CANDELA

Operator's Manual

CE 0123

P/N 8501-00-1510 Rev D

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.
Federal law also requires this device to be utilized under the direction of a physician and it should only be used by healthcare professionals authorized under state law to treat patients. All persons treating patients with this device should check to determine whether they are authorized healthcare professionals under the applicable state law.

(EC Authorized Representative)
Scanlan Group B.V.
Tupolevlaan 32
1119 NZ Schiphol-Rijk
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)

Section 1

Applications
Description
Specifications

APPLICATIONS

The Candela Vbeam system is a flashlamp-excited, pulsed dye laser indicated for the treatment of benign cutaneous vascular lesions, benign vascular gynecological lesions and periorbital wrinkles.

The Vbeam delivers pulses of laser energy at a wavelength that passes through the dermis and epidermis 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 width 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 eradication 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).

DESCRIPTION

Laser System

The Vbeam (Figure 1-1) is a 595nm pulsed, flashlamp excited dye medical laser controlled by an embedded microprocessor. 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 Vbeam 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 also includes the unique MegaDye dye cartridge, that enables the system to deliver many thousands of pulses before requiring dye replacement.

The laser head is cooled by the circulation of deionized 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.

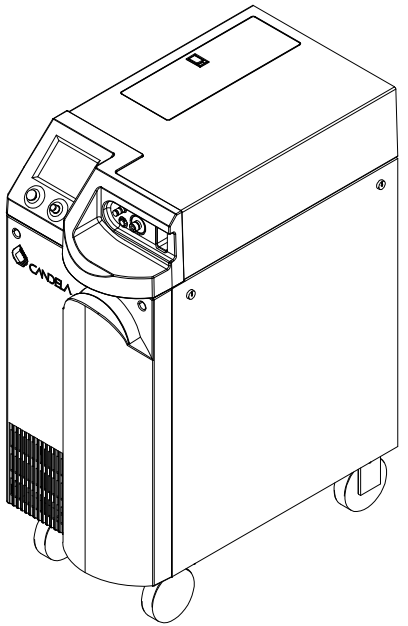
The output of the laser is delivered through an optical fiber coupled to removable sliders. A distance gauge is placed against the skin to ensure proper focusing and spot placement on the treatment area

Dynamic Cooling Device™ (DCD™)

The laser system incorporates a skin cooling device built into the system enclosure referred to as the dynamic cooling device (DCD). The DCD consists of an electrically controlled spray nozzle located at the treatment end of the handpiece and 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.

FIGURE 1.1
LASER SYSTEM



Delivery System

The delivery system (Figure 1-2) consists of an optical fiber, removable optical slider, replaceable distance gauge and handpiece assembly.

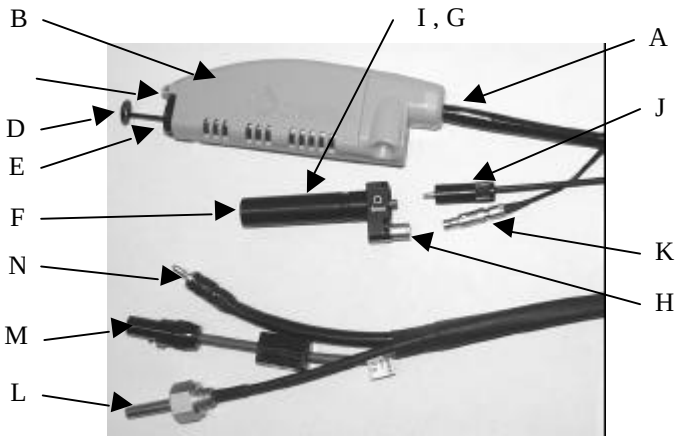
CAUTION!

DUE TO POSSIBLE EXPOSURE TO LASER RADIATION, THE OPTICAL FIBER SHOULD BE REPLACED BY SERVICE PERSONNEL ONLY.

Each spot size requires a separate slider and distance gauge to be installed in the handpiece. The only exception is that the 10 mm distance gauge is used for both the 10 mm slider and the 3 mm x 10 mm slider

The handpiece assembly contains the DCD spray nozzle, safety electronics and the trigger switch (fingerswitch). The spray nozzle is located near the distance gauge at the treatment end of the handpiece. The fingerswitch is located on the top of the handpiece.

FIGURE 1.2
DELIVERY SYSTEM



LETTER	DESCRIPTION	LETTER	DESCRIPTION
A	Electrical , Cryogen Line	H	Sense Size Connection
B	Handpiece Assembly	I	Slider
C	Cryogen Delivery Tube	J	Distal Fiber Connector
D	Laser Aperture	K	Sense Wire Connector
E	Distance Gauge	L	Proximal Fiber Connector
F	Glass Window	M	Handpiece Control Connector
G	Lenses	N	Cryogen Input Connector

Fiber Pole

The fiber pole supports the delivery system cable as shown in Figure 1.3. This device will keep the cable suspended and reduce the weight of the delivery system during use. The fiber pole can be disconnected from the side-mounting block without the use of tools. Grasp the pole near the mounting block and pull straight upward to release the spring catch. See Figure 1.4. Reattach the fiber pole by inserting the pole into the mounting block. Press the pole firmly to lock it into the spring catch. The fiber pole is properly inserted if distinct steps are evident as the pole is rotated.

FIGURE 1.3

FIGURE 1.4

Handpiece Holder

A metal wire handpiece holder is mounted on the right side of the laser system. It is installed by field service personnel during the system installation. See Figure 1.5. This holder is used to retain the delivery system during pauses in treatment or transport. It is not necessary to remove the distance gauge before inserting the delivery system into this holder. The holder is designed to retain the entire handpiece when used. See Figure 1.6.

FIGURE 1.5

FIGURE 1.6

Table 1-1
Specifications

Laser Type	Flashlamp-excited, pulsed dye laser
Wavelength	595 nanometers (nm)
Method of Optical Output	Lens-coupled optical fiber with user selectable slider spot sizes.
Maximum Delivered Energy	6 joules (J)
Stability of Output Energy	±14%
Pulse Repetition Rate	1.5 Hz repetitive pulsing
Pulse Duration	0.45-40 milliseconds
Beam Spot Sizes	5 millimeters, 7 millimeters, 10 millimeters, & 3x10 elliptical
Cooling Method	Ambient air
Dimensions (HxWxD)	43.5”x 18”x 32” (111 x 46 x 81 cm)
Weight	300 lbs (140 kg)
Cryogen	HFC 134a

ELECTRICAL REQUIREMENTS

Table 1-2 lists Electrical Requirements for the Vbeam. In the US, a Hospital Grade, NEMA L6-30R electrical receptacle, or equivalent, is required. For Vbeam systems shipped internationally, customers must supply a suitable plug and receptacle.

CAUTION!

THE POWER PLUG MUST BE INSTALLED BY A QUALIFIED PERSON, IN ACCORDANCE WITH IEC REQUIREMENTS AND THE APPROPRIATE NATIONAL ELECTRICAL CODE.

The power receptacle must be within seven feet (two meters) of the intended laser system location, and must be earth-grounded. The safety ground wire of the power system (green or green with a yellow stripe) is an acceptable ground for the laser system, provided it is terminated only to an earth ground stake or dedicated ground grid. Poor grounding can interfere with the operation of the system. The input power line should be free of transients (spikes, sags and/or surges). A dedicated branch circuit is recommended.

NOTE

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

TABLE 1-2 ELECTRICAL REQUIREMENTS

USA	208 V~
Europe	230 V~
Asia Pacific	200 V~
(Maximum line-voltage variation ± 10%)	50/60 Hz, single-phase, 20 A maximum at 230 VAC. A 30 A service is recommended

ENVIRONMENTAL REQUIREMENTS

Before installation of the Vbeam, 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.

NOTE

Installation of the Vbeam system must be performed by a Service Representative. Following installation, a Nurse 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.

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 (19° and 29°C) should be maintained in the laser room. 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. Remove the footswitch tubing from the connector, located under the front of the laser. A handle located under the front lip 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.

If it becomes necessary to relocate the Vbeam, call Candela Customer Service or the distributor for details. Failure to do so may result in damage to the system, and may void any warranty.

Mobile Use

The Vbeam has not been designed for mobile use.

Section 2

Hazards Precautions Safety Features

LASER ROOM PRECAUTIONS

1. Identify the laser room clearly. Post appropriate warning signs in prominent locations at all entrances to the laser room.
2. Cover all windows, portholes, etc. with opaque material to prevent unintended viewing or laser light escaping from the laser room.
3. When the Vbeam 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.
4. 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.

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:

1. 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.

2. An oxygen-rich atmosphere is created and dissipates over the face. Transient local concentrations of oxygen can greatly accelerate combustion.

3. During treatment, the laser beam strikes combustible material, which absorbs the laser energy, and the material is heated above its combustion point. This may occur simply by singeing the tip of a single dry hair.

4. This momentary, and possibly 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.

5. 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 CAN BE EXTREMELY DANGEROUS AND SHOULD BE SERVICED ONLY BY THOSE QUALIFIED TECHNICIANS WHO HAVE RECEIVED APPROPRIATE TRAINING ON THE VBEAM FROM CANDELA.

OPTICAL PRECAUTIONS

CAUTION!

USE ONLY SAFETY EYEWEAR WITH AN OPTICAL DENSITY OF ^{3}4.9 @ 591-597 NM.

The laser beam emitted by the Vbeam 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 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.

The laser aperture of the Vbeam 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 half angle beam divergence for each handpiece is shown in the following table.

To avoid vision hazards, everyone within the NOHD (see Table 2-1) of the Vbeam must wear appropriate eye protection available from Candela.

Table 2-1
NOHD/ Handpiece Comparison

Handpiece Spot Diameter, mm	Half Angle Beam Divergence, radians	NOHD, meters
5	0.033	148
7	0.030	231
10	0.036	188
3 x 10	0.052 x 0.034	162

CAUTION!

THE LASER BEAM EMITTED BY THE VBEAM 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:

1. Appoint one person responsible for the laser system controls during the procedure.
2. Ensure that all personnel wear appropriate safety eyewear whenever the laser system is on.
3. Never look directly into the laser beam even when wearing protective eyewear.
4. Never allow the laser beam to be directed at anything other than the targeted area or the calibration port.
5. Never permit reflective objects such as jewelry, instruments or mirrors to intercept the laser beam.
6. When the Vbeam is not in use, place it in STANDBY state to prevent accidental pulsing.
7. When the Vbeam is unattended, remove the key from the keyswitch to prevent unauthorized use.

ELECTRICAL & MECHANICAL HAZARDS

The Vbeam 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 has been disconnected from the line voltage. Therefore, no part of the exterior housing should be removed, except by a trained and authorized technician.

The Vbeam 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.

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 is well balanced, it weighs more than 300 pounds (almost 140 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

Dye & 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.

The dye cartridge and triplet quencher should be replaced by an authorized Service Representative only, who will dispose of it properly.

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 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

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: In case of skin contact, immediately flush skin with plenty of water

for at least 15 minutes, while removing contaminated clothing and shoes. Call a physician. Wash contaminated clothing before reuse. 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.

NOTE to Physicians
Because of possible disturbances of cardiac rhythm, catecholamine drugs such as epinephrine should only be used with special caution in situations of emergency life support.

FIRE HAZARD

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.

ELECTRO-MAGNETIC INTERFERENCE

The Vbeam was designed to comply with IEC 601-1-2 (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 601-1-2 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 Vbeam have been reduced as far as practical without compromising functionality.

If interference from the Vbeam 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 or the affected equipment into another room.

SAFETY FEATURES

Keylock Switch

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

Laser Stop Switch (Emergency Off)

When this red switch (located on the lower left side of the control panel) is pressed, the Vbeam is shut down immediately.

STANDBY and READY Operating States

The system operates in one of two states: STANDBY or 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 laser emission is enabled. When the laser system is not being used, it should be returned to the STANDBY 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 above the control panel is illuminated.

An audible beep indicates that the next action will release laser energy. If the laser is being pulsed repetitively, the system will emit a beep simultaneously with every pulse.

Remote (CDRH) Interlock

An external connector for a remote interlock switch is provided on the back of the system enclosure. This interlock switch can be connected to the doors of the laser room. If the door is opened and the Vbeam is in the READY state, the laser system completely shuts down. For more information on installation of a remote interlock, please call Candela Service.

Section 3

System Operation Features

CONTROL PANEL SWITCHES

The Vbeam control panel is located on the left side the laser system. It consists of an On/Off keylock switch, a Laser Stop (emergency off) push-button switch, and a Touch Screen Display Panel (Display Panel). The Display Panel (Figure 3.1) provides a simple graphical user interface for the operator. The operator uses this interface to select the system operating state, laser operating parameters, DCD parameters and output energy calibration.

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

The keylock switch has three positions: "⏻" (off), "⏻" (on), and "**S**" (start). To start the laser, turn the key from the "⏻" position to the "**S**" position, then release. The switch returns to the "⏻'' position once the laser system starts.

Laser Stop Switch
When the red Laser Stop switch is pressed, the laser system shuts down immediately. To restart the system, turn the keylock switch to the "**S**" position, and then release.

Figure 3.1
Touch Screen Display Panel

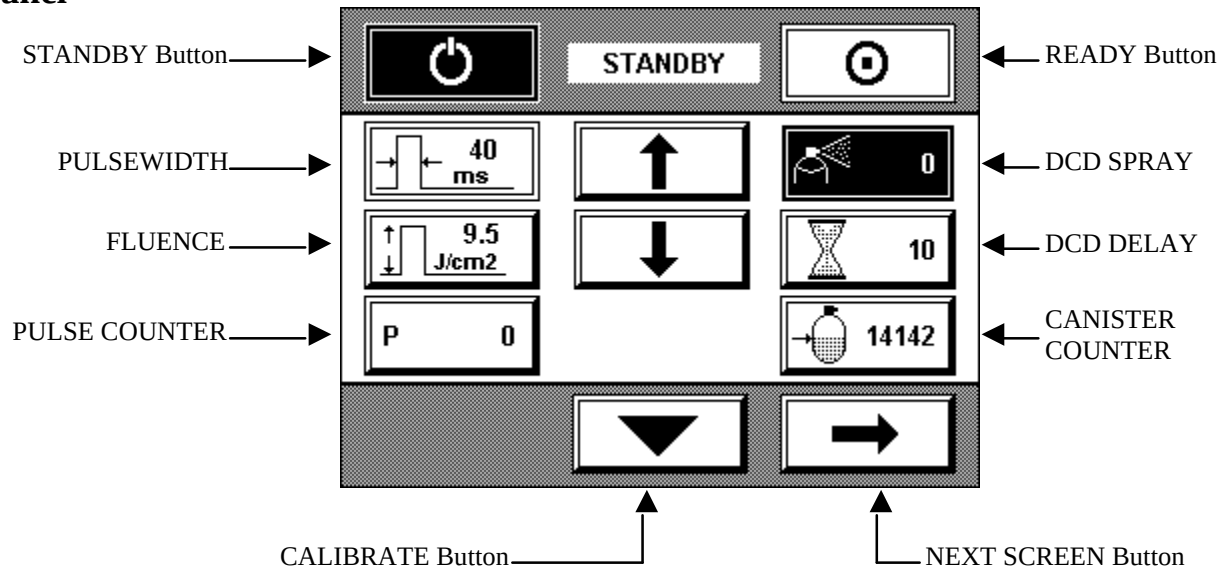
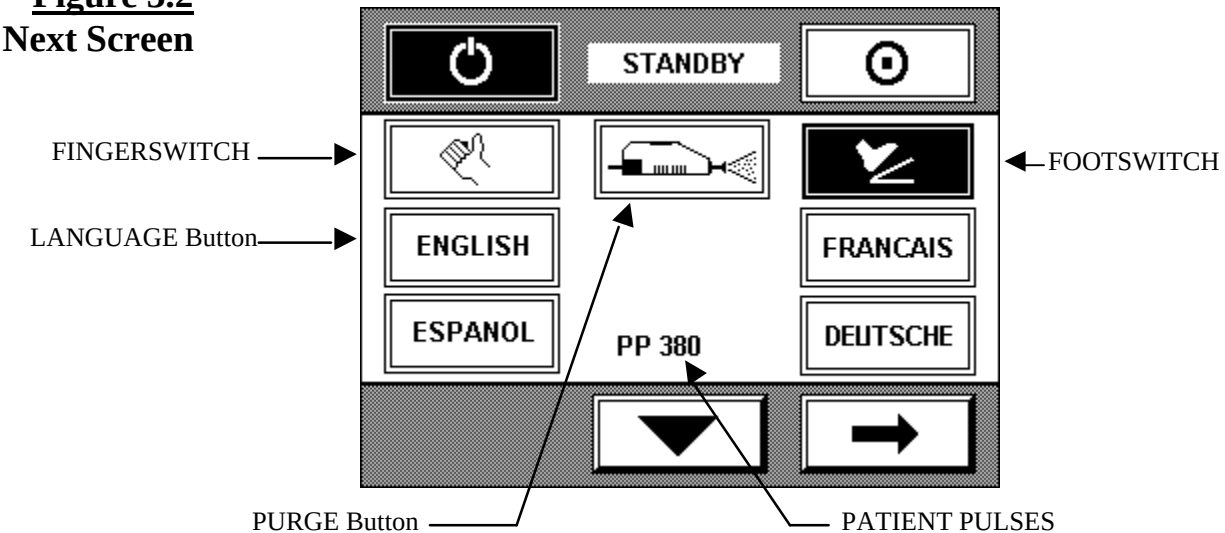


Figure 3.2
Next Screen



SYSTEM STATE

The system state status is located in the center, top section of the display. The system operates in one of two states: STANDBY or READY.

Standby

When in STANDBY, the high voltage power supply is turned off and laser emission is disabled.

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

The Vbeam automatically enters STANDBY state 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.

CAUTION!

DO NOT ENTER THE READY STATE WITHOUT A FIBER INSTALLED.

Ready

When in READY the high voltage power supply is turned on and laser emission is enabled.

This state is selected by pressing the READY button. The background for the title text of the READY button is set to BLACK 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. A blue indicator light above the display panel is illuminated to indicate that the laser is in the READY state.

The window area below the System Status menu bar contains the buttons associated with the Main Menu when the operator has selected this menu via the NEXT button as described above.

OPERATING PARAMETERS

The laser operating parameters; Fluence, Pulse Width, DCD Spray, and DCD Delay can each be set individually by the operator. To change a parameter, press the appropriate button and use the up or down arrows to adjust the value to the desired setting. The background for the selected parameter is set to BLACK to indicate that the numeric settings can be modified.

Fluence

The Fluence parameter is the amount of energy density delivered to the selected spot size.

The setting is adjustable in increments of 0.5 J/cm^2 between the lower and upper values given below for each Slider:

Slider	1.5 ms to 40 ms Pulse Width	0.45 ms Pulse Width
5 mm	4.0-15.0 J/cm^2	3.0-5.0 J/cm^2
7 mm	4.0-15.0 J/cm^2	4.0-8.0 J/cm^2
10 mm	3.0-7.5 J/cm^2	3.0-4.0 J/cm^2
3 mm x 10 mm	7.0-25.0 J/cm^2	7.0-13.0 J/cm^2

To ensure that the selected energy density is delivered, the laser will automatically require that a calibration procedure be performed if the Fluence parameter has been changed. The Fluence parameter last selected is retained in memory when the laser system is turned off. If the slider is changed, the laser will automatically select the lowest possible fluence for the new slider.

Pulse Width

The Pulse Width parameter is the duration of the energy density pulse delivered to the patient and can be set to between 0.45-40 milliseconds. To ensure that the selected energy density is delivered, the laser will automatically require that a calibration procedure be performed if the Pulse Width parameter has been changed. The Pulse Width parameter value last selected is retained in memory when the laser system is turned off.

DCD Spray

The DCD Spray parameter adjusts the duration of the cryogen spray applied to the patient. The DCD Spray can be turned off (“O”) or set to a duration of between 20 and 100 milliseconds.

When the DCD Spray parameter is changed, the remaining number of spray pulses displayed on the CANISTER COUNT button is automatically adjusted .

DCD Delay

The DCD Delay parameter adjusts the duration of the time between the DCD cryogen spray and the laser pulse. The delay is adjustable between 10 and 100 milliseconds.

SYSTEM COUNTERS

The Display Panel contains two system Counter/Reset buttons. The Pulse Counter and Reset button and the Cryogen Counter and Reset Switch

Pulse Count/Reset

The Pulse Count parameter 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 PULSE COUNT button for approximately 4 seconds. The system acknowledges the selection by responding with a short beep tone and by setting the count value displayed within the PULSE COUNT button to zero.

Canister Count/ Reset

The Canister Count parameter indicates the total number of DCD Spray pulses remaining in the cryogen canister for the selected spray duration.

When the counter reaches zero and the cryogen canister is empty, a warning message window will prompt the operator to replace the cryogen canister. 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 4 seconds.

CAUTION!

- **FAILURE TO INSTALL THE APPROPRIATE SIZE CANISTER FOR YOUR LASER OR FAILURE TO REPLACE IT WHEN PROMPTED BY THE 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".**
- **DO NOT RESET SYSTEM PULSE COUNTERS WITHOUT REPLACING THE CANISTER.**
- **DO NOT INSTALL PARTIALLY USED CANISTERS.**
- **YOUR SYSTEM HAS BEEN CONFIGURED FOR A SPECIFIC SIZE GENTLECOOL CANISTER. ONLY INSTALL THE APPROPRIATE SIZE CANISTER AS INDICATED BELOW:**

Canister Size	Candela P/N	Laser Type
1000 gr	**1600-00-0210**	**Vbeam**

The system acknowledges the selection by responding with a short beep tone and by setting the count value displayed within the CANISTER COUNT button to the number of counts available from a full canister of cryogen. (This value depends on the preset value of the DCD SPRAY parameter.)

Figure 3-3
DCD Pulses

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

OTHER CONTROLS

Calibrate Button

The calibration procedure is initiated by pressing the CALIBRATE button. Note that the system will initiate the calibration procedure automatically if READY state is entered, a calibration is required, and the handpiece is inserted into the cal port.

After calibration, the system is in 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 Width parameters have not been changed and no more than thirty minutes have elapsed since the last calibration.

Trigger Switch:

Fingerswitch button
Footswitch button

Laser emission is generated by depressing the trigger switch, provided the system is calibrated. Press the NEXT button to display the FINGERSWITCH and FOOTSWITCH buttons (Figure 3.2). Press the button of the desired option. The background of the selected button will change to BLACK.

When the trigger switch is pressed, DCD Spray (if DCD Spray is on) and laser pulses are delivered at the distal end of the handpiece.

The trigger switch must be pressed to its travel limit and released to deliver a single laser and a DCD Spray pulse. To deliver continuous laser pulses and DCD pulses, the trigger switch must be pressed to its travel limit and held.

Purge Button

The purge button (Figure 3.2) is used to remove air from the handpiece assembly when a new canister is placed in the system.

Language Button

The language button (Figure 3.2) is used to select which language will be shown on the display. The background of the selected language button will change to BLACK.

Patient Pulses

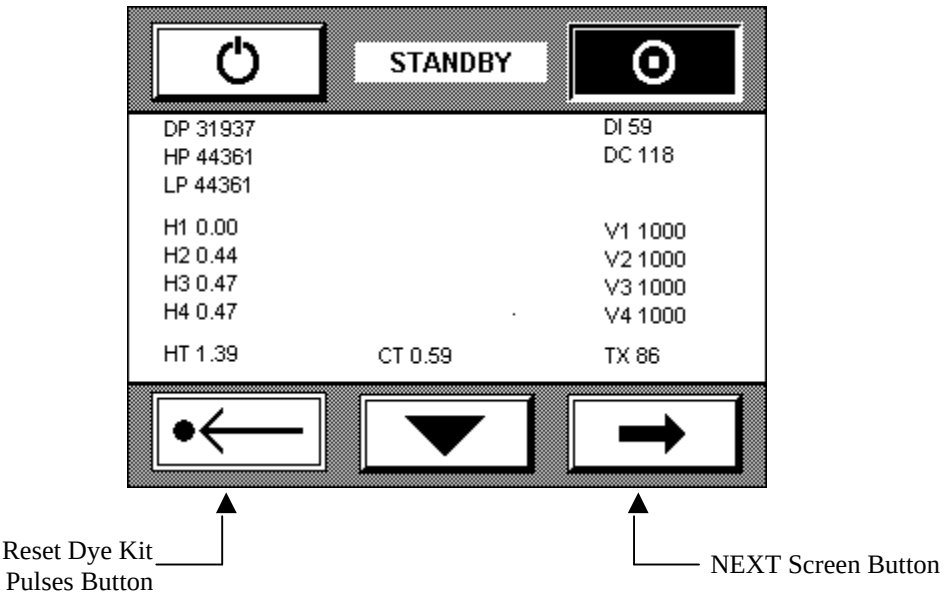
The patient pulses display (Figure 3.2) shows the total amount of pulses delivered by the laser system. It does not include calibration pulses. The patient pulses display can only be reset by a Service technician.

Laser Variables

The Laser Variables display screen (Figure 3.4) is used by Candela Field Service when trouble-shooting or servicing the laser system. It contains important information about some of the operating parameters of the laser system. The Vbeam laser system should never be used for patient treatments with the Laser Variables screen displayed on the front panel.

If a problem occurs with the laser system, Candela Field Service may request the customer to access the Laser Variables screen to obtain additional operational information. To enter the Laser Variables screen, press the “NEXT” button for four seconds or longer. To exit the Laser Variables screen, press the NEXT button. The Reset Dye Kit Pulses button (shown on this screen) is not operational unless a Field Service Diagnostic Computer is connected to the laser system.

Figure 3.4
Laser Variables Screen



Calibration Port

The calibration port (Cal Port) is used to measure the laser output energy. The handpiece must be inserted into the calibration port in order to initiate this procedure.

The distance gauge must be removed, and the handpiece cleaned and dried before the handpiece is placed in the calibration port.

Remote (CDRH) Interlock

The remote interlock connector, located on the upper rear panel, 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 middle section of the front panel of the laser system. To enable the footswitch, press the Next button to go to the next screen and press the footswitch button. The fingerswitch will be disabled.

Circuit Breaker

The circuit breaker is located on the rear panel of the laser system, to the right of the power cord, and must be in the ON position for the laser system to operate.

Section 4

System Start-Up

LASER SYSTEM START-UP

1. Cover windows with an opaque material to prevent unintended viewing.
2. Post laser warning sign near each entrance to the laser suite.
3. Ensure an adequate number of protective eyewear is available. Proper eyewear will filter light at a wavelength of 591-597 nm with an O.D. of 4.9 or greater. Put protective eyewear on.
4. Plug the laser into the correct electrical outlet. Ensure that the main circuit breaker on the lower rear panel is in the "ON" position.
5. Start the laser by turning the key to the "S" or start position and release. The system will now enter the warm-up state (approx. 25 min). After the warm-up the system will enter the STANDBY state.
6. Calibrate the laser fluence to be delivered to the patient:
   a. Install the desired Slider spot size. Depress white button on side of handpiece to install or remove a slider. Make sure the Slider clicks into place.
   b. Select FLUENCE parameter on the control panel.
   c. Remove the distance gauge if attached.
   d. Insert the handpiece into the CAL port until it clicks into place and stops.
   e. Press the CAL switch and follow the instructions on the control panel display. Remove calibrated handpiece.
   f. Install the distance gauge. Make sure the spot size on the distance gauge matches the slider spot size. (Note: Use the 10 mm distance gauge for both the 10 mm slider and the 3 mm x 10 mm slider.) When attaching the distance

gauge, hold handpiece pointing downward. Do not look directly into the calibrated handpiece. Take care not to inadvertently press the fingerswitch as the laser will fire.

7. Turn the DCD Control on (0 is OFF) and set the spray duration and delay parameters.
8. Perform treatment. Place the laser into STANDBY after use. Document laser use.

NOTES

- **To return the pulse counter to zero, press the PULSE COUNT button for 3 - 5 seconds.**
- **After replacing the cryogen canister, press the CANISTER COUNT button for 3 - 5 seconds to reset the canister count. Only use when a new canister is added.**
- **The laser system will not allow treatment pulses until a calibration has been performed after any one of the following conditions:**
  1) **Laser is turned on;**
  2) **FLUENCE or PULSE WIDTH parameter is changed;**
  3) **Specific faults occur;**
  4) **In STANDBY for more than 30 minutes;**
  5) **Slider is changed.**
- **To ensure proper fluence, the user must perform a calibration when the fiber or slider window has been cleaned or replaced.**


Vbeam

Section 5

Calibration Procedure

CALIBRATE PROCEDURE

CAUTION!

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

The Vbeam requires that the laser be calibrated prior to patient treatment. During calibration, the handpiece is inserted into the Cal Port 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.

- Select the desired Slider and insert it into the handpiece assembly. Make sure the Slider is properly seated within the handpiece.
- Select the desired Fluence and Pulse Width parameter values via the Display Panel.
- Remove the distance gauge, if installed, and insert the handpiece into the Cal Port until it clicks into place.
- Press the CALIBRATE button on the Display Panel and follow the instructions provided in the calibration message windows.

Pressing CANCEL allows the operator to return to the Main screen. The operator can then adjust the laser output parameters as needed before continuing the procedure.

After successful completion of the calibration procedure, install the distance gauge making sure the spot size on the distance gauge matches the spot size setting on the slider. (Note: Use the 10 mm distance gauge for both the 10 mm slider and the 3 mm x 10 mm slider.)

NOTE

If the desired Fluence cannot be reached, the next highest available fluence will be automatically selected. The system displays the following message: MAX FLUENCE = XX J/cm^2

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


Vbeam

Section 6

Maintenance/ Troubleshooting

CAUTION!

THE ELECTRICAL AND LASER RADIATION HAZARDS PRESENT WHILE SERVICING THE VBEAM CAN BE EXTREMELY DANGEROUS IF PROPER SAFETY PRECAUTIONS ARE NOT TAKEN. THE VBEAM IS TO BE INSTALLED AND SERVICED ONLY BY QUALIFIED AND AUTHORIZED TECHNICIANS APPROPRIATELY TRAINED BY CANDELA.

CLEANING AND DISENFECTION

The exterior of the laser system may be cleaned 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.

Handpiece

To clean and disinfect the handpiece,

- Wipe the exterior surface with a gauze pad or towelette moistened with a hospital grade disinfectant solution. Take care to avoid contaminating the internal optical surfaces of the handpiece. Whenever cleaning the handpiece with an alcohol solution, dry the area thoroughly prior to beginning a laser procedure.

Distance Gauge

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

To Clean the Distance Gauge:

- Clean by wiping with a gauze pad moistened with alcohol, hospital grade disinfectant or a 10% bleach solution. Allow the distance gauge to dry before use.

CAUTION!

THE WINDOW ON THE END OF THE SLIDER MAY BECOME SOILED WITH NORMAL USAGE. TO ENSURE PROPER FLUENCE DELIVERY, IT IS IMPORTANT TO INSPECT AND CLEAN THE WINDOW FREQUENTLY SO DEBRIS DOES NOT GET BURNED INTO THE WINDOW SURFACE.

CAUTION:

When windows on fibers/sliders get dirty or burnt, the amount of energy passing through the window and delivered to the patient may be reduced.

After replacing/cleaning a dirty or burnt fiber/slider window, always recalibrate.

Slider Window

To clean or replace the slider window: (refer to Figure 6.1)

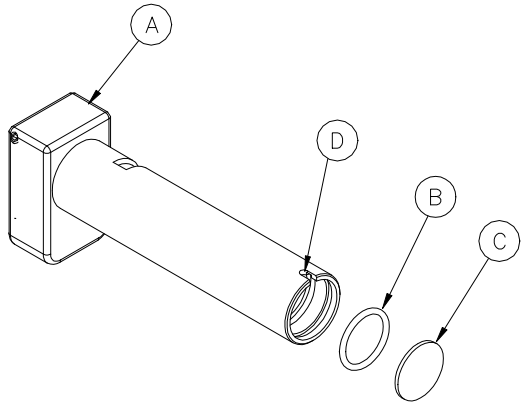
1. Wear dustless gloves to prevent smudges or fingerprints on window.
2. Place the laser into STANDBY state and remove the slider from the fiber assembly.
3. Look through the slider window while pointing the slider's far end towards a ceiling light. Rotating the slider at this position will cause the debris on the window to rotate, making it more apparent.
4. Working over a clean surface, remove the o-ring (Item 1) that is holding the window (Item 2) in place. Use tweezers or a pointed object in notch to gently pull the o-ring towards the center of the window until the o-ring is free from the groove.
5. Turn the slider up-side down allowing the window to fall out. (If needed, gently tap the side of the slider with your finger)
6. (Used windows only) Clean the window in a 70% or 95% alcohol solution.
7. Re-inspect the window and compare with the **Window Acceptability** Chart supplied with each window kit. If unacceptable, replace the window.

8. Grasp the window by the edges and place it back into the slider so it is resting flat on the ledge.

9. Reinsert the o-ring into the groove. Use the tip of the tweezers or a pointed object and gently push the o-ring fully into the groove being careful not to touch the window.

10. Calibrate the system per section 5.

Figure 6.1
Slider Assembly



A	Slider Spot Size
B	Window
C	O-ring
D	O-ring Tweezer Access

SLIDER ASSEMBLY INSTALLATION AND REPLACEMENT

To avoid damage to the optical fiber, take care when handling the assembly, limiting bends to a radius of 6 inches (15 cm) or greater. Refer to figure 6.2 for slider replacement.

CAUTION!

LASER RADIATION IS PRESENT WHEN THE SLIDER IS REMOVED WITH THE LASER IN THE READY STATE. PLACE THE LASER IN THE STANDBY STATE WHEN REPLACING THE SLIDER.

FAILURE TO FOLLOW RECOMMENDED PROCEDURE MAY LEAD TO DAMAGE OF THE OPTICAL FIBER AND/OR HARM TO THE PATIENT OR USER.

The Vbeam handpiece contains the slider assembly, which determines the spot size of the delivered laser energy. The spot size can be changed by changing the slider that is installed in the handpiece. The handpiece, slider and all their associated components are shown in figure 6.2.

The following steps detail how to insert a slider into the handpiece and attach all required connections.

1. Place the system in the STANDBY state and place the handpiece assembly on a table or other flat surface.

2. Insert the slider into the handpiece by depressing the white button. The slider should lock into position when fully inserted. (See figure 6.3)
3. Carefully insert the fiber into the fiber receptacle and turn the fiber connector clockwise until it is tight. (See figure 6.4) **Caution must be used when installing the fiber so as not to damage the end of the fiber.** NOTE: Make sure the fiber is tight in the connector or the fiber may be damaged during use.
4. Connect the slider detection connector. To fasten the connector, the red dots (visible on the connector) must be aligned. (See figure 6.5)
5. Place the system in the READY state and calibrate the new slider per section 5.

To change the slider, disassemble the delivery system in the reverse order of assembly as follows:

1. Place the system in the STANDBY state and place the handpiece assembly on a table or other flat surface.
2. Disconnect the slider detection connector.
3. Disconnect the fiber by turning the connector counter-clockwise to loosen it. **Caution must be used when removing the fiber so as not to damage the end of the fiber.**
4. Remove the slider from the handpiece by depressing the white button.

NOTE: NEVER DISCONNECT THE SLIDER IF THE FIBER AND SLIDER DETECTION CONNECTOR ARE STILL CONNECTED! This will cause damage to the fiber.

Figure 6.2
Handpiece Assembly with Slider

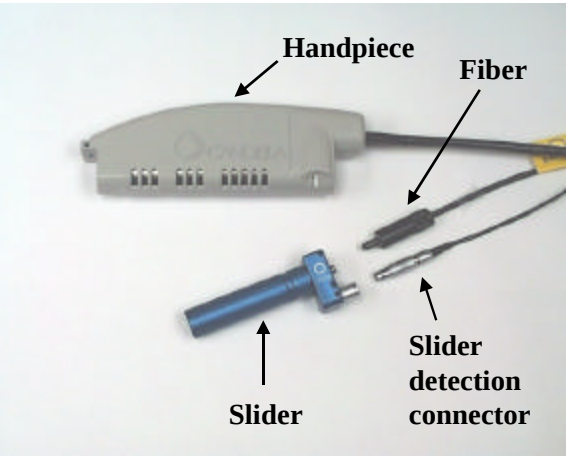


Figure 6.3
Slider Inserted into Handpiece

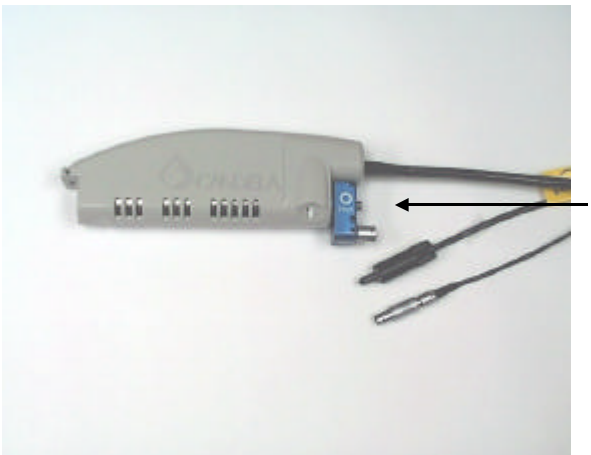
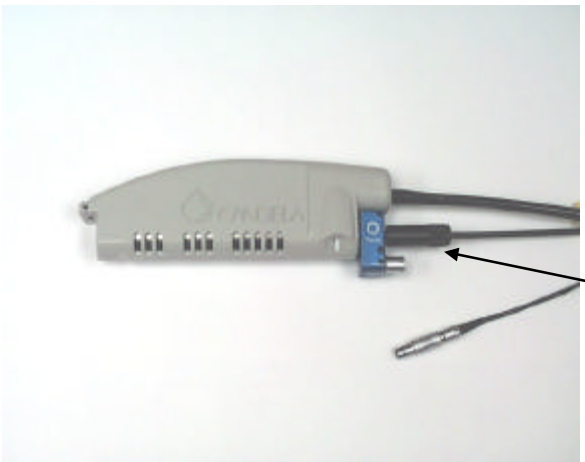


Figure 6.4
Fiber Inserted into Slider



Insert fiber as shown; remember to tighten by turning clockwise

Figure 6.5
Slider Detection Connector Inserted into Slider

HANDPIECE ASSEMBLY REPLACEMENT

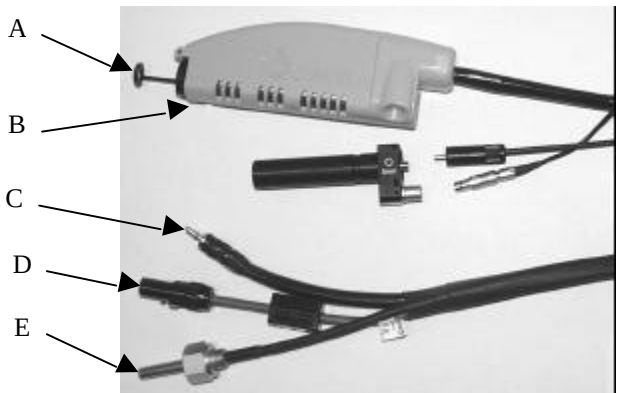
See Figure 6.6 for handpiece assembly diagram.

1. Turn the laser system **off.**
2. Remove the new handpiece assembly from the package.
3. Use the “Slider Assembly Installation and Replacement” procedure in the previous section to remove the slider from the old handpiece and install it into the new handpiece. Connect the fiber and slider detection connectors according to the procedure.
4. Insert the new handpiece into the calport.
5. Disconnect the handpiece control connector from the handpiece control receptacle on the front of the laser system. Plug in the new connector.
6. Disconnect the old cryogen output connector from the cryogen output receptacle on the front of the laser system by pushing the knurled connector on the front of the laser system away from you while gently pulling the mating connector from the knurled connector. Release the knurled connector.
7. Connect the new output connector by pushing in the knurled connector while pushing the new connector in until it stops. Release the knurled connector.

CAUTION!

PERIODICALLY CHECK THAT THE CYROGEN SPRAYS IN THE CENTER OF THE DISTANCE GAUGE TO MAINTAIN PROPER COVERAGE.

Figure 6.6
Handpiece Assembly



A	Distance Gauge
B	Handpiece
C	Cryogen Input Connector
D	Handpiece Control Connector
E	Optical Fiber Connector

CYROGEN CANISTER

CAUTION!

THE CONTENTS OF THE CRYOGEN CANISTER ARE UNDER PRESSURE. READ THE MATERIAL SAFETY DATA SHEET (MSDS) AND THE LABEL ON THE CANISTER BEFORE HANDLING.

REPLACEMENT

Follow the instructions shipped with each replacement canister.

DISPOSAL

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

TROUBLE-SHOOTING

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 circuit breaker.
	The laser system circuit breaker is in the "off" position.	Switch the circuit breaker to the "on" position.
	The keylock switch was not fully engaged.	Turn the keylock switch fully clockwise to the "S" position and release.
	The external interlock is defeated.	Check the remote CDRH interlock connection. If connected to a door, make sure the door is closed.
Laser pulses, no cryogen is delivered	The DCD spray setting is set to zero “O”.	Select the DCD spray and use the “up arrow” to increase the spray setting.
Cryogen leak	The tubing in the delivery system is broken.	Remove the cryogen canister or disconnect the handpiece assembly from the laser. Call Service.
Warm-up time has exceeded 60 minutes	The water temperature control circuitry failed.	Call Service.

Ineffective fluence response	System or Fiber is 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. Depress the Canister Count switch for 5 seconds to reset the canister count.
Purge is required	Bubbles have been detected in the cryogen line.	Press the purge switch until problem resolves. If problem persists, call Service.
Hour glass appears during calibration	The system is verifying the wavelength.	Wait approximately 10 minutes. If hour glass does not go away, call Service.

FAULT 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 Service and report the Fault Number. Fault processing automatically places the system into the Standby state.

Fault Messages

FAULT	***DESCRIPTION***	***ACTION***
Fault 1	Calport Switch Malfunction	Remove handpiece from the Cal Port. Press READY. If the message reappears, call Service.
Fault 2	ROM Checksum Failure	Call Service.
Fault 3	Shutter Malfunction	When pulsing the laser, firmly press on the fingerswitch or footswitch until the laser pulses.
Fault 4	High Voltage Power Supply (HVPS) Fault	Make sure the laser is approximately 15” from the wall. Cycle the power off then on. If problem persists, call Service.
Fault 5	HVPS Tolerance Error	Reset fault and continue. If problem persists, call Service.
Fault 6	Calibration Malfunction	Make sure that the slider is installed properly. Check that the window on the end of the slider is clean. Lower the Fluence parameter. If the problem persists call Service.

Fault 7	Coolant Temperature Malfunction	Call Service
Fault 8	DCD Over Pressure	Leave open the cover that accesses the cryogen canister for 15 minutes and/or remove canister for two minutes and re-install. If problem persists, call Service.
Fault 9	DCD Warm-up Timeout	Call Service.
Fault 10	Slider Detection Fault	Call Service for replacement handpiece.
Fault 11	Wavelength Out of Range	Recalibrate the system. If fault persists, call Service.
Fault 12	Energy Out of Range	Recalibrate the system. If fault persists, call Service.
Fault 13	Trigger Switch Malfunction	When pulsing the laser, firmly press on the fingerswitch or footswitch until the laser pulses. If problem persists, call Service.
Fault 14	Simmer Power Supply Fault	Call Service.
Fault 15	Low Transmission Fault	Swap slider and if problem continues replace fiber. If problem still persists, call Service.

Candela will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other necessary information that will assist your qualified technical personnel to repair those parts of equipment which are designated by Candela as repairable.


Vbeam

Section 7

Labeling

LABELS

Government-required warning and other labels appear on the Vbeam. All laser operators should be familiar with the location and meaning of the labels.

The symbol on the rear panel of the laser is placed there to draw the attention of the operator to the manual for further information concerning the main circuit breaker. The circuit breaker should be placed in the “off” position when the system is not being used. When the system is to be used, the circuit breaker must be moved to the “on” position. If during operation the circuit breaker is tripped, the operator should contact Service for assistance. Even if the problem is one that can be remedied without a service call, it is essential that Service be notified of the occurrence and consulted as to the appropriate response.

See the following figures for label locations.

Label 1 These labels indicate where the fuse replacement information is located.

Label 2 Caution should be taken when using the Vbeam in the presence of flammable anesthetics.

Label 3 Not used.

Label 4 Indicates the emission of laser energy from this device.

Label 5 Contains the key laser parameters and the classification per the IEC standards.

Label 6 Indicates that additional label information is contained in the operator’s manual.

Label 7 Indicates the place that laser light will be exiting the device.

Label 8 Informs the user that voltages within the laser are dangerous when the covers are removed and should only be serviced by qualified personnel.

Label 9 Indicates the degree of protection against electric shock and indicates an ungrounded applied part.

Label 10 Indicates that if the fiber or the cover over the laser head is removed, laser radiation, in excess of AEL class 1, will exit.

Label 11 Indicates that the device contains a remote interlock switch that can be connected to a door to shutdown the laser should a person enter the room during laser emission.

Label 12 Indicates, for service personnel, that lethal voltages may be present for hours after the laser is shut off. The grounding rod should be used to discharge any remaining voltage before servicing.

Label 13 If present, indicates that the laser is approved to UL or ETL standards.

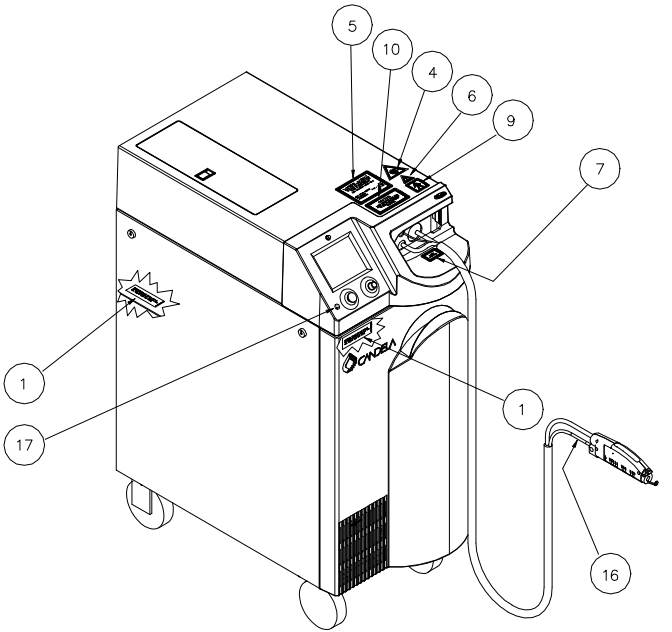
Label 14 Indicates that this product complies with the DHHS radiation performance standards for laser products.

Label 15 Displays the voltage and current requirements for the system, as well as the manufacturing model number, serial number and date of manufacture.

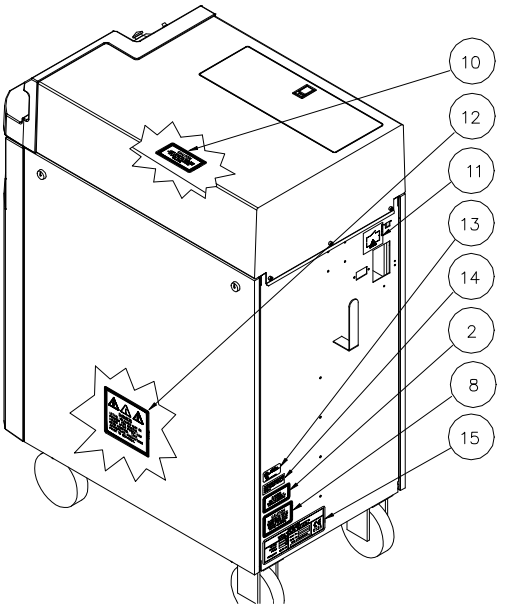
Label 16 Indicates that laser light will be exiting from this device.

Label 17 Indicates that the Emergency Laser Stop Red Push Button will turn off the laser quickly.

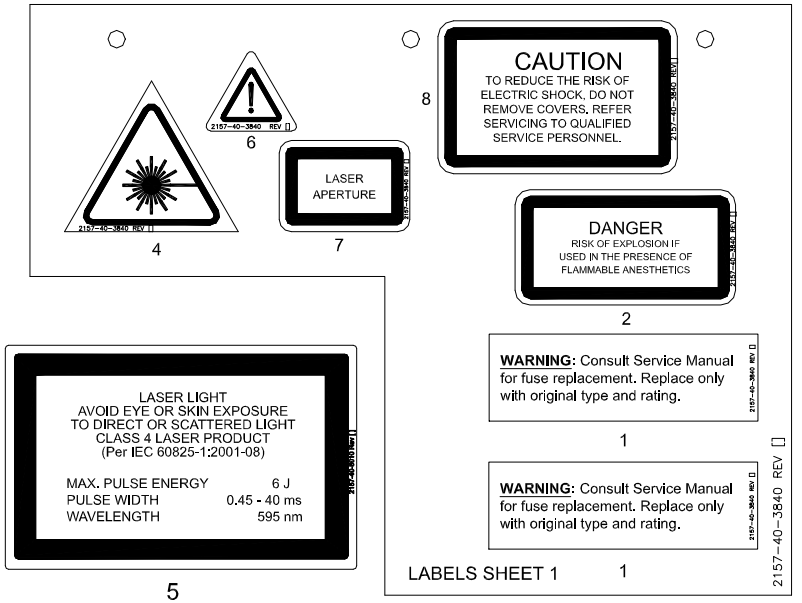
Label Locations

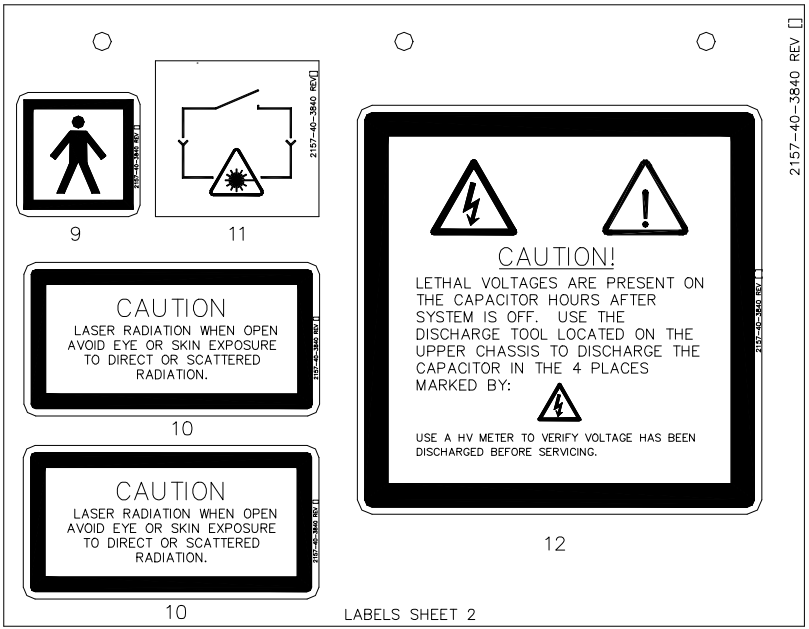


Label Locations



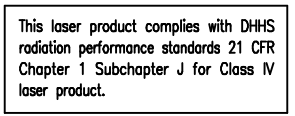
Label Identification



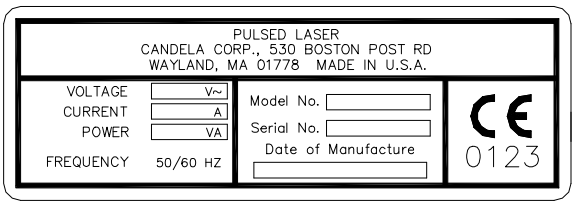

2157-40-3840 REV []
9
11
2157-40-3840 REV []
CAUTION!
LETHAL VOLTAGES ARE PRESENT ON THE CAPACITOR HOURS AFTER SYSTEM IS OFF. USE THE DISCHARGE TOOL LOCATED ON THE UPPER CHASSIS TO DISCHARGE THE CAPACITOR IN THE 4 PLACES MARKED BY:
USE A HV METER TO VERIFY VOLTAGE HAS BEEN DISCHARGED BEFORE SERVICING.
12
CAUTION
LASER RADIATION WHEN OPEN AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION.
10
CAUTION
LASER RADIATION WHEN OPEN AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION.
10
LABELS SHEET 2

13
(for ETL Versions)

14

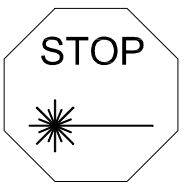


15



16

17



Section 8

Accessory List

Standard Accessories:

Description	Quantity
Vbeam Laser System with DCD	1
Delivery System with Fiber and Handpiece	1
Mega V dye cartridge	1
5mm Slider	1
7mm Slider	1
10 mm Slider	1
3X10mm Slider	1
5 mm Distance Gauge	1
7 mm Distance Gauge	1
10 mm/3 x 10 mm Distance Gauge	1
Cryogen Canister	12
Physician Spectacles	1
Physician Goggles	1
Patient Goggles	1
Operator's Manual	1
Keys/Ring w/ Candela Logo	1
Laser Warning Sign	1
Service Information Label	1
Canister Empty Valve	1
Handpiece Holder	1
Replacement Window Kit	1

Standard Accessories: (continued)

Description	Quantity
Footswitch	1
Fiber Pole	1
Marketing Tool Kit	1

Optional Accessories:

DCD Canister Warmer	1


Vbeam

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.

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 an internal laser energy meter. The system determines the high voltage level necessary to select each attainable energy density setting.

The internal laser energy meter itself must be calibrated at least once a year by a qualified service technician. This calibration requires using 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 10 mJ. This procedure is part of the normal preventive maintenance service procedure.

PARTS LIST

1. IBM compatible computer
2. Candela's WinMaint software
3. Energy meter (OPHIR with L40(150)A, FL250A or 10A-P head)
4. 9 pin to 9 pin cable
5. Potentiometer adjustment tool
8. Energy meter snout
9. Oscilloscope
10. Monochromater

PROCEDURE

Note

Use the same laser energy meter for all of the following laser energy detector calibrations. Make sure all personnel in the area are wearing safety eyewear appropriate for the Vbeam.

HEAD AND DETECTOR CALIBRATIONS

1.1 Calibrate the system at 9.5 J/cm², 10ms, 7mm spot size

1.2 Connect scope probes to the CPU/Laser I/O PCB as follows:
Channel 1: Probe on TP30, return on TP15, 5V/div
Channel 2: Probe on TP4, return on TP18, 1V/div
Timebase = 100 us/div Trigger = CH 1, falling edge at 2 V
Pulse the laser and adjust the delay on the scope to view the signal on channel 2. The signal should be a positive pulse with a rise time of 100-150 us, then a flat top portion, and then a very fast (≤ 10 us) fall time. The rise and fall time are not that important. This test is to measure the flat top portion only and verify it is within specification.
Pulse flat top time = _____ us (75 us minimum)

1.3 Connect channel 1 of the scope to TP29 and repeat step 1.2.
Pulse flat top time = _____ us (75 us minimum)

1.4 Connect channel 1 of the scope to TP26 and repeat step 1.2.
Pulse flat top time = _____ us (75 us minimum)

1.5 Connect channel 1 of the scope to TP22 and repeat step 1.2. Then disconnect scope probes from the CPU/Laser I/O PCB.
Pulse flat top time = _____ us (75 us minimum)

1.6 Go to the PULSE screen and set it up as follows:

1.6.1 Go to SETUP, select DATA, and select the following variables to display:
head total cal total trnsmssn wave 1 wave 4

1.6.2 Go to the SETUP menu and select GRAPH/STAT. Select the head total and the cal total to do statistics. Verify graphing is OFF. Exit the GRAPH/STAT window.

1.6.3 Click on RESET.

1.7 Go to READY and push the down arrow to calibrate.

1.8 Remove the fiber from the receptacle and install the energy meter snout. Pulse the laser and adjust R57 until the head detector total, displayed on the PULSE screen, is equal to the OPHIR reading times the snout factor of 1.08.

1.9 Click on RESET in the statistics window. Determine the head detector calibration error by pulsing 5 times, filling in the following table for each pulse, and calculating the error. Record the OPHIR energies as displayed on the meter, then multiply the average by the snout factor, 1.08. The average head reading is the "mean' value in the statistics window.

Pulse #	OPHIR Energy, J	Head Detector Energy, J
1		
2		

3		
4		
5		
Average =		(B)
x 1.08 =	(A)	

% error = (B/A - 1) x 100 = _____%
The error must be ± 2% or less. If not, repeat Steps 1.5 and 1.10.

1.10 Remove the snout and install delivery system. Tape a white piece of paper onto the entrance and exit slits of a monochromator. Position the monochromator at least 1 foot away from the slider. Align the slider so the beam is hitting the white paper at the entrance slit of the monochromator. This can be done with eyewear on because a faint red light will be visible for alignment.

1.11 Place a shield on top of the monochromator to block any light getting around the monochromator. Remove eyewear and pulse the laser, observing the paper at the exit slit. Adjust the wavelength on the monochromator to maximize the light on the exit slit. If it is too bright to accurately find a maximum, add thicken the paper on the entrance slit. Record this wavelength. Record to 4 significant digits (eg., 593.6 nm).

Wavelength = _____ nm

1.12 Put eyewear back on and insert the handpiece into the calport.

1.13 Adjust R78 and pulse the laser until the wavelength reading on the Toggle screen matches the wavelength measured in the previous step.

CALPORT DETECTOR CALIBRATION

NOTE: If the 10A-P OPHIR meter head is used, the meter head must be 1" from the handpiece for an accurate reading. If the L40(150)A or FL250A heads are used, the meter head must be 6" from the handpiece to prevent damage to the meter head.

2.1 Remove the snout and install the fiber. Verify that the pulse width is still set at 10 msec and the 7 mm slider is installed. Select 9.5 J/cm² go to READY and calibrate.

2.2 Click on RESET in the statistics window. Aim the handpiece at the OPHIR meter head the appropriate distance away and pulse 5 times, recording the

OPHIR energies and the average (mean) head in the following table. Then calculate the average transmission.

Pulse #	OPHIR Energy, J	Head Detector Energy, J
1		
2		
3		
4		
5		
Average	(A)	(B)

Transmission = (A / B) x 100 = _____%
The transmission should be greater than 80%. If it is not, inspect the window and lenses in the slider and replace if necessary.

2.3 Insert the handpiece into the calport, adjust R27, and pulse the laser until the transmission displayed on the Toggle screen matches the transmission in the previous step. If there is not enough adjustment on R27, add or remove ceramic discs, P/N 1301-00-7496 as needed.