CANDELA

Operator's Manual

CE 0123

8501-00-1766 Revision C

January 2005

WARNING!

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

Federal (USA) restricts this device to sale by or on the order of a physician. Federal and other international regulations also require that this device be utilized under the direction of a trained physician.
This device should only be used by trained healthcare professionals authorized under applicable local law to treat patients. All persons treating patients with this device should ensure that they are authorized to treat patients under the applicable US State or applicable international laws.

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Section 1

Applications
Descriptions
Specifications

APPLICATIONS

This manual provides operating instructions for users of the GentleYAG Laser System and the GentleYAG Limited Edition (LE) systems. The GentleYAG LE system differs from the GentleYAG by having only one delivery system with three spot sizes (10, 12, and 15 mm) , a maximum repetition rate of 2 Hz, and a pulse duration of 3 - 100 ms.

The Candela *GentleYAG* is a flashlamp-excited, Nd:YAG (Neodymium-doped Yttrium Aluminum Garnet) laser. Pulsed laser energy is emitted at a nominal wavelength of 1064 nanometers (nm). This wavelength causes maximum energy absorption by targeting specific chromophores in tissue In addition, the laser pulse duration is controlled to be equal to or shorter than the thermal relaxation time of the target, to minimize heat transfer to surrounding tissues. This principle was first described by Anderson and Parrish.(1).

For Instructions on the specific applications and the treatment parameters for each indication please refer to the Treatment Guidelines for the GentleYAG (Candela Part Number 8502-00-0867).

DESCRIPTIONS

The *GentleYAG* , Figure 1-1, consists of an Nd:YAG 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.

Laser System

The *GentleYAG* Laser System consists of an Nd:YAG laser head, a power supply and a coolant water circulator. The laser head contains the cavity mirrors, solid-state

laser medium (Nd:YAG - *Neodymium Yttrium Aluminum Garnet rod*), and two high-intensity xenon flashlamps that excite the laser medium. A calibration port with an internal fluence meter is located on the right-hand side of the front of the laser. This

port is used to calibrate the output of the handpiece at selected fluence levels. The circulation of coolant water at a controlled temperature regulates the temperature of the laser head.

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

The systems deliver laser energy at a wavelength of 1064 nm with a pulsewidth of 250 microseconds to three hundred milliseconds. The output of the laser is delivered to the area of treatment through an optical fiber with a treatment handpiece attached to its distal end. A trigger (fingerswitch or footswitch) controls the delivery of pulses. The laser delivers pulses at a rate of up to ten per second, depending on the pulsewidth, rep rate and spot size setting.

The user selects the desired energy density (fluence) level, and enables or disables the laser at the control panel.

The laser systems are equipped with interlocks that disable laser emissions if the remote interlock circuit is open or the fiber is removed.

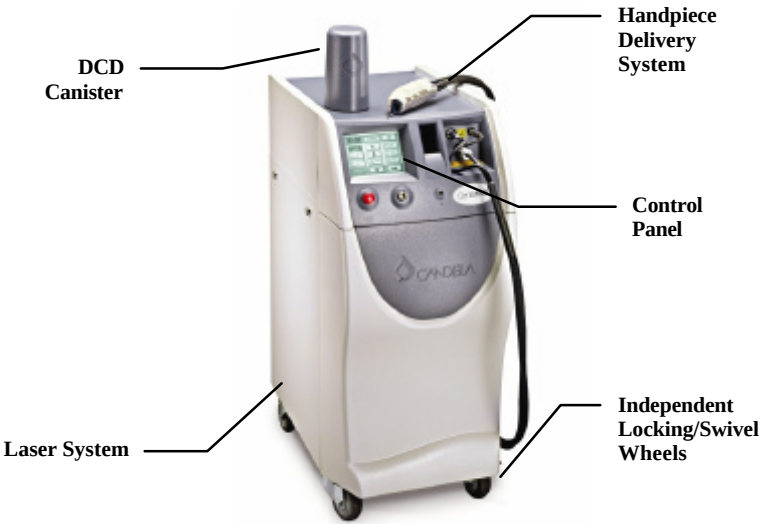
Dynamic Cooling Device (DCD)

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.

The laser systems can be purchased with an optional skin cooling device 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, a cryogen reservoir canister and associated electronic control circuitry located in the top of 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 or after the laser pulse. Controls are provided on the laser front panel for the adjustment of the spray burst duration and for the timing delay between the spray burst and the laser pulse.

FIGURE 1.1
LASER SYSTEM



Handpiece Delivery System

Multiple handpiece delivery systems are offered with the laser system. The GentleYAG includes three delivery systems (1.5/3 mm slider, 6/8/10 mm slider, 12/15/18 mm slider) and the GentleYAG LE includes one delivery system (10/12/15 mm slider). Each delivery system (Figure 1.2) consists of a cable assembly, replaceable distance gauge and a handpiece assembly.

The cable assembly contains the fiberoptic, cryogen input line and valve control wires. If the laser system is equipped with the optional DCD, the handpiece assembly will contain the DCD spray nozzle, safety and detection electronics, focusing lenses, and an output window to protect the lenses from dust and debris. The spray nozzle is located near the distance gauge at the treatment end of the handpiece.

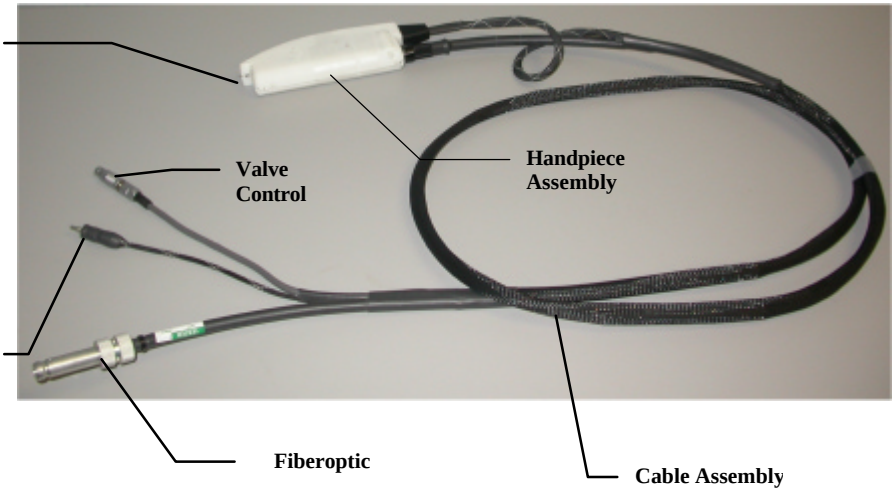


FIGURE 1.2
HANDPIECE DELIVERY SYSTEM

Distance Gauges

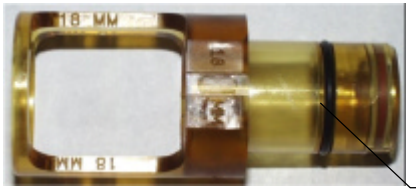
There are several different circular type distance gauges available for use with the GentleYAG system. The GentleYAG includes 5 types of amber distance gauges and 4 types of black distance gauges. (The GentleYAG LE includes 3 types of amber distance gauges.) Each distance guage is designed to be used with respective spot sizes with the exception of the 8 mm distance gauge. The 8 mm distance gauge should be used for both the 8 mm and 6 mm treatment spotsizes. It is important to use the correct distance gauge for the spot size that the laser system is adjusted for.

The five types of amber distance gauges are for use with spot sizes from 6 mm to 18 mm. Each of the amber distance gauges also contains a window to offer extra protection for the lenses in the handpiece. Removal and cleaning of the windows is explained in section 6 of this manual.

WARNING

Use only distance gauges designed for the GentleYAG or damage to the optical pathway will occur. These are distinguishable by the presence of an exterior blue O-ring. The 1.5 mm distance gauges do not have an exterior O-ring and are designed exclusively for GentleYAG. Refer to Figure 1.3.

FIGURE 1.3
GentleYAG
DISTANCE GAUGE
(18 mm EXAMPLE)



The amber distance gauge is installed by inserting it, window end first, into the distal end of the handpiece. Align one of the flat areas on the side of the distance gauge with the spray nozzle and gently push until seated in the handpiece. To remove the distance gauge, pull it straight out.

Note: A properly installed distance gauge has virually no gap between the distance gauge and the distal end of the delivery system.

Note: The distance gauge does not rotate when installed.

Caution

DO NOT USE A SMALLER DISTANCE GAUGE WITH A LARGER TREATMENT SPOTSIZE. THE LASER BEAM WILL PERMANENTLY DAMAGE THE DISTANCE GAUGE. DO NOT USE A DISTANCE GAUGE WITH VISIBLE SIGNS OF DAMAGE OR EXCESSIVE DETERIORIATION.

The four black distance gauges are for use with the 1.5mm and 3 mm spots only. There are two types of distance gauges for each spot size and they are labeled on the support leg similar to the amber distance gauges. Each spot size has a small and large distance gauge with either a small or large treatment ring at the end. The large ring offers increased visibility when the treatment area is relatively flat. The small ring works better when the treatment area is on a curved surface or in close proximity to protrusions.

The 3 mm distance gauge is inserted and removed from the handpiece using the same technique as for the amber distance gauges. The 3 mm distance gauge does not have a window in it. This is because the procedures associated with this spot size deliver less energy to the treatment area and create much less debris. Note that there is a window at the end of the 1.5/3 mm slider to keep the lenses in it clean. Figures 1.4 and 1.5 show the two types of 3 mm distance gauges.

The 1.5 mm distance gauge is significantly different from all the other distance gauges. This distance gauge contains a lens and a window to help keep the lens clean. Care must be used when handling this distance gauge to ensure that the lens remains clean. The recommended method of holding the 1.5 mm distance gauge is by grasping it firmly on the support leg. Figures 1.6 and 1.7 show the two types of 1.5 mm distance gauges

FIGURE 1.4
GentleYAG
3 mm SMALL
DISTANCE
GAUGE

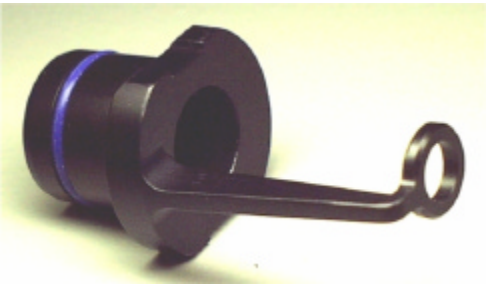


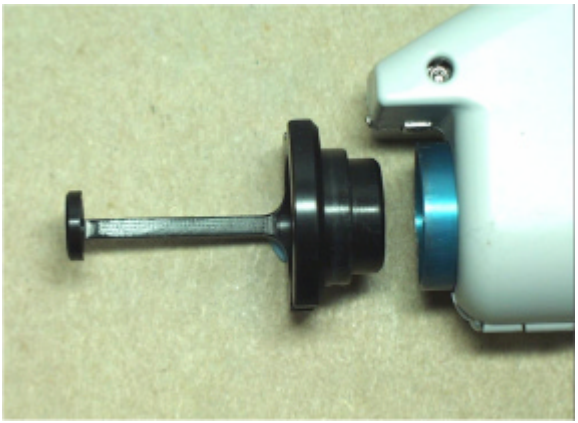
FIGURE 1.5
GentleYAG
3 mm LARGE
DISTANCE
GAUGE

FIGURE 1.6
GentleYAG
1.5 mm SMALL
DISTANCE
GAUGE

FIGURE 1.7
GentleYAG
1.5 mm LARGE
DISTANCE
GAUGE

The 1.5 mm distance gauge attaches to the delivery system in a different manner than all the other distance gauges. Instead of inserting it into the handpiece slider tube, the 1.5 mm distance gauge is inserted directly onto the laser output end of the slider. This end of the slider only protrudes out of the handpiece when the slider is adjusted for the 1.5 mm spot. Figure 1.8 shows a close-up view of the small 1.5 mm distance gauge before it is inserted into the handpiece slider.

FIGURE 1.8
1.5 mm SMALL DISTANCE GAUGE AND HANDPIECE SLIDER



The proper method to install the 1.5 mm is as follows:

1. Grasp the distance gauge by the support leg.
2. Insert the distance gauge into the end of the slider while rocking it back and forth once or twice. This will ensure that it is centered onto the slider when installed.

To remove the 1.5 mm distance gauge, grasp the support leg and gently rock it back and forth while pulling it out from the slider.

Caution

THE 1.5 MM DISTANCE GAUGES CONTAIN A BUILT-IN LENS AS PART OF THE ASSEMBLY. THEY ARE THE ONLY DISTANCE GAUGES THAT SHOULD BE USED WHEN THE DELIVERY SYSTEM SLIDER IS ADJUSTED FOR A 1.5 MM SPOT SIZE. USE OF ANY OTHER DISTANCE GAUGE WILL RESULT IN AN INCORRECT SPOT SIZE AND THE FLUENCE DELIVERED TO THE TREATMENT AREA WILL BE INCORRECT.

When the laser system is in the READY state, the aiming beam will illuminate. The aiming beam should always be in or near the center of the distance gauge treatment circle. The amber distance gauges and the 3 mm distance gauges are self aligning when they are inserted in the delivery system.

The 1.5 mm distance gauge is not fully self-aligning so it may need to be readjusted if the aiming beam is not near the center of the treatment ring. If this occurs, place the laser in the STANDBY state and remove the distance gauge. Then reinsert the 1.5 mm distance gauge using one or two rocking motions as it is pressed onto the slider. Recheck the centering of the aiming beam to verify that it is installed properly.

Caution

DO NOT USE A SMALLER DISTANCE GAUGE WITH A LARGER TREATMENT SPOTSIZE. THE LASER BEAM WILL PREMANENTLY DAMAGE THE DISTANCE GAUGE. DO NOT USE A DISTANCE GAUGE WITH VISIBLE SIGNS OF DAMAGE OR EXCESSIVE DETERIORIATION.

Refer to Section 6 of this manual for instructions on cleaning and maintenance of handpieces and distance gauges.

Fiber Pole

The *GentleYAG* is equipped with a fiber pole assembly to assist in supporting the weight of the delivery systems. The fiber pole is adjustable and can be removed from the laser systems for easy storage.

Figure 1.9 shows the fiber pole attached to the laser system and ready for use. The hook at the end of the fiber pole supports the delivery systems, but allows the fiber to slide freely through it (to prevent kinks and bends). The black knob is used to lock all three pivoting joints within the arm. To adjust the fiber pole, turn the black knob counter clockwise and move the pole to the desired position. Tighten the black knob clockwise to hold the fiber pole in position.

CAUTION

When using the fiber pole to support the delivery system, make sure there are no sharps bends in the delivery system. The GentleYAG 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 may be damaged.

The fiber pole may be folded for storage as shown in figure 1.10. 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, 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.

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FIGURE 1.9
FIBER POLE ASSEMBLY

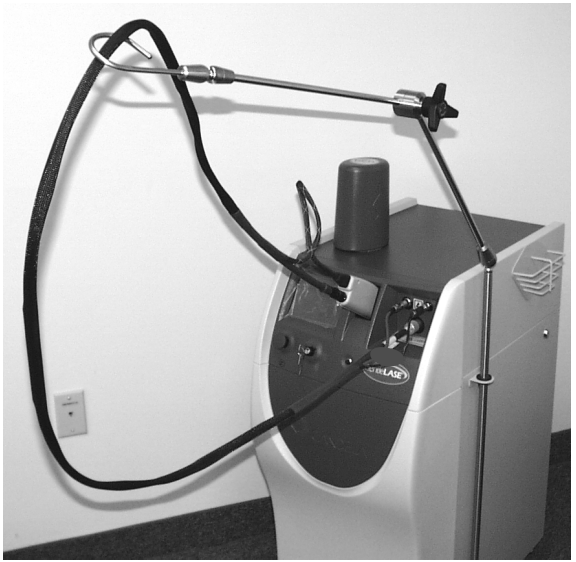


FIGURE 1.10
FIBER POLE FOLDED

LOCKING/ SWIVEL WHEELS

The *GentleYAG* is equipped with wheels. The two front wheels are capable of swiveling, which makes parking in tight spaces easy.

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.

SPECIFICATIONS

Table 1-1 Specifications

Table 1-1 Specifications for the *GentleYAG*.

Laser Type	Flashlamp-excited, long-pulse Nd:YAG laser
Wavelength	1064 nm
Method of Optical Output	Lens-coupled optical fiber to handpiece.
Maximum Delivered Energy per pulse	80 J
Accuracy of Output Energy	± 20%
Pulse Repetition Rate	Up to 10 Hz. (Up to 2 Hz for LE systems)
Pulse Duration	0. 250 -300 milliseconds (3 ms to 100 ms for LE systems)
Aiming Device	Class 1 Laser Diode (per EN 60825-1), 520-550 nm, 5.0 mW
Treatment Spot Sizes (Diameter)	1.5, 3, 6, 8, 10, 12, 15, and 18 mm (10, 12, and 15 mm for LE systems)
Cooling Method	Air to water heat exchanger

Table 1-1
Specifications Cont.

Dimensions (HxWxD)	35” x 16” x 28”
Weight	210 lbs (95 kg)
Cryogen	HFC 134a
Voltage and Current	220-230V 50/60HZ single phase 16A
Miscellaneous (per 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 GentleYAG is a Class 4 laser product with a Class 1 aiming beam per EN60825-1 Laser Hazard Classification.. *The GentleYAG Laser System is* a Class II medical device per FDA 21 CFR 878.4810, and a Class llb (Rule 9), non-invasive, active device according to Annex lX of Directive 93/42/EEC.

GentleYAG comply with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated July 26, 2001

ELECTRICAL REQUIREMENTS

ELECTRICAL REQUIREMENTS

Table 1-2 lists Electrical Requirements for the GentleYAG Laser System.

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 GentleYAG 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 1-2 for electrical service requirements.

For International installations, the power connections should be made with a grounded 2-conductor plug and receptacle pair. The plug & receptacle must be rated for the service line voltage at a minimum, and capable of handling 3680 VA (see Table 1-2 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.

GentleYAG Electrical Requirements: 220 V - 230 V~, 50/60 Hz, 3680 VA

TABLE 1-2 ELECTRICAL REQUIREMENTS

Installation Site Electrical Service Requirements	
United States	208 V - 240 V~, 60 Hz, 30 Amp, center-tapped, single phase, dedicated branch circuit with earth ground conductor.
Worldwide	220 V - 230 V~ (+/-10%) 50/60 Hz, >16 Amp*, single phase, dedicated branch circuit with earth ground conductor. *Note: GentleYAG may be suitable for hookup to a 230 V~, 16 Amp dedicated service. Voltage dips and low line conditions may cause the mains breaker to trip periodically. The user should consult a qualified Electrician to verify mains quality before connecting to a 16 Amp service.

GROUND CONTINUITY TESTS

Your laser system requires a connection to earth ground to reduce the risk of electric shock. To verify that this safety feature is functioning properly, we recommend 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 you are 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 & light or battery and buzzer combination may be alternatively used to verify a ground connection between any unpainted conductive surface and the plug's ground pin if an Ohmmeter is not available. An adequate ground connection will be indicated by illumination of the light or sounding of the buzzer.

ENVIRONMENTAL REQUIREMENTS

Before installation of the *GentleYAG 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.

NOTE

Installation of the *GentleYAG* 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 *GentleYAG Laser System*.

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 MSDS sheet (8501-00-1701) for 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.

Relocation

Avoid placing the laser system near heating outlets or other sources of air currents that could cause uneven cooling in the laser system. Care should always be taken when moving the *GentleYAG* Laser System. Remove the footswitch tubing from the connector (located in the rear of the laser) before moving. Guide the *GentleYAG* by

grasping the left and right side edges of the front bezel or guide using the rear handle. 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 *GentleYAG*, call Candela Customer Service or your distributor for details. Failure to do so may result in damage to the system, and may void any warranty.

Mobile Use

The *GentleYAG* Laser is not designed for mobile use.

Transport & Storage

For transport and storage of *GentleYAG* , the temperature must be kept between 40° and 110° F (4.5° and 43° C), and humidity between 20% and 80% (non-condensing). Ambient atmospheric pressure is suitable with no restrictions.

WARNING

DO NOT EXPOSE TO TEMPERATURES BELOW 4.5°C OR DAMAGE MAY OCCUR. IF LASER IS EXPOSED TO TEMPERATURES BELOW 4.5°C, CONTACT CANDELA TECHNICAL SUPPORT PRIOR TO 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 *GentleYAG is* in operation, restrict entry and limit access to the laser room to those personnel 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.

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:

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

CAUTION!

OPTICAL PRECAUTIONS

USE ONLY SAFETY EYEWEAR WITH AN OPTICAL DENSITY OF [3] 6.3 @ 1064 NM.

The laser beam emitted by the *GentleYAG is* capable of causing loss of vision. The laser operates at 1064 nm, which falls within the invisible, near-infrared region of the electromagnetic spectrum. While not visible to the eye, it is still capable of inflicting damage. Remember this and take precautions to avoid inadvertent exposure. The cornea and lens of the eye are transparent to invisible light. Any energy emitted by the *GentleYAG* 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 *GentleYAG is* at the distal end of the handpiece. The beam enlarges as 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 the following table.

To avoid vision hazards, everyone within the NOHD (see Table 2-1) of the *GentleYAG* must wear appropriate eye protection. Protective eyewear is supplied with each laser, and is available from a variety of vendors including Candela.

Table 2-1 NOHD/ Handpiece Comparison

Handpiece Slider Spot Size	Full Angle Beam Divergence	NOHD(m) per EN60825-1:2002
1.5-3 mm slider at 1.5 mm	0.224	16.3
1.5-3 mm slider at 3 mm	0.082	78.1
6-8-10 mm slider	0.071	190
12-15-18 mm slider	0.079	172
10-12-15 mm slider (LE System)	0.079	172

Maximum delivered energy per EN60825-1:2002 is 96 J.

CAUTION!

THE LASER BEAM EMITTED BY THE GENTLEYAG 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 *GentleYAG is* not in use, place it in STANDBY state to prevent accidental pulsing.
7. When the *GentleYAG is* unattended, remove the key from the keyswitch to prevent unauthorized use.

ELECTRICAL & MECHANICAL HAZARDS

The *GentleYAG* 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 *GentleYAG* 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 *GentleYAG* laser delivery systems utilize 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 tab.

The *GentleYAG Laser System* weighs approximately 210 pounds (95 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

There are no known chemical hazards associated with the *GentleYAG Laser System*.

The laser system uses a Hydroflourocarbon (HFC), cryogen, in the optional Dynamic Cooling Device (DCD).

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: 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.

NOTE: To Physicians

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

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 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 ft 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 low 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 (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 an unanticipated spray of cryogen. The following table gives some exposure guidelines:

	Visual outer edge of spray	Hand detection of outer edge of spray
Direct release from canister	27 inches	31 inches
Release from tip of handpiece	19 inches	23 inches

For specific customer situations contact Candela Technical 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.

Laser Fiber Fire Hazard:

GentleYAG 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 a 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 plume may contain viable tissue particulate.

Please reference the American National Standard for Safe Use of Lasers (ANSI A136.3.-1996), section 7.3 Laser Generated Air Contaminants (LGAC).

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.

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.)

When removing hair, shave excess hair away before beginning laser treatment to reduce odor and char.

ELECTRO-MAGNETIC INTERFERENCE

The *GentleYAG Laser System* has been 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 *GentleYAG* have been reduced as far as practical without compromising functionality.

If interference from the *GentleYAG* 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 *GentleYAG* or the affected equipment into another room.

Refer to accompanying Declaration and Guidance document (part number 8501-00-1736) for additional information and guidance.

Warning

When treating patients with this laser system 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.

SAFETY FEATURES

Keylock Switch

This key-operated switch controls electrical power to the laser system. The *GentleYAG* 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 Emergency Stop Switch

When the red switch with this label 

underneath (located on the lower left side of the control panel) is pressed, the *GentleYAG is* shut down immediately.

PFN Charged

An audible beep will be heard when the laser is ready to deliver a pulse of energy.

Lasing

An audible beep will be heard and the control panel flashes three Lasing Triangle symbols to indicate that the laser is releasing laser energy.

Ready Lamp

The blue lamp mounted near the control panel is illuminated when the laser is in the Ready state.

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 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 to the right of the Display Panel is illuminated.

Remote 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 *GentleYAG is* in the Ready state, the laser system completely shuts down. For more information on installation of a remote interlock, please call Candela Service

Note: The interlock must be in position to operate the device.

ENVIRONMENTAL PROTECTION

Disposal Hazards & Guidance

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 & 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 risks associated with exposure. The gloves should be disposed of in the same manner as contact parts.

Other than patient-contact parts, all external components & accessories can be disposed of as regular trash. Most internal components that make up the laser system can also be disposed of as regular trash with the exception of the high voltage capacitor and an integrated battery located on the laser I/O printed circuit board. The high voltage capacitor must be disposed of through a hazardous waste company because of two potential hazards:

1. Shock hazard – Once removed from the system the capacitor can accumulate a potentially lethal charge.
2. Dielectric oil – The oils used in the high voltage capacitor, silicon or soybean, are not considered hazardous, but must be disposed of in a manner consistent with local regulations.

Batteries:

An IC located on the Laser I/O printed circuit board (beneath front cover) contains an

integrated Lithium-ion battery, which is not replaceable or user-serviceable. The IC designated "U7" must be removed and disposed of separately from the laser system in accordance with local disposal laws regulating battery disposal.

The fluid in the coolant circulation system contains distilled water and can be disposed of as regular water.

If disposal of the laser system or its accessories becomes a problem in your area, contact Candela for instruction.

Hazardous Material & Hazardous Waste

If the laser system includes a DCD option, the GentleCOOL™ canister is classified as "hazardous". Refer to the following matrix:

Item	Hazardous category	Comments
GentleCOOL™ 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"

Refer to associated Material Safety Data Sheets (MSDS) for further information on safety, handling, first aid and disposal.


GentleYAG

Section 3

System Operation & Features

CONTROL PANEL

The *GentleYAG* control panel (Figure 3.1) located on the front of the laser system, consists of an On/Off Keylock 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 (Figure 3.2) 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.

Figure 3.1
Control Panel

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

The keylock switch has three positions: "O" (off), "⏻" (on), and "◈" (start). To start the laser, turn the key from the "⏻" position to the "◈" position, then release. The switch spring returns to the "⏻" position. The laser system starts in a few seconds and four quick audible beeps will sound.

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 "◈" position, and then release.

Laser Aperture
The laser aperture is located at the distal end of the handpiece (see Figure 6.3).

Figure 3.2
Touch Screen Display Panel

Main Screen

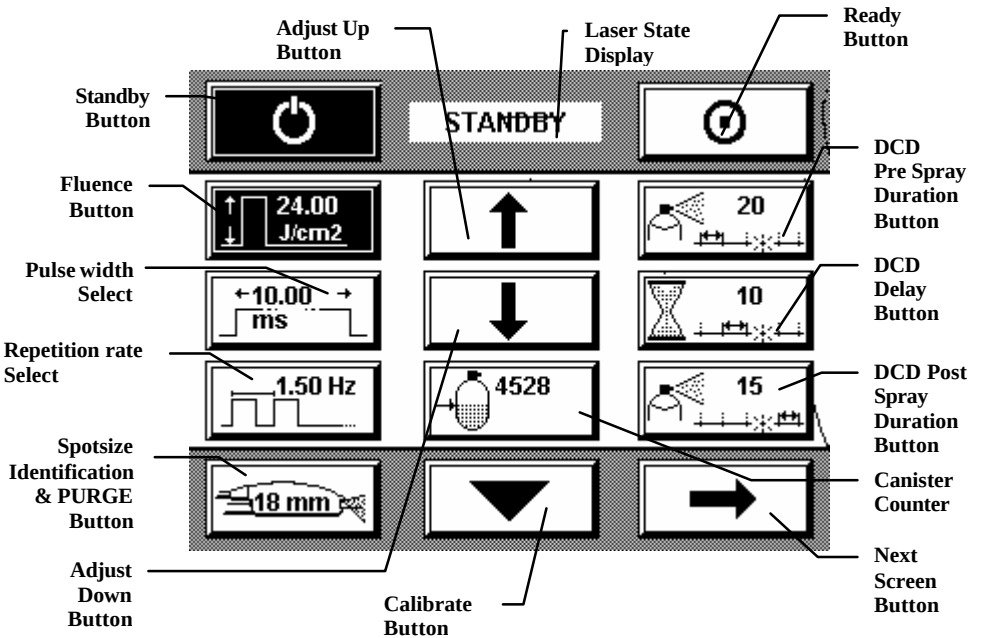


Figure 3.3
Next Screen

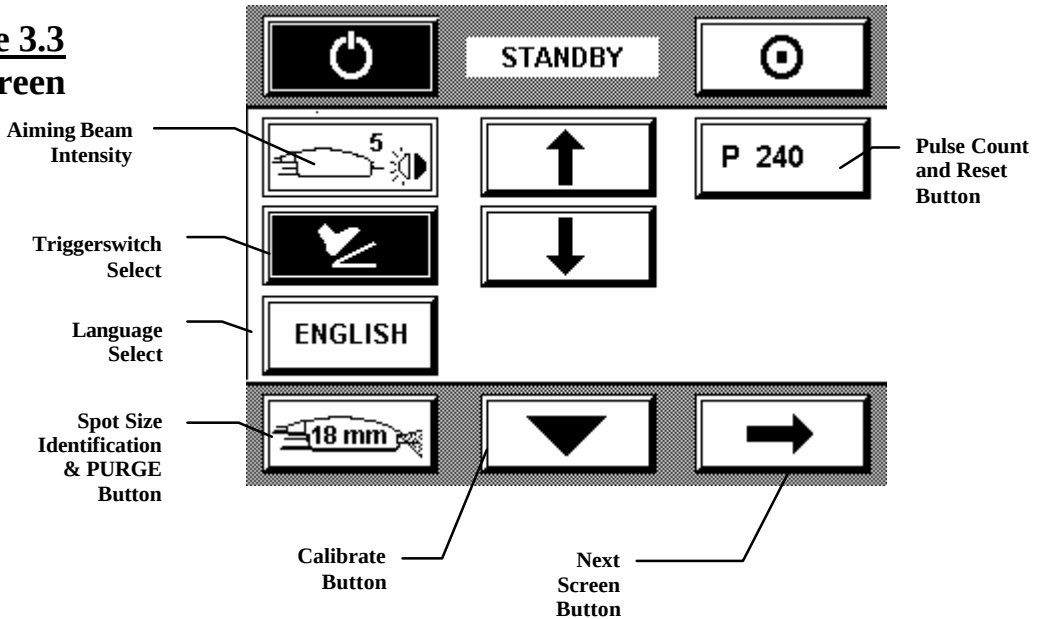
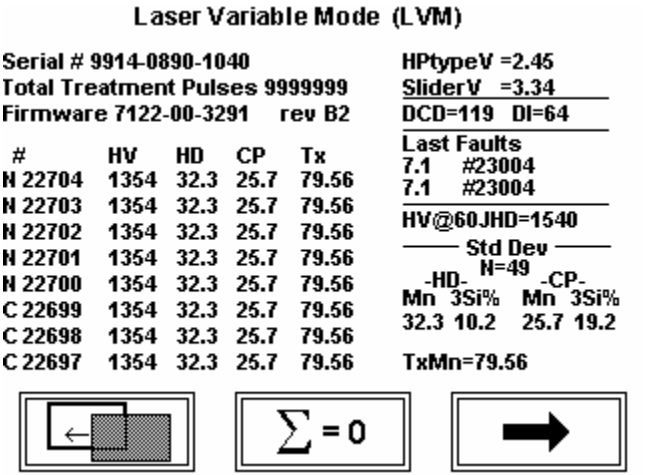


Figure 3.4
Laser Variable Mode

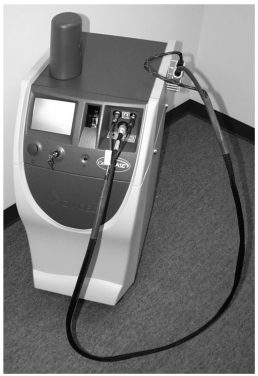


Laser Variable Mode (LVM) is a read-only display of system parameters. This screen should not be used during normal operation of the laser. It is used to assist service personnel in trouble-shooting the laser. The laser system can not be pulsed in this mode. LVM is accessed by depressing and holding the Next button until the LVM screen appears. LVM can be exited by one of the following: the next button, cycle system power, or pulse the laser (if in READY). **Note: The contents of this screen may vary and is shown for reference only.**

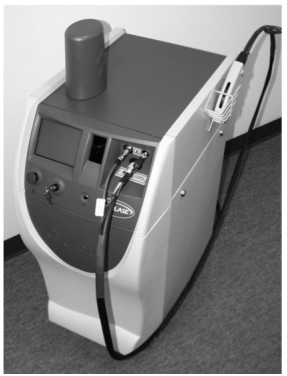
Figure 3.5
Handpiece Basket

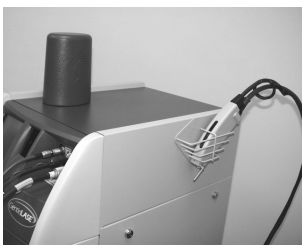
The handpiece basket provides convenient handpiece storage. The basket has two positions: in-use & storage. The in-use position allows the user a quick convenient place to park the handpiece while in-use. The storage position (rear basket slot) is designed to remove excess slack from the delivery system. This reduces the risk of damage to the delivery system while not in use.

Handpiece Placement: In-use



Handpiece Placement: Storage





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 *GentleYAG* automatically enters STANDBY state following the initial warm-up period, which occurs when the laser system is first powered up.

If the laser has been inactive in the READY STATE 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, the beam shutter is opened, the aiming beam is illuminated, 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.

The blue Ready indicator, "  ", located below the control panel display is illuminated when the laser is in the READY state. See Section 7 for the location of the Ready indicator.

The window area below the System Status menu bar contains the buttons associated with the Main Menu.

OPERATING PARAMETERS

The laser operating parameters 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 their numeric settings can be modified.

Fluence

To ensure that the selected energy density is delivered accurately, the laser will automatically require that a calibration procedure be performed if the Fluence parameter has been changed. For safety purposes, the Fluence parameter will always default to the lowest fluence for a given spot size when the laser is turned on.

NOTE

The Fluence parameter is the amount of energy density delivered to the selected spot size. The Fluence setting is adjustable in various increments of J/cm^2 for different spot sizes as shown in the following tables (3.1 to 3.8). To calculate the energy from the handpiece in Joules, multiply the fluence by the area (p r ^{2}) for the spot size selected.

Pulsewidth

The Pulsewidth parameter adjusts the duration of the laser pulse. The available pulsewidths for the fluences and spot sizes selected are indicated in Tables 3.1 to 3.8.

Repetition Rate

The "Repetition Rate" is a user selectable parameter on the front panel. It limits the speed of the laser pulsing (in HZ) to the maximum rate selected, thereby allowing the user to best maintain control during the treatment. The product has the following "Repetition Rate" selections: 0 HZ (single pulse mode) and the multi-pulse modes, .5HZ, 1 HZ, 1.5 HZ, 2 HZ, 3 HZ, 5 HZ, 7HZ and 10 HZ. In multi-pulse mode, the laser will pulse at a steady rate as long as the delivery system's trigger is depressed. Not all selections are available. The availability of the selections depends on the combination of other parameters selected (spot size, fluence, and pulse width). Refer to Tables 3.1 to 3.8 for available selections. **Note**: The actual repetition rate observed during pulsing may be slower than the "Repetition Rate" selected and displayed on the front panel. The displayed value is intended to represent a maximum pulse "Repetition Rate". The "Repetition Rate" will never exceed the displayed setting on the display panel.

Table 3.1
1.5 mm Fluence, Pulsewidth, Repetition Rate Ranges

Available Fluence Settings for the 1.5 mm Spot (J/cm^2)				
200	300	380	460	540
220	320	400	480	560
240	340	420	500	580
260	360	440	520	600
280				

Notes:
1. Repetition rate can be set to 0 (single pulse), 0.5, 1.0, 1.5 and 2.0 for all fluences. The repetition rate setting is a maximum setting. The actual repetition rate achieved may be less depending on selected fluence, pulsewidth and DCD settings.
2. Pulsewidth can be set from 10 ms to 100 ms in 10 ms increments and from 125 ms to 300 ms in 25 ms increments. Longer pulsewidths reduce the achieved repetition rate.

Table 3.2
3 mm Fluence, Pulsewidth, Repetition Rate Ranges

Available Fluence Settings for the 3 mm Spot (J/cm^2)				
50	110	170	260	380
60	120	180	280	400
70	130	190	300	420
80	140	200	320	440
90	150	220	340	460
100	160	240	360	

Notes:
1. Repetition rate can be set to 0 (single pulse), 0.5, 1.0, and 1.5 for all fluences. The repetition rate setting is a maximum setting. The actual repetition rate achieved may be less depending on selected fluence, pulsewidth and DCD settings.
2. Pulsewidth can be set from 10 ms to 100 ms in 10 ms increments and from 125 ms to 300 ms in 25 ms increments. Longer pulsewidths reduce the achieved repetition rate.

Table 3.3
6 mm Fluence, Pulsewidth, Repetition Rate Ranges

Available Pulsewidths (ms)	Minimum Fluence (J/cm^2)	Maximum Fluence (J/cm^2)	Maximum Repetition Rate (Hz)
0.25	6.0	23.0	7 (note 2)
0.30	6.0	27.0	10 (note 2)
0.35	6.0	30.0	10 (note 2)
0.40	6.0	30.0	10 (note 2)
0.45	6.0	30.0	10 (note 2)
0.50	6.0	30.0	10 (note 2)
3.0	35.0	200.0	2 (note 4)
5.0	35.0	200.0	2 (note 4)
10 to 100 (10 ms increments)	35.0	200.0	2 (note 4)
125-300 (25 ms increments)	35.0	200.0	2 (note 4)

Notes:

1. Fluence increments are 1 J/cm^2 from 6 to 30 J/cm^2 and 5 J/cm^2 from 35 to 200 J/cm^2.
2. Maximum Repetition Rate = 3 Hz for 6 -11 J/cm^2, 5 Hz for 12-20 J/cm^2, 7 Hz for 21-23 J/cm^2, 10 Hz for 24 -30 J/cm^2
3. The repetition rate setting is a maximum setting. The actual repetition rate achieved may be less depending on selected fluence, pulsewidth and DCD settings.
4. The maximum repetition rate is 1.5 Hz at fluences greater than 110 J/cm^2 with a 3 ms pulsewidth. Longer pulsewidths reduce the achieved repetition rate.

Table 3.4
8 mm Fluence, Pulsewidth, Repetition Rate Ranges

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Available Pulsewidths (ms)	Minimum Fluence (J/cm^2)	Maximum Fluence (J/cm^2)	Maximum Repetition Rate (Hz)
0.25	6.0	13.0	7 (note 2)
0.30	6.0	15.0	10 (note 2)
0.35	6.0	18.0	10 (note 2)
0.40	6.0	20.0	10 (note 2)
0.45	6.0	20.0	10 (note 2)
0.50	6.0	20.0	10 (note 2)
3.0	35.0	150.0	2 (note 4)
5.0	35.0	150.0	2 (note 4)
10 to 100 (10 ms increments)	35.0	150.0	2 (note 4)
125-300 (25 ms increments)	35.0	150.0	2 (note 4)

Notes:

1. Fluence increments are 1 J/cm^2 from 6 to 20 J/cm^2 and 5 J/cm^2 from 35 to 150 J/cm^2.
2. Maximum Repetition Rate = 3 Hz for 6 J/cm^2, 5 Hz for 7-11 J/cm^2, 7 Hz for 12-13 J/cm^2, 10 Hz for 13 -20 J/cm^2
3. The repetition rate setting is a maximum setting. The actual repetition rate achieved may be less depending on selected fluence, pulsewidth and DCD settings.
4. The maximum repetition rate is 1.5 Hz at fluences greater than 60 J/cm^2 with a 3 ms pulsewidth. Longer pulsewidths reduce the achieved repetition rate.

Table 3.5
10 mm Fluence, Pulsewidth, Repetition Rate Ranges

Available Pulsewidths (ms)	Minimum Fluence (J/cm^2)	Maximum Fluence (J/cm^2)	Maximum Repetition Rate (Hz)
0.25	6.0	8.0	7 (note 2)
0.30	6.0	10.0	10 (note 2)
0.35	6.0	11.0	10 (note 2)
0.40	6.0	12.0	10 (note 2)
0.45	6.0	12.0	10 (note 2)
0.50	6.0	12.0	10 (note 2)
3.0	35.0	100.0	2 (note 4)
5.0	35.0	100.0	2 (note 4)
10 to 100 (10 ms increments)	35.0	100.0	2 (note 4)
125-300 (25 ms increments)	35.0	100.0	2 (note 4)

Notes:

1. Fluence increments are 1 J/cm^2 from 6 to 12 J/cm^2 and 5 J/cm^2 from 35 to 100 J/cm^2.
2. Maximum Repetition Rate = 5 Hz for 6-7 J/cm^2, 7 Hz for 8 J/cm^2, 10 Hz for 9-12 J/cm^2.
3. The repetition rate setting is a maximum setting. The actual repetition rate achieved may be less depending on selected fluence, pulsewidth and DCD settings.
4. The maximum repetition rate is 1.5 Hz at fluences greater than 40 J/cm^2 with a 3 ms pulsewidth. Longer pulsewidths reduce the achieved repetition rate.

Table 3.6
12 mm Fluence, Pulsewidth, Repetition Rate Ranges

Available Fluence Settings for the 12 mm Spot (J/cm^2)				
10	22	34	46	58
12	24	36	48	60
14	26	38	50	62
16	28	40	52	64
18	30	42	54	66
20	32	44	56	68
				70

Notes:

1. Repetition rate can be set to 0 (single pulse), 0.5, 1.0, 1.5, and 2.0 for all fluences. The repetition rate setting is a maximum setting. The actual repetition rate achieved may be less depending on selected fluence, pulsewidth and DCD settings.
2. The available pulsewidth settings for each fluence are: 3 ms, 5 ms, 10-100 ms (in 10 ms increments), and 125 ms to 300 ms (in 25 ms increments).
3. The maximum repetition rate is 1.5 Hz at fluences greater than 26 J/cm^2 with a 3 ms pulsewidth. Longer pulsewidths reduce the achieved repetition rate.

Table 3.7
15 mm Fluence, Pulsewidth, Repetition Rate Ranges

Available Fluence Settings for the 15 mm Spot (J/cm^2)			
6	12	22	34
7	14	24	36
8	16	26	38
9	18	28	40
10	20	30	42
		32	44

Notes:
1. Repetition rate can be set to 0 (single pulse), 0.5, 1.0, 1.5, and 2.0 for all fluences. The repetition rate setting is a maximum setting. The actual repetition rate achieved may be less depending on selected fluence, pulsewidth and DCD settings.
2. The available pulsewidth settings for each fluence are: 3 ms, 5 ms, 10-100 ms (in 10 ms increments), and 125 ms to 300 ms (in 25 ms increments).
3. The maximum repetition rate is 1.5 Hz at fluences greater than 16 J/cm^2 with a 3 ms pulsewidth. Longer pulsewidths reduce the achieved repetition rate.

Table 3.8
18 mm Fluence, Pulsewidth, Repetition Rate Ranges

Available Fluence Settings for the 18 mm Spot (J/cm^2)			
6	10	18	26
7	12	20	28
8	14	22	30
9	16	24	

Notes:
1. Repetition rate can be set to 0 (single pulse), 0.5, 1.0, 1.5, and 2.0 for all fluences. The repetition rate setting is a maximum setting. The actual repetition rate achieved may be less depending on selected fluence, pulsewidth and DCD settings.
2. The available pulsewidth settings for each fluence are: 3 ms, 5 ms, 10-100 ms (in 10 ms increments), and 125 ms to 300 ms (in 25 ms increments).
3. The maximum repetition rate is 1.5 Hz at fluences greater than 12 J/cm^2 with a 3 ms pulsewidth. Longer pulsewidths reduce the achieved repetition rate.

The following operating parameters will only be displayed when the optional Dynamic Cooling Device is installed.

DCD Pre Spray

The DCD Pre Spray Adjust parameter adjusts the duration of the cryogen spray applied to the patient before the laser pulse. The DCD Pre Spray can be turned off ("O") or set to a duration from 20 milliseconds to 100 milliseconds in increments of 10 milliseconds. The 1.5/3 mm delivery system can access three additional pre-spray settings of 10, 15, and 25 ms. Also, to access pre spray times above 30 ms with this delivery system, hold down the UP arrow on the display for at least 5 seconds.

There are default minimum spray settings for the 15 mm (30 ms pre-spray) and 18 mm (40 ms pre-spray) spots. These default settings represent the minimum spray time required to cover their respective spot sizes. The user can choose to set the pre-spray below the default settings by adjusting the pre-spray setting on the front panel.

CAUTION

Overriding the default minimum pre spray durations may result in localized laser burns. If it becomes absolutely necessary to override the defaults settings, do so with caution.

CAUTION. .
DCD spray is not allowed at rep rates greater than 2 Hz.

DCD Delay

The DCD Delay Adjust parameter adjusts the duration of the time between the DCD cryogen spray and the laser pulse. The delay selectable range is 3, 5, 10-150 milliseconds, in increments of 10 milliseconds.

DCD Post Spray

The DCD Post Spray Adjust parameter adjusts the duration of the cryogen spray applied to the patient after the laser pulse. The DCD Post Spray can be turned off ("O") or set to duration between 10 and 50 milliseconds, in increments of 10 milliseconds.

When the DCD Pre or Post Spray Adjust parameters are changed, the canister counter is updated to reflect the change.

Canister Counter/ Reset

The Canister Counter is a decrement counter that keeps track of the number of cryogen spray pulses contained within a canister. The count decrements with each pulse of the laser if the DCD is in the "ON" state. When the count reaches zero, the message "REPLACE CANISTER" appears and the canister must be replaced. Use of a canister after the counter reaches zero may result in inadequate canister pressure, and therefore, inadequate cryogen spray. Any residual cryogen left in the canister is there as a margin of safety for both you and your client. Instructions for replacing the canister are shipped with each canister. Install only new, full cryogen canisters. Installation of a partially used canister will cause the canister count to be incorrect. Once the new canister is installed, the canister counter must be reset. This is done by holding the canister counter button down for several seconds until a new count appears. The canister counter is updated when spray duration is changed, and with

each pulse of cryogen including purges. Canister counts for each of the combined Pre and Post Spray durations are shown in tables 3.9 and 3.10.

Table 3.9
Cryogen Spray Durations and Pulse Counts for Spot Sizes From 6 mm to 18 mm

Spray Duration (ms)	Pulses Available (Post Spray = 0)	Pulses Available (Post Spray = 50)
20	16,232	4,637
30	10,821	4,058
40	8,116	3,607
50	6,492	3,246
60	5,410	2,951
70	4,637	2,705
80	4,058	2,497
90	3,607	2,318
100	3,246	2,164

Table 3.10
Cryogen Spray Durations and Pulse Counts for the 1.5/3 mm Delivery System

Spray Duration (ms)	Pulses Available (Post Spray = 0)	Pulses Available (Post Spray = 50)
10	45,754	7,625
15	30,502	7,039
20	22,877	6,536
25	18,301	6,100
30	15,251	5,719
40	11,438	5,083
50	9,150	4,575
60	7,625	4,159
70	6,536	3,812
80	5,719	3,519
90	5,083	3,268
100	4,575	3,050

CAUTION!

FAILURE TO INSTALL THE APPROPRIATE SIZE CANISTER FOR YOUR LASER OR FAILURE TO REPLACE IT AS INSTRUCTED CAN LEAD TO ADVERSE CLINICAL OUTCOMES INCLUDING BURNS.

SUCH 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 TREATMENT AREA**
- **DO NOT ATTEMPT TO USE THE CANISTER BEYOND THE FIRST OCCURRENCE OF THE "REPLACE CANISTER" MESSAGE.**
- **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 gram	1600-00-0210	GentleYAG

SYSTEM COUNTERS

There are two pulse counters: Treatment Pulse Counter (shown on the "next" screen) and Total Pulse Counter (shown on the "Laser Variable" Mode Screen). Both counters keep track of delivered pulses but only the Treatment Pulse Counter can be reset. The Total Pulse Counter is used to keep track of the total number of laser pulses delivered by the laser system. The Treatment Pulse Counter is used to keep track of the number of pulses used in a treatment session. Both pulse counts exclude pulses used during calibration.

Pulse Count/ Reset

The Treatment Pulse Count is reset to zero by pressing the PULSE COUNT button for approximately 3 seconds. The system acknowledges the selection by responding with a short beep tone and by setting the lower count value displayed within the PULSE COUNT button to zero. The Total Pulse Counter (shown on the "Laser Variable" Mode Screen) can not be reset to zero.

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 trigger switch is depressed. The handpiece must be fully inserted into the cal port during the calibration routine.

After calibration, the system is in READY state and the trigger switch is enabled. The operator can switch between READY state and STANDBY state as needed without recalibrating provided that the fluence parameters have not been changed and no more than thirty minutes has elapsed since the last calibration.

Language Select

The language select button displays messages in the selected language. Press the down or up arrow to select the desired language.

Spotsize Identification & Purge Button

This dual purpose button displays the current delivery system spotsize, and when depressed delivers a cryogen PURGE pulse. The purge button is used to remove air from the handpiece assembly when a new canister or delivery system is installed. The system will prompt the user when a purge is necessary. This action must be done with the handpiece removed from the calibration port and pointed in a safe direction.

Aiming Beam Button

This button located on the second screen allows the user to select from six aiming beam intensities. The green aiming beam, which is visible only in the READY state, serves as a treatment area target as well as an emissions warning device. The aiming beam cannot be turned OFF.

Repetition Rate

This button is used to select the repetition rate on the main screen.

Next Screen Button

This button is used to access available screens. There are two operating screens and one auxiliary screen(Laser Variable Mode- LVM) See Figures 3.1-3.3 for descriptions.

OTHER CONTROLS

Laser emission is generated by depressing the trigger switch, provided the system is in the READY state & calibrated.

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

Triggerswitch:

Fingerswitch
Footswitch

The fingerswitch or footswitch can be selected with this button. Depress this button and use the "UP" or "DOWN" arrows to choose the triggerswitch type. For safety reasons only one type of triggerswitch can be active at one time. For example, if the footswitch is selected the fingerswitch will be disabled.

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 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 the laser room door(s) is 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 remote interlock is not in use, the supplied jumper must be plugged into the interlock connector. The circuit requires a switch with a minimum rating of 24 VDC at 250 mA (1/4 Amp).

Footswitch Connector

The footswitch connector is located on the rear panel of the laser system. The footswitch connector is a rigid tube with a smooth taper. To install the footswitch, push the pneumatic footswitch hose over the connector (tube). Pull to remove. The length of the footswitch tubing can be shortened, if desired, using scissors.

On/Off Mains Switch

The on/off main switch is located on the rear panel of the laser system and must be in the ‘1’ (on) position for the laser system to operate. Always place the on/off main switch in the ‘0’ (off) position when the laser is not in use.

Section 4

System Start-Up

LASER SYSTEM START-UP

1. Cover treatment room windows with an opaque material to prevent unintended viewing.
2. Post laser warning signs at each entrance of the treatment room.
3. Ensure an adequate number of protective eyewear is available. Proper eyewear will filter light at a wavelength of 1064 nm with an O.D. of 6.3 or greater.
4. Plug the laser into the correct electrical outlet. Ensure that the main circuit breaker on the upper rear panel is in the "ON" position.
5. Select and install the desired delivery system. Insure that the fiber connector at the laser is secure.
6. Set up the delivery system on the fiber pole as per section 1 of this manual.
7. Inspect and verify that the handpiece window is clean.
8. The keylock switch has three positions: "O" (off), "O" (on), and " ◇ " (start). The switch returns to the "O'' position once the laser system starts and a "power on" audible beep will sound. To start the laser system, turn the keyswitch fully clockwise from the O to the start ◇ position, and then release. Once released the keyswitch will return to the on "O" position similar to an automobile ignition switch . There may be a delay of several seconds before the system initializes. This is normal. The system will now enter the warm-up state (approx. 25 min). 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 touchscreen to remind the user to perform user verification tests. The warning will read " "Perform Delivery System Test."

10. Perform User Verification Tests as outlined in Section 6 of this document.

Important !

The delivery system should be checked at the beginning of each treatment day for proper operation. In addition, check the delivery system if there is an unexplained treatment response noted or the delivery system has been dropped.

11 After tests are completed, depress the Check Box on the screen displaying the "Perform Delivery System Test." message.

12. Select the desired laser system operating parameters as follows:
    a. Select Fluence
    b. Select Pulsewidth
    c Select Repetition Rate
    d. If system has the DCD option, set DCD for desired spray duration and delay parameters

    NOTE: If you experience difficulty setting the operating parameters, check Tables 3.1 to 3.7 and ensure the settings are allowed for the selected spot size.

    e. Fully insert the handpiece into the CAL port.
    f. Press the CAL switch and follow the instructions on the display panel.

Note: Repetition rate may be adjusted before or after calibration

Note: Before calibration a message will appear on the touchscreen for the user to “Confirm Treatment Parameters”. After confirming, the “check box” must be pressed prior to proceeding with the calibration.

g. Remove calibrated handpiece when CAL is complete.

Note: After calibration the laser will return to STANDBY mode for safety reasons. This is to allow the user to install distance gauge.

13. Install distance gauge and press the READY button. Aim the handpiece at a white piece of paper and inspect the aiming laser for circular uniformity and clarity.

Note: If the aiming laser spot is not uniform, check for distance gauge interference. Replace bent distance gauge if necessary. If using the 1.5 mm distance gauge, ensure that the aiming beam is at or near the middle of the distance gauge ring. If not, remove and install the distance gauge again to correct the problem. The distance gauge must be replaced if correct results can not be achieved.

Important !

Do not operate laser if 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 for Service.

14 Perform laser treatment.

Note: In some cases, when treating large areas, a PURGE fault may appear as a result of the accumulation of reflected heat. If this happens, allow delivery system to cool before continuing treatment. Place laser in STANDBY state and check the windows on the distance gauge and handpiece slider. Dirty windows will reflect laser energy back into the handpiece which will heat it up and cause PURGE faults. If possible, replace with a cool delivery system.

16. Place the laser into STANDBY after use. Document laser use.

CAUTION!

Failure to initiate a calibration after cleaning/replacing the window or delivery system may result in the delivery of excessive laser energy.

NOTES

- **To return the pulse counter to zero, press the PULSE COUNT button for 3 seconds.**
- **A calibration will automatically be required when:**
  1) **Laser is turned on;**
  2) **FLUENCE parameter or pulsewidth parameter changed;**
  3) **Delivery system changed;**
  4) **Slider plunger depressed;**
  5) **Slider position changed;**
  6) **Specific faults occur;**

NOTES (continued)

  7) **In STANDBY for more than 30 minutes;**
- **The user must remember to initiate a calibration after:**
  1) **Cleaning or replacing a window in the handpiece Slider.**
  2) **Replacing the delivery system.**
  3) **Changing the treatment spot size**

Section 5

Calibration Procedure

CALIBRATE PROCEDURE

CAUTION!

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

The *GentleYAG* requires that the laser be calibrated prior to each patient treatment. During calibration, the handpiece without the Distance Gauge is inserted into the Cal Port allowing an internal energy meter to measure the laser output energy delivered at the handpiece. The system adjusts itself until the desired output is obtained. Usually 3 - 15 laser pulses are required before calibration is complete.

- Inspect and verify that the handpiece Slider window is clean.
- Select the desired Delivery System. Make sure the Delivery System is properly connected and secured.
- Put on laser safety eyewear.
- Select the desired Fluence parameter values via the Display Panel.
- Remove the Distance Gauge from the handpiece.

- Fully insert the handpiece into the Cal Port.
- Press the CALIBRATE button on the Display Panel and follow the instructions provided in the calibration message window.
- Remove handpiece from the Calport when instructed to do so and install distance

Pressing “X” allows the operator to return to the Main screen in Standby. The operator can then adjust the laser output parameters as needed before restarting the calibration procedure.

After successful completion of the calibration procedure, remove the Delivery System from the Calport, install the Distance Gauge and begin treatments.

During calibration the software performs a delivery system transmission check. If the delivery system transmission is low, the software will display a message to clean the HP Slider window. The user can stop the calibration by pressing “YES” and clean the HP Slider window (see Section 6 for window cleaning procedure) or press “NO” to continue the calibration. The performance of the delivery system is improved by using a clean or new HP Slider window. Clean optics will increase the life of the delivery system.

NOTE

If the desired fluence cannot be reached, a FAULT will be displayed. If this occurs, decrease the fluence and perform another calibration. When this happens, the laser system is degraded and does not have sufficient energy to calibrate properly. A dirty window on the handpiece slider may be the cause of the problem. Clean or change the window using the instructions in Section 6 (Maintenance and Troubleshooting section). If the problem cannot be corrected, the system may require service. Call Candela Service for more information.

If a higher fluence is desired immediately, change the delivery system to one with a smaller spot size.

Section 6

Maintenance/ Troubleshooting

CAUTION!

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

THE GENTLEYAG LASER SYSTEM SHOULD BE SERVICED ONLY BY QUALIFIED TECHNICIANS WHO HAVE RECEIVED APPROPRIATE TRAINING FROM CANDELA. ANY ATTEMPT BY AN UNAUTHORIZED PERSON TO PERFORM ANY SERVICE PROCEDURE MAY RESULT IN PERSONAL INJURY AND WILL VOID ANY WARRANTY ON THE LASER SYSTEM.

FIBER-OPTIC DELIVERY SYSTEM

The *GentleYAG* 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 6 inches (15 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

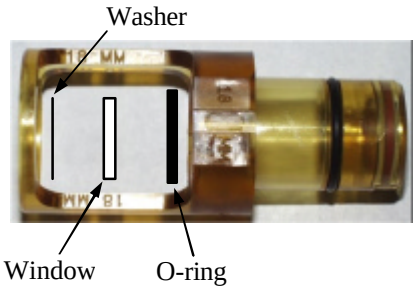
or replace the distance gauge and slider windows before repeating this test. Use of a damaged fiber-optic delivery system is dangerous and must be avoided. If damage is suspected discontinue use immediately.

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

WINDOWS

Windows have been designed into distance gauges (with the exception of the 3mm distance gauge) and slider to protect the delivery system optics. Due to the nature of some procedures, the windows will require frequent cleaning and/or replacement to maintain proper system performance. Windows should be maintained in accordance with Candela procedure 8502-00-0847 *GentleYAG*. Assembly pictures and procedures specific to *GentleYAG* delivery systems are included in this section.

Note: Special instructions for the 18mm distance gauge The 18mm distance gauge contains a metal washer next to the window. Please note the proper order of assembly when cleaning or replacing the window (shown right).



WATER COOLING SYSTEM

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

The system is cooled with distilled 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 within the box protruding from the rear of the laser. Turn the filler cap counter-clockwise to remove. Inspect level by looking into tank. Fill with distilled water if the level is below the base of the filler neck or if a system message indicates a fault code preceded by a "7".

CLEANING AND DISINFECTING

The exterior of the laser system should 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 an alcohol solution. Ethyl or isopropyl alcohol with strength of 70% - 90% makes a good general purpose disinfectant.

Handpiece

To clean and disinfect the Delivery System handpiece:)
Immediately after each treatment session, wipe the exterior surface of the handpiece body with a gauze pad moistened with an alcohol solution (see last paragraph). Take care to avoid contaminating the internal optical surfaces of the handpiece. When 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. Proper care of the handpiece distance gauge will result in improved laser performance.

To Clean/Disinfect the Distance Gauge Assembly: Clean by wiping with gauze pad moistened with an alcohol solution and allow to dry.

Note: Special instructions for the 18 mm distance gauge
The 18 mm distance gauge contains a metal washer next to the window. Please note the proper assembly when cleaning or replacing the window

Note: Special instructions for the 1.5mm distance gauge
The 1.5 mm distance gauge contains a lens and a window. Please note the proper assembly when cleaning or replacing the window

Distance Gauge and HP Slider Window

CAUTION!

ONLY USE GENTLEYAG REPLACEMENT WINDOWS IN HANDPIECE AND SLIDER OR PERMANENT DAMAGE WILL OCCUR.

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

ALWAYS PUT THE LASER SYSTEM INTO "STANDBY" OR "OFF" WHEN CHANGING A DELIVERY SYSTEM OR DISTANCE GAUGE WINDOW OR WHEN A HANDPIECE SLIDER WINDOW IS CLEANED OR REPLACED.

WHEN THE HANDPIECE SLIDER WINDOW OR THE DISTANCE GAUGE WINDOW BECOMES DIRTY OR BURNT, THE AMOUNT OF ENERGY DELIVERED TO THE PATIENT MAY BE REDUCED.

AFTER REPLACING A DIRTY OR BURNT WINDOW THE LASER SYSTEM MUST BE RECALIBRATED.

AFTER REPLACING/CLEANING A DIRTY WINDOW, (OR CLEANING A DIRTY LENS ON THE 1.5 MM DISTANCE GAUGE) YOU MAY NEED TO REDUCE THE FLUENCE TO OBTAIN PRIOR RESPONSE.

Figure 6.1
Distance Gauge
(6 mm to 18 mm)

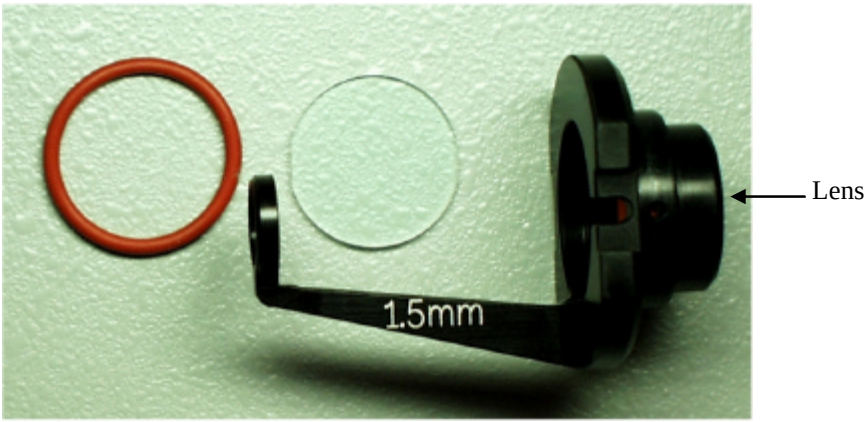
For 6 mm to 18mm Amber Distance Gauges

To clean or replace the Distance Gauge window: (figure 6.1)

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 Distance Gauge window is held in a groove in the rear (non treatment) end of the assembly with an O-ring. A notched access in the groove allows easy removal of the O-ring and window.
4. With the treatment end of the distance gauge pointing downwards, remove the O-ring 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. (If needed, gently tap the side of the Distance Gauge with your finger).
6. (Used windows only)
   a. Clean the windows in an alcohol solution. Rinse thoroughly with clean water, and dry with a lint free tissue.
   b. Re-inspect the window and if unacceptable, discard window and replace with a new one.
7. Grasp the new or cleaned window by the edges and place it back into the Distance Gauge assembly so it is resting flat on the ledge.
8. 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. Perform a Calibration Procedure per section 5. Then slide the Distance Gauge back into the HP.

Figure 6.2
Distance Gauge
(1.5 mm)



For 1.5 mm Black Distance Gauges

To clean or replace the Distance Gauge window: (figure 6.2)

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 Distance Gauge window is held in a groove in the front (treatment) end of the assembly with an O-ring. A notched access in the groove allows easy removal of the O-ring and window. Note that the non-treatment end of the distance gauge contains a lens. This lens is not removable by the customer. If the lens becomes dirty, use the cleaning process at the end of this procedure.
4. With the treatment end of the distance gauge pointing upwards, remove the O-ring 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. (If needed, gently tap the side of the Distance Gauge with your finger).
6. (Used windows only)
   a. Clean the windows in an alcohol solution. Rinse thoroughly with clean water, and dry with a lint free tissue.
   b. Re-inspect the window and if unacceptable, discard window and replace with a new one.
7. Grasp the new or cleaned window by the edges and place it back into the Distance Gauge assembly so it is resting flat on the ledge.
8. 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. Perform a Calibration Procedure per section 5. Then slide the distance gauge back into the HP.

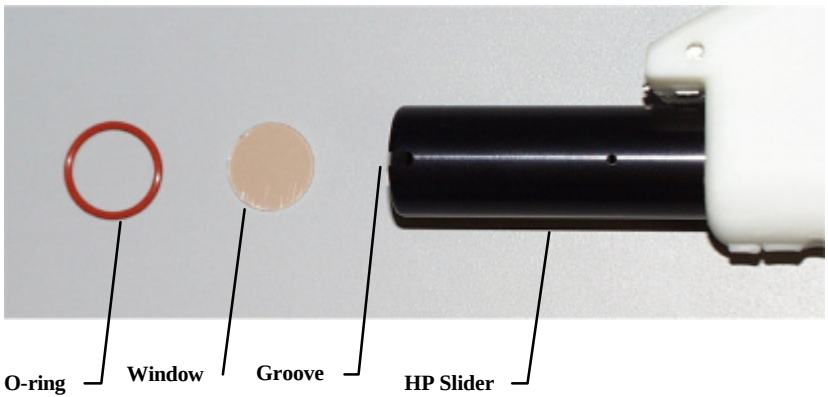
To clean the 1.5 mm Distance Gauge lens: (figure 6.2)

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 Distance Gauge lens is on the non-treatment end of the distance gauge. The lens can not be removed by the customer but it can be cleaned while it is in the distance gauge.
4. Wipe the lens ONCE with a tissue dampened with alcohol and then discard the tissue.
5. Use a second tissue that is dry and wipe the lens ONCE to clean off the alcohol. Discard the tissue
6. Repeat steps 4 and 5 (wiping only once with each tissue) until the dirt on the lens is removed or no improvement is seen.
7. In most cases, only the side of the lens that is exposed on the non-treatment end of the distance gauge will become dirty. The side of the lens that is on the treatment end of the distance gauge should remain clean since it is protected by the window in the distance gauge. However, if this side of the lens becomes dirty, remove the distance gauge window and then perform steps 4 and 5 until the lens is clean.
8. Perform a Calibration Procedure per section 5. Then slide the distance gauge back into the HP.

To clean or replace the HP Slider window: (figure 6.3)

1. Wear dustless gloves to prevent smudges or fingerprints on lens.
2. Turn the laser OFF. Remove the Distance Gauge. Slide the HP Slider through the front of the HP; exposing the slider window or remove the HP Slider entirely from the rear of the HP assembly. The window is held in a groove in the front end of the Handpiece Slider with an O-ring. A notched access in the groove allows easy removal of the O-ring and window.
3. With handpiece pointing upward, remove o-ring 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. Then turn the handpiece slider upside down, allowing the window to fall out onto a clean surface. (If needed, gently tap the side of the handpiece slider with your finger).
4. (Used windows only)
   c. Clean the windows in an alcohol solution. Rinse thoroughly with clean water, and dry with a lint free tissue.
   d. Re-inspect the window and if unacceptable, discard window and replace with a new one.
5. Grasp the new or cleaned window by the edges and place it back into the handpiece slider so it is resting flat on the ledge.
6. 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.
7. Slide the HP Slider back into the HP. Select a spot size. Then perform a Calibration Procedure per section 5.

Figure 6.3
Handpiece Slider Close-up



HANDPIECE DELIVERY SYSTEM REPLACEMENT

The handpiece delivery system should be replaced with the system turned off. Refer to figures 6.4 and 6.5 for installation and removal of the handpiece delivery system. When not in use, the delivery systems should be stored in the supplied plastic case with the plastic caps over the ends of the fiber.

Removing the Delivery System:

1. Remove the Valve Control by grasping the connector near the red dot and pulling 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 delivery system into supplied storage case with plastic end caps on the fiber for protection.

Connecting the Handpiece Delivery System:

1. To install the Fiber-optic:
   a. Carefully insert the Fiber-optic Connector into the Fiber-optic Receptacle until it clicks in or stops.

CAUTION!

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

2. 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.
3. 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.

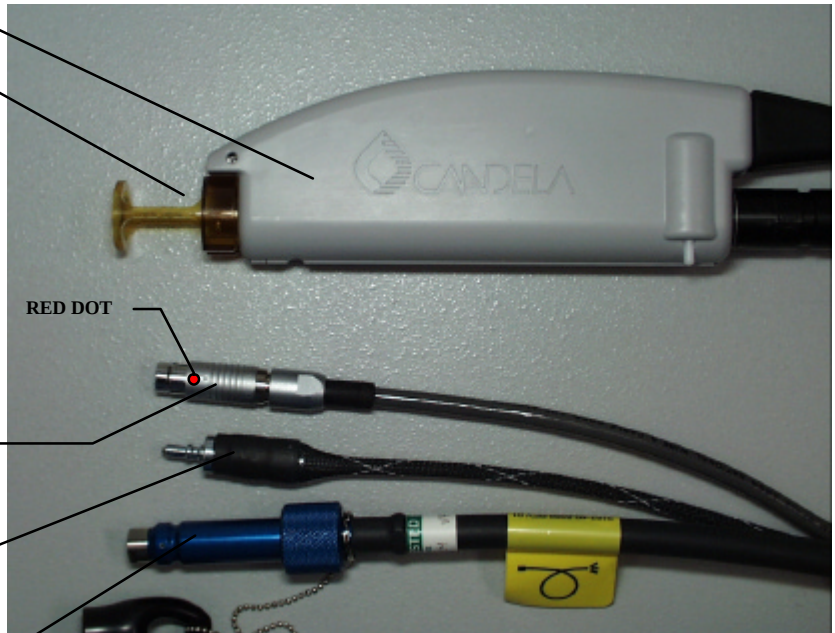


Figure 6.4
Handpiece Delivery System Close-up

Figure 6.5
Control Panel Close-up

CRYOGEN 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.

Additionally, once the canister is installed, the canister count must be reset. If the newly installed canister is at room temperature or cooler, a 20 - 25 minute WARM-UP period will be needed prior to use. The WARM-UP screen will appear once the laser is switched to the READY state if additional warming is required.

CANISTER WARMER

A canister warmer is available and may be used to hold canisters and minimize the warm –up period..

CRYOGEN LEAK

If a major cryogen leak occurs, disconnect the delivery system from the laser or remove the canister from the laser. Ventilate the room thoroughly and call Service to correct the problem.

For additional information, refer to the MSDS sheets supplied with each cryogen canister.

DISPOSAL

Disposal of the canister can be achieved by contacting a waste disposal company. Alternatively, the canister may be emptied following the instructions that come with each canister and disposing in the trash.

USER VERIFICATION TESTS

Overview of Tests:

This section contains information regarding three tests. Each test should be performed for the indicated hand pieces 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 tests 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 1301-00-8291 included in the accessory kit supplied with the laser.
- VPYAG distance gauge.

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 Air Bubble Detector: Verifies that air bubbles in the cryogen line are detected and the associated “fault” message is displayed on the system.

Test #1 Cryogen Alignment

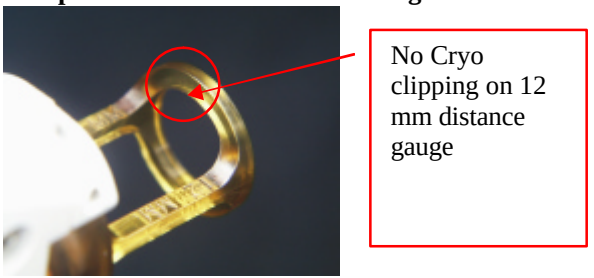
Purpose:
To verify the cryogen spray nozzle is properly aligned with the distance gauge ring. This procedure is for all delivery systems.

Procedure:

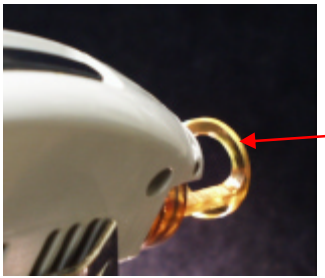
1. Put the laser in "standby". Caution- laser should remain in "Standby" mode for duration of test
2. Select "DCD –on".
3. Install GentleYAG 12mm distance gauge PN 7122-00-3109. The 1.5/3 mm handpiece must be set at the 3 mm spot size.
4. Select 30ms of DCD Spray.
5. Point hand piece away from objects and personnel (toward the floor). View the contact ring of distance gauge, looking from the hand piece.
6. Press 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.

Acceptable No mist on contact ring



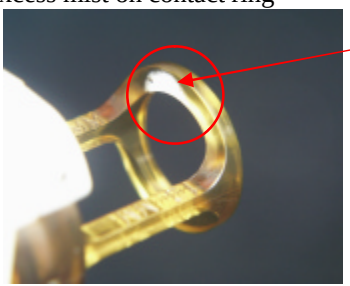
Acceptable
Small amount of mist on contact



Small Cryo clipping on 12 mm distance gauge

Unacceptable results

Excess mist on contact ring



Cryo clipping on 12 mm distance gauge

Results

Acceptable alignment- no further action needed

Unacceptable alignment, repeat the test with a different distance gauge.

Repeat test results

If the test shows acceptable alignment with the new distance gauge, discard the original distance gauge.

If the result is still “unacceptable”, replace hand piece or contact Candela Technical Support.

Test #2 - Cryogen Coverage:

Purpose:

To verify the proper spray duration required to fill the distance gauge ring. (Note: the distance gauge ring is larger than the spot size marking). Table 6-1 shows the available distance gauges for the GentleYAG laser system.

Table 6-1
Available Distance Gauges

GentleYAG Distance Gauge	Part Number
1.5mm	7122-00-3556 (small)\ 7122-00-3561 (large)
3mm	7122-00-3535 (small) 7122-00-3534 (large)
8mm	7122-00-3502
10mm	7122-00-3503
12mm	7122-00-3109
15mm	7122-00-3504
18mm	7122-00-3505

Note: The part numbers shown for the 8 mm to 18 mm distance gauges are for packages of 5 distance gauges.

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.
If you use multiple delivery systems, these checks should be made utilizing the smallest and largest distance gauge for each delivery system.

Procedure:

1. **Put on appropriate laser safety glasses**
2. Put the laser in "Standby" Caution- laser should remain in "Standby" mode for duration of test.
3. Select "DCD –on".
4. Install appropriate distance gauge from Table 6.2 below.
5. Select "Spray Duration" shown in Table 6-2.
6. Place hand piece distance gauge over desired distance gauge spots on the template (1301-00-8291). For 6 mm to 18 mm spot sizes, use the 8 mm to 18 mm spots on the template in the area listed for GL/GYAG Family Spot Sizes. For the 1.5 mm and 3mm spot sizes, use the distance gauges with the small treatment ring. Place the distance gauge over the 5 mm spot on the template in the area listed as Vbeam Spot Sizes.
7. Press purge button.
8. Remove hand piece QUICKLY from template**.**

9. 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.

Table 6-2
Spray Settings for Fill Test

Distance Gauge Spot Size	Spray Duration Setting
1.5 mm (small)	30 ms
3 mm (small)	30 ms
8 mm	30 ms
10 mm	30 ms
12 mm	40 ms
15 mm	50 ms
18 mm	60 ms

Note: Use the 8 mm distance gauge and 8 mm spot on the template when testing the 6 mm spot size.

Test #3 Cryogen Air Bubble Detection

Purpose:

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

Important: This procedure must be done with each GentleYAG handpiece delivery system in your possession. The subsystem being tested is inside of each delivery system, not in the laser 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 Electrical Connector installed, disconnect the Cryogen Connector (see Figure 3).

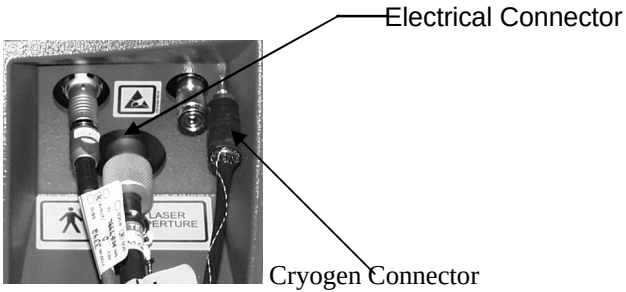


Figure 3 - Delivery System Connections

4. Set the DCD spray on the front panel to the highest setting.
5. Set the FLUENCE to the lowest setting (this varies by spot size).
6. Enter the “Ready” mode, and calibrate the laser by pressing on the footswitch.
7. Remove the handpiece from the CALPORT and aim in direction away from personnel (such as the floor).

8. Depress the footswitch to pulse laser continuously until a “PURGE REQUIRED” window box appears on the user screen and lasing ceases. This should happen in less than 50 pulses.

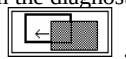
Results	Comments	Action
If you get “PURGE REQUIRED”	This particular handpiece passed the test	You may continue use of this handpiece
If “PURGE REQUIRED” does not occur	This particular handpiece failed the test	**Discontinue use of this handpiece and call Candela Tech Support** at (508) –358-7637 ex 336 or (800) –733-8550 ex 336

9. Reconnect the Cryogen Connector (see Figure 3) and press reset to use the system, or repeat the test on other GentleYAG handpiece delivery systems.

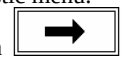
10. Depress “purge” may be required until the line is refilled.

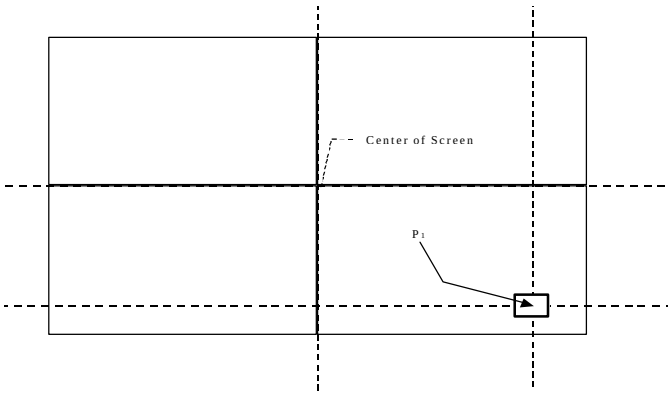
TOUCHSCREEN CALIBRATION PROCEDURE

The *GentleYAG* incorporates a routine to calibrate the touchscreen of the laser. This touchscreen calibration should only be performed when the touchscreen is not responding correctly.

The routine can be entered from the diagnostic menu of the laser by pressing the touchscreen calibration button.  .

NOTE: To access the diagnostic menu:

Press and hold the next button  for 3 seconds.



When the touchscreen calibration is initiated the screen is cleared and the following appears:

1) Using a cotton swab or small blunt tipped instrument press the center of the flashing box until it disappears.

2) A similar box will appear in the opposite corner of the screen. Repeat step 1.

3) Two smaller boxes will appear when steps 1&2 have been completed. Press both of these buttons until they disappear.

4) "TOUCHSCREEN Calibration Successful" will appear if the calibration is complete. If the calibration is unsuccessful, the system will return to step 1. This process will repeat 2 times.

5) If the calibration is not successful, software will use default parameters that will still allow use of your laser.

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 " " 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 Pre and Post spray settings are set to zero “O”.	Select the DCD Pre or Post spray and use the “up arrow” to increase the spray setting.

TROUBLE-SHOOTING

SITUATION / SYMPTOM	PROBABLE CAUSE or INDICATOR	SOLUTION
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 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 3 seconds to reset the canister count.

TROUBLE-SHOOTING

SITUATION / SYMPTOM	PROBABLE CAUSE or INDICATOR	SOLUTION
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 problem persists, call Service
Laser will not enter the READY state	Triggerswitch is depressed.	De-activate Triggerswitch
Aiming beam missing in the READY state	• Damaged or broken fiber • Bad aiming laser or driver circuit	• Replace delivery system • Otherwise call for service.

TROUBLE-SHOOTING

SITUATION / SYMPTOM	PROBABLE CAUSE or INDICATOR	SOLUTION
Aiming beam appears dim	• Intensity set too low • Dirty distance gauge and/or slider windows • Dirty or damaged slider optics • Failing aiming laser	• Set aiming beam intensity using button provided on "NEXT" screen • Clean or replace windows Otherwise call for service.
Aiming beam appears non-uniform	• Dirty distance gauge and/or slider windows • Dirty or damaged slider optics • 1.5 mm distance gauge not installed properly on end of slider	• Clean or replace windows • Replace delivery system

FAULT / 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 Candela Service and report the Fault Number. Fault processing automatically places the system into the Standby state. The following conditions are considered outside of 'normal' system operation and will display a warning or fault message

.

FAULT	#	DESCRIPTION
1 – BUBBLE DETECT CIRCUIT FAULT	1.1	HP Bubble Circuit Test didn't detect a change in the signal (with DCD-enabled HP).
	1.2	Canister Bubble Circuit Test didn't detect a change in the signal (with DCD-enabled HP).
2 – ROM CHECKSUM	2	Calculation of checksum at power-up does not match checksum value in memory.
3 – ROTARY SOLENOID FAULT	3.1	Shutter isn't in correct state when checked. Does not respond to actuation to correct state.
	3.2	Aperture isn't in correct state when checked. Does not respond to actuation to correct state.
4 – HVPS FAULT	4.1	HVPS reported a fault (Watch dog time-out)
	4.2	HVPS Communications Time-out

5 – HV TOLERANCE FAULT	5.1	CAL completion HV sample to Ready entry HV smp not within +-3% at End of Charge (EOC) OR HV Reference and HV sample not within +-5% at End of Charge
	5.2	No EOC signal present within 3 secs after HV setting
	5.3	No EOC signal present after DCD pre-spray already occurred.
6 – CALIBRATION FAULT	6.2	Expected Head Energy (xHD) is calculated > Max CAL HD Energy of 100 J.
	6.3	Laser failed to CAL to desired Fluence within 20 pulses.
	6.4	CAL required a HV > 1200V for desired Fluence.
7 – DI WATER SYSTEM FAULT	7.1	DI temp < 60degC when not in warm-up.
	7.2	DI temp > 70degC while in Ready state.
	7.3	DI pressure switch does not change when power turned on. OR DI pump is not ON or DI pressure switch not actuated.
	7.4	DI temp < Thermistor Open Temperature (5) OR DI temp > Thermistor Shorted Temp (98) while in Ready state
8 – DCD SYSTEM FAULT	8.1	DCD pressure < 105 psi while in READY & INT_DCD & HP w/DCD & spray setting is non-zero.
	8.2	DCD Pressure > 135 psi & INT_DCD
	8.3	DCD Valve Current was not detected while spraying

9 – WARM-UP TIMEOUT	9.1	DI temperature < 62degC after 60 minute warm-up
	9.2	DCD pressure < 105psi after 60 minute warm-up (Only when DCD enabled)
10 – DELIVERY SYSTEM FAULT	10.1	HP type changed or unrecognized while in Ready
	10.4	Fiber not detected while in Ready
	10.5	Slider button pressed while in Ready State. Cannot change spot-size while in Ready.
12 – ENERGY OUT OF RANGE FAULT	12.1	On last treatment pulse, the head energy (HD) was 14% lower than expected head energy (xHD).
	12.2	On last treatment pulse, the head energy (HD) was 14% higher than expected head energy (xHD).
	12.3	The head energy (HD) of the last pulse > Max Treatment HD Energy of 105J.
	12.4	The HD total energy is not evenly balanced between each subpulse (+-20%)
13 – TRIGGER SWITCH FAULT	13	The redundant trigger switches were in two different states for > 1 second while in ready.
14 – SIMMER FAULT	14	The simmer did not start or dropped out while in ready.

15 TRANSMISSION FAULT	15.1	Transmission (Tx) is < 70% w/HD or CP energy >1.5J (Aper < 30% w/HD>6J or CP energy>2.5)
	15.2	Transmission (Tx) is > 100% w/HD or CP energy >1.5J (Aper >50% w/HD>6J or CP energy>2.5)
18 CIRCUIT CAL FAULT	18.1	HD CktCal Test Energy incorrect or chksum corrupt.
	18.2	DI Factor chksum corrupt
	18.3	DCD Factor chksum corrupt
19– MODULATOR FAULT	19.1	IGBT Trigger Fault
	19.2	7875uf capacitor charge status incorrect
	19.3	Lasing Timer Fault
	19.4	Lasing Power Fault
	19.5	HV Dump Fault

Warning Messages

Replace Can (Only with DCD Option)	Canister pulse count reaches zero “0”, or when air detected at the canister.	Replace DCD canister & reset canister counter when ever this message appears.
Purge (Only with DCD Option)	Air was detected in the cryogen lines. Bubble percentage is outside of tolerable range (~15% bubbles)	With handpiece removed from the calibration port, depress the purge button until the message clears.
Exit to Clean Window	Delivery System Transmission is low. Transmission is < 75% - Delivery system degrading -	Examine HP Slider window. If necessary, clean or replace window.

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

Section 7

Labeling Symbols

LABELS

The *GentleYAG* 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.

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 on/off mains switch. The mains switch should be placed in the "0" position when the system is not being used. When the system is to be used, the mains switch must be moved to the "1" position.

See the following figures for label locations:

Label 1 Indicates to the user that precautions for handling "Electrostatic Sensitive" device are applicable for the nearby delivery system connector. This label is required by agencies to indicate static sensitive connections, where electrostatic discharge could potentially damage components of a labeled connection. The user should take anti-static precautions prior to accessing this connection. Such precautions include simply discharging one's body to a known grounded point prior to making a connection to the delivery system connector. A good grounding point is the fiber receptacle. The label is located near the delivery system connections.

Label 2 Multi-combined label. Label is located near the delivery system connections.

A. The “Man” indicates that the delivery system is equipped with a “Type B” applied part.

B. Indicates the emission of laser energy from this device.

C. Indicates this is the laser aperture.

Label 3 The Emergency Laser Stop Red Push Button will turn off the laser quickly. Located on front display bezel.

Label 4 This label indicates that the protective panel encloses Class 4 laser light. Label located on rear side of top cover.

Label 5 Multi-combined label. Label is located on rear panel above AC input receptacle.

A. Indicates that accompanying documents contain electrical connection information. That information will be found in the Electrical Requirements section of this manual. Label is located on rear panel above AC input receptacle.

B. Indicates Footswitch control hose connection.

C. Indicates the location of the remote interlock circuit that can be connected to a door switch to shutdown 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.

Label 6 Risk of electrical shock if serviced by unauthorized persons. There are lethal voltages inside the system enclosure. Label is located on rear panel.

Label 7 Indicates a hot surface when unit is powered. The hot surface warning applies strictly to the water in the water reservoir; which is only accessible when the water reservoir cap is removed. Label is located on top surface of the reservoir cover.

Label 8 Indicates that the reservoir is filled with water. The reservoir should be kept full to the base of the filler neck with distilled water. The label is located on top surface of the reservoir cover.

Label 9 Laser Identification label. 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. This label is located on the rear panel.

Label 10 Multi-combined label. Located on lower rear panel.

A. Indicates laser emission characteristics and classification per the IEC/EN standards.

B. Indicates that this device emits laser energy.

C. CE mark with 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.

D. Indicates compliance with a branch of the US FDA which regulates laser equipment. *GentleYAG* has one labeling deviation pursuant to Laser Notice No. 50, dated July 26, 2001, where the "Danger" label required by 21 CFR 1040.10 (g) was replaced with a label bearing the same technical content defined under IEC/EN 60825-1.

E. Indicates U.S. patents that may be covered on this laser system.

Label 11 If present, indicates that the laser is approved to UL or ETL standards.

Label 12 Indicates that the laser can be a mechanical tilt hazard; if the laser were not kept upright.

Label 13 (DCD option only) Indicates a hot surface when unit is powered. The hot surface warning 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 is located on top cover near DCD opening.

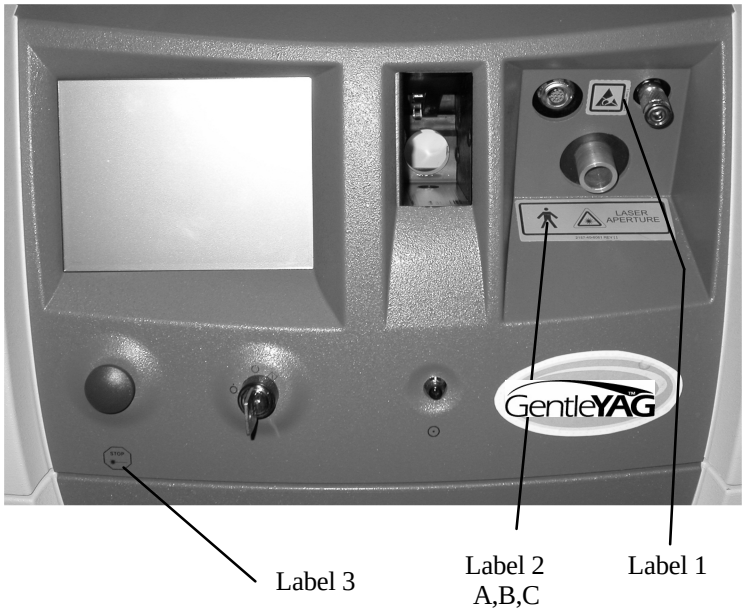
Label 14 International symbol indicating that laser light will be exiting from the distal end of this cable. This label is wrapped around fiberoptic cable near system connections.

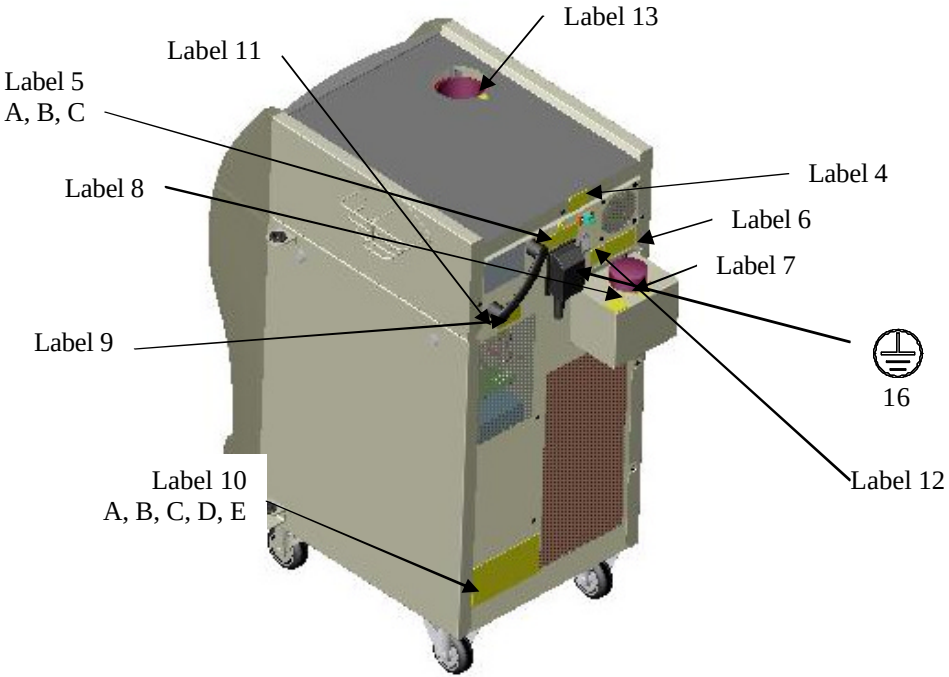
Label 15 Handpiece delivery system identification information. Wrapped around electrical cable near system connections.

Label 16 Safety ground symbol. This symbol located on the power cord entry box tab indicates the location of the primary system safety ground. The screw adjacent to this symbol should never be tampered with or removed.


GentleYAG

Label Locations




Label 13
Label 11
Label 5
A, B, C
Label 8
Label 4
Label 6
Label 7
Label 9
16
Label 10
A, B, C, D, E
Label 12


Label 13

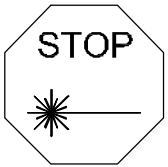
Label Locations

Label Identification

1

2-A,B,C

Label Identification



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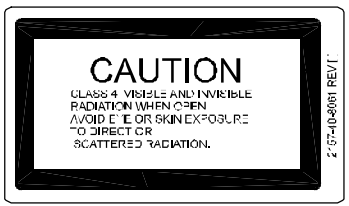
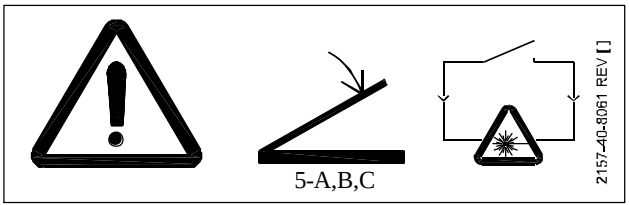
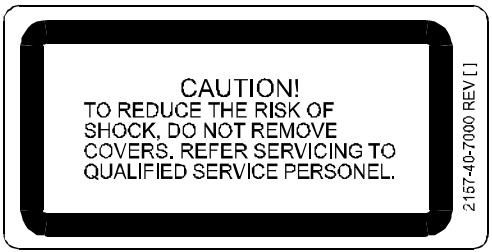


4


2157-40-8061 REV [ ]

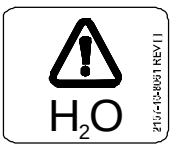
5-A,B,C


CAUTION!
TO REDUCE THE RISK OF
SHOCK, DO NOT REMOVE
COVERS. REFER SERVICING TO
QUALIFIED SERVICE PERSONEL.
2157-40-7000 REV [ ]

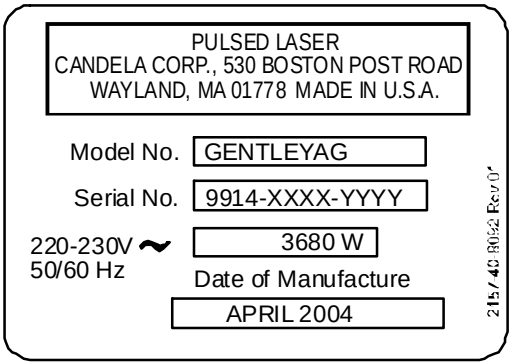
6

Label Identification

7 and 13

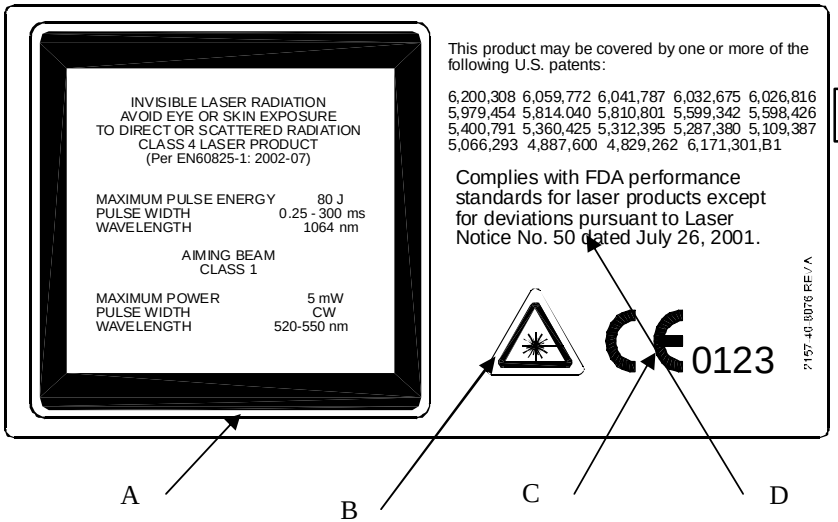


8


PULSED LASER
CANDELA CORP., 530 BOSTON POST ROAD
WAYLAND, MA 01778 MADE IN U.S.A.
Model No.
GENTLEYAG
Serial No.
9914-XXXX-YYYY
220-230V
50/60 Hz
3680 W
Date of Manufacture
APRIL 2004

9

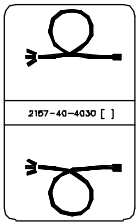
Label Identification



E

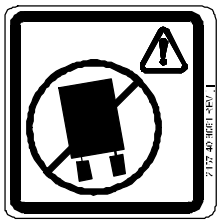
10-A,B,C,D,E

Label Identification



14

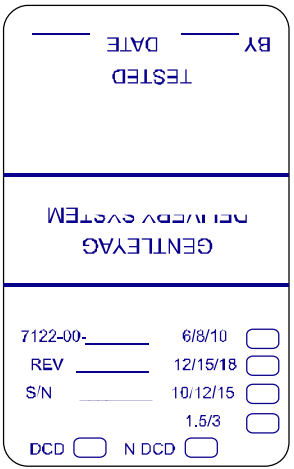
11



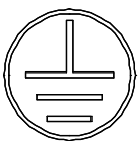
12

Label Identification

15



16



Mains Power Symbols

The mains power switch is Located on rear of the system and is marked with "¦ " and " O ".
The "¦ " indicates the switch position in which the system is connected to the mains.
The " O " indicates the switch position in which the system is disconnected from the mains.

The  on the ID label indicates that the system operates on alternating current.

Keylock Switch Symbols

The keylock switch symbol  means “off” only for a part of equipment. When the keylock switch is in this position, all circuits have been de-energized with the exception of the keylock switch circuit itself.

The keylock switch symbol  means “on” only for a part of equipment. When the keylock switch is in this position, all circuits are energized and the device will be fully functional.

The keylock switch symbol  means “start”. This is a spring-loaded keylock switch position. It is used to initiate the system operation. This position does not initiate the release of laser energy.


GentleYAG

Section 8

Accessory List

Packing List

Description	**Quantity**
Note: Items with * are not included with the LE System	
GentleYAG (or GentleYAG LE)Laser System	1
Fiber Pole	1
Footswitch (15 foot)	1
8 mm Distance Gauge Kit*	1
10 mm Distance Gauge Kit	1
12 mm Distance Gauge Kit	1
15 mm Distance Gauge Kit	1
18 mm Distance Gauge Kit*	1
Accessory Kit (includes)	1
• 1.5mm Distance Gauge (small)*	1
• 1.5mm Distance Gauge (large)*	1
• 3mm Distance Gauge (large)*	1
• 3mm Distance Gauge (small)*	1
• Treatment Guidelines	1
• Operator's Manual	1
• Eyewear Selection Table	1
• Replacement Window Kit (Qty 25)	1
• Label Kit	1
• Physician Spectacle	1

Packing List (continued)

Description	Quantity
• Physician Goggles	1
• Patient Goggle	1
• Key Ring w/Candela Tag	2
• Canister Empty Valve	1
• Laser Warning Sign	1
• Service Information Label	1
• CE Declaration of Conformity	1
• EC Certificate	1

Available Options:

Description	
No DCD Option (includes)	
• 1.5/3mm Delivery System without DCD	1
• 6/8/10 mm Delivery System w/o DCD	1
• 12/15/18 mm Delivery System w/o DCD	1
Marketing Kit	

Available Options (continued)

Description

DCD Option (includes)

- DCD Unit 1
- 1.5/3mm w/ DCD Delivery System 1
- 6/8/10 mm w/DCD Delivery System 1
- 12/15/18 mm w/DCD Delivery System 1
- 12 Pack of Cryogen 1

DCD Canister Warmer

LE No DCD Option (includes)

- 10/12/15/ mm Delivery System w/o DCD 1

LE DCD Option (includes)

- DCD Unit 1
- 10/12/15 mm w/DCD Delivery System 1
- 12 Pack of Cryogen 1

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 GENTLEYAG CAN BE EXTREMELY DANGEROUS IF PROPER SAFETY PRECAUTIONS ARE NOT TAKEN. THE GENTLEYAG LASER 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.

INTERNAL 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 high voltage level necessary to provide the correct delivered energy for the currently selected energy density 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 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 10mJ. This procedure is part of the normal preventive maintenance service procedure.

There are five major steps that must be done to complete this procedure properly:

1. Starting the Circuit CAL procedure
2. Laser Head (HD) Circuit CAL (0-120J, 0-20J ranges)
3. Cal Port (CP) Circuit CAL (0-120J, 0-20J ranges)
4. Verification of Circuit CAL factors
5. Final verification of User Calibration Energy

PARTS LIST

1. Energy meter (OPHIR with L40(150)A head)
2. A known good 10/12/15mm or 12/15/18mm Delivery System with a clean window.

CAUTION!

Make sure all personnel in the area are wearing safety eyewear appropriate for the GentleYAG.

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 Customer Service for further information.

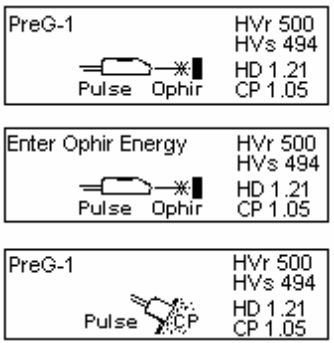
Once the Circuit CAL procedure has been started, the previously saved CAL parameters will be erased. The Circuit CAL procedure must be completed in order to use the laser for treatment again.

INTERNAL CALIBRATION

STARTING THE CIRCUIT CAL PROCEDURE

1. Set the DCD prespray and postspray to 0. From the Main screen, go to the Laser Variable Mode (LVM) screen by pressing and holding the Next Screen (right arrow) button for at least two seconds.

2. Press the Circuit CAL button  and a pop-up keypad will appear. Enter the eight digit access code of 12357111. The Circuit CAL screen should now be shown.



3. Install a GENTLEYAG 12/15/18 delivery system. (For an LE system, use the 10/12/15 delivery system.) Set the slider for 15 mm.

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

4. There are 3 typical icon screens (shown at left) that are displayed during each of these Circuit Cal's and they are described below.
   1) Pulse into the Ophir meter
      Pulse once when the HVr and HVs voltages are within 20V of each other.
      The handpiece is directed into the Ophir meter
   2) Enter the Ophir energy using keypad
      Always enter to two decimal places.
   3) Pulse into Cal Port

   Note the HVr (reference or set voltage), HVs (sample or actual voltage), HD (Laser Head energy [J]), CP (Cal Port energy [J]) are displayed to the right of each screen.

LASER HEAD (HD) CIRCUIT CAL (0-120J, 0-20J RANGES)

The Circuit CAL basically pulses the laser into an external meter and then into the systems Cal Port at a low and high energy to calculate a slope and offset difference between the two. There are three steps that are completed during the 0-120J Circuit CAL. First, the energy measurement circuit pregain (PreG) is measured at a low energy, then a low point (LoPt) energy is measured, and finally a high point (HiPt) energy is measured to allow for calculation of the

slope and offset. The 0-20 Circuit CAL uses the pregain from the 0-120J range so only requires the LoPt and HiPt measurements.

5. Press the "**0-120J**" button beneath the "**HD**" column for 1 second to begin the HD circuit calibration procedure. The system enters Ready automatically.

6. The screen will prompt the user (with Icons) when to pulse the laser into the Ophir energy meter, when to enter the Ophir meter reading (using the keypad), and when to pulse into the calport.

   NOTE: Set the Ophir meter on the 30J range. After completing the LoPt, change the Ophir meter to the 100J range.

7. On completion, the laser "dumps" (popping sound) the stored energy and the screen displays "SUCCESSFUL HD CAL"

8. Press the "**0-20J**" button beneath the "**HD**" column for 1 second to begin the HD circuit calibration procedure.

9. The screen will prompt the user (with Icons) when to pulse the laser into the Ophir energy meter, when to enter the Ophir meter reading (using the keypad), and when to pulse into the calport.

   NOTE: Set the Ophir meter on the 30J range for this entire CAL.

10. On completion, the laser "dumps" (popping sound) the stored energy and the screen displays "SUCCESSFUL HD CAL"

CAL PORT (CP) CIRCUIT CAL (0-120J, 0-20J RANGES)

The Circuit CAL basically pulses the laser into an external meter and then into the systems Cal Port at a low and high energy to calculate a slope and offset difference between the two. There are three steps that are completed during the 0-120J Circuit CAL. First, the energy measurement circuit pregain (PreG) is measured at a low energy, then a low point (LoPt) energy is measured, and finally a high point (HiPt) energy is measured to allow for calculation of the slope and offset. The 0-20 Circuit CAL uses the pregain from the 0-120J range so only requires the LoPt and HiPt measurements.

11. Press the "**0-120J**" button beneath the "**CP**" column for 1 second to begin the CP circuit calibration procedure.

12. The screen will prompt the user (with Icons) when to pulse the laser into the Ophir energy meter, when to enter the Ophir meter reading (using the keypad), and when to pulse into the calport.

    NOTE: Set the Ophir meter on the 30J range. After completing the LoPt, change the Ophir meter to the 100J range.

13. On completion, the laser "dumps" (popping sound) the stored energy and the screen displays "SUCCESSFUL CP CAL"

14. Press the "**0-20J**" button beneath the "**CP**" column for 1 second to begin the CP circuit calibration procedure.

15. The screen will prompt the user (with Icons) when to pulse the laser into the Ophir energy meter, when to enter the Ophir meter reading (using the keypad), and when to pulse into the calport.

    NOTE: Set the Ophir meter on the 30J range for this entire CAL.

16. On completion, the laser "dumps" (popping sound) the stored energy and the screen displays "SUCCESSFUL CP CAL"

VERIFICATION OF CIRCUIT CAL FACTORS

The Circuit CAL for all internal energy circuits has now been completed. The energy circuit factors should be verified prior to exiting the Circuit CAL screens. The Factors screen displays all the pertinent Circuit CAL factors as well as provides a Test button to ensure that the Circuit CAL's were done properly.

17. Press the Factor button.

18. Verify the pregain is not exactly 15000, and is between 12000 and 25000.

19. Verify that the slope (m factor) for both ranges of the HD and CP are 1 +-10% and that the offset (b factor) for both ranges of the HD and CP are 0 +-15%.

20. Verify the Aper Factor is 0.700 +-20%.

21. Press the Test button. Verify that "Pass" is displayed in all eight locations.

22. If any of these verifications fails, the Circuit CAL needs to be repeated. If it fails more than once, then contact Candela Customer Service for service.

FINAL VERIFICATION OF USER CALIBRATION ENERGY

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

23. Press the Exit button. This will return the user to the Main user screen.
24. Complete the following Calibrations using the specified spot size, fluence, and pulse width from the tables below. After each Calibration, enter Ready and Pulse 3 times into the Ophir meter. Record each Ophir energy.
25. Calculate the Average Ophir energy and then the %difference from the expected energy.
26. Verify the % 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 Customer Service for service.

15mm, 6.0J/cm2, 3ms Expected Energy = 10.6J		15mm, 44.0J/cm2, 3ms Expected Energy = 77.7J	
Pulse #	OPHIR Energy, J	Pulse #	OPHIR Energy, J
1		1	
2		2	
3		3	
Avg		Avg	
%Diff		%Diff	

The following test is not required for “LE” systems.

10mm, 6.0J/cm2, 0.50ms Expected Energy = 4.7J		10mm, 12.0J/cm2, 0.50ms Expected Energy = 9.4J	
Pulse #	OPHIR Energy, J	Pulse #	OPHIR Energy, J
1		1	
2		2	
3		3	
Avg		Avg	
%Diff		%Diff	

27. Circuit Calibration is complete; the laser can safely be used.