTANCE GAUGE, LENS AND/OR WINDOWS.

The Vbeam laser delivery system utilizes fiber optics that can be damaged if subjected to excessive bending. To avoid damage to the optical fiber, limit bends to a radius of 5 inches (13 cm) or greater.

The delivery system should be checked before each procedure by observing aiming beam quality. The beam as viewed against a white sheet of paper should have intensity, homogeneous distribution and a well-defined circumference. If the aiming beam is non-existent, discontinue use immediately as the fiber may be broken. A dim aiming beam may also indicate a broken fiber or dirty or damaged windows. Clean or replace the distance gauge window(s) before repeating this test. Use of a damaged fiber optic delivery system is dangerous and must be avoided. If damage is suspected, discontinue use immediately. **Important: Always recalibrate the laser after fixing, cleaning or replacing the delivery system, distance gauge, window(s) and/or PL lens. Failure to initiate a calibration after cleaning/replacing the parts may result in delivery of excessive laser energy.**

Always cap the proximal connector of the fiber with the attached rubber cap whenever the fiber is not installed on the laser.

Windows and Lens

Warning!
ALWAYS PUT THE LASER SYSTEM INTO "STANDBY" OR "OFF" AND REMOVE THE DISTANCE GAUGE FROM THE HANDPIECE WHEN CHECKING, CLEANING AND/OR REPLACING THE DELIVERY SYSTEM, DISTANCE GAUGE, LENS AND/OR WINDOWS.

Due to the nature of some procedures, the windows and lens will require frequent cleaning and/or replacement to maintain proper system performance. They should be maintained in accordance with the cleaning and disinfection procedures given in this section. Assembly pictures and procedures specific to the Vbeam delivery systems are included in this section.

Each Smart distance gauge assembly contains two windows to protect the delivery system optics and its internal lenses (Figure 6.2). In addition to these windows, the Pigmented Lesion (PL) distance gauge also contains a removable lens in the gauge ring housing (Figure 6.3) where direct contact with the skin treatment surface occurs.

The handpiece contains one internal handpiece window that can be installed or removed easily using the Window Removal Tool supplied with each laser (Figure 6.4).

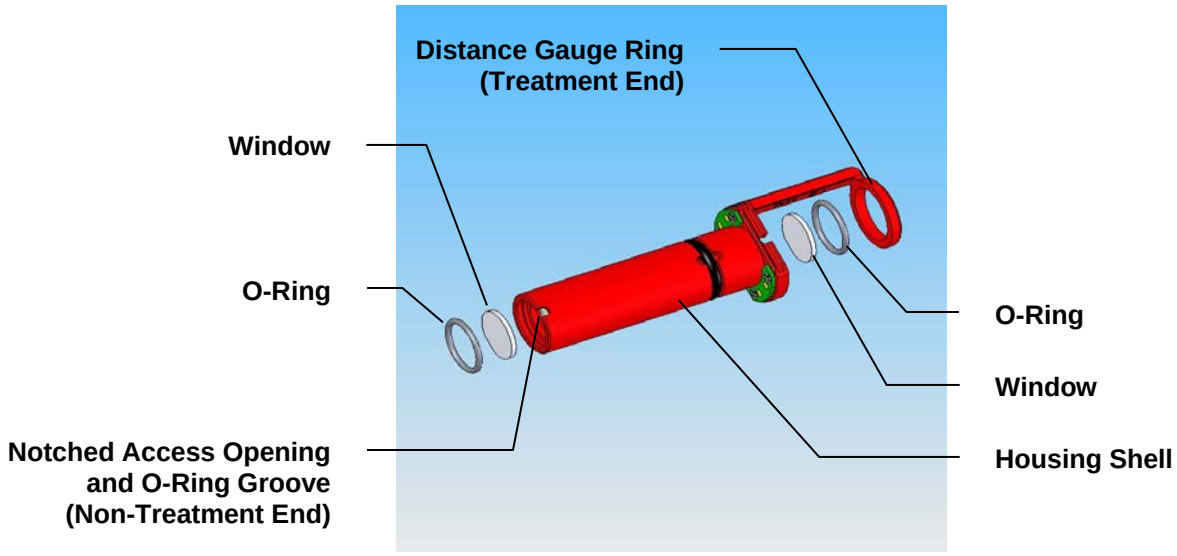


Figure 6.2: Smart Gauge Windows

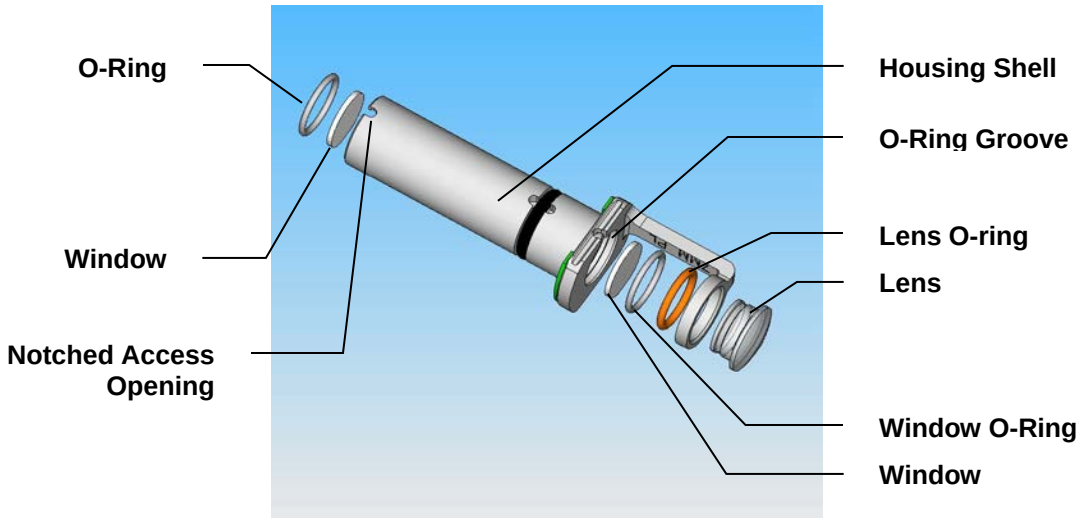


Figure 6.3: Pigmented Lesion Distance Gauge Windows and Lens

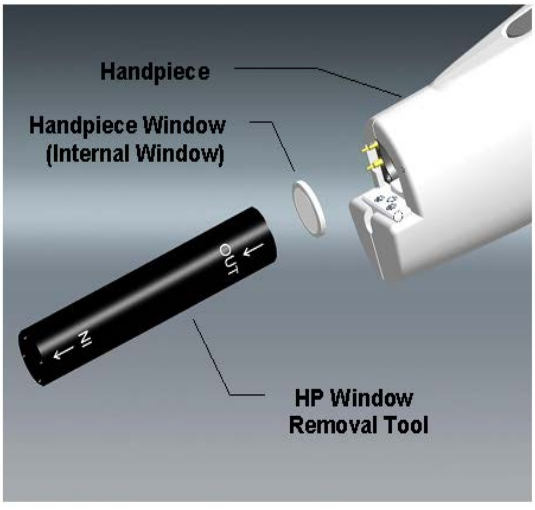


Figure 6.4: Handpiece Window and Removal Tool

Cleaning and Disinfection

Warning!

ALWAYS PUT THE LASER SYSTEM INTO "STANDBY" OR "OFF" AND REMOVE THE DISTANCE GAUGE FROM THE HANDPIECE WHEN CHECKING, CLEANING AND/OR REPLACING THE DELIVERY SYSTEM, DISTANCE GAUGE, LENS AND/OR WINDOWS.

Warning!

Always recalibrate the laser after fixing, cleaning or replacing the delivery system, distance gauge, window(s) and/or PL lens. Failure to initiate a calibration after cleaning/replacing the window(s), lens, distance gauge and/or delivery system may result in the delivery of excessive laser energy.

Warning!

Always perform the User Verification Tests per Section 6 of this Manual to check the delivery system and distance gauge for proper operation at the beginning of each treatment day or each time it is replaced on the laser system. In addition, use the User Verification Tests to check the delivery system and/or distance gauge if there is an unexplained treatment response noted or the delivery system and/or distance gauge has been dropped. **Discontinue use of your laser delivery system or distance gauge if you suspect a problem.**

The Laser System

The exterior of the laser system may be cleaned weekly with a soft cloth slightly moistened with a solution of mild soap and water. Do not use harsh detergents. To disinfect the exterior of the laser system, use a soft cloth moistened with hospital-grade disinfectant or alcohol solution.

The Delivery System Handpiece

The outer shell and internal window of the Delivery System Handpiece need to be kept clean and free of residue build up. The procedures given below provide instructions for the proper cleaning/disinfection of the Delivery System Handpiece outer shell and its internal window.

To clean and disinfect the handpiece:

Immediately after each treatment session, put the laser in STANDBY and wipe the exterior surface of the handpiece body with a gauze pad moistened with a hospital grade disinfectant solution or alcohol solution. Take care to avoid contaminating the internal optical surfaces of the handpiece. After cleaning the handpiece, dry the area thoroughly prior to the beginning of a laser procedure.

To clean or replace the handpiece window:

This procedure requires the use of the Handpiece Window Removal Tool shown in Figure 6.4 (Candela P/N 7122-00-3761).

1. Turn off the laser system.
2. Remove any distance gauge that may be inserted in the handpiece and set aside.
3. Wear dustless gloves to prevent smudges or fingerprints on the handpiece window.
4. Fully slide the Handpiece Window Removal Tool in the handpiece port with the "OUT" arrow pointing in the OPPOSITE direction away from the laser aperture. (**Note:** The "OUT" arrow indicates the direction in which the handpiece internal window will be removed.)
5. Slowly rotate the Window Removal Tool to make a ¼ turn in a counterclockwise or clockwise direction. This will exert a magnetic pull on the handpiece internal window causing it to attach itself to the Window Tool.
6. Slowly pull the Window Removal Tool out in the direction of the "OUT" arrow. The handpiece window should be magnetically attached to the proximal end of this tool.
7. Remove the handpiece window from the tool to clean.
    a. Clean the window with a lint free tissue or towelette moistened with clean isopropyl alcohol. Wipe only once with each tissue.
    b. Re-inspect the window and compare to the Window and Lens Acceptability Chart (Figure 6.8). If unacceptable, discard window and replace with a new one.
8. Grasp the clean or new window by the edges and magnetically attach it to the other end of the Window Tool where the "IN" arrow is located (orientation of the window does not matter).
9. Carefully slide the Window Removal Tool in the direction of the "IN" arrow back in the handpiece port until it comes to a full stop.
10. Slowly rotate the Window Removal Tool to make a ¼ turn in a counterclockwise or clockwise direction. This will release the handpiece window from the Window Removal Tool.
11. Slowly pull the Window Removal Tool out. Verify that the handpiece window is no longer attached to the tool and that it attached itself inside the handpiece.
12. Hold the handpiece under a bright light to verify that the handpiece window is fully magnetically connected to the bottom surface (flat) of the handpiece port and that the window fully covers the internal delivery system optics.
13. Reinsert the distance gauge. The distance gauge should be able to slide in without any obstacles. If unable to insert the distance gauge, the handpiece window may not be properly set. Repeat Steps 2-12 until the handpiece window can be properly set in place.

Warning!
Always verify that the handpiece window is properly set in its place.

14. Turn on the laser and allow it to warm-up.

15. Calibrate the laser per Section 5 of this Manual.

Warning!

ALWAYS PERFORM A LASER CALIBRATION AFTER REPLACING/CLEANING A DIRTY OR BURNT WINDOW OR PL LENS.

The Distance Gauges

The distance gauge is the only part of the handpiece to contact the patient. This is an item that should be replaced when signs of degradation or difficulty in cleaning occur. Proper care will result in improved laser performance.

Warning!

ALWAYS PUT THE LASER SYSTEM INTO "STANDBY" OR "OFF" AND REMOVE THE DISTANCE GAUGE FROM THE HANDPIECE WHEN CHECKING, CLEANING AND/OR REPLACING THE DELIVERY SYSTEM, DISTANCE GAUGE, LENS AND/OR WINDOWS.

Warning!

Always perform the User Verification Tests per Section 6 of this Manual to check the delivery system and distance gauge for proper operation at the beginning of each treatment day or each time it is replaced on the laser system. In addition, use the User Verification Tests to check the delivery system and/or distance gauge if there is an unexplained treatment response noted or the delivery system and/or distance gauge has been dropped. **Discontinue use of your laser delivery system or distance gauge if you suspect a problem.**

Warning!

Always recalibrate the laser after fixing, cleaning or replacing the delivery system, distance gauge, window(s) and/or PL lens. Failure to initiate a calibration after cleaning/replacing the window(s), lens, distance gauge and/or delivery system may result in the delivery of excessive laser energy.

The Smart Gauges

Each assembly has an outer housing shell and two windows that need to be kept clean and free of residue build-up. The procedure below provides instruction for the proper cleaning/disinfecting of the Smart Gauges.

To Clean/Disinfect the housing shell and mask:

1. Clean the Distance Gauge mask, post and exposed section of housing shell with a gauze pad moistened with hospital-grade disinfectant or equivalent.
2. Be sure **not** to wipe clean the green circuit board on the Distance Gauge (Figure 6.5).

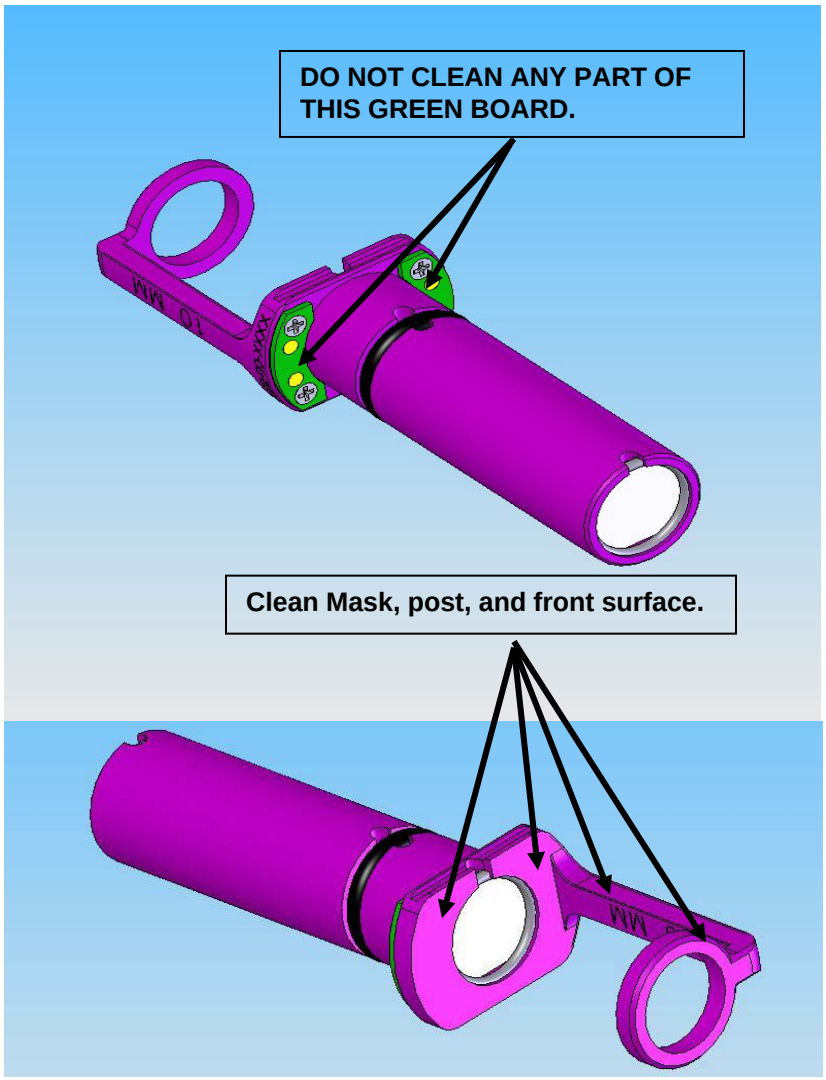


Figure 6.5: Smart Distance Gauge Cleaning

Caution!

- **DO NOT USE HEAT, STEAM OR AUTOCLAVES TO STERILIZE THE DISTANCE GAUGE OR COMPLETELY SUBMERGE IT IN CLEANING SOLUTIONS OR WATER. USE A PAD MOISTENED WITH DISINFECTANT OR ALCOHOL SOLUTION TO WIPE CLEAN THE DISTANCE GAUGE AS INSTRUCTED IN THIS MANUAL OR DAMAGE TO THE DETECTION ELECTRONICS WILL OCCUR.**
- **DO NOT DISASSEMBLE THE DISTANCE GAUGE TO PERFORM REPAIRS. ONLY CLEAN OR REPLACE THE DISTANCE GAUGE WINDOWS OR PL LENS AS INSTRUCTED IN THIS MANUAL.**
- **ONLY USE VBEAM REPLACEMENT WINDOWS IN THE DISTANCE GAUGE OR PERMANENT DAMAGE MAY OCCUR.**
- **THE DISTANCE GAUGE, IT'S WINDOWS, AND THE PL LENS MAY BECOME SOILED WITH NORMAL USAGE. TO ENSURE PROPER FLUENCE DELIVERY, IT IS IMPORTANT TO INSPECT AND CLEAN THE DISTANCE GAUGE, ITS WINDOWS AND THE PL LENS FREQUENTLY SO DEBRIS DOES NOT GET BURNED INTO THE WINDOW OR LENS SURFACE.**
- **WHEN THE DISTANCE GAUGE WINDOWS OR PL LENS BECOME DIRTY OR BURNT, THE AMOUNT OF ENERGY DELIVERED TO THE PATIENT MAY BE REDUCED. THEREFORE, AFTER REPLACING/CLEANING A DIRTY OR BURNT DISTANCE GAUGE WINDOW OR PL LENS, ALWAYS RECALIBRATE THE LASER.**

To clean or replace the distance gauge windows:

1. Wear dustless gloves to prevent smudges or fingerprints on lens.
2. Put the laser in STANDBY and remove the distance gauge assembly from the handpiece.
3. The windows are located on both ends of the distance gauge (treatment and non-treatment end). They are each held in grooves by O-rings. A notched access opening near the edge of the grooves on both ends allows easy removal of the O-rings. (Figure 6.2 and Figure 6.3)
4. With the treatment end of the distance gauge pointing downwards, remove the O-ring from the non-treatment end with tweezers or poke a pointed object into the notch. Gently pull the O-ring toward the center of the window to free the O-ring from the groove.
5. Turn the assembly upside down, allowing the window to fall out onto a clean surface.
6. Repeat Steps 4 – 5 to remove the second window from the treatment end of the distance gauge starting with the non-treatment end of the distance gauge facing downwards.
7. Clean the window:
    a. Clean the window with a lint free tissue or towelette moistened with clean isopropyl alcohol. Wipe only once with each tissue.
    b. Re-inspect the window and compare to the Window and Lens Acceptability Chart (Figure 6.8). If unacceptable, discard the window and replace with a new one.
8. One window at a time, grasp the new or cleaned window by the edges and place it back into the distance gauge so that it is resting flat on the ledge. Reinsert the O-ring into the groove. Use the tip of the tweezers or a pointed object to gently push the O-ring fully into the groove, being careful not to touch the window.

9. Re-insert the distance gauge back in the handpiece and insert into the Calport.

10. Perform the Calibration Procedure per Section 5.

NOTE: ONLY USE VBEAM REPLACEMENT WINDOWS IN THE DISTANCE GAUGE OR PERMANENT DAMAGE MAY OCCUR.

Warning!
ALWAYS PERFORM A LASER CALIBRATION AFTER REPLACING/CLEANING A DIRTY OR BURNT WINDOW OR PL LENS.

PL Distance Gauge

The PL Distance Gauge contains a housing shell with two windows and a lens that needs to be clean and free of residue build-up. The procedure below provides instruction for the proper cleaning/disinfecting of the PL Distance Gauge.

Warning!
ALWAYS PUT THE LASER SYSTEM INTO "STANDBY" OR "OFF" AND REMOVE THE DISTANCE GAUGE FROM THE HANDPIECE WHEN CHECKING, CLEANING AND/OR REPLACING THE DELIVERY SYSTEM, DISTANCE GAUGE, LENS AND/OR WINDOWS.

To Clean/Disinfect the housing shell and mask:

1. Clean the Distance Gauge mask, post and exposed section of housing shell with a gauze pad moistened with hospital-grade disinfectant or equivalent.
2. Be sure **not** to wipe the green circuit board on the Distance Gauge (Figure 6.6).

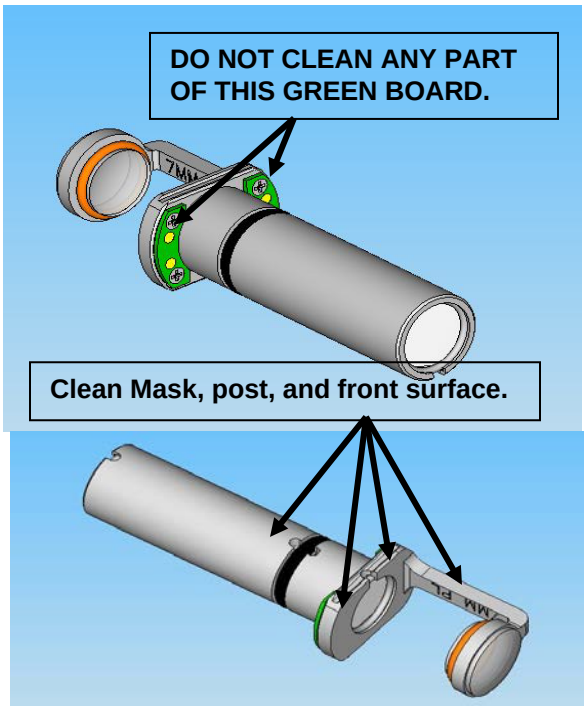


Figure 6.6: PL Distance Gauge Cleaning

To clean or replace the PL distance gauge windows:

Use the same procedure described earlier in this Section for cleaning or replacing the Smart distance gauge windows.

Caution!

The PL Lens will require frequent cleaning during treatments because it is in constant contact with the skin. We recommend keeping a soft lint free tissue or towelette moistened with alcohol on-hand while treating with the PL lens to facilitate frequent wiping and prevent debris from sticking to the lens.

To clean the PL lens:

1. Wear dustless gloves to prevent smudges or fingerprints on the lens.

2. Put the laser in STANDBY and remove the distance gauge assembly from the handpiece.

3. The meniscus-shaped lens in the distance gauge ring is held in place by an O-ring. Remove the lens for cleaning by removing the O-ring then holding the edges of the lens and pulling it straight out (Figure 6.7).

4. Clean the lens:
    a. Clean the lens with a lint free tissue or towelette moistened with clean isopropyl alcohol. Wipe only once with each tissue.
    b. Re-inspect the lens and compare to the Window and Lens Acceptability Chart (Figure 6.8). If unacceptable, discard the lens and replace with a new one.

5. Install the lens by:
    a. Hold the distance gauge with the ring facing up.
    b. Place the lens above the ring, verifying it is not crooked. This is very important, or else the lens may chip when sliding it through the ring.
    c. Slide the lens only at its edges into the ring until it is mounted and resting on the ring.
    d. While holding the lens in the distance gauge ring, slide the O-ring back on the lens to secure it in its place. (See Figure 6.6).
6. Recalibrate laser per the Calibration Procedure in Section 5.

Warning!

ALWAYS RECALIBRATE THE LASER AFTER REPLACING/CLEANING A DIRTY OR BURNT WINDOW OR PL LENS

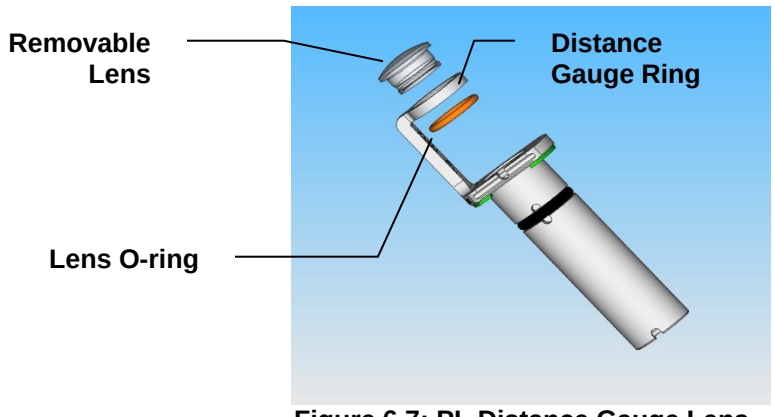


Figure 6.7: PL Distance Gauge Lens

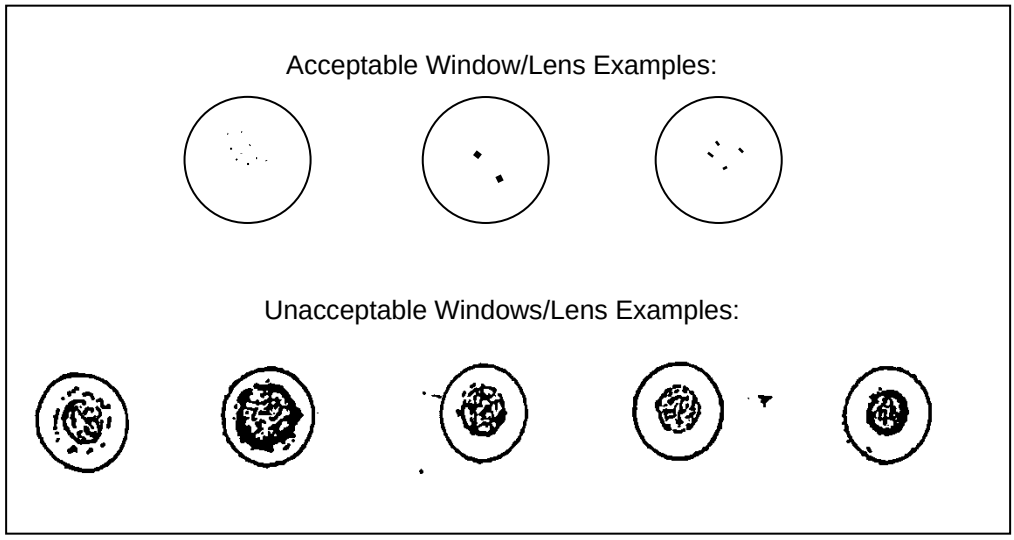


Figure 6.8: Window and Lens Acceptability Chart

Handpiece Delivery System Replacement

The handpiece delivery system should be replaced with the system turned off. When not in use, the delivery systems should be stored in the supplied case with the plastic cap over the end of the fiber. The delivery system connectors and their receptacles on the laser system can be seen in Figures 6.9 and 6.10. Refer to these figures for installation and removal of the handpiece delivery system.

Removing the Delivery System:

1. Remove the Valve Control by grasping the connector near the red dot and pulling it straight back.

2. Remove the Cryogen Line, using two hands, by pushing the knurled Cryogen Line Receptacle toward the laser and pulling the Cryogen Line Connector away from the laser.

3. Remove the Fiber-Optic by gently pulling the connector straight out of the receptacle.

4. Place the delivery system into supplied storage case with plastic end cap on the fiber for protection.

Connecting the Delivery System:

1. Turn the laser system OFF.

2. Remove the new handpiece assembly from the package. Locate the Fiber-optic, Cryogen line and Valve control connectors (delivery system cable assembly) and receptacles (Control Panel).

3. To install the Fiber-optic, carefully insert the Fiber-optic connector into the Fiber-optic receptacle until it clicks into place.

Caution!
IF THE FIBER IS NOT SEATED PROPERLY, DAMAGE TO THE FIBER COULD OCCUR.

4. Connect the Cryogen Line, using two hands, by pushing the knurled Cryogen Line Receptacle and the Cryogen Line Connector toward the laser until it stops. Release the knurled connector. The male and female ends of the connectors fit together.

5. Locate the mating RED DOTS on the Valve Control connector and receptacle. Connect the Valve Control by aligning the RED DOT on the Valve Control receptacle with the RED DOT on the Valve Control Connector and pushing in the connector until it stops.

6. Perform the User Verification Tests given in this Section.

Figure 6.9 Handpiece Delivery System Close-Up

Figure 6.10: Control Panel Close-up of Delivery System Receptacles

Cryogen Canister

Caution!
THE CONTENTS OF THE CRYOGEN CANISTER ARE UNDER PRESSURE. READ THE MSDS CANDELA P/N 8501-00-1701 AND THE LABEL ON THE CANISTER BEFORE HANDLING.

Canister Replacement

To replace a DCD canister please follow these easy steps:

1. With the laser turned off, pull the empty canister out of the laser system.
2. Install the new canister by placing it into the DCD receptacle and gently pushing it into place until it the two retention brackets lightly snap into place.
3. Turn the laser on and allow it to warm up
4. Verify that the laser system is in STANDBY mode.
5. Press the Cooling Spray Menu Button on the Main Screen to access the DCD Counter and Reset Button. Press this button for 3 seconds until the counter is reset.
6. Point the delivery system handpiece away from objects and bystanders (toward the floor). Press the Purge Button several times until all air bubbles have been purged out of the handpiece.
7. Perform the User Verification Tests given in this Section.

Figure 6.11: Cryogen Canister Replacement

8. Choose the laser system settings and calibrate the laser per the Calibration Procedure in Section 5.

Cryogen Leak

For additional information, refer to the MSDS sheets (Candela P/N 8501-00-1701) supplied with each cryogen canister.

Canister Disposal

The canister can be disposed of by a waste disposal company or completely by emptying it (as per the instructions enclosed with each canister) and disposing of it in the trash. (See Section 2, Environmental Protection in this Manual).

Laser MegaDye Cartridge and Dye Change Kit

The Vbeam laser system routinely monitors the laser beam energy output and the wavelength of the laser dye solution. After a number of pulses or an extended period of time, the absorbency of the dye eventually deteriorates and reduces the energy output of the laser. When this happens, the Vbeam MegaDye Cartridge can be replaced by an authorized user without the presence of a Candela Service Representative to restore the energy.

WARNING!

THE LASER DYE CARTRIDGE AND ITS CONNECTING SYSTEM COMPONENTS CONTAIN THE LASER DYE AND TRIPLET QUENCHER SOLUTION WHICH IS A TOXIC AND FLAMMABLE HAZARDOUS MATERIAL. THIS HAZARDOUS MATERIAL AND/OR WASTE SHOULD BE HANDLED AND DISPOSED OF ONLY BY TRAINED AND AUTHORIZED PERSONS KNOWLEDGEABLE ABOUT BUT NOT LIMITED TO THE DYE CARTRIDGE REPLACEMENT PROCEDURE (Candela P/N 7122-85-3776), USED DYE KIT RETURN PROCEDURE (Candela P/N 7122-85-3780), THE VBEAM DYE CARTRIDGE ASSEMBLY MATERIAL SAFETY DATA SHEET (MSDS, Candela P/N 7121-90-9940) AND HAZARDOUS MATERIAL LABELING REQUIREMENTS. PROTECTIVE EYEWEAR AND GLOVES MUST BE WORN BY ALL PERSONS DURING THIS PROCEDURE AT ALL TIMES.

The Vbeam MegaDye Cartridge Assembly

The Vbeam MegaDye Cartridge Assembly contains the hazardous dye solution in its storage cartridge and must be handled with care per the instructions provided with the Laser Dye Change Kit and in this Manual. The MegaDye Cartridge is protected by a MegaDye Cartridge Top Cover, Dye Cartridge Interlock switch, a bumper bar and a bumper bar support platform (Figure 1.2). The top cover must be installed at all times in order for the laser to start or operate. Removal of the top cover will release the Dye Cartridge interlock switch and prevent the laser from operating.

The MegaDye Cartridge can be easily removed or installed by pressing the quick connect fittings that allows quick removal or installation of the dye cartridge.

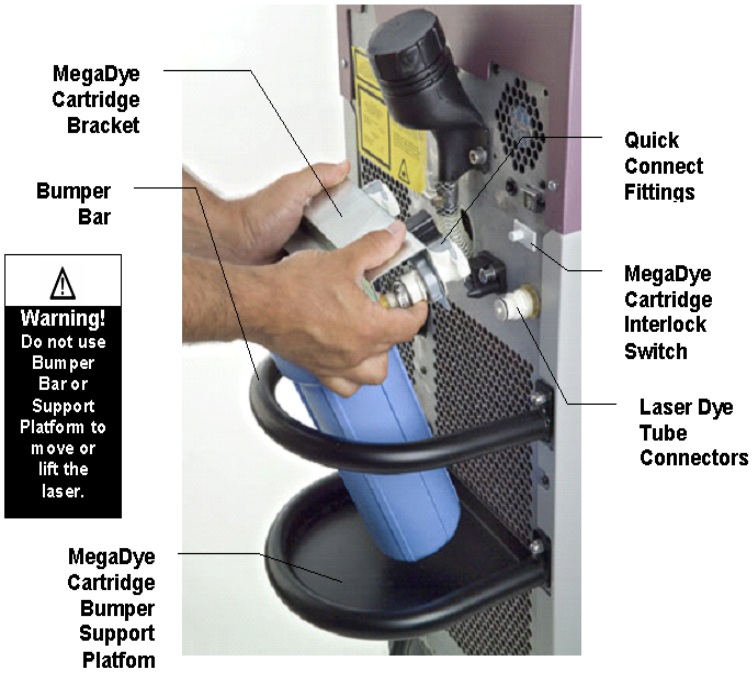


Figure 6.12: MegaDye Cartridge

The Vbeam MegaDye Cartridge Replacement Procedure

Warning!

The Laser Dye Cartridge Replacement Procedure is included in the Laser Dye Change Kit. Follow all instructions and procedures provided in the Laser Dye Change Kit when changing the dye cartridge.

In Case of a Spill or Exposure to the Laser Dye Solution

The Dye Solution may be harmful by inhalation, ingestion or skin absorption. Handle the used MegaDye Cartridge with care at all times. See the Vbeam Cartridge Assembly MSDS Candela P/N 7121-90-9940 for more complete information. The toxicity and health hazard data of the Dye Solution has not been established.

Following a spill or exposure:

1. Evacuate the area and close off to all personnel.
2. In case of **eye contact**, immediately flush eyes with water for at least 15 minutes.
   In case of **skin contact**, remove contaminated clothing immediately and flush skin with soap and water.
   In case of **inhalation**, remove to fresh air.
   In case of **ingestion**, drink 2 to 4 glasses of water, induce vomiting and call a physician.
3. Obtain an OSHA/MSHA approved respirator, rubber gloves, and safety goggles.
4. If there is a spill, absorb the spilled liquid with vermiculite, dry sand or similar material.
5. Obtain a container that can be sealed securely. Carefully sweep up material into container and seal.
6. Ventilate the area and wash the spill site after material pick up is complete. Refer to the MSDS for disposal procedures.

Water Cooling System

Caution!

The cooling water is heating to 65°C. Do not stick fingers into the water tank. Avoid splashing of heated water.

The system is cooled with distilled (DI) water. The water level should be checked monthly if the system is used daily, and every 6 months if used weekly. The water tank is located inside the laser and is connected to the reservoir filler bottleneck protruding from the rear of the laser.

To check the water level or if the system message indicates a fault code preceded by a “7”, turn off the laser and allow it to cool down. Turn the filler cap counter-clockwise to remove. Inspect the water level by looking into the reservoir filler bottleneck. Fill with DI water until the water fills up to within ½ to 1 inch from the top of the reservoir filler bottleneck and install the filler cap back on. Turn on the laser and allow operation for 15 seconds then turn the system off. Remove the filler cap to check the water level and refill with more DI water if needed. Repeat the procedure until the water reservoir is filled within ½ to 1 inch from the top of the bottleneck. After the reservoir is completely refilled, restart the laser system and allow the system to warm up.

Touch Screen

Touch Screen Care and Cleaning

Always handle the touch screen with care. It is recommended to periodically clean the glass touch screen surface:

- Use isopropyl alcohol or a non-abrasive glass cleaner. Avoid using cleaners other than glass cleaners. Do not use any vinegar-based solutions.
- Apply the cleaner with a soft cloth. Avoid using gritty cloths.
- **Always** dampen the cloth and then clean the screen.

User Verification Tests

Warning!

Always perform User Verification tests as outlined in this section at the start of each treatment day and when the handpiece is changed. Check the delivery system for any damage (i.e.: dropped). **Discontinue use of your laser delivery system if you suspect a problem.**

Overview of Tests

This section contains information regarding three tests. Each test should be performed for the indicated handpieces at the beginning of each treatment day. In addition, check the delivery system if there is any concern about the delivery system's performance or the delivery system has been dropped. Discontinue use of the delivery system if problems are noted in any of these test or you suspect/observe other factors that may affect performance.

You will need the following supplies to perform these tests:

- Laser Safety Glasses
- Cryogen Coverage Template, Candela P/N 1301-00-8291 (included in the accessory kit supplied with the laser).
- Vbeam 10 mm distance gauge
- White paper

The following tests are described in this section:

1. Cryogen Alignment: Verifies the cryogen spray nozzle is properly aligned with the distance gauge ring.

2. Cryogen Coverage: Verifies the spray duration required to fill the distance gauge ring.

3. Cryogen Bubble Detector: Verifies that bubbles in the cryogen line are detected and the associated "fault" message is displayed on the system.

4. Beam Alignment: Verifies that the laser and aiming beam are in alignment with the distance gauge.

Test 1: Cryogen Alignment

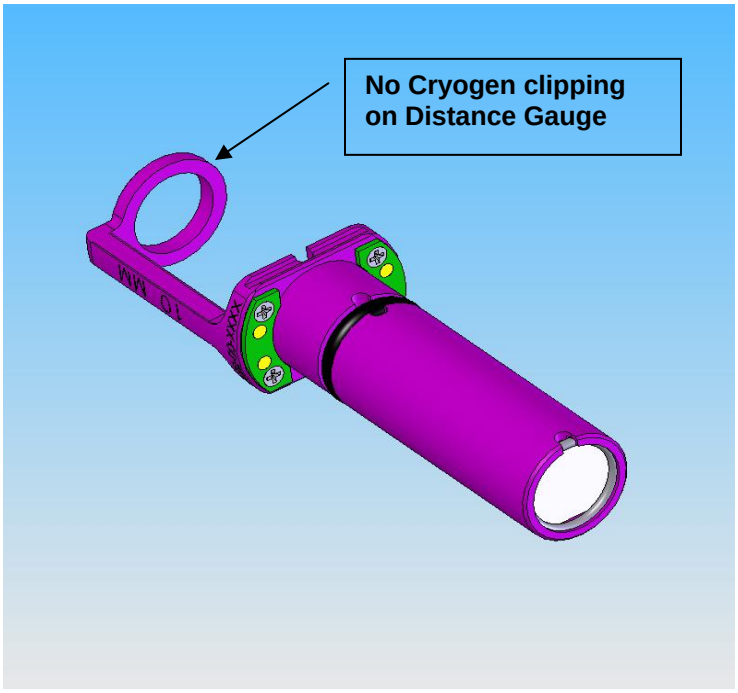
Purpose: To verify the cryogen spray nozzle is properly aligned with the distance gauge ring.

Procedure:

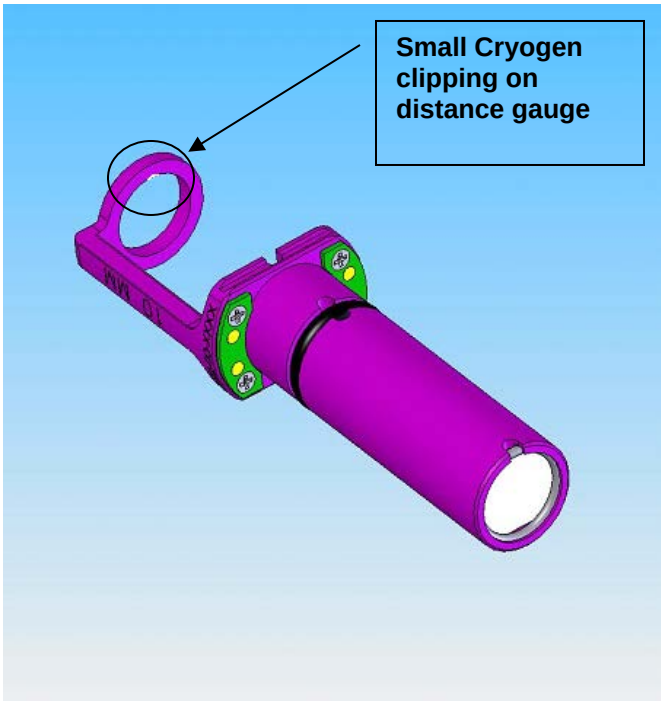
1. Put the laser with the delivery system installed in STANDBY. **Caution- laser should remain in STANDBY mode for the duration of the test.**
2. Press the Cooling Button to select the Medium DCD setting.
3. Install Vbeam 10mm distance gauge.
4. Point handpiece away from objects and personnel (toward the floor). View the contact ring of the distance gauge, looking from the handpiece.
5. Press and release the Purge button.

DCD spray should flow completely through the contact ring. There may be a minimal spray mist seen hitting the contact ring. No spray should be spraying beyond outside of the contact ring. Please see below the “Acceptable” and “Unacceptable” pictures.

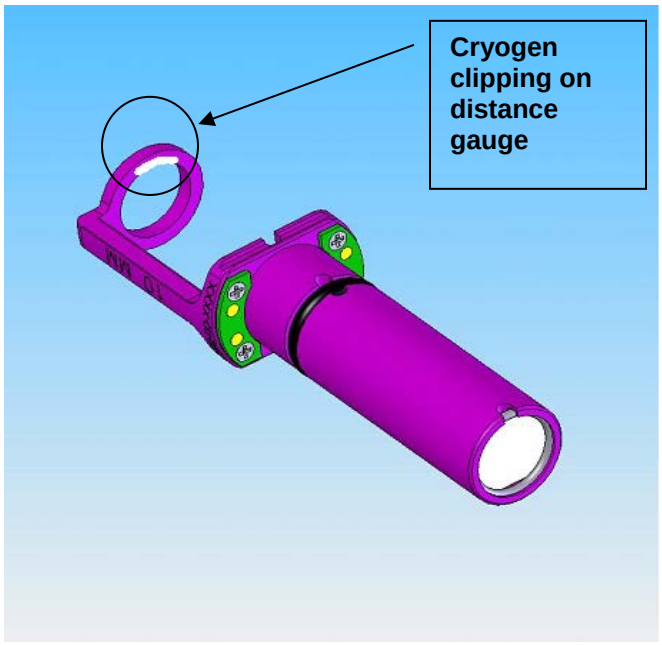
Acceptable:
No mist on contact ring



Acceptable:
Small amount of mist on contact



Unacceptable results:
Excess mist on contact ring



Results

- **Acceptable alignment – no further action needed.**
- **Unacceptable alignment – repeat the test with a different distance gauge.**

Repeat Test results

- **If the tests show acceptable alignment with the new distance gauge, contact Candela Technical Support to review results.**
- **If the result is still "unacceptable", try a different handpiece (if available) or contact Candela Technical Support.**

Test 2: Cryogen Coverage

Purpose: To verify the proper spray duration required to fill the distance gauge ring. (Note: Distance gauge ring is larger than the spot size marking).

Note: The below tests and values are not intended to represent treatment parameters, but rather provide a check on proper functionality of the handpiece and provide a reference for the user to help identify changes in the handpiece operation.

Procedure:

1. Put on appropriate laser safety glasses.
2. Put the laser in STANDBY. **Caution – laser should remain in STANDBY mode for the duration of the test.**
3. Install 10 mm distance gauge.
4. Press the Cooling Button to select the Medium DCD setting.
5. Place the distance gauge over the Vbeam 10 mm distance gauge spot on the template (Candela P/N 1301-00-8291).
6. Press and release the Purge button
7. Remove handpiece QUICKLY from template.
8. THE DCD Spray should completely fill the inner spot.

Note: Spray outside of the spot is acceptable as long as the inner spot is completely filled. (This spray may be from reflected spray off the paper). If the spot does not fill or a leak is noted, the handpiece assembly should be replaced or contact Candela Technical Support.

Caution!

Periodically check that the cryogen sprays through the center and fills the distance gauge ring area to maintain proper coverage.

Test 3: Cryogen Bubble Detection

Purpose: To ensure that bubbles in the cryogen line are detected and the associated "fault" message is displayed on the system.

Procedure:

1. Insure that the installed DCD canister is not empty. **Warning: Put on appropriate laser safety glasses.**
2. Turn on the system and allow the "WARM UP" to complete.
3. With the ALL OTHER DELIVERY SYSTEM CONNECTORS INSTALLED, disconnect the Cryogen Connector (Figure 6.9 and 6.10).
4. Install the 10 mm distance gauge into the handpiece and install the handpiece into the calport.
5. Press the Cooling Menu Button to enter the Cooling Spray Settings Window and set the DCD spray to 100 ms and the delay to 20 ms.
6. Set the FLUENCE to the lowest setting.
7. Enter the READY mode, and calibrate the laser by pressing on the footswitch.
8. Remove the handpiece from the Calport and aim in a direction away from personnel (such as the floor).
9. Depress the footswitch to pulse the laser continuously until a PURGE REQUIRED window box appears on the user screen and lasing ceases. This should happen in less than 50 pulses.
10. Reconnect the Cryogen Connector (Figure 6.9 and 6.10). Depress "PURGE" may be required until the line is refilled.

Test 4: Beam Alignment

Purpose: This procedure is designed to help identify a misaligned distance gauge on your delivery system. This test also verifies that the aiming laser beam is working properly.

Procedure:

1. Put on appropriate laser safety glasses. **Warning – laser will enter READY mode for the duration of the test.**
2. Install the desired distance gauge spot size for your laser treatment.
3. **Press the READY Button (if in STANDBY) on the Main Screen. Do not press the fingerswitch or the footswitch to pulse the laser. Aim the handpiece at a white piece of paper and inspect the aiming laser beam for circular uniformity and clarity. If the aiming beam spot is not uniform, press the STANDBY Button to put the laser in STANDBY mode. Check for distance gauge interference. Fix or clean the distance gauge per Section 6 of this manual or replace if correct results cannot be achieved. Repeat Beam Alignment test until satisfactory results are achieved.**

Note: Always repeat this procedure for each distance gauge prior to use.

Important!

Discontinue use of the laser system if the aiming beam is not present! This may be an indication of a broken fiber optic. Replace the delivery system and perform the Beam Alignment Test to see if this corrects the problem. If this does not fix the problem, contact Customer Service.

Warnings Related to Delivery System

Warning:

The fact that your laser delivery system passes the applicable tests contained in this "User Verification Section" does not guarantee that your laser delivery system is problem-free. Discontinue use of your laser delivery system if you suspect a problem with it.

Warning:

Use of a delivery system/handpiece with problems could result in adverse effects such as burns, scarring (hyper-tropic and / or atrophic) and / or hyper pigmentation / hypo pigmentation.

Do not use a dropped delivery system/handpiece until after testing.

Dropping the delivery system can result in damage and can affect the life of the delivery system, calibration, cryogen spray alignment, or bubble sense detection resulting in possible patient burns. **If the delivery system is dropped the user tests must be performed before use.**

Note: The laser beam alignment can be altered: 1) by dropping a delivery system/related component or 2) by the laser beam passing through a burn spot or pits on the optics. A laser beam that is altered or misdirected could result in heating, charring and possible ignition of associated components along with possible user and patient burns. Purge faults could indicate an excessive heating problem.

Do not use a handpiece if cryogen is not aligned with the delivered energy spot /aiming beam or the cryogen spray pattern is unusual. If this is noted contact Candela Technical Support and discontinue use of the handpiece.

Do not use a handpiece if cryogen is found to be leaking from the hand piece nozzle tip or a reduced cryogen flow is noted. Discontinue use until the cause is determined and eliminated. Purge the lines in order to flush the valve. If problem persists, do not use. Contact Candela technical support.

Treatment Related WARNINGS

Warning:

Tilting the distance gauge can result in an elliptical energy spot verses a circular spot and affect the distribution pattern of the cryogen. The distance gauge must be held perpendicular to the treatment spot. Crescent burns on the patient may occur.

Warning:

Overlapping of treatment spot size areas may result in crescent and general patient burns

Warning:

Selecting too short of cryogen spray duration for a given spot size may result in patient burns and other adverse effects.

Warning:

Failure to replace the cryogen canister when the “replace canister” message appears could result in patient burns.

Warning:

Failure to keep fiber tips and slider optics free of dust and debris can lead to possible patient burns.
Laser energy striking dust and debris on optics including fiber tips will damage them which could lead to possible patient burns. When components of the delivery system are not attached to the laser system, such as the proximal end connector, cover to prevent dust and debris from collecting on optics and exposed fiber tips.

Warning:

Failure to keep windows at optimum may result in patient burns
Follow product’s delivery system cleaning protocols
Replace/clean windows according to protocol in Section 6 of this manual.

Warning:

Failure to replace windows properly after cleaning can result in failure of the lens or window and may cause patient burns
Improper window insertion could result in lens or window failure and cause burns.

When removing a window for cleaning, carefully note the window surface that was exposed to debris and the direction in which such window surface faces. When re-inserting the window, ensure that the window surface that was exposed to debris faces the same direction as it did prior to removal.

Troubleshooting

These troubleshooting solutions do not replace the instructions or procedures given in this Manual. Review all instructions and procedures in this Manual before performing the following troubleshooting solutions.

General Laser System Troubleshooting Solutions

Table 6.1: General Troubleshooting Solutions

Situation / Symptom	Probable Cause or Indicator	Solution
The System cannot be turned on.	The power is not connected properly	Reseat the power cable and check the circuit breaker.
	The laser system circuit breaker is in the “Off” position	Switch the circuit breaker to the “On” position
	The key-lock switch was not fully engaged	Turn the key-lock switch fully clockwise to the “Start” position and release.
	The external interlock is defeated	Check the remote interlock connection. If connected to a door, make sure the door is closed.
Laser pulses, no cryogen is delivered	The DCD Spray settings are set to zero “0”.	Select the DCD Spray “up arrow” button to increase the spray setting
Cryogen leak	Tubing breaks in the delivery system	Remove the cryogen canister or disconnect the handpiece assembly from the laser. Call Service.
Warm-up Time has exceeded 60 minutes	The water or cryogen temperature control circuitry failed	Call Customer Service.
Ineffective fluence response	System or fiber has degraded	Perform a calibration procedure per Section 5. Call Service if problem persists.
Replace Canister Message Appears	There is insufficient cryogen in the canister	Replace the cryogen canister with a new canister supplied by Candela and press the DCD Counter and Reset Button (See Section 6).
Purge Required	Bubbles have been detected in the cryogen line	Press the purge switch until problem resolves. This must be done with the handpiece outside of the calibration port. If the problem persists, call Service.
Laser will not enter the READY state	Trigger Switch is depressed	De-activate the Trigger Switch

Table 6.1: General Troubleshooting Solutions		
Situation / Symptom	**Probable Cause or Indicator**	**Solution**
Aiming beam missing in the READY state	❖ Damaged or broken fiber ❖ Bad aiming beam laser or driver circuit	❖ Replace delivery system ❖ Or Call Technical Support
Aiming beam appears dim	❖ Intensity set too low ❖ Dirty distance gauge windows ❖ Dirty or damaged slider optics ❖ Failing aiming laser	❖ Set aiming beam intensity using button provided ❖ Clean or replace windows ❖ Or Call Technical Support
Aiming beam appears non-uniform	❖ Dirty distance gauge windows ❖ Dirty or damaged slider optics	❖ Clean or replace windows ❖ Replace distance gauge ❖ Replace delivery system

Fault and Warning Messages

A fault message typically occurs due to a system malfunction. Sometimes clearing the fault and retrying the previous operation can be successfully accomplished without further faults occurring. If the fault message persists, call Technical Support and report the Fault Number. Fault processing automatically places the system into the Standby state. The following conditions occur outside of normal system operation. When the system enters a fault condition, it beeps and displays a warning or fault message. These solutions do not replace the instructions or procedures given in this Manual. Review all instructions and procedures in this Manual before performing the following troubleshooting solutions.

Troubleshooting Solutions for Fault and Warning Messages

Table 6.2: Troubleshooting Fault Messages

Situation / Symptom	Fault No.	Reason	Solutions
Fault 1 – Bubble Detect Circuit Fault	**1.1**	Handpiece Bubble Circuit Test Failure	Put laser in STANDBY. ❖ Check DCD spray settings to make sure it is “ON”. ❖ Press the Purge button to purge air bubbles out of the handpiece. ❖ Check DCD Canister and make sure it is full and replace if needed. If the canister is full, try reinstalling or replacing the canister. ❖ Replace with a new or spare delivery system.
	1.2	Canister Bubble Circuit Test Failure	❖ Check DCD spray settings to make sure it is “ON”. ❖ Press the Purge button to purge air bubbles out of the handpiece. ❖ Check DCD Canister and make sure it is full and replace if needed. If the canister is full, try replacing or reinstalling the canister. ❖ Replace with a new or spare delivery system.
Fault 3- Shutter Fault	**3.1**	Shutter isn’t in correct state when checked or does not respond to actuation to correct state.	❖ Go to STANDBY then try to calibrate laser. ❖ Restart the laser and recalibrate laser. Call Candela Technical Support if problem persists.
Fault 4 – HVPS Fault	**4.2**	High Voltage Power Supply Communications Time-out.	Turn off laser for at least 5 seconds. Restart and calibrate laser. If persistent messages appear, call Candela Technical Support.
Fault 5 – HV Tolerance Fault	**5.1**	High Voltage Power Supply tolerance fault.	Turn off laser for at least 5 seconds. Restart and calibrate laser. If persistent messages appear, call Candela Technical Support.
	5.2	High Voltage Power Supply charge time-out.	Turn off laser for at least 5 seconds. Restart and calibrate laser. If persistent messages appear, call Candela Technical Support.

Table 6.2: Troubleshooting Fault Messages			
Situation / Symptom	**Fault No.**	**Reason**	**Solutions**
Fault 6- Calibration Fault	**6.2**	Laser failed to complete calibration to desired Fluence within 20 pulses. ❖ Damaged or dirty windows and/or dist. gauge lenses. ❖ Laser mobility shocks may have shifted the laser head out of alignment ❖ Worn delivery system components ❖ Aging laser dye solution, dye cartridge, fluid system and/or laser head components. ❖ Low power input or output	Recalibrate laser after each step in the order given below until a successful calibration is achieved: 1. Put laser in STANDBY. Check, clean and/or replace distance gauge windows. 2. Clean or replace handpiece window 3. Change fluence by two settings up or lower. 4. Try a different distance gauge. 5. If available, install a spare delivery system. If problem persists, contact Candela Technical Support.
Fault 7 – Deionized (DI) Water System Fault	**7.1**	DI water under-temperature	Go to STANDBY and allow sufficient time for laser to warm-up. Verify that the laser room environment and temperature meets all requirements per Section 2 of this Manual. Verify that the water level is correct. If fault message is persistent, contact Candela Technical Support.
	7.2	DI water over-temperature	Turn off laser and allow sufficient time for it to cool down. Verify that the laser room environment and temperature meets all requirements per Section 2 of this Manual. Verify that the water level is correct. If fault message persists, contact Candela Technical Support.
	7.3	DI Water Pump Pressure Fault. Low or no DI water pressure and/or flow. ❖ DI water system pressure switch does not change when power turned on. ❖ DI water pump is not ON or DI pressure switch is not actuated. ❖ DI water level is low and/or there are air bubbles flowing through the fluid system.	Turn laser OFF. ❖ Check DI water level (the base of the reservoir filler bottleneck should be filled with DI water). Refill reservoir if needed. ❖ Check for DI water leaks underneath the laser. If water leak is present, call Service. ❖ Restart and turn off laser 2-3 times to allow fluid system to pump water and flush out air bubbles. If problem persists contact Candela Technical Support.
	7.4	Temperature Sensor Fault (sensor circuit open or shorted).	Contact Candela Technical Support.

Table 6.2: Troubleshooting Fault Messages			
Situation / Symptom	**Fault No.**	**Reason**	**Solutions**
Fault 8 – DCD System Fault	**8.1**	Low DCD pressure. ❖ Cryogen Canister may be empty ❖ Bubbles need to be purged out of new canister ❖ Flow of cryogen may be obstructed ❖ Overheated delivery system or DCD canister ❖ DCD Settings may be out of range.	❖ Remove and reinstall DCD canister. ❖ Install a new canister If fault persists, contact Candela Technical Support
	8.2	High DCD pressure. ❖ Bubbles need to be purged out of new canister ❖ Flow of cryogen may be obstructed ❖ Overheated delivery system or DCD canister ❖ DCD Settings may be out of range.	❖ Shut down laser and allow cooling. Check room temperature and open DCD and Storage Compartment lid to allow ventilation. Restart laser. ❖ Install a new canister If fault persists, contact Candela Technical Support
	8.3	DCD Valve Fault	Reinstall or replace the delivery system. If problem persists, contact Candela Technical Support.
	8.4	DCD Temperature Sensor Fault	Contact Candela Technical Support.
Fault 9 – Warm-Up Timeout	**9.1**	DI water temperature not in normal range after 60 minutes.	Contact Candela Technical Support.
	9.2	DCD pressure not in normal range after 60 minutes.	Contact Candela Technical Support.
Fault 10 – Delivery System Fault	**10.1**	Unrecognized distance gauge while in READY state	Reinstall Distance Gauge; or insert a spare distance gauge; or rotate the distance gauge 180° and re-insert into the handpiece. Calibrate the laser. If problem persists, call Candela Technical Support.
	10.2	Handpiece disconnected while in READY State.	Remove delivery system. Reinstall delivery system and calibrate laser. If problem persists, contact Candela Technical Support.
	10.3	Distance Gauge disconnected while in READY State.	Reinstall Distance Gauge; or insert a spare distance gauge; or rotate the distance gauge 180° and re-insert into the handpiece. Calibrate the laser. If problem persists, call Candela Technical Support.

Table 6.2: Troubleshooting Fault Messages			
Situation / Symptom	**Fault No.**	**Reason**	**Solutions**
Fault 10- (Continued)	**10.4**	Fiber not detected while in READY State.	❖ Remove delivery system and reinstall. Calibrate laser. ❖ Replace delivery system with a spare or new delivery system. Calibrate laser. If fault persists, contact Candela Technical Support.
	10.5	Distance Gauge not supported.	The system or handpiece does not support the installed distance gauge. Install a spot size that is supported.
Fault 11- Wavelength Fault	**11**	Wavelength out of range. ❖ Dye solution may need wavelength adjustment ❖ Dye solution may need to be replaced	❖ Repeat Calibration ❖ Replace MegaDye Cartridge per Dye Cartridge replacement procedure. If problem persists, contact Candela Technical Support.
Fault 12 – Energy Out-of-Range Fault	**12.1**	Laser head energy of last treatment pulse was low	Try to recalibrate the laser system. Contact Candela Technical Support.
	12.2	Laser head energy of last treatment pulse was high	Try to recalibrate the laser system. Contact Candela Technical Support.
	12.3	Laser head energy of last treatment pulse was greater than maximum allowed	Try to recalibrate the laser system. Contact Candela Technical Support.
	12.4	Laser head energy not balanced	Try to recalibrate the laser system. Contact Candela Technical Support.
	12.5	Laser head energy detector malfunction	Try to recalibrate the laser system. Contact Candela Technical Support.
Fault 13 – Trigger Switch Fault	**13**	Redundant trigger switch fault	Contact Candela Technical Support.
Fault 14 – Simmer Fault	**14**	Simmer Circuit fault	Contact Candela Technical Support.

Table 6.2: Troubleshooting Fault Messages			
Situation / Symptom	**Fault No.**	**Reason**	**Solutions**
Fault 15 – Transmission Fault	**15.1**	Low Transmission ❖ Dirty windows in distance gauge and/or handpiece ❖ Damaged lenses in distance gauge. ❖ Incorrect windows were installed ❖ Worn delivery system	Recalibrate laser after each step in the order given below until a successful calibration is achieved: 1. Clean and/or replace windows in distance gauge and/or handpiece. 2. Try another distance gauge (the same size if available). If this distance gauge works, contact Customer Service to replace bad one. 3. Verify that there is one flat on the window edge and/or replace the window (Vbeam windows only). 4. Replace the delivery system. If problem cannot be fixed, call Candela Technical Support.
	15.2	High Transmission ❖ Windows missing ❖ 3mm or 5mm distance gauges only: Worn filter in 3mm or 5mm distance gauge.	Recalibrate laser after each step in the order given below until a successful calibration is achieved: 1. Verify that the distance gauge has both windows (input and output) and that the handpiece has a window. 2. If problem persists for 3mm and 5mm distance gauge, replace 3mm or 5mm distance gauge. Contact Candela Technical Support if problem persists.
Fault 16 – Replace Canister	**16**	Displays if canister bubble is detected in READY and DCD is enabled. ❖ Bubbles need to be purged out of new canister ❖ Cryogen Canister may be empty ❖ Flow of cryogen may be obstructed	❖ Press Purge Button to purge bubbles out of cryogen line ❖ Check canister to see if it is empty. Replace if needed. ❖ If the canister is full, take it out and reinstall then press Purge Button. If problem persists, contact Candela Technical Support.
Fault 17 – Purge Required	**17**	Bubbles detected in handpiece ❖ Air bubbles need to be purged out of cryogen fluid lines ❖ Cryogen Canister may be empty ❖ Cryogen line may be obstructed ❖ Overheated delivery system	❖ Press Purge Button to purge bubbles out of cryogen line ❖ Check canister to see if it is empty. Replace if needed. ❖ If canister is full, take it out and reinstall then press Purge Button. If problem persists, contact Candela Technical Support.

Table 6.2: Troubleshooting Fault Messages			
Situation / Symptom	**Fault No.**	**Reason**	**Solutions**
Fault 18 – Circuit Calibration Fault	**18.1**	Energy Circuit Calibration Fault	Contact Candela Technical Support.
	18.2	DI Circuit Calibration Fault	Contact Candela Technical Support.
	18.3	DCD Circuit Calibration Fault	Contact Candela Technical Support.
Fault 19 – Laser Fault	**19.1**	Laser Trigger Fault	Contact Candela Technical Support.
	19.3	Laser Timer Fault.	Contact Candela Technical Support.
	19.4	Laser Head Power Fault	Contact Candela Technical Support.
	19.5	High Voltage Dump Fault	Contact Candela Technical Support.
Fault 20 – Dye System Fault	**20.1**	Dye Pump Fault	Turn off laser. ❖ Check for dye leaks at dye cartridge. ❖ Reinstall Dye Cartridge and Dye Cartridge Top Cover back properly in place. Restart laser. If fault remains, contact Candela Technical Support.
	20.2	Dye Cartridge Top Cover may not be fully or properly installed in place.	Turn off the laser. ❖ Remove and properly reinstall the Dye Cartridge Top Cover back in place. Restart laser. If fault remains, contact Candela Technical Support
	20.3	No Dye Cartridge present	❖ Install Dye Cartridge per Dye Cartridge Replacement Kit instructions. ❖ Remove and properly reinstall Dye Cartridge and the Dye Cartridge Top Cover back in place. Restart laser. If fault remains, contact Candela Technical Support.
Fault 21 – Code Update Fault	**21**	Code Update did not complete properly.	Contact Candela Technical Support.
Fault 22 – Processor Comm. Fault	**22**	Processor internal communications Fault	Contact Candela Technical Support.

Table 6.2: Troubleshooting Fault Messages			
Situation / Symptom	**Fault No.**	**Reason**	**Solutions**
Fault 23- Device Comm. Faults	**23**	Device Communications Fault	Contact Candela Technical Support.
Fault 24- Triplet Quencher Fault	**24.2**	Triplet Quencher addition exceeded its limits.	Contact Candela Technical Support
	24.3	Triplet Quencher Pump Fault	Contact Candela Technical Support

THIS PAGE LEFT BLANK INTENTIONALLY

Section 7: Labels and Symbols

The Candela laser has been labeled in accordance with domestic and international agency standards. All laser operators should be familiar with the location and meaning of the labels. See Figures 7.3, 7.4, 7.5 and 7.6 at the end of this Section for label locations.

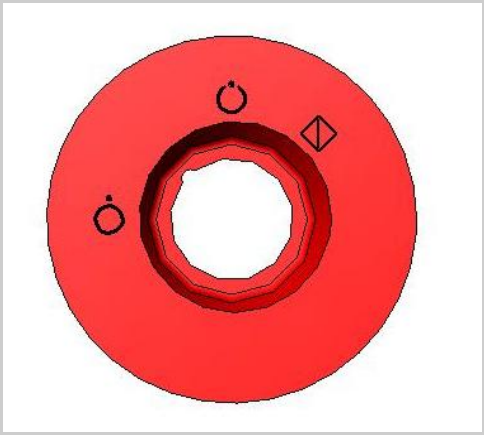
General Label/Symbol

General Label/Symbol	
 **General Symbol/Label: Important Note, Caution, Warning or Danger Messages**	**This General Symbol can be found throughout the Operator's Manual and on the Laser.** The purpose is to draw the attention of the operator to the location of this symbol for important notes or additional information to avoid personal injuries or damage to property.

Mains Switch (or Circuit Breaker) Symbols

Mains Switch Label and Symbols (Located on rear panel)		
 **Figure 7.1: Mains Switch**	 **Mains Switch Label**	The symbol label was placed next to the Mains Switch to draw the attention of the operator to the Manual for further information concerning the On/Off Mains Switch. The Mains Switch should be placed in the "O" position when the system is not being used. When the system is to be used, the Mains Switch should be moved to the "| "position.
	|	**Located on the Mains Switch (rear panel)** Indicates the **"ON"** switch position in which the system is connected to the mains.
	O	**Located on the Mains Switch (rear panel).** Indicates the **"OFF"** switch position in which the system is disconnected from the mains.
	~	**Located on the ID Label (rear panel).** Indicates that the system operates on alternating current.

Key-lock Switch Symbols

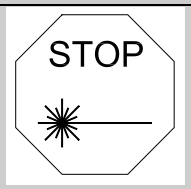
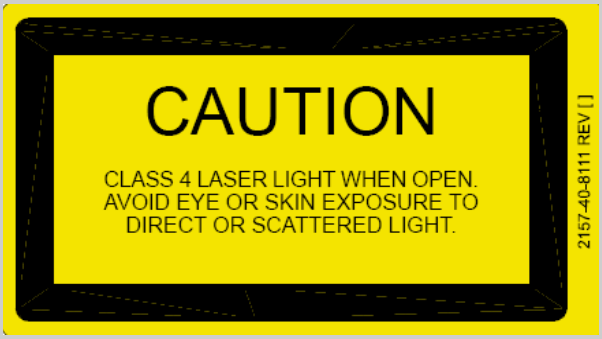
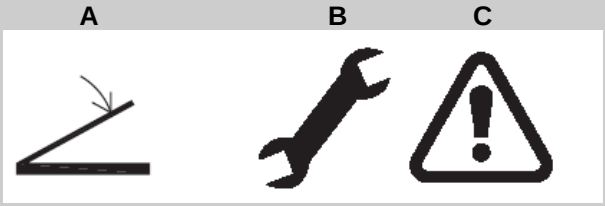
Key-lock Switch Symbols (Located on Front Bezel)		
 **Figure 7.2 Key-lock Switch on Front Bezel Display**		**Off** The key-lock switch symbol means "**OFF**". When the key-lock switch is in this position, all circuits have been de-energized with the exception of the key-lock switch circuit itself.
		**On** The key-lock switch symbol means "**ON**". When the key-lock switch is in this position, all circuits are energized and the device will be fully functional.
		**Start** The key-lock switch symbol means "**START**". This is a spring-loaded key-lock switch position. It is used to initiate the system operation. This position does not initiate the release of laser energy.

Laser System State Status Symbols

System State Status Button Symbols (Located on the Upper Section of the Main Screen Menu)	
	**Standby State.** When YELLOW, the symbol indicates that the laser emission is disabled. The laser can warm-up and be fully warmed-up in STANDBY state.
	**Ready State.** This symbol appears on the Laser System Status bar (top section of the screen) on the Main Screen Menu and the blue light above the Calport illuminates when the laser enters Ready State.
	**Warming Up in Standby State.**
Same as Standby State	**Needs Calibration in Standby State.**
	**Lasing in Ready State. (Note: Always wear protective gear when using lasing)**

Laser System Labels and Symbols

The Vbeam Laser Systems have been labeled in accordance with domestic and international agency standards. All laser operators should be familiar with the location and meaning of the labels.

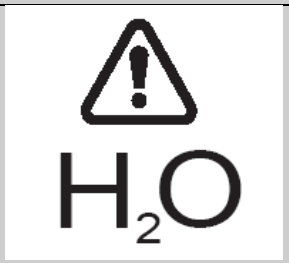
Laser System Labels and Symbols	
 **Label 1: Caution: Laser Radiation**	**Label 1: Located on the Front Display Bezel of the laser.** Indicates the emission of laser energy from this device.
 **Label 2: Emergency Laser Shut-down Stop Switch Label.**	**Label 2: Emergency Laser Stop Red Push Button (Front Display Bezel).** Pushing this button will turn off the laser quickly.
 **Label 3: Caution - Class 4 Laser Label.**	**Label 3: Located on rear side of top cover.** This label indicates that the protective panel encloses a Class 4 laser light.
 **Label 4: Multi-combined Label.**	**Label 4: Silk-screened on the Dye Cartridge Cover (rear panel).).** A. Indicates the location of the Footswitch control hose connection (directly above the label). B. The label indicates the location of the USB Software Upgrade Port (directly above the label on the rear panel). Read and follow all software upgrade instructions and procedures shipped with the USB Memory Stick. Call Candela Clinical, Sales or Service to inquire about the latest Vbeam laser system software upgrades. C. CAUTION – The Software Upgrade Port is not a standard USB port. Do not connect any devices to this port unless instructed by a Candela Support Representative. Never connect powered devices to this port.
 **Label 5: Interlock Switch Label**	**Label 5: Located on rear panel above the Interlock Switch.** Indicates the location of the remote interlock circuit that can be connected to a door switch to shut down the laser should a person enter the room during laser emission. The symbol illustrates that an OPEN connection at this point will inhibit the lasing function.

Laser System Labels and Symbols

Label 6 and 7: Heat or Hot Surface Warning Label applies when unit is powered and/or after it is turned off.

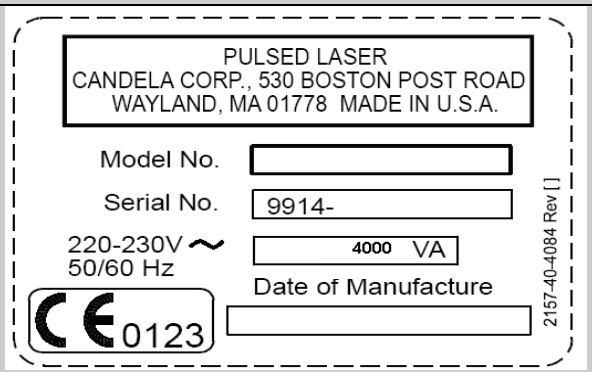
Label 6: : Inside the DCD and Storage Compartment near DCD Heater opening
The hot surface warning label applies strictly to the heater band which is only accessible when the cryogen tank is removed. Accidental contact with the heater band will not cause a burn but may cause an involuntary knee-jerk reaction resulting in an injury.

Label 7: Located on the MegaDye Cartridge Bracket underneath the MegaDye Cartridge Top Cover (rear panel of the laser)
The hot surface warning label applies strictly to the MegaDye Cartridge Bracket which is only accessible when the MegaDye Cartridge Top Cover is removed. Accidental contact with the heated metal bracket will not cause a burn but may cause an involuntary knee-jerk reaction resulting in an injury.



Label 8: Water Reservoir Label

Label 8: Silk-screened on the Dye Cartridge Cover (rear panel).
Indicates that the reservoir is filled with distilled water. The reservoir should be kept full up to 1 - 2 inches above the base of the filler neck with distilled water.



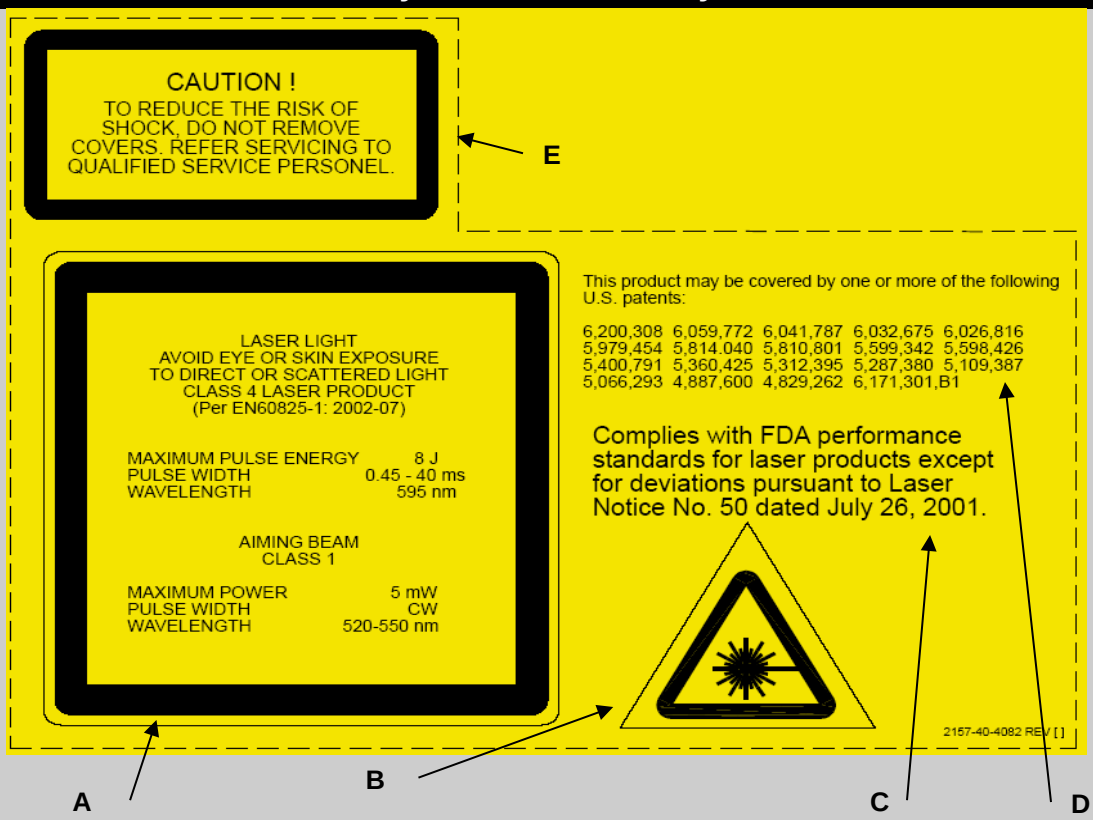
Label 9: Laser Identification Label

Label 9: Located on the rear panel.
This label is marked with the VA rating for the system, as well as the model number, serial number and date and place of manufacture. The label includes the CE mark (in the lower left corner of the label) with the registration number of Candela's ISO Registrar. When present, this marking indicates compliance with the European Medical Device Directive. Refer to the Declaration contained inside the accessory kit for details of compliance.

Label 10: UL/ETL Compliance Label

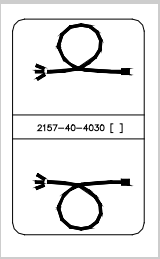
Label 10: Located on the rear panel.
If present, indicates that the laser is approved to UL or ETL standards.

Laser System Labels and Symbols



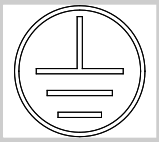
Label 11: Multi-combined Label.
Located on rear panel.

A. Indicates laser emission characteristics and classification per the IEC/EN standards.
B. Indicates that this device emits laser energy.
C. Indicates compliance with a branch of the US FDA which regulates laser equipment.
D. Indicates U.S. patents that may be covered on this laser system.
E. CAUTION: Risk of electrical shock if laser covers are removed or serviced by unauthorized persons. There are lethal voltages inside the system enclosure.



Label 12: International Symbol Label for Laser Energy Emission

Label 12: Wrapped around fiber optic cable near delivery system connections.
Indicates that laser light will be exiting from the distal end of this cable.



Label 13: Safety Ground Symbol Label

Label 13: Located on the rear panel of the laser.
Indicates the location of the primary system safety ground. The screw adjacent to this symbol should never be tampered with or removed.

Laser System Labels and Symbols

Label 14: Toxic Material Hazard Label

Label 14: Located on the top bracket above the Dye Cartridge connectors (rear panel of the laser).
The Candela Vbeam Dye Cartridge and its connectors contain a toxic dye solution.

Read and follow all information and procedures found in the Vbeam MegaDye Cartridge Replacement and Return Procedure (Candela P/N 7122-85-3776), the Vbeam Cartridge MSDS (Candela P/N 7121-90-9940), the Vbeam Cartridge with Triplet Quencher MSDS (Candela P/N 7121-90-0960)
Room ventilation, eyewear and protective gloves are required when performing the Dye Cartridge Replacement procedure to prevent harmful exposure to the toxic dye solution.

A B

Label 15: Caution: Dye Cartridge Cover Removal and Replacement

Label 15: Silk-screened on the Dye Cartridge Cover (rear panel).
A. CAUTION: DO NOT REMOVE the Dye Cartridge Cover until after shutting down the laser and the laser system has cooled down significantly. Accidental or premature removal of this cover could result in unwanted exposure to the heated or HOT surface of the Dye Cartridge Bracket. Refer to Label 7 for additional information.
B. The arrow Indicates the direction in which the Dye Cartridge Cover should be removed.

A B

Label 16: DCD Label

Label 16: Located in the DCD and Storage Compartment
A. The “snowflake” indicates the location for inserting the DCD Cryogen Canister.
B. Candela GentleCool™ 1000 gram Cryogen Canisters (Candela P/N 1600-00-0210) should be used on this Vbeam Laser System. Also, refer to Cryogen MSDS 8501-00-1701 for additional information.

Label 17: WEEE Label

Label 17: Located on the rear panel of the laser.
This is the Waste Electrical and Electronic Equipment (WEEE) Directive Label. This label indicates that the Vbeam laser system and its components cannot be disposed of as regular trash. Contact Candela for disposal information.

Label 18: IEC Type B Applied Part Label

Label 18: Delivery System Information (located on the front panel of the laser)
The “Man” indicates that the delivery system is equipped with a “Type B” applied part.

Label 19: Do Not Push

Label 19: (not pictured) appears on either side of the device.
Cautions the user not to push sideways on the system.

Label 20: Consult the Operator's Manual

Label 20: Located on the rear panel of the laser.
Refer to the Operator's Manual for the safe use of this device.

Label Locations

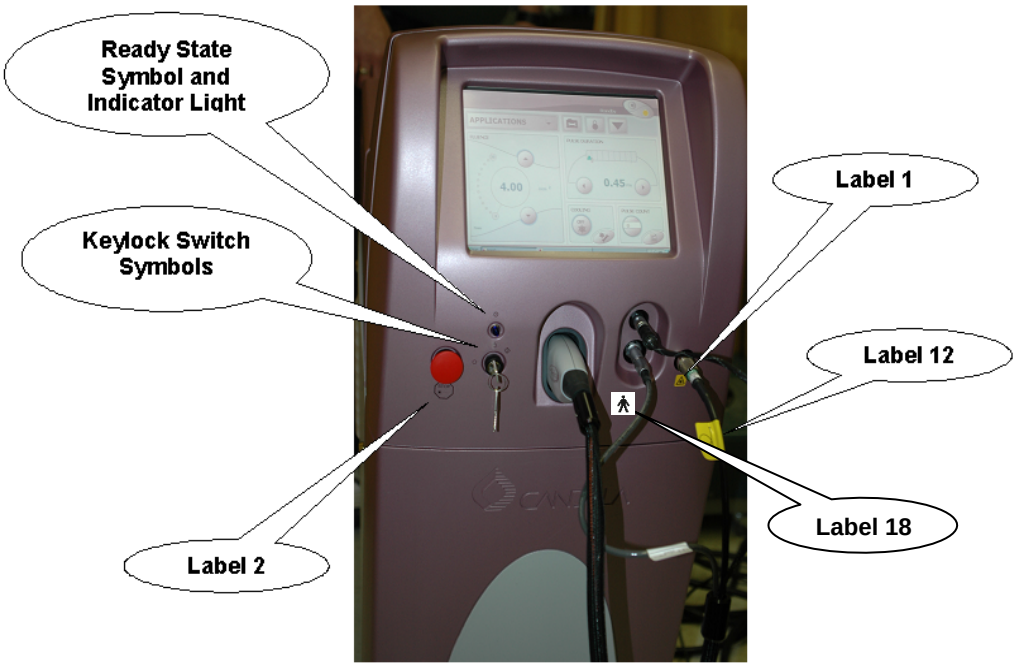


Figure 7.3: Control Panel and Delivery System Label Locations

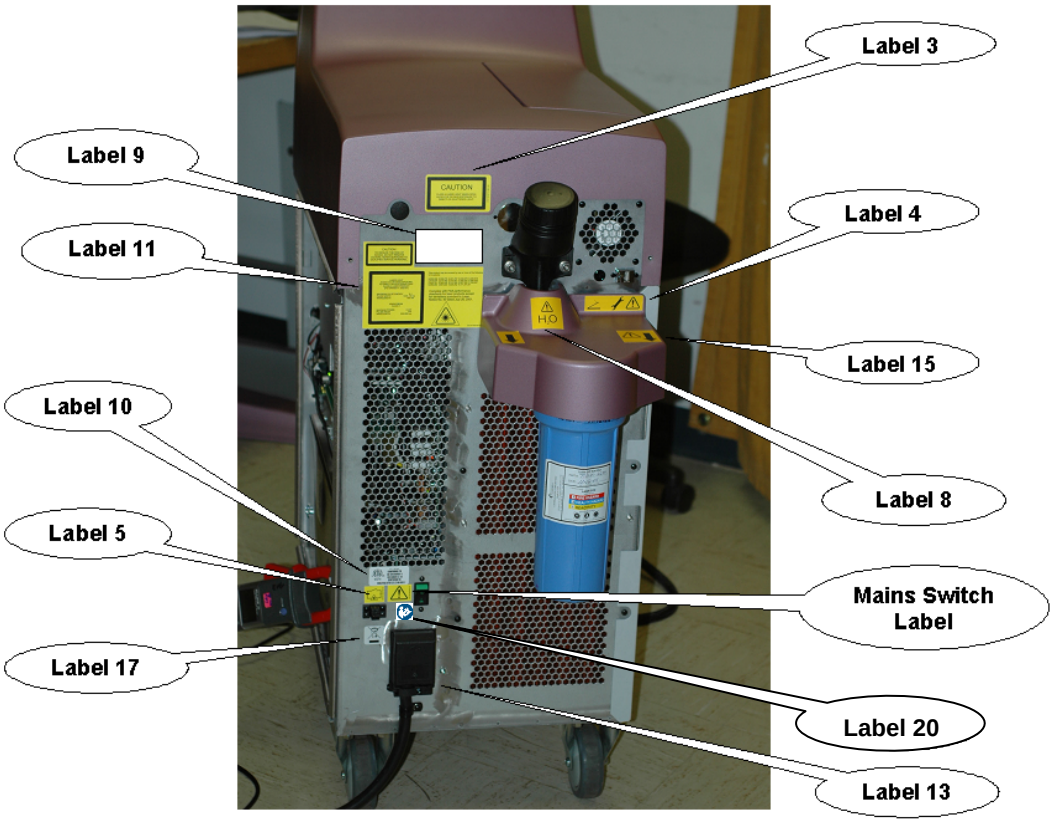


Figure 7.4: Laser System Label Locations

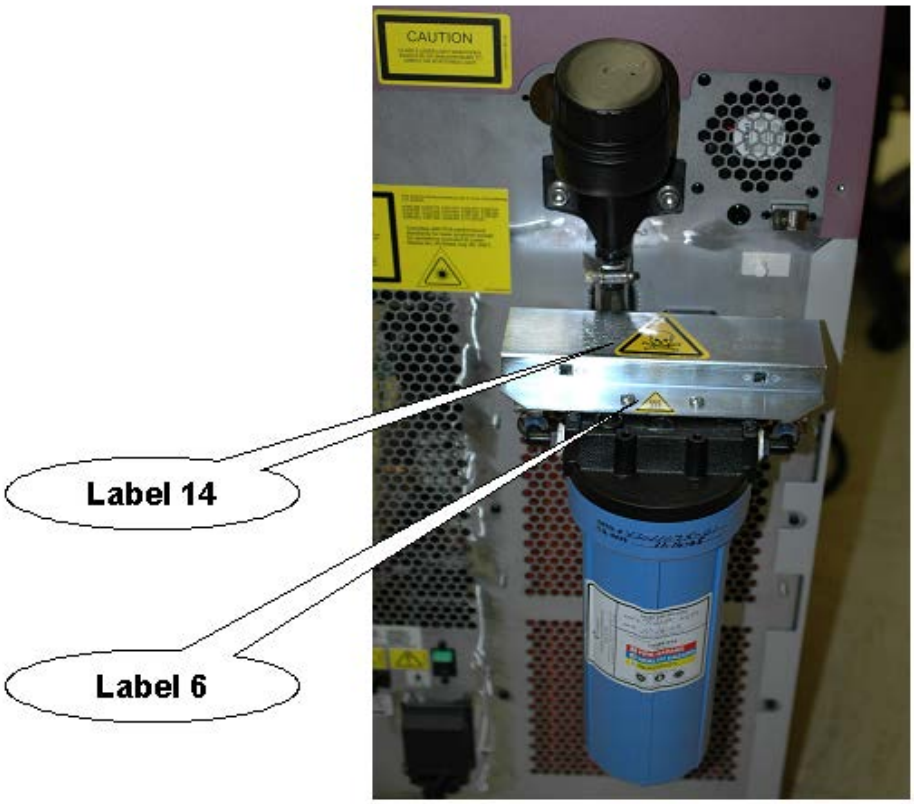


Figure 7.5: Dye Cartridge Bracket Labels

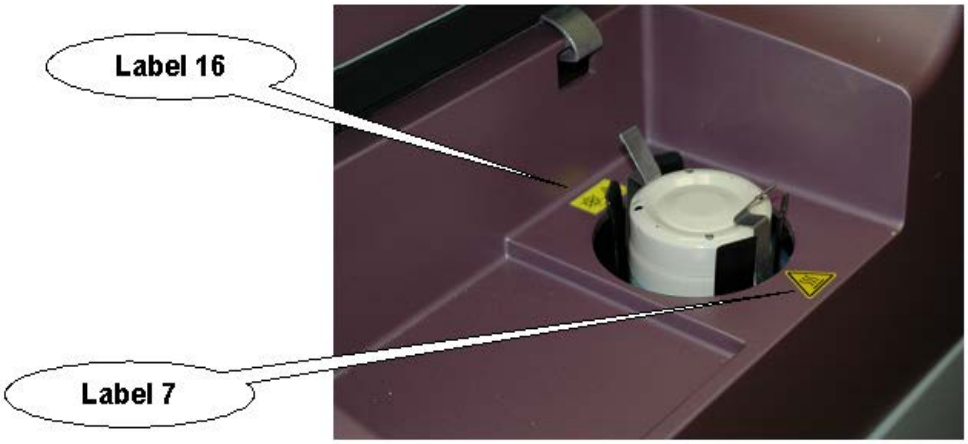


Figure 7.6: DCD Labels inside DCD Storage Compartment

Section 8: Laser System Packing Lists, Accessories and Replacement Parts

Packing Lists

Vbeam Perfecta Laser System Accessories and Part Numbers

Description	Packing List Quantity	Part Number
Vbeam Perfecta Laser System (standard color)	1	9914-00-0300
Perfecta Delivery System with Fiber and Handpiece	1	7122-00-3692
3mm Distance Gauge	1	7122-00-3582
5mm Distance Gauge	1	7122-00-3581
7mm Distance Gauge	1	7122-00-3580
7mm PL Distance Gauge	1	7122-00-7557
10mm Distance Gauge	1	7122-00-3579
10mm PL Distance Gauge	1	7122-00-7558
3 x 10mm Distance Gauge	1	7122-00-3589
12mm Distance Gauge	1	7122-00-3578

Vbeam Platinum Laser System Accessories and Part Numbers

Description	Packing List Quantity	Part Number
Vbeam Platinum Laser System (standard color)	1	9914-00-0310
Platinum Delivery System with Fiber and Handpiece	1	7122-00-3691
3mm Distance Gauge	1	7122-00-3582
5mm Distance Gauge	1	7122-00-3581
7mm Distance Gauge	1	7122-00-3580
10mm Distance Gauge	1	7122-00-3579
3 x 10mm Distance Gauge	1	7122-00-3589
12mm Distance Gauge	1	7122-00-3578

Vbeam Aesthetica Laser System Accessories and Part Numbers

Description	Packing List Quantity	Part Number
Vbeam Aesthetica Laser System (standard color)	1	9914-00-0320
Aesthetica Delivery System with Fiber and Handpiece	1	7122-00-3690
7mm Distance Gauge	1	7122-00-3580
7mm PL Distance Gauge	1	7122-00-7557
10mm Distance Gauge	1	7122-00-3579
10mm PL Distance Gauge	1	7122-00-7558

Accessory Kit and Parts Included with All New Vbeam Laser Systems

The following items are included in the shipping package for all new Vbeam Laser Systems. They can also be ordered individually as replacement or spare parts.

Laser Parts and Accessory Kit		
Description	**Quantity**	**Part Number**
MegaDye Cartridge	**1**	**7122-00-3776**
Cryogen Canisters, 12 pack	**1**	**1600-00-0212**
Fiber Pole and Clamp Assembly	**1**	**7122-00-3810**
Footswitch	**1**	**5103-00-0030**
Blue Plastic Eyewear	**1**	**8095-00-0475**
Rare Earth Eyewear	**1**	**8095-00-0460**
Patient Goggles	**1**	**8095-00-0470**
Operator's Manual	**1**	**8501-00-1780**
Keys/Ring with Candela Logo	**1**	**1301-00-3409**
Laser Room Warning Sign and Labels	**1** **1**	**2157-40-5000** **2157-40-8122**
Vbeam Replacement Windows Kit (Qty of 25 Windows)	**1**	**7122-00-3770**
Window Removal Tool	**1**	**7122-00-3761**
Distance Gauge Tray	**1**	**1301-00-8668**
Window Cartridge	**1**	**7122-00-3592**
Canister Empty Valve	**1**	**3430-02-0010**
Cryogen Template	**1**	**1301-00-8291**
Treatment Guidelines	**1**	**8502-00-0891**

Replacement or Spare Parts

Vbeam Laser Delivery System and Distance Gauge Kits

The following Laser Delivery System and Distance Gauge Kits can be ordered as replacement or spare kits:

Designated Laser System	Description	Part Number
Vbeam Perfecta	One Perfecta Handpiece and matching Distance Gauges (one of each for the following spot sizes) for 3, 5, 7, 7 PL, 10, 10 PL, 3 x 10 and 12 mm Spot Sizes	0800-00-0310
Vbeam Platinum	One Platinum Handpiece and matching Distance Gauges (one of each for the following spot sizes) for 3, 5, 7, 10, 12, and 3x10mm Spot Sizes	0800-00-0320
Vbeam Aesthetica	One Aesthetica Handpiece and matching Distance Gauges (one of each for the following spot sizes) for 7, 7 PL, 10 and 10 PL mm Spot Sizes	0800-00-0330

Cryogen Packs and Dye Change Kit

Part	Description	Part Number
GentleCool™ Cryogen	Case of 12 canisters	1600-00-0212
User Dye Cartridge Replacement Kit	One Replacement MegaDye Cartridge, MSDS datasheet, MegaDye Cartridge Replacement Procedure, MegaDye Cartridge Return procedure, a face visor, a pair of protective gloves and MegaDye Cartridge hazardous materials/waste protective gear	7122-00-3776

Section 9: Service Internal Calibration Procedure

Note

The procedures contained in this section are service procedures to be performed by appropriately trained technicians. They are not to be performed by the user.

Caution!

THE ELECTRICAL AND LASER RADIATION HAZARDS PRESENT DURING SERVICING OF THE VBEAM CAN BE EXTREMELY DANGEROUS IF PROPER SAFETY PRECAUTIONS ARE NOT TAKEN. THE VBEAM IS TO BE SERVICED ONLY BY QUALIFIED TECHNICIANS WHO HAVE RECEIVED APPROPRIATE TRAINING FROM CANDELA. ANY ATTEMPT BY AN UNAUTHORIZED PERSON TO PERFORM ANY SERVICE PROCEDURE WILL VOID ANY WARRANTY ON THE LASER SYSTEM.

Calibration Schedule

The measurement circuits should be calibrated annually to insure accurate delivery of treatment energy. Measurement circuit calibration should be performed by a qualified Candela Service person as part of a “preventative maintenance” visit. During the visit, other subsystems of the laser system will be inspected, adjusted (if necessary) and/or repaired as required. Contact Candela Customer Service for details on “preventative maintenance” or a service contract (if available).

Preface

In normal operation, the Calibration procedure is provided for the user to calibrate the energy output of the laser system. During that procedure, the handpiece is inserted in the calibration port, the laser is pulsed, and the energy output of the handpiece is read by internal laser energy detectors. The system determines the power and energy levels necessary to provide the correct delivered energy for the currently selected fluence setting.

The internal laser energy measurement circuits themselves must be calibrated at least once a year by a qualified service technician. The internal energy calibration procedure (or "Laser Energy Circuit CAL") is described in this section. The procedure requires an external laser energy meter whose calibration is traceable to the appropriate national standards agency. The external laser energy meter used must be appropriate for the specified output of the laser system, with an accuracy of ± 6% or better, and a resolution of 1mJ. This procedure is part of the normal preventive maintenance service procedure.

Parts List

1. Energy meter (OPHIR with L40 (150)A head)

2. Delivery System with known good transmission (85%)

3. 7 or 10mm Distance Gauge with clean windows

4. Wavelength measuring device or filter (See Wavelength Circuit CAL)

Warning!

- **Make sure all personnel in the area are wearing safety eyewear appropriate for the Vbeam Laser System.**
- **Improper internal calibration of this laser system will cause delivery of lower or higher fluences and potential burning of patients. This procedure must be followed precisely for proper results. If the "Final verification of User Calibration Energy" section fails, contact Candela Technical Support for further information.**
- **Once the Laser Energy Circuit CAL procedure has been started, the previously saved CAL parameters will be erased and the Laser Energy and Wavelength Circuit CAL procedures must be completed in order to use the laser for treatment again.**

Internal Calibration

Starting the Circuit Calibration Procedure

1. Prior to starting the Circuit CAL, verify that the Laser Head and Optical Rail are properly aligned (ref. 8503-01-0858).

2. Install the delivery system with a 7 mm Distance Gauge.

Note

When pulsing into the Ophir energy meter, the meter head must be 6" from the handpiece to prevent damage to the meter head.

3. Go to the Main Screen. Set the DCD Spray to OFF.

4. Press and hold the wrench/file icon for a few seconds until a keyboard shows up on the screen. Enter the code 882347 to go to the Circuit CAL screen. Note that other Maintenance Mode tab selections are grayed out providing no access to their functionality. Also note that the Cal DCD button and the HD1, HD2 and CP option boxes are not selectable.

Laser Energy Circuit CAL (0-10J, 0-3J RANGES)

The Laser Energy Circuit CAL basically pulses the laser into an external meter and then into the system's Calport at low and high energies to calculate slope and offset calibration values.

5. Put on Vbeam laser safety eyewear. Warning: The laser will enter the READY mode for the entire calibration procedure.

6. Press the Cal Energy Ckt button to begin the Circuit CAL. A message will appear on the screen: "Are you sure you want to calibrate the Energy Circuits? All factors reset when initiated". Press "Yes" to initiate the Energy Circuit calibration and the laser will enter the READY State. Warning: Once the calibration is initiated, the Laser Energy and Wavelength calibrations must be calibrated correctly and successfully completed in order to use the laser for treatments.

7. Carefully follow the prompts at the bottom of the screen.
    a. There are two typical prompts displayed.
        i. "Pulse HP in OPHIR (expect ~ 1.000). Pulse Laser and Enter Ophir Data". This means to aim the handpiece (HP) to pulse the laser into the external Ophir meter head and then enter the Ophir energy (in this case the expected OPHIR reading should be within 1.000 Joules) using the keypad that will pop-up after the first laser pulse.
        ii. "Pulse HP in Calport". This means to insert the handpiece in the Calport and then pulse the laser.

    b. Make sure that you wait sufficient time (at least 3-5 seconds) between pulses to allow the software to measure the energy properly.

    c. The laser software will automatically set internal parameters and prompt the technician to pulse the laser while directing the delivery system output into the Ophir meter or the Calport as the calibration progresses. When pulsing into the Ophir, a keypad will pop up so that the technician can enter the Ophir reading (If the Ophir doesn't read any energy, then enter a "0".) All entries into the pop up keypad must be entered in Joules (J). The keypad has a fixed decimal point and accepts entries as follows:
        i. Example 1: If the meter is reading **0.769J**, the technician will enter **769** into the keypad. This will appear as 0.769 on the keypad.
        ii. Example 2: If the meter is reading **4.35J**, the technician will enter **4350** (must add the "0" at the end to make it J). This will appear as 4.35 on the keypad.

    d. If the laser software is prompting for the technician to pulse into the Calport and the laser is mistakenly pulsed into the Ophir, a "PreGain Error" may occur. If this error or any other error happens, restart the procedure.

8. The software will prompt the technician with "Circuit Cal Successful" when it is complete.

9. Press the CAL Factors tab. If the PreGain for HD1 or HD2 show 150 or 100 respectively with a b factor of 0, then the calibration was not completed successfully and needs to be restarted. If the PreGain for CP shows 12 or 7 with a b factor of 0, then the calibration was not completed successfully and needs to be restarted.

10. Press the CAL Test tab. Press the Ckt Cal Test button. Ensure that all Pass/Fail indicators for HD1, HD2 and CP (in the Sts Column) show "PPPP". If these do not show "P", then the Circuit CAL needs to be restarted.

Wavelength Circuit CAL

Once the Laser Energy Circuit CAL procedure is completed, the Wavelength Circuit CAL procedure MUST be performed. For proper results, a successful calibration of the Laser Energy Circuit CAL is required before performing the Wavelength Circuit CAL procedure.

The wavelength can be measured using but not limited to the following measuring tools – an Ocean Optics USB2000 Fiber Optic Spectrometer; Candela's Wavelength Filter (P/N 7122-00-3840); or a monochromator. Follow all instructions provided by the wavelength measuring device or filter of your choice to get an accurate wavelength measurement.

11. Put on Vbeam laser safety eyewear. Warning: The laser will be in READY mode for the entire calibration procedure.

12. Press the Cal WL button to start the Wavelength Circuit CAL procedure. A message will appear: "Do you want to do a WL Ckt Cal?". Press "Yes" and the laser will enter the READY State.

13. Carefully follow the prompts at the bottom of the screen to measure and enter the laser beam wavelength:

    a. "Pulse at Monochromator" will appear at the bottom of the screen.
        i. Pulse laser to measure wavelength.
        ii. Make sure that you wait sufficient time (at least 3-5 seconds) between pulses to allow the wavelength measuring device or filter to measure the wavelength properly.
        iii. Measure wavelength per the wavelength measuring device or filter instructions.
    b. "Enter Monochromator data" will appear at the bottom of the screen after pulsing and a keypad will appear. Use the keypad to enter the wavelength reading. More than one pulse can occur while the keypad is on the screen; however, **only one wavelength reading will be entered.** The wavelength reading entered into the pop up keypad must be entered in the following manner:
        i. Example 1: If the meter is reading 594 nm, the technician will enter "5940" (the keypad has a fixed decimal point at tenths of nm) into the keypad. This will appear as 594.0 on the keypad.
        ii. Example 2: If the meter is reading 592.3 nm, the technician will enter "5923" into the keypad. This will appear as 592.3 on the keypad.

        Wavelength Guidelines: The "measured" wavelength MUST fall between 592 and 596 nm. If the "measured" wavelength falls outside of the stated range, contact Candela Technical Support before proceeding.

        iii. "Pulse at Monochromator" will appear AGAIN at the bottom of the screen. This is the final pulse. Put the handpiece in the Calport and pulse the laser one time to complete the WL circuit calibration procedure.

14. The software will prompt the technician with "Circuit Calibration Successful" when it is complete.

15. Press the CAL Test tab. Press the Ckt Cal Test button. Ensure that all Pass/Fail indicators for WL (in the Sts Column) show "PPPP". If these do not show "P", then the Circuit CAL needs to be restarted.

Final Verification of User Calibration Energy

The final step is to complete some user calibrations and to verify the energy is within specification.

16. Press the Exit MM button. This will return the user to the Main Screen.

17. Complete the Calibrations Table using the specified spot size, fluence, and pulse width (See Table 9.1 on the next page). After each Calibration, pulse 3 times into the Ophir meter. Record each Ophir energy reading.

18. Note that on entry to Ready State (Ready Button pressed or started CAL), if a fault 18.3 appears, then the Circuit CAL was not completed successfully and needs to be repeated.

19. Calculate the average Ophir energy using the table and then the percentage difference from the expected energy.

20. Verify the percentage difference of each table is within ± 14%. If this verification fails, the Circuit CAL needs to be repeated. If it fails more than once, then contact Candela Technical Support for service.

Table 9.1 Calibration Table			
7 mm, 7.0 J/cm^2 , 3 ms Expected Energy = 2.69 J		7 mm, 20.0 J/cm^2 , 3 ms Expected Energy = 7.70 J	
Pulse #	**Ophir Energy (J)**	**Pulse #**	**Ophir Energy (J)**
1		**1**	
2		**2**	
3		**3**	
Average (J)		**Average (J)**	
Percent Difference (%)		**Percent Difference (%)**	

21. If the Circuit Calibration is successfully complete without failure, the laser can be safely used.