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GentleMax Pro® Plus



System User Manual

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GentleMax Pro Plus Laser System Operator's Manual

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NO UNAUTHORIZED MODIFICATION OF THIS PRODUCT IS ALLOWED.

CAUTION

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

CAUTION

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CAUTION

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

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In case of any potential adverse reactions arising from the treatment, contact Candela at Toll Free: 1-(800) 73–LASER Customer Service and the regional competent authority.

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Preface

Welcome to the Candela Corporation GentleMax Pro Plus Laser System Operator's Manual.

This GentleMax Pro Plus is a 755nm and 1064nm laser system. Note that some of the images you will see in this manual may show components that are a different color than your GentleMax Pro Plus system, but any differences are only aesthetic in nature.

Intended Audience

Only qualified personnel, who are fully trained in the proper use of the system and are informed of all system safety hazards should operate, maintain or troubleshoot this equipment.

The target patient population are the ones presenting with indications that are listed under "Indications for Use" on page 27.

Conventions

This guide uses the following conventions:

Text Conventions

- **Bold** – Indicates software screen names and items (buttons, fields, tabs, and so on).
- Consecutive numbers indicate steps of action which must be followed in sequential order.
- Bullets indicate listing of data, options, or objects in no particular order.
- Cross-references indicate the location of additional information regarding the chosen topic. References may include figures, tables, and headings on specific pages or entire chapters.

Warning, Caution, and Note Conventions

WARNING

WARNS THE USER REGARDING ACTIONS THAT MAY RESULT IN PHYSICAL DAMAGE TO THE SYSTEM OR PERSONAL INJURY.

CAUTION

Cautions the user regarding actions that may result in operational issues or data loss.

NOTE: Identifies important points, helpful hints, special circumstances, or alternative methods.

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Safety

Follow this Operator's Manual

To maintain patient safety, read and follow all warnings, cautions and notes listed in this operator's manual, on equipment labels, and instructions for any accompanying accessories used in conjunction with the GentleMax Pro Plus laser system.

Site of Operation

Space Requirements

NOTE: Installation of the laser system 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 system. An in-depth clinical training is required of a physician and any operator under the direction of the physician to become proficient in the use of the GentleMax Pro Plus laser system.

NOTE: Treatment rooms associated with the use of Cryogen require special precautions. Refer to the "Chemical Hazards" on page 17 and to MSDS (Candela Part Number 8501-00-1701) for General Treatment Area Guidelines.

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

NOTE: Avoid placing the laser system near heating outlets or other sources of air currents that could cause uneven cooling in the laser system.

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Air Quality

NOTE:

- **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.**

Relocation



WARNING

DO NOT USE THE FIBER POLE OR DELIVERY SYSTEM AS A HANDLE TO LIFT OR MOVE THE LASER SYSTEM. THEY WERE NOT DESIGNED TO BE USED AS HANDLES TO SUSTAIN THE WEIGHT OF THE LASER SYSTEM FOR RELOCATING.

NOTE: Care should always be taken when moving the GentleMax Pro Plus laser system. Before moving the laser system, disconnect the footswitch tubing from the connector located on the rear panel of the laser system and the delivery system from the front of the laser system (place the delivery system into its original box for transportation if necessary). 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.

NOTE: If it becomes necessary to relocate the laser system, contact a Candela Service Representative for details. Failure to do so may result in personal injuries or damage to the system and may void any warranty.

Mobile Use

The GentleMax Pro Plus laser system is not designed for mobile use.

Precautions

- Identify the laser room clearly. Post appropriate warning signs in prominent locations at all entrances to the laser room.

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- It is recommended that all windows be opaque or covered. All reflective surfaces must also be covered or removed.
- When the GentleMax Pro Plus laser system is in operation, restrict entry and limit access to the laser room only to personnel that are both essential to the procedure and well trained in laser safety precautions.
- Make sure that all laser room personnel are familiar with the laser system controls and know how to shut down the laser system instantly in an emergency.

CAUTION

- **Avoid the use of flammable anesthetics or oxidizing gases, such as nitrous oxide and oxygen. The high temperature produced during normal use of the laser system may ignite some materials, for example, cotton or gauze pads when saturated with oxygen.**
- **Allow solvents or adhesives and flammable solutions, used for cleaning and disinfecting, to evaporate before the laser system is used.**
- **Pay close attention to the danger of ignition of endogenous gases.**

Flash Fire Hazards

WARNING

DO NOT USE PRODUCT IN AN OXYGEN-RICH ENVIRONMENT.

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

- Oxygen is administered through a mask, endotracheal tube, or nasal cannula. Leakage of oxygen generally occurs near the eye region where a tight seal of the mask is difficult to maintain, near the nasal area when a cannula is used, or near the mouth when an endotracheal tube is used.
- An oxygen-rich atmosphere is created and dissipates over the face. Transient local concentrations of oxygen can greatly accelerate combustion.
- During treatment, the laser beam strikes combustible material which absorbs the laser energy and heats the material above its combustion point. This may occur simply by singeing the tip of a single dry hair.
- 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.

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- 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 by-products 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 GentleMax Pro Plus laser system can be extremely dangerous and should be serviced only by qualified technicians who have received appropriate training on the GentleMax Pro Plus laser system from Candela.

Optical Precautions and Hazards

WARNING

ALL PERSONNEL IN THE VICINITY OF THE LASER MUST KEEP EYEWEAR ON AT ALL TIMES DURING TREATMENT PROCEDURE.

Laser Eye Hazards and Safety Eyewear

CAUTION

Use only safety eyewear with an optical density of ≥ 6.7 for 755 nm and eyewear with an optical density of ≥ 6.5 for 1064 nm. Safety eyewear that is designed for use with other laser systems may not provide adequate protection. Please use the dual wavelength eyewear supplied with the system.

The laser beam emitted by the GentleMax Pro Plus laser system is capable of causing loss of vision. The laser system operates at 755 nm and 1064 nm, which do not fall within the visible spectrum. The cornea and lens of the eye are transparent to invisible light. Any energy emitted by the GentleMax Pro Plus laser system that enters the eye will be focused directly on the retina. Direct contact of the laser beam on the retina can cause temporary clouded vision, retinal lesions, long-term Scotian (vision absence in an isolated area), long term photo-phobia (sensitivity to light), or loss of vision.

Nominal Ocular Hazard Distance

The laser aperture of the GentleMax Pro Plus laser system is at the distal end of the handpiece. The beam enlarges as the distance from the handpiece increases. The Nominal Ocular Hazard Distance (NOHD) is the distance at which the beam is so big it is no longer dangerous to the unprotected eye. The Maximum Permissible Exposure (MPE) is the fluence

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value at which the beam is no longer dangerous to the unprotected eye. It is the fluence value at the NOHD. It is also the value used to calculate the optical density (OD) of the laser safety eyewear.

Table 1 provides this NOHD along with the full angle beam divergence and the MPE for each laser wavelength.

To avoid vision hazards, everyone within the NOHD of the GentleMax Pro Plus laser system must wear appropriate eye protection available from Candela.

CAUTION

The laser beam emitted by the GentleMax Pro Plus laser system should never be directed at any part of the body other than the intended site of treatment or testing.

NOTE: The MPE values refer to the eyewear, not the NOHD.

Table 1 Vision Hazards GentleMax Pro Plus Laser System NOHD Zone and MPE

Spot Diameter (mm)	Beam Divergence Full Angle (radians)		NOHD (meters)		MPE (J/m^2)	
	755 nm	1064 nm	755 nm	1064 nm	755 nm	1064 nm
1.5 *	N/A	0.151	N/A	23	N/A	2.29
3 *	0.110	0.110	106	64	2.4	9.2
5 *	0.080	0.080	92	55	6.6	25.2
6	0.043	0.043	182	107	9.5	36.7
8	0.043	0.043	237	123	16.8	65.2
10	0.043	0.043	297	126	26.3	101.9
12	0.068	0.068	119	80	88.5	343.6
15	0.068	0.068	146	85	138.3	536.8
18	0.068	0.068	145	85	199.2	773
20 *	0.125	0.125	173	100	245.9	954.3
22 *	0.125	0.125	174	100	297.5	1154.7
24 *	0.125	0.125	173	101	354.1	1374.2
26 *	0.121	0.121	155	92	415.5	1612.8
3x10 *	0.076	0.076	282	148	7.9	30.6

(*) Optional spot sizes

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CAUTION

The laser beam emitted by the GentleMax Pro Plus laser system should never be directed at any part of the body other than the intended site of treatment or testing.

Optical Safety Precautions

Follow these precautions to ensure optical safety:

- Appoint one person responsible for the laser system controls during the procedure.
- Ensure that all personnel wear appropriate safety eyewear whenever the laser system is on.
- Never look directly into the laser beam, even when wearing protective eyewear.
- Never allow the laser beam to be directed at anything other than the targeted area or the calibration port.
- Never permit reflective objects such as jewelry, instruments or mirrors to intercept the laser beam.
- Never look directly into the delivery system handpiece unless the fiber cable is disconnected from the laser system.
- When the GentleMax Pro Plus laser system is not in use, place it in **Standby** mode to prevent accidental pulsing.
- When the GentleMax Pro Plus laser system is unattended, remove the key from the key-switch or use the password-protected lock button (see "Lock Button" on page 77) on the touch screen to prevent unauthorized use.

Electrical and Mechanical Hazards

WARNING

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

High Voltage Electrical Hazard

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

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Fiber Optics

The GentleMax Pro Plus laser system utilizes fiber optics that can be damaged if installed or subjected to excessive bending. To avoid damage to the fiber optics, limit bends of the fiber cable to a radius of 6 inches (15 cm) or greater. Failure to follow recommended procedures may lead to damage to the fiber cable or delivery system and/or harm to the patient or operator. When damaged, the fiber cable or delivery system becomes a potential fire hazard (see "Fire Hazards" on page 19).

Laser System Mobility Care and Wheel Locks

To prevent the laser system from moving, at least one of the front wheels must be locked. For instructions, see "Laser System Wheels" on page 54.

Although the GentleMax Pro Plus laser system is well balanced, it weighs at least 260 lbs (118 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 GentleMax Pro Plus laser system.

Cryogen

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

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

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

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Guidelines for Cryogen Treatment Rooms

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

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

General Treatment Room Guidelines

- The minimum treatment room size should be 5 x 8 ft or 40 sq. ft. (1.52 x 2.44 m or 3.71 m^2), based on an 8 ft. (2.44 m) ceiling. Any treatment area smaller than 513 sq. ft. (47.66 m^2), but larger than 40 sq. ft. (3.71 m^2), should have a 130 cubic feet per minute (CFM) or higher fan in use during treatments with Cryogen. It should be used in an exhaust mode. Since Cryogen is heavier than air, it will settle toward the floor. If at all possible, have the exhaust fan lower rather than at ceiling height. A smoke evacuator is not a substitute.
- All treatment areas should have cross ventilation. At least one ventilation opening should be at floor level. If at all possible, one ventilation opening should be to outdoors. Both opening sizes should be approximately the same area.
- Refer to MSDS sheet (Candela Part Number 8501-00-1701) for further information.

Frostbite Risks

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

Table 2 Frostbite Prevention in Treatment Rooms

Source of Cryogen Release	Visual outer edge of spray	Hand detection of outer edge of spray
Direct release from Cryogen canister	27" (686 mm)	31" (787 mm)
Release from tip of handpiece (spray nozzle)	19" (483 mm)	23" (584 mm)

For specific customer situations, contact a Candela Service Representative.

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Fire Hazards

Refer to the ANSI Z136.3 – 2011 - American National Standard for Safe Use of Lasers in Health Care Facilities and ANSI Z136.1 – 2007 - American National Standard for Safe Use of Lasers.

Treatment Area

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

Anesthetics

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

Instruments

Since laser energy is reflected by most shiny surfaces, all instruments used with the laser system should have brushed, burnished, or blackened, non-reflective surfaces.

Laser Fiber Fire Hazard

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

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

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Laser Generated Air Contaminants Hazards

Laser Plumes

Laser plume may contain viable tissue particulate.

Refer to the American National Standard for Safe Use of Lasers (ANSI Z136.3 – 2011), Section 7.4 Laser Generated Air Contaminants.

A mechanism for decreasing Laser Generated Air Contaminants (LGACs) should be used. Based on the type of condition being treated by the laser system, there may be a higher incidence of LGAC.

NIOSH Hazard Controls

Refer to 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 (https://www.cdc.gov/niosh/docs/hazardcontrol/hc11.html).

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

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Electromagnetic Interference

The GentleMax Pro Plus laser system is designed to have no degradation in essential performance or cause interference in the operation of other equipment when used in the EMC environment described in the following tables. Refer to the guidance in these tables for additional information.

A portion of IEC 60601-1-2 deals with measurements of unwanted radio frequency emissions generated from a product. Both radiated emissions (radiated through the air) and conducted emissions (conducted into the AC Mains) are measured. Radiated and conducted emissions from a product have been known to interfere with the performance of other equipment in the vicinity. The emissions from the GentleMax Pro Plus laser system have been reduced as far as practical without compromising functionality. Follow all maintenance guidelines and other guidance in this manual to ensure proper operation of the system.

WARNING

THE GENTLEMAX PRO PLUS SYSTEM IS EMC COMPLIANT WHILE USING THE CABLES AND ACCESSORIES LISTED IN APPENDIX C. THE USE OF ITEMS NOT LISTED IN APPENDIX C MAY NEGATIVELY AFFECT EMC PERFORMANCE.

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which (CISPR 11 class B is normally required) this equipment might not offer adequate protections to radio-frequency communications services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

WARNING

PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT (INCLUDING PERIPHERALS SUCH AS ANTENNA CABLES AND EXTERNAL ANTENNAS) SHOULD BE USED NO CLOSER THAN 30 CM (12 INCHES) TO ANY PART OF THE GENTLEMAX PRO PLUS AND ACCESSORY CABLES. OTHERWISE, DEGRADATION OF THE PERFORMANCE OF THE SYSTEM COULD RESULT.

If interference from the GentleMax Pro Plus 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 GentleMax Pro Plus laser system or the affected equipment into another room.

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WARNING

- **THE GENTLEMAX PRO PLUS LASER SYSTEM SHOULD NOT BE USED ADJACENT TO OR STACKED WITH OTHER EQUIPMENT. IF ADJACENT OR STACKED USE IS NECESSARY, THE EQUIPMENT SHOULD BE OBSERVED TO VERIFY NORMAL OPERATION IN THE CONFIGURATION IN WHICH IT WILL BE USED.**
- **WHEN TREATING PATIENTS WITH THE LASER SYSTEM AND USING THE DYNAMIC COOLING DEVICE (DCD) IN CONJUNCTION WITH AN ECG MONITORING DEVICE ATTACHED TO THE PATIENT, INTERFERENCE WITH THE ECG MONITORING DEVICE MAY RESULT.**
- **CARE MUST BE TAKEN WITH PATIENTS WHO HAVE AN IMPLANTED PACEMAKER. PACEMAKER MAY BE AFFECTED BY AN ELECTRICAL "PLASMA EFFECT" WHEN TREATING NEAR OR AT THE SITE OF THE IMPLANT.**

Table 3 Emission (IEC 60601-1-2, Section 7)

Emissions Test	Standard	Classifications	Compliance
Radiated emission Freq. range 30-1000 MHz.	CISPR 11	Group 1 Class A	Complies
Conducted emission Freq. range 150 kHz to 30 MHz.		Group 1 Class A 208/230 VAC 220 VAC 60HZ	
Harmonics current emission.	IEC 61000-3-2	Not Applicable	Exempted
Voltage changes, voltage fluctuations and flicker test.	IEC 61000-3-3		

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Table 4 Immunity (IEC 60601-1-2, Section 7)

Emissions Test	Standard	Classifications	Compliance
Immunity from Electrostatic discharge (ESD).	IEC 61000-4-2	8kV contact discharges & 15 kV air discharges.	Complies
Immunity from Radiated electro-magnetic fields.	IEC 61000-4-3	3.0 V/m 80 MHz ÷ 2.7 GHz, 80% AM, 1kHz.	Complies
Immunity from Proximity field from wireless communications equipment.	IEC 61000-4-3	List of frequencies (Table 9) from 9 V/m up to 28 V/m, PM (18 Hz or 217 Hz), FM 1 kHz.	Complies
Immunity from Electrical Fast transient (EFT).	IEC 61000-4-4	± 2kV on 230 VAC / 220 VAC 60 Hz Tr/Th – 5/50ns, 100 kHz.	Complies
Immunity from Surge.	IEC 61000-4-5	± 1.0kV DM / 2.0kV CM on 230 VAC / 220 VAC 60 Hz. Tr/Th – 1.2/50 (8/20) us.	Complies
Immunity from conducted disturbances induced by RF fields.	IEC 61000-4-6	3.0 & 6.0 V_{RMS} on 230 VAC / 220 VAC 60 Hz. Applicator cables 0.15 ÷ 80 MHz, 80% AM, 1kHz.	Complies
Immunity from power frequency magnetic field.	IEC 61000-4-8	30 A/m, 50 & 60 Hz.	Complies
Immunity from Voltage dips, short interruptions and voltage variations.	IEC 61000-4-11	Not Applicable.	Exempted

If interference from the GentleMax Pro Plus 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 GentleMax Pro Plus laser system or the affected equipment into another room.

WARNING

THE GENTLEMAX PRO PLUS LASER SYSTEM SHOULD NOT BE USED ADJACENT TO OR STACKED WITH OTHER EQUIPMENT. IF ADJACENT OR STACKED USE IS NECESSARY, THE EQUIPMENT SHOULD BE OBSERVED TO VERIFY NORMAL OPERATION IN THE CONFIGURATION IN WHICH IT WILL BE USED.

WARNING

WHEN TREATING PATIENTS WITH THE LASER SYSTEM AND USING THE DYNAMIC COOLING DEVICE (DCD) IN CONJUNCTION WITH AN ECG MONITORING DEVICE ATTACHED TO THE PATIENT, INTERFERENCE WITH THE ECG MONITORING DEVICE MAY RESULT.

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WARNING

CARE MUST BE TAKEN WITH PATIENTS WHO HAVE AN IMPLANTED PACEMAKER. PACEMAKER OPERATION MAY BE AFFECTED BY AN ELECTRICAL "PLASMA EFFECT" WHEN TREATING NEAR OR AT THE SITE OF THE IMPLANT.

Delivery System Precautions

WARNING

THE DELIVERY SYSTEM PASSING THE USER VERIFICATION TESTS ON PAGE 139 DOES NOT GUARANTEE THAT THE DELIVERY SYSTEM IS PROBLEM-FREE. DISCONTINUE USE OF THE LASER SYSTEM IF YOU SUSPECT A PROBLEM WITH IT.

WARNING

USE OF A DELIVERY SYSTEM/HANDPIECE WITH PROBLEMS COULD RESULT IN ADVERSE EFFECTS SUCH AS BURNS, SCARRING (HYPERTROPHIC OR ATROPHIC), OR HYPER/HYPOPIGMENTATION.

Do not use a dropped delivery system/handpiece until after testing. Dropping the delivery system can result in damage and can affect the life of the delivery system, calibration, Cryogen spray alignment, or bubble sense detection resulting in possible patient burns. If the delivery system is dropped, the user verification tests on page 139 must be performed before using the laser system.

NOTE: The laser beam alignment can be altered:

- by dropping a delivery system/related component
- by the laser beam passing through a burn spot or pits on the optics.

  A laser beam that is altered or misdirected could result in heating, charring, and possible ignition of associated components along with possible operator and patient burns. Purge faults could indicate an excessive heating problem.

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

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

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Treatment Related Precautions

WARNING

- **ALL PERSONNEL IN THE VICINITY OF THE LASER MUST KEEP EYEWEAR ON AT ALL TIMES DURING TREATMENT PROCEDURE.**
- **TILTING THE DISTANCE GAUGE CAN RESULT IN AN ELLIPTICAL ENERGY SPOT VERSES A CIRCULAR SPOT AND AFFECT THE DISTRIBUTION PATTERN OF THE CRYOGEN. THE DISTANCE GAUGE MUST BE HELD PERPENDICULAR TO THE TREATMENT SPOT OR CRESCENT BURNS ON THE PATIENT MAY OCCUR.**
- **OVERLAPPING OF TREATMENT SPOT SIZE AREAS MAY RESULT IN CRESCENT AND GENERAL PATIENT BURNS.**
- **SELECTING TOO SHORT OF CRYOGEN SPRAY DURATION FOR A GIVEN SPOT SIZE MAY RESULT IN PATIENT BURNS AND OTHER ADVERSE EFFECTS.**
- **FAILURE TO REPLACE THE CRYOGEN CANISTER WHEN THE "REPLACE CANISTER" MESSAGE APPEARS COULD RESULT IN PATIENT BURNS.**
- **FAILURE TO KEEP WINDOWS, SLIDER ATTACHMENTS, AND THE FIBER TIPS FREE OF DUST AND DEBRIS CAN LEAD TO POSSIBLE PATIENT BURNS.**
- **LASER ENERGY STRIKING DUST AND DEBRIS ON OPTICS INCLUDING FIBER TIPS WILL DAMAGE THEM WHICH COULD LEAD TO POSSIBLE PATIENT BURNS. WHEN COMPONENTS OF THE DELIVERY SYSTEM ARE NOT ATTACHED, SUCH AS THE FIBER CABLE OR SLIDER ATTACHMENTS, COVER THEM WITH SUPPLIED CAPS TO PREVENT DUST AND DEBRIS FROM COLLECTING ON AND IN THEM.**
- **FAILURE TO KEEP WINDOWS PROPERLY CLEAN MAY RESULT IN PATIENT BURNS.**
- **SEE PAGE 117 FOR DELIVERY SYSTEM AND WINDOWS CLEANING PROTOCOLS AND PAGE 147 FOR REPLACING PARTS PROTOCOLS.**
- **FAILURE TO RE-INSTALL WINDOWS PROPERLY AFTER CLEANING OR IMPROPER WINDOW INSERTION CAN RESULT IN FAILURE OF THE WINDOW AND MAY CAUSE PATIENT BURNS.**
- **WHEN REMOVING A WINDOW FOR CLEANING, CAREFULLY NOTE THE WINDOW SURFACE THAT WAS EXPOSED TO DEBRIS AND THE DIRECTION IN WHICH SUCH WINDOW SURFACE FACES. WHEN RE-INSERTING THE WINDOW, ENSURE THAT THE WINDOW SURFACE THAT WAS EXPOSED TO DEBRIS FACES THE SAME DIRECTION AS IT DID PRIOR TO REMOVAL.**

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Environmental Protection: Disposal Hazards and Guidance

Used Delivery System Accessories

Residues that accumulate on the delivery system windows and distance gauge during normal use may contain infectious viable tissue particulate. Under certain conditions, contact with viable tissue particulate can put an operator at risk for contracting disease. Therefore at the end of its useful life, the distance gauge, windows, and cleaning materials should be disposed of in a way that minimizes risk of exposure.

Such methods of disposal include, but are not limited to, disposal in a bio-hazard container (if available), incineration, or disposal as sealed waste in a plastic bag discarded with regular trash. Non-porous gloves should be worn during treatment and when servicing patient-contact parts to reduce risk associated with exposure. The gloves should be disposed of in the same manner as contact parts.

Laser System Components and Accessories

The Waste Electrical and Electronic Equipment (WEEE) Directive Label  on the rear of the laser system indicates that the GentleMax Pro Plus laser system and its components cannot be disposed of as regular trash; however, the canister can be disposed of as regular trash if it is emptied of all pressure. For information on purging the canister, see page 154. Contact a Candela Service Representative for disposal instructions.

Hazardous Material and Hazardous Waste

The DCD GentleCool Cryogen canister is classified as "pressure hazardous". It must be disposed of as hazardous waste or shipped as hazardous material. A canister may be vented to empty and then be disposed of in the trash as "non-hazardous" waste.

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



WARNING

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

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Intended Use

Indications for Use

For instructions on the specific applications and recommended treatment parameters for each indication, including treatment contraindications, precautions and patient selection, refer to the Candela Treatment Guidelines for the GentleMax Pro Laser System (Candela Document Part # 8502-00-1896).

The GentleMax Family of Laser Systems is indicated for the following at the specified wavelength:

755 nm

- Temporary hair reduction: stable long-term or permanent reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen. On all skin types (Fitzpatrick I-VI) including tanned skin.
- Treatment of benign pigmented lesions.
- Treatment of wrinkles.
- The photocoagulation of dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias).

1064 nm

- Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen. The lasers are indicated on all skin types (Fitzpatrick 1-VI) including tanned skin.
- Photocoagulation and hemostasis of pigmented and vascular lesions such as- but not limited to port-wine stains, hemangioma, warts, telangiectasia, rosacea, Venus lake, leg veins and spider veins, coagulation and hemostasis of soft tissue, Benign pigmented lesions such as, but not limited to lentigines (age spots), solar lentigines (sun spots), cafe-au-lait macules, seborrheic keratosis, nevi, chloasma, verrucae, skin tags, keratosis, tattoos (significant reduction in the intensity of black and/or blue-black tattoos) and plaques.
- The laser is indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

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- Treatment of wrinkles
- Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes, Trichophyton rubrum and T. mentagrophytes, and/or yeast Candida Albicans, etc.).

Pre-Treatment Preparation

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

Contraindications and Precautions

- **Accutane** – Wait 6 months after the completion of Accutane therapy.
- **Tattoos** – Do not treat tattooed skin, including decorative, permanent makeup, and radiation port tattoos.
- **Photosensitivity** – History of photosensitivity to 755 nm or 1064 nm light.
- **Pregnancy** – Refer to Candela Corporation Policy Number 0920-23-0814.
- **Seizure disorders** – Do not treat patients with a history of light-triggered seizures.
- **Medications** – Patients taking daily anticoagulation therapy, iron supplements, herbal supplements such as ginkgo, ginseng or garlic may bruise more readily.
- **Photo-sensitizing medications** – Medications that induce photosensitivity within or above the 755 nm or 1064 nm wavelength range. Refer to Candela Corporation Drugs That May Cause Photosensitivity, Part Number 0920-23-0011. Stop the medication if possible for 3-5 days prior to treatment.
- **Herpes Simplex Virus (HSV) 1 & 2** – Do not treat if active lesion(s) are present within the intended treatment area. Patients with a known history of frequent HSV 1&2 lesions should begin prophylaxis prior to treatment as prescribed by their physician.
- **Poorly controlled medical conditions** – These patients should be carefully evaluated by their physician for medical clearance.
- **Active skin infection** – Avoid treatment of open wounds and skin that is actively infected.
- **Cold sensitivity** – Use caution when treating patients with Raynaud phenomenon.
- **Keloid scarring** – Perform test spots prior to treating larger areas.

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- **Implanted medical devices** – Pacemakers, cardioverters, and other implantable devices or fillers, consult a physician.
- **Minimize overlapping** – Divots or 1/8-inch (3 mm) moon hypopigmentation or hyperpigmentation may occur if overlap is greater than 30%.
- **Tanned skin** – Do not treat recently tanned skin. Blisters and hypopigmentation or hyperpigmentation may occur. Allow tan to fade prior to treatment. When in doubt, compare treatment area with limited sun exposure area.
- **Increased hair growth** – Hair removal by lasers or intense pulsed light sources can cause increased hair growth in some individuals. Based upon currently available data, the highest risk groups for this response are females of Mediterranean, Middle Eastern and south Asian heritage, treated on the face and neck.

Skin Preparation for Treatment

- Topical anesthetics may be used prior to laser hair removal (LHR) per anesthetic manufacturer's directions. HOWEVER, the topical anesthetics should be removed from the skin prior to treatment.
- Skin must be clean and dry; remove all lotions, perfumes, make-up, deodorant, self tanners, etc.
- When cleaning the skin with alcohol, make sure the alcohol is completely removed and the area rinsed prior to treatment.
- Shave area to be treated immediately before treatment. DO NOT leave any stubble on skin.
- DO NOT treat long hair, as the external hair acts as a heat sink and may burn the skin.
- Patients should not tweeze, wax, or have electrolysis 6 weeks before treatment.

Test Areas

Perform test areas when a concern exists regarding the potential response to treatment.

NOTE: Cooling methods should be evaluated when treating test areas, since laser parameters may need to be adjusted, depending upon epidermal cooling methods.

- Select a small area in the anticipated treatment site.
- Apply a series of pulses with several fluences.
- Evaluate the sites in two weeks.
- Treatment may proceed when the expected treatment response is noted.

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Laser Treatment Considerations

WARNING

ALL PERSONNEL IN THE VICINITY OF THE LASER MUST KEEP EYEWEAR ON AT ALL TIMES DURING TREATMENT PROCEDURE.

- Perform the user verification tests on page 139 prior to each treatment session.
- Position patient comfortably and confirm that the patient and everyone in the treatment room are wearing the correct protective eyewear.
- Always hold the laser handpiece perpendicular, flat/flush and in contact to the skin to apply laser energy, otherwise an uneven application of Cryogen and energy may occur and an untoward skin reaction may occur.
- The aiming beam and laser beam are dimensionally identical, so the aiming beam can be used to accurately define the treatment area. The spot should be absolutely circular if the handpiece is held at the appropriate 90 degree angle.
- To prevent debris build up on the inside of the distance gauge and maintain good visibility, follow the procedures on page 117.
- Always observe the epidermal response throughout the treatment and adjust the fluence and epidermal cooling (DCD or Air) as needed.

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Preventing Untoward Effects and Decreasing Discomfort

- Cool compress or cold gel packs may be applied immediately after treatment to decrease discomfort.
- Large areas that are divided into sections need to be cooled just prior to treatment.
- After each laser pulse, a gentle rub of the area with a dry gauze pad or gentle rub with a gloved hand may minimize discomfort.

Treating Specific Body Areas

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

Post-Treatment Care

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

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Expected Responses

Laser Hair Removal

- Perifollicular edema/erythema, urticaria.
- Singed hair may result if the treatment area isn't well shaved.
- The appearance of perifollicular edema and erythema may be altered if a topical anesthetic is used, as the topical may cause vasoconstriction or erythema.
- After LHR the treated hair may not shed for several weeks. Patient should be reassured that the hair will eventually exfoliate.
- Approximately 20% reduction of hair growth noted 4 - 8 weeks following each procedure.

Vascular Lesions

- Vasoconstriction of facial and leg veins, transient urticaria.
- Gradual fading over several weeks to months.
- Purpura may occur and commonly resolves within 14 days.
- Additional treatments may be performed to achieve desired vessel response.

Benign Pigmented Lesions

- Immediate (tan to brown) darkening of the lesion is the preferred endpoint. At times, possible frosting/whitening of the lesion can occur. For darker skin types, avoid frosting/whitening of the lesion
- Slight peri-lesional erythema and urticaria.
- Formation of superficial red-brown scale which resolves within 7 - 14 days.
- Gradual fading over 4 - 6 weeks.

Wrinkles

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

Onychomycosis

- Temporary sensation of heat
- Mild edema

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Untoward Responses

- Burning, blistering, scabbing, crusting, hypopigmentation, hyperpigmentation, purpura, or herpes simplex activation, in rare cases, scarring may result.
- Hypopigmentation or hyperpigmentation may not appear for 1 - 2 weeks and in rare cases may last for months or longer.

  If hypopigmentation or hyperpigmentation occurs treatment should not be performed until pigmentation returns to normal

Laser hair Removal

- Hair removal by lasers or intense pulsed light sources can cause paradoxical hypertrichosis or increased hair growth in some individuals. Based upon currently available data, the highest risk groups for this response are females of Mediterranean, Middle Eastern and south Asian heritage, treated on the face and neck. In some cases this is due to insufficient fluence in the treatment area or spread of heat to the surrounding areas.
- Follicultis or acneiform eruptions
- Leukotrichia (white hair growth) has been reported in rare cases and may be temporary or permanent. It is thought to be a result of insufficient thermal damage to the hair follicle, allowing for regrowth of depigmented hairs.

Vascular Lesions

- Superficial thrombophlebitis has been documented in literature in the treatment of vascular lesions.

Benign Pigmented Lesions

- Whitening of the lesion post treatment.

Determining the End of Treatment

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

Reduction of Plume and Hair Odor in Treatment Room

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

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Epidermal Cooling

Candela's GentleMax Pro Plus laser system offers a choice delivery systems:

- Medium Spot Standard Dynamic Cooling Device (DCD).
- Small Spot DCD.
- Large Spot DCD.
- Medium Spot Standard Air Compatible Cooling (ACC).
- Large Spot ACC.

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The DCD delivery systems may be used with the GentleMax Pro Plus laser system to cool and protect the epidermis, and to reduce pain. The laser system software allows the operator to set the DCD spray and delay settings and the Cryogen sprays the skin before the laser pulse is delivered to cool the skin.

The composition of the Cryogen is a nonflammable, non-poisonous compressed gas (HFC 134a). This material is used frequently as a propellant in asthma inhalers. Canisters of Cryogen are dispensed in amounts of 2.2 lbs (1 kg). Canisters are shipped separately from the laser system. The frequency of Cryogen canister replacement is directly related to how much the laser system is used. Recommended spray durations and delay times are offered on the treatment guideline sheets by application.

The ACC delivery system must be hooked up with a compatible air cooling system that delivers continuous, reduced temperature air that can cool the skin prior to, during, and following the laser pulse.

CAUTION

For air cooling, set the epidermal protection according to the instructions provided by the manufacturer of the cooling system.

NOTE: Epidermal cooling performance may be reduced (i.e., variation in air flow rates and temperatures) when using the ACC air clip. Please adjust the laser or cooling parameters appropriately.

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Special Considerations When Using DCD

Cryogen Spray

Do not spray Cryogen into the eyes or into an open wound. The DCD spray should be sufficient to cover the spot on the skin and provide epidermal cooling in opposition to the heat generated from the laser system. It is important to maintain both skin protection and patient comfort, so adjust the spray parameters accordingly, keeping in mind the patient's skin type. Begin with suggested guidelines and increase or decrease settings based on the skin reaction and the patient's tolerance.

WARNING

- **WHEN TREATING PATIENTS WITH THE LASER SYSTEM AND USING THE DYNAMIC COOLING DEVICE (DCD) IN CONJUNCTION WITH AN ECG MONITORING DEVICE ATTACHED TO THE PATIENT, INTERFERENCE WITH THE ECG MONITORING DEVICE MAY RESULT.**
- **REFER TO CANDELA POLICY FOR PREGNANCY AND THE USE OF LASERS (POLICY NUMBER 0920-23-0814).**

CAUTION

- **A buildup of frost may occur on the distance gauge or Cryogen nozzle during extended treatments. Wipe the distance gauge or Cryogen nozzle (with an alcohol-soaked gauze) to prevent accumulation of frost.**
- **If crescent shaped marks, welts, or wheals are noted during treatment, the fluence or DCD settings should be adjusted immediately. Not making such an adjustment can result in subsequent crusting, blistering, and other adverse reactions.**
- **Crescents may result from not holding the distance gauge properly. If problem persists, discontinue treatment and see "User Verification Tests" on page 139.**
- **Replacement canisters of Cryogen are available for order by part number. The Candela GentleCool canisters are only available as 2.2 lbs (1000 g) canisters. To order, see Appendix C.**
- **Do not use flammable products on the skin or in the vicinity of the laser system.**

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Chapter 1 Treatment Applications

Laser Hair Removal and Treatment of Pigmented and Vascular Lesions

The GentleMax Pro Plus laser system is designed for the treatment of unwanted hair, pigmented lesions, vascular lesions, and wrinkles. The GentleMax Pro Plus laser system treats all skin types quickly, comfortably, and effectively. The laser system does this by creating a beam of high-intensity light that penetrates deep into the skin tissue where it delivers a controlled amount of therapeutic heat. Meanwhile, the Dynamic Cooling Device protects the upper layers of the skin with a cooling burst of Cryogen (see "Epidermal Cooling").

This unique laser system contains two separate laser heads, an Alexandrite and a Nd:YAG (Neodymium-doped Yttrium Aluminum Garnet) which, when pulsed, produce laser energy emitted at nominal wavelengths of 755 nm and 1064 nm, respectively. The outputs of the two laser heads are optically combined on the laser rail so that their beam paths are identical as they exit the laser system. This allows the use of a single delivery system which can output either the 755 nm or 1064 nm wavelengths. The output energy is delivered to the skin through an optical fiber delivery system which may cool the surface of the skin through either air or Cryogen cooling.

The Candela GentleMax Pro Plus laser system delivers its therapeutic effect by causing maximum energy absorption of targeted chromophores in skin. For example, in the case of laser hair removal or the treatment of pigmented lesions, the targeted chromophore is melanin; for vascular lesions, the target chromophore is hemoglobin. In both cases, a thermal injury is created in the immediate area of the chromophore ultimately resulting in the desired therapeutic outcome.

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

The Candela GentleMax Pro Plus laser system also provides additional protection to the surface of the skin from unwanted thermal injury. It delivers either cooling air or evaporative Cryogen to the surface of the skin, depending upon the delivery system being used, the recommended treatment parameters, and the choice of cooling methodologies of the practitioner.

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Epidermal Cooling

Candela's GentleMax Pro Plus laser system offers two choices of epidermal cooling with its delivery systems:

- Dynamic Cooling Device (DCD)
- Air Compatible Cooling (ACC)

The DCD delivery system may be used with the GentleMax Pro Plus laser system to cool and protect the epidermis, and to reduce pain. The laser system software allows the operator to set the DCD spray and delay settings and the Cryogen sprays the skin before the laser pulse is delivered to cool the skin.

The composition of the Cryogen is a nonflammable, non-poisonous compressed gas (HFC 134a). This material is used frequently as a propellant in asthma inhalers. Canisters of Cryogen are dispensed in amounts of 2.2 lbs (1000 gr). Canisters are shipped separately from the laser system. The frequency of Cryogen canister replacement is directly related to how much the laser system is used. Recommended spray durations and delay times are offered on the treatment guideline sheets by application.

The ACC delivery system must be hooked up with a compatible air cooling system that delivers continuous, reduced temperature air that can cool the skin prior to, during, and following the laser pulse.

CAUTION

For air cooling, set the epidermal protection according to the instructions provided by the manufacturer of the cooling system.

NOTE: Epidermal cooling performance may be reduced (i.e., variation in air flow rates and temperatures) when using the ACC air clip. Please adjust the laser or cooling parameters appropriately.

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Chapter 2 System Overview

Overview of the GentleMax Pro Plus Laser System



Figure 2-1 GentleMax Pro Plus Laser System

Laser System

The GentleMax Pro Plus laser system consists of an Alexandrite laser head and a Nd:YAG laser head, a power supply, and a coolant water circulator. The laser head contain the cavity mirrors, solid-state laser medium rod, and two high-intensity xenon flashlamps that excite the laser medium. A calibration port, or "calport", with an internal meter, calibrates 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.

A microprocessor-based system controller monitors and directs all system functions. The operator selects parameters and monitor operations through electronic controls and a touch screen display panel or "touch screen". The touch screen gives the service technician access to the system controller, both to obtain information and to control system functions for maintenance and for troubleshooting.

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The laser head is cooled by the circulation of deionized (DI) or distilled water, which in turn is cooled by ambient air passing through a heat exchanger. A combination of heaters and heat exchangers maintain the temperatures of various system components within the optimum range for efficient laser operation.

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

The output of the laser is delivered through an optical fiber coupled to one of the removable slider attachments (see "Slider Attachments" on page 44). The slider attachment contains the internal focal lenses. The distance gauge (see "The following table presents the types of delivery systems, the fiber cables supported by the delivery systems, and the slider attachments and distance gauges supported by the fiber cables:" on page 45) is placed against the skin to ensure proper focusing and spot placement on the treatment area. A trigger switch (fingerswitch or footswitch) controls the delivery of the pulses.

The operator selects the desired energy density (fluence) level and enables or disables the laser at the touch screen or from the handpiece. Depending on the fluence, pulse duration and spot size setting, the laser delivers pulses at a repetition rate of up to 10 Hz per second.

The laser system is equipped with interlocks that will disable the laser emissions if the remote interlock circuit is open or when the fiber is removed. A green aiming beam is provided to illuminate the treatment area. The aiming beam and treatment beam are dimensionally identical, so the aiming beam can be used to accurately define the treatment pulse location. The aiming beam is illuminated when the laser system enters **Ready** mode.

Delivery System

The GentleMax Pro Plus is configurable for use with the DCD, which is internal to the system, or used in conjunction with an external air cooling system. There are five different delivery system configurations:

- Standard Medium Spot Delivery System (DCD), which consists of:
  - Standard Medium Spot DCD handpiece.
  - Standard Fiber cable.
  - 6/8/10 mm slider attachment.
  - 12/15/18 mm slider attachment.
  - 6, 8, 10, 12, 15 and 18 mm distance gauges (6 mm and 8 mm spot sizes share the same distance gauge).
- Air Cooling Compatible (ACC) delivery system, which consists of:
  - ACC handpiece
  - Standard Fiber cable.

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- 6/8/10 mm slider attachment.
- 12/15/18 mm slider attachment.
- 6, 8, 10, 12, 15 and 18 mm distance gauges (6 mm and 8 mm spot sizes share the same distance gauge).
- Air clip

- Small Spot Delivery System (DCD), which consists of:
  - Small Spot DCD handpiece.
  - Standard Fiber cable.
  - 1.5 mm slider attachment.
  - 3 mm slider attachment.
  - 5 mm slider attachment.
  - 3x10 mm slider attachment.
  - 1.5, 3, 5 & 3x10 mm distance gauges.
- Large Spot Delivery System (DCD), which consists of:
  - Large Spot DCD handpiece.
  - Large Spot Fiber cable.
  - 20/22/24 mm slider attachment.
  - 26 mm slider attachment.
  - 24 mm distance gauges (supports 20/22/24 spot sizes).
  - 26 mm distance gauge (supports only 26 mm spot size).
- Large Spot Delivery System (ACC), which consists of:
  - Large Spot ACC handpiece.
  - Large Spot Fiber cable.
  - 20/22/24 mm slider attachment.
  - 26 mm slider attachment.
  - 24 mm distance gauges (supports 20/22/24 spot sizes).
  - 26 mm distance gauge (supports only 26 mm spot size).

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DCD Delivery Systems

Standard Medium Spot DCD Handpiece

The Standard Medium Spot DCD delivery system has a Standard Medium Spot DCD handpiece which delivers the DCD cryogen spray just prior to the lasing energy. The DCD components are incorporated in the lower section of the Standard Medium DCD handpiece.

The Standard Medium Spot DCD handpiece also contains a fan to cool it and reduce bubble faults, a serviceable air filter in front of the fan that can be cleaned or replaced, and a user-serviceable window held in place with a magnetic cover (E).

Large Spot DCD Handpiece

The optional Large Spot DCD delivery system has a Large Spot DCD handpiece which delivers the DCD cryogen spray just prior to the lasing energy. The DCD components are incorporated in the lower section of the Large Spot DCD handpiece.

The Large Spot DCD handpiece also contains a fan to cool it and reduce bubble faults, a serviceable air filter in front of the fan that can be cleaned or replaced, and a user- serviceable window held in place with a magnetic cover (E).

Small Spot DCD Handpiece

The Small Spot DCD delivery system has a Small Spot DCD handpiece which delivers the DCD cryogen spray just prior to the lasing energy. The DCD components are incorporated in the lower section of the Small Spot DCD handpiece.

The Small Spot DCD handpiece contains a fan to cool it and reduce bubble faults and a serviceable air filter in front of the fan that can be cleaned or replaced.



Figure 2-2 Standard DCD Handpiece Components

A	Standby/Ready Button	**D**	Window Holder
B	Air Vent	**E**	Laser Aperture/Distance Gauge
C	Fingerswitch		

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ACC Delivery System

ACC Handpiece

The ACC delivery system has a ACC handpiece (see Figure 2-3), which can be used by itself (non-cooling treatments) or with an air clip attached to deliver refrigerated air to the treatment area. The ACC handpiece also contains a user-serviceable window held in place with a magnetic cover.

CAUTION

For air cooling, set the epidermal protection according to the instructions provided by the manufacturer of the cooling system.

NOTE: Epidermal cooling performance may be reduced (i.e., variation in air flow rates and temperatures) when using the ACC air clip. Please adjust the laser or cooling parameters appropriately.

An air clip (G) attaches to the bottom of the ACC Medium Spot and/or Large Spot handpiece to interface with a Zimmer-type cooling device. The air clip attaches by inserting the nose of the handpiece into the latch at the front of the air clip (see Figure 2-4) and then pressing the back down until it clicks into place (see Figure 2-5). The air clip is removed by pressing the two back tabs (C) to release it from the handpiece (see Figure 2-6).

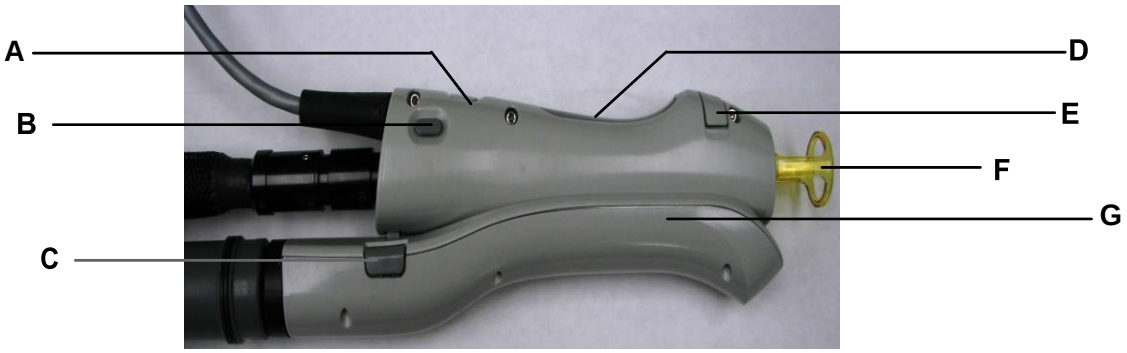


Figure 2-3 ACC Handpiece Components

A	Standby/Ready Button
B	Slider Lock Button
C	Air Clip Tab (one on each side of Air Clip)
D	Fingerswitch
E	Window Holder
F	Laser Aperture/Distance Gauge
G	Air Clip

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Figure 2-4 Attaching the ACC Air Clip



Figure 2-5 Locking the ACC Air Clip



Figure 2-6 Releasing the ACC Air Clip



Figure 2-7 ACC Handpiece Removed from the ACC Air Clip

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Fiber Cable

The fiber cable for all delivery systems consists of a proximal connector (A in Figure 2-8) and a slider (B), into which is inserted a slider attachment (see "Slider Attachments" on page 44). To prevent damage to the fiber cable, at each end of the fiber there is a 1 ft (30 cm) section of steel tubing that prevents the cable from bending by more than a 6 in (15 cm) radius.

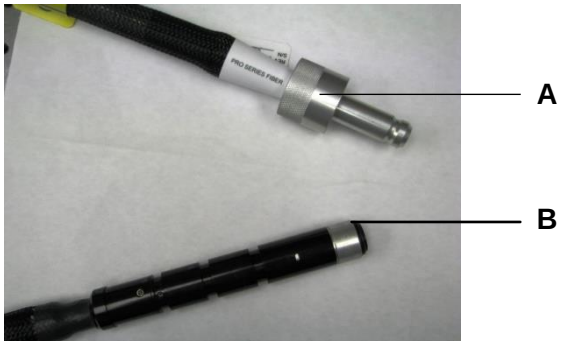


Figure 2-8 Fiber Cable Assembly

A	Proximal Connector
B	Slider with 12/15/18 mm Slider Attachment Inserted

Slider Attachments

The slider attachments (Figure 2-9) snap into the end of the slider and contain two or more lenses and one protective window. The protective window is held in the slider attachment with two different methods, depending on the type of slider attachment:

- 26 mm, 20/22/24 mm, 12/15/18 mm, 6/8/10 mm and 5 mm slider attachments: the window is held in with a window retainer. To remove the window for cleaning or replacement, unscrew the window retainer.
- 1.5 mm, 3 mm, and 3x10 mm slider attachments: the window is held in with an O-ring. To remove the window for cleaning or replacement, first remove the O-ring by pushing it out at the notch in the end of the slider attachment.

See Appendix B (Maintenance) for more information on removing the windows.

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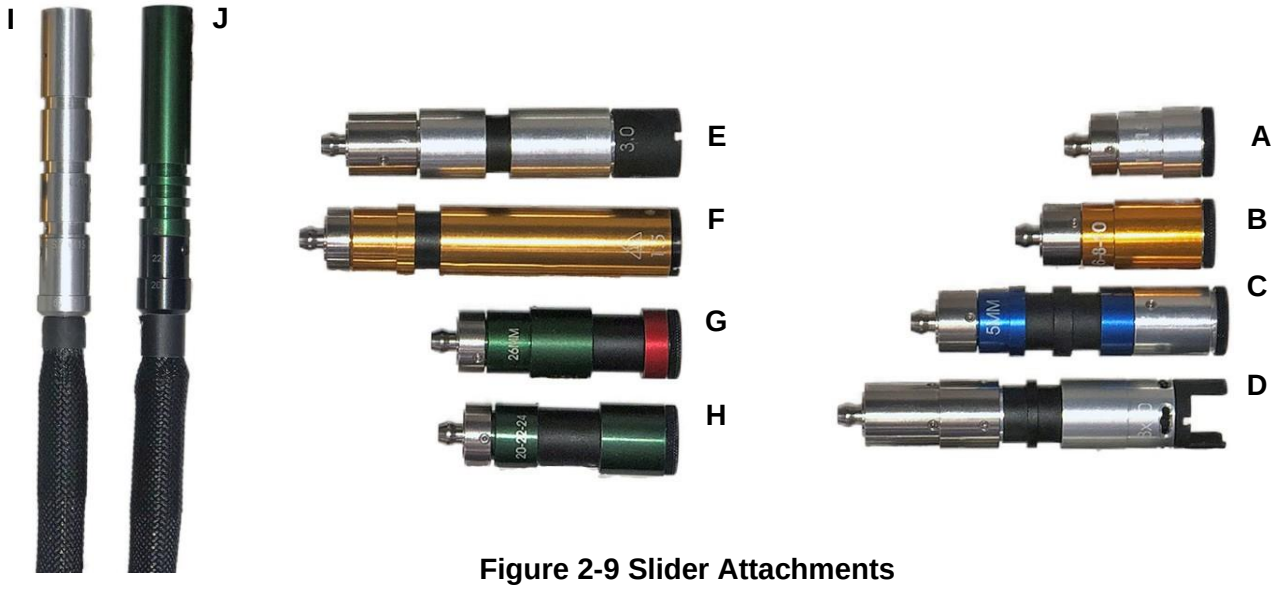


Figure 2-9 Slider Attachments

A	12/15/18 Slider Attachment
B	6/8/10 Slider Attachment
C	5 mm Slider Attachment
D	3x10 mm Slider Attachment
E	3 mm Slider Attachment
F	1.5 mm Slider Attachment
G	26 mm Slider Attachment
H	20/22/24 mm Slider Attachment
I	Fiber Cable
J	Fiber cable for 20/22/24 Slider Attachment

The following table presents the types of delivery systems, the fiber cables supported by the delivery systems, and the slider attachments and distance gauges supported by the fiber cables:

Delivery System	Fiber Cable	Slider Attachments (Spot Sizes)	Distance Gauges
Standard Medium-Spot Delivery System (DCD)	Standard Fiber Cable (Silver)	6/8/10 mm	(6-8, same one), 10
		12/15/18 mm	12, 15, 18
Air Cooling Compatible (ACC) Delivery System	Standard Fiber Cable (Silver)	6/8/10 mm	(6-8, same one), 10
		12/15/18 mm	12, 15, 18

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Delivery System	Fiber Cable	Slider Attachments (Spot Sizes)	Distance Gauges
Small-Spot Delivery System (DCD)	Standard Fiber Cable (Silver)	1.5 mm	1.5
		3 mm	3
		3 x 10 mm	3 x 10
		5 mm	(6-8, same one) 6
Large Spot Delivery System (DCD)	Large-Spot Fiber Cable (Green)	20/22/24 mm	24 (shared for all 3 spot sizes)
		26	26
Large Spot Delivery System (ACC)	Large-Spot Fiber Cable (Green)	20/22/24 mm	24 (shared for all 3 spot sizes)
		26	26

Distance Gauges

The removable distance gauge sizes are included with the GentleMax Pro Plus laser system. The distance gauge is the only part of the laser system that comes in contact with the patient. It is inserted into the handpiece and is keyed to go in a specific orientation, so it does not block the flow of coolant (Cryogen or air).

See Chapter 5: **Performing a Laser Treatment** for more information on inserting the distance gauges.

The distance gauge should never be inserted into the calibration port (calport), see "Calibration Port" on page 57.

Some distance gauges contain a distance gauge ring. It is placed against the skin to ensure proper beam size, spot placement, and coolant overlap of the treatment spot. The ring should be parallel with the skin for proper coolant overlap.

NOTE: Distance gauges that have "sticks" with no ring must be held so the sticks are perpendicular to the skin for proper overlap of the coolant and the laser beam.

The distance gauge should be kept clean during treatment and fully cleaned after a treatment. For instructions, see "Distance Gauges" on page 117.

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Fiber Pole

CAUTION

- **To reduce the risk of personal injury and damage to the delivery system cables, use the fiber pole to support the delivery system cables at all times. When not in use, insert the handpiece in the calport or into a holder, if provided. This removes excess fiber cable slack from the delivery system and the possibility of damage to property or personal injury from stepping on, tripping, or running the wheels over the fiber cable.**
- **When using the fiber pole to support the delivery system, make sure there are no sharp bends in the delivery system cables. The fiber cable can be damaged if subjected to excessive bending. Never pulse the laser system if the delivery system cables bend radius is less than 6 in (15 cm), because it will damage the fiber cable.**

The adjustable fiber pole supports the delivery system cables. It keeps the cables suspended and reduces the weight of the delivery system during use. The fiber pole slides vertically in a receptacle with a clamp, located behind and to the right of the touch screen. The height and the angles of the upper and lower shafts of the fiber pole are adjustable. The fiber pole freely rotates and the hanging cradle slides along the upper shaft to reduce stress on the delivery system cable, which prolongs the life of the delivery system. The delivery system cable can also be clamped in the cradle or allowed to slide through the cradle.

When not in use, the fiber pole can be folded and retracted back into the system for storage.

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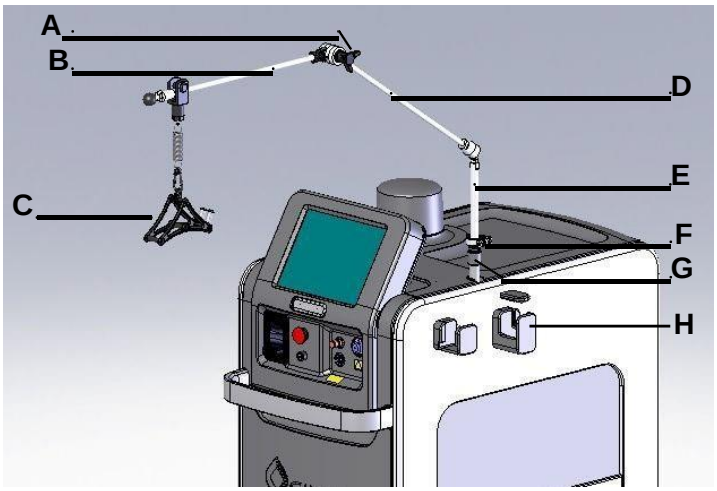


Figure 2-10 Fiber Pole with Cradle

A	Large Black Knob (for adjusting the angle)
B	Upper Support Shaft
C	Cradle
D	Fiber Pole
E	Lower Support Shaft
F	Clamp
G	Receptacle
H	Handpiece Holder

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Adjusting the Height of the Fiber Pole

For this procedure, use Figure 2-10 for reference.

1. Hold the fiber pole's lower support shaft (**E**) with one hand and rotate the locking clip on the clamp (**F**) to loosen the clamp so the fiber pole freely slides in the receptacle (**G**).

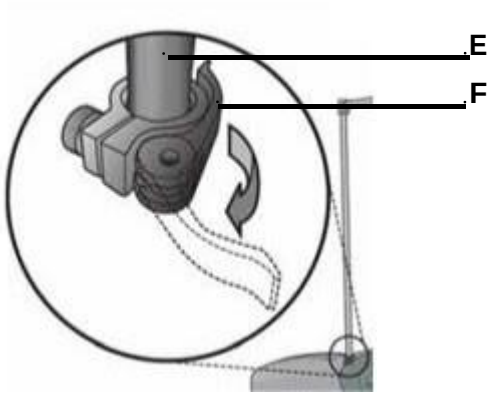


Figure 2-11 Rotating the Fiber Pole Locking Clamp

2. Adjust to the desired height and rotate the locking clip to tighten the clamp (**F**) on the fiber pole.

NOTE: The bottom of the support shaft, which inserts into the clamp, has a red band that indicates the maximum height has been exceeded. Do not clamp the pole at or below this point.



Figure 2-12 Red Band at Bottom of the Fiber Pole Support Shaft

3. After the proper height is set, extend the swing arm portion of the fiber pole and adjust the angle by loosening the large black knob (**A** in Figure 2-10).

4. Once the desired orientation is established, lock the arm by tightening the knob.

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Adjusting the Cradle of the Fiber Pole

1. The cradle (**C**) can freely slide along the upper support shaft (**B**) of the fiber pole to reduce stress on the fiber.

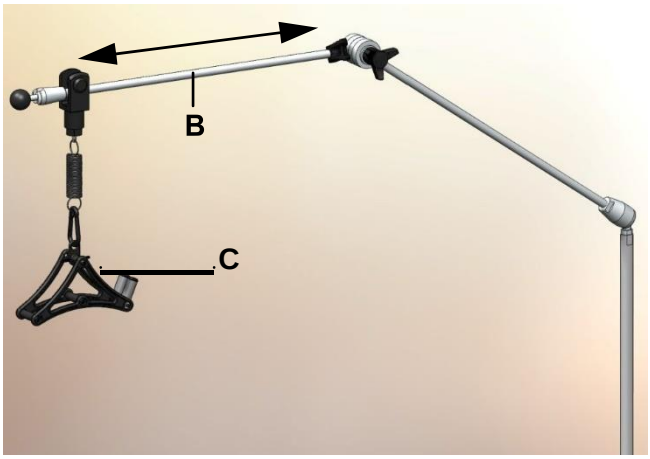


Figure 2-13 Sliding the Cradle

2. Use the adjustable clip (**H**) (see Figure 2-14) to limit the movement of the assembly when the upper support shaft is at a high angle.



Figure 2-14 Adjusting the Clip to Limit Sliding

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Attaching the Delivery System Cables to the Cradle

1. Push back on the cradle capped pin (**I**) to open up the slot at the top of the cradle.

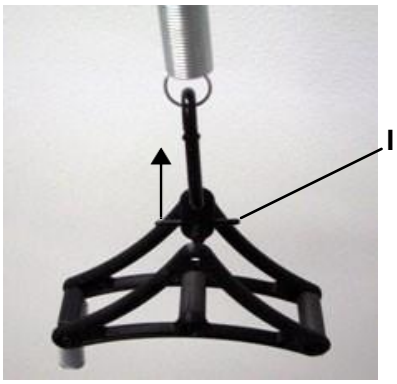


Figure 2-15 Cradle Capped Pin

2. Slide the delivery system cables through the slot so the delivery system cables rest on the cradle.



Figure 2-16 Inserting Delivery System Cables in the Cradle

3. Release the cradle capped pin (**I**) to close the slot so that the cable does not fall out. The slot does not close all the way.

Removing the Delivery System Cables from the Cradle

1. Push back on the cradle capped pin (**I** in Figure 2-15) to open up the slot at the top of the cradle.
2. Slide the delivery system cables through the slot to remove them.
3. Release the cradle capped pin to close the slot.

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Locking/Unlocking the Delivery System Cables in the Clamp

The delivery system cables can slide freely through the cradle or can be locked to the cradle to restrict sliding.

1. To lock the delivery system cables to the clamp to restrict sliding, rotate the clamp (**J**) up and insert the fiber cable into the clamp (see Figure 2-17). Only the thinner section of the fiber cable, starting 14 in (36 cm) behind the slider, fits into this clamp.

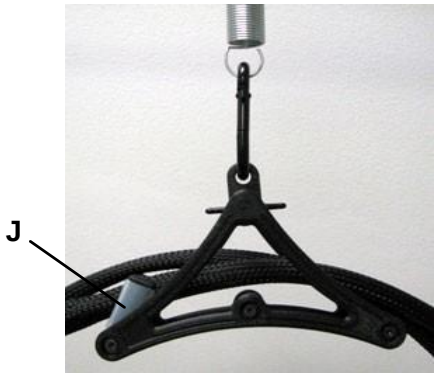


Figure 2-17 Locking the Delivery System Cables to the Cradle

2. To unlock the delivery system cables from the clamp so that the delivery system cables slide freely through the cradle, rotate the clamp (**J**) down (see Figure 2-18).

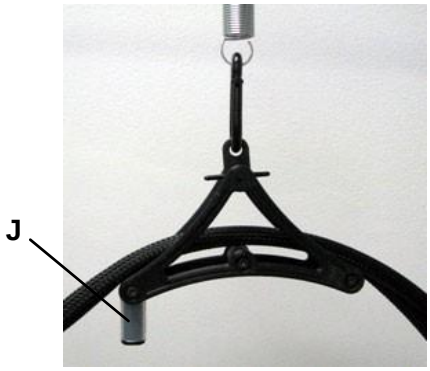


Figure 2-18 Unlocking the Delivery System Cables from the Cradle

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Attaching a Third-Party Cooling Hose

There are two options for attaching a cooling hose provided by the cooling device manufacturer to the system:

1. Option 1: Attach the hose to the pole provided with the third-party cooling device.

   a. To insert the hose into the holder on the pole provided with the third-party cooling device, carefully squeeze the hose at the point of insertion (see Figure 2-19), and firmly, but gently push the hose into the holder until secure.



Figure 2-19 Attaching the Cooling Hose to the Cooling Device Pole

2. Option 2: Attach the hose to the GentleMax Pro Plus cradle.

   a. To insert the hose into the GentleMax Pro Plus cradle, position the hose at the point of attachment to the cradle and secure the hose to the cradle with a strip of Velcro (see Figure 2-20). To prevent sharp bends in the hose and ensure a proper air flow, attach additional Velcro strips, as shown.



Figure 2-20 Attaching the Cooling Hose to the GentleMax Pro Plus Cradle

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Folding and Retracting the Fiber Pole

1. Remove the delivery system cables from the cradle (see "Removing the Delivery System Cables from the Cradle" on page 51).
2. Loosen the large black knob (**A** on Figure 2-10) and fold the arm back onto itself.
3. Loosen the clamp (**F** on Figure 2-10) and lower the fiber pole (**E** on Figure 2-10).
4. Rotate the fiber pole so it is over the top of the laser system and pointing to the rear of the laser system.

   The fiber pole can be removed after the arm has been folded back on itself by loosening the clamp (**F** on Figure 2-10) and pulling the pole straight up until it comes out of the support tube.

Handpiece Holder

The handpiece holder provides a resting place for the handpiece with the distance gauge attached. The handpiece must point toward the rear of the laser when placing the handpiece into the holder.

Footswitch

The energy is delivered through the laser system when the footswitch is depressed. The amount of energy delivered and the length and rate of pulses delivered depends on the settings selected during setup. The footswitch is connected to the footswitch connector on the system's rear panel (see Figure 2-23).

Laser System Wheels

The laser system is equipped with two sets of wheels. The two front wheels swivel, which makes parking in tight spaces easy. The two rear wheels do not swivel, allowing for direct movement of the laser system.

The front wheels contain levers which lock the wheels, preventing them from moving.



Figure 2-21 Front Wheel Locks

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Locking the Wheels

To lock the front wheels, turn one of the front wheels to the side and press down on the On lever.

Unlocking the Wheels

To unlock the front wheels, either press down on the Off lever or lift up the On lever.

Safety Features

The GentleMax Pro Plus laser system has several safety features that include a key-lock switch, laser emergency stop switch, pulse forming network (PFN) audible alert, lasing audible alert, **Ready** mode lamp light, **Ready** and **Standby** modes, and a remote interlock.

Key-Lock Switch

This key-operated switch controls the electrical power to the laser system. The laser system only operates with the supplied Candela key. When the laser is not in use, remove the key from the key-lock switch. For instructions, see page 58.

Laser Emergency Stop Switch

When the red laser emergency stop switch is pressed, the GentleMax Pro Plus laser system immediately shuts down.

PFN Audible Alert

When the pulse forming network (PFN) is fully charged and the laser system is ready to deliver a pulse of energy, an audible beep alert sounds.

Lasing Audible Alert

When the **Ready** indicator changes to a lasing symbol, indicating the laser system is releasing laser energy, an audible beep alert sounds.

Standby and Ready Modes

The system operates in one of two modes: **Standby** and **Ready**.

In **Standby** mode, the laser emission is disabled. The operator must put the system into **Ready** mode to enable laser emission.

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In **Ready** mode, the laser pulses are generated by pressing the selected trigger switch (fingerswitch or footswitch). As a safety precaution, there is a delay of two seconds before the system enters **Ready** mode and the laser emission is enabled. When the laser system is not being used, return it to **Standby** mode. The laser system automatically reverts back to **Standby** mode after two minutes of inactivity in **Ready** mode. The operator selects operating mode through the display panel. The system mode displays on the display panel. When the system is in **Ready** mode, **Standby/Ready** button on the handpiece illuminates.

Remote Interlock

An external connector (CDRH plug) for a remote interlock switch is provided on the rear panel of the laser system. This interlock switch connects to the doors of the laser treatment room. If the door is opened and the laser system is on, the laser system goes into **Standby** mode**.** For more information on installing the remote interlock, call a Candela Service Representative.

NOTE: The remote interlock (CDRH plug) must be in position to operate the device.

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Front Panel of the GentleMax Pro Plus

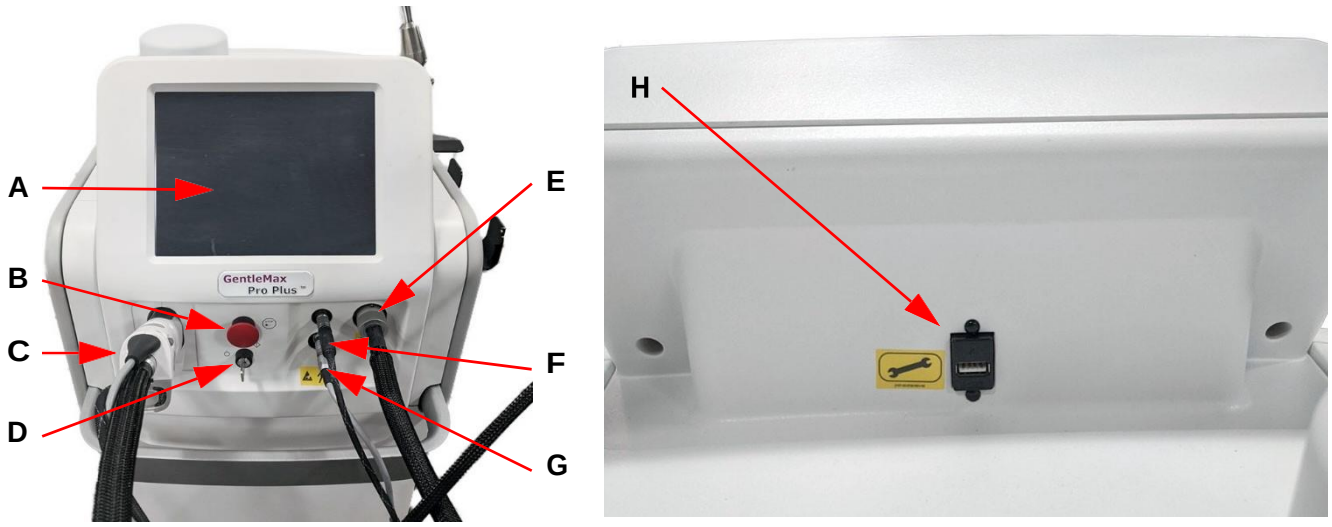


Figure 2-22 Front Panel of GentleMax Pro Plus Laser System

A	Touch Screen
B	Emergency Stop Button
C	Calibration Port
D	Key-Lock Switch
E	DCD/Cryogen Connection
F	Fiber Cable Receptacle
G	Electrical Connection
H	USB port (located on the rear of the touch screen)

Touch Screen

The touch screen (**A** in Figure 2-22) provides a simple Graphic User Interface (GUI) for the operator. This interface allows the operator to select the system operating mode, laser operating parameters, DCD parameters, and output energy calibration.

Emergency Stop Button

When the red emergency stop button (**B** in Figure 2-22) is pressed, the laser system shuts down immediately.

Calibration Port

The calibration port or "calport" (**C** in Figure 2-22) measures the laser output energy.

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Key-Lock Switch

The following table explains the available key-lock switch (**D** in Figure 2-22) positions:

	**Off** When the key is in the **Off** position, the laser system shuts off.
	**On** All circuits are energized and the laser system is fully functional (only after the key-lock switch is moved to the **Start** position and then back to **On**).
	**Start** This is a spring-loaded key-lock switch position. It is used to initiate the laser system operation. This position does not initiate the release of laser energy.

The Authorized user can use the keyswitch to turn the laser on. The keyswitch can prevent unauthorized use. When the system is unattended, remove the key from the keyswitch or use the password-protected lock button (see "Lock Button" on page 77) on the touch-screen to prevent unauthorized use.

Handpiece Delivery System Receptacle

The handpiece delivery system receptacle consists of connections for the DCD/Cryogen cable (**E** in Figure 2-22), fiber cable (**F**), and electrical cable (**G**).

Handle

The handle (see Figure 2-22) enables the operator to roll the system around on its wheels.

USB Port

The USB port (**H** in Figure 2-22) is used by the Candela Service Representative for diagnostics and software upgrades. Unless instructed by Candela, DO NOT install any device in the USB port while treating a patient.



CAUTION

The operator should not connect devices/unauthorized devices to the USB port.

Software updates are to be performed only by Candela-Authorized service personnel.



NOTE: The remote interlock (CDRH plug) must be in position to operate the device.

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Rear Panel of the GentleMax Pro Plus

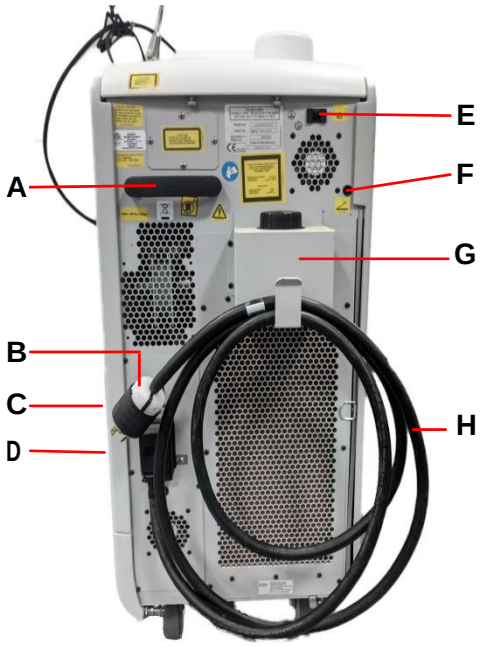


Figure 2-23 Rear Panel of GentleMax Pro Plus Laser System

A	Handle
B	Mains Power Switch
C	Mains Power Indicator
D	Mains Power CABLE
E	Remote Interlock (CDRH plug)
F	Footswitch Connection
G	Water Reservoir
H	Air Filter

Handle

The handle (**A** in Figure 2-23) enables the operator to roll the system around on its wheels.

Mains Power Switch and Power Cable

The mains power switch (circuit breaker) (**B** in Figure 2-23) and the mains power cable (**D**) provide power to the laser system. The mains power switch must be in the **ON** position for the laser system to operate. Always place the mains power switch in the **OFF** position when the laser system is not in use.

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Energy is not delivered by the laser system when the power is turned on. The key-lock switch must be in the **On** position and the **Standby/Ready** button on the touch screen must be selected before laser energy is delivered.

The power cable is approximately 11 ft (3.4 m) long 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 10 ft (3 m) of the intended laser system location.

Mains Power Indicator

The mains power indicator (**C** in Figure 2-23) shows when the laser system is on.

Remote Interlock

An external connector (CDRH plug) for a remote interlock switch (**E** in Figure 2-23) is provided on the rear panel of the laser system. This interlock switch provides a connection for the optional device that connects to the doors of the laser treatment room. If the door is opened and the laser system is on, the laser system goes into **Standby** mode**.** For more information on installing the remote interlock, call a Candela Service Representative.



NOTE: The remote interlock (CDRH plug) must be in position to operate the device.

Footswitch Connector

The footswitch connects into the footswitch connector (**F** in Figure 2-23).

Water Reservoir

The laser head is cooled with deionized water (DI) or distilled water, which is in turn cooled by ambient air passing through a heat exchanger. The water reservoir (**G** in Figure 2-23) holds about 1 gallon (3.8 liters) of DI water.

Air Filter

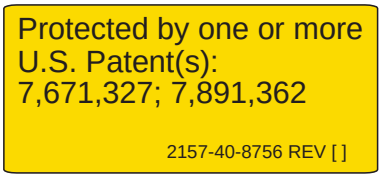
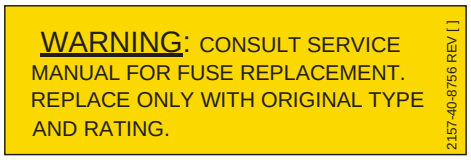
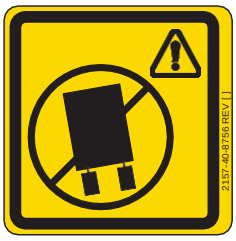
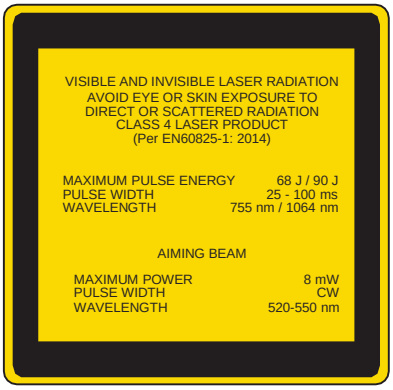
An air filter (**H** in Figure 2-23), for filtering dust, is removable for cleaning.

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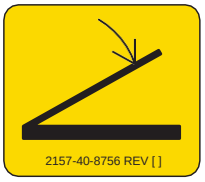
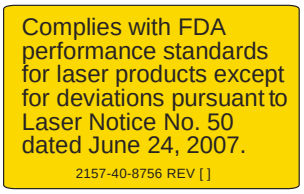
Labels and Symbols

The GentleMax Pro Plus laser system has been labeled in accordance with domestic and international agency standards. All operators should be familiar with the location and meaning of the labels.

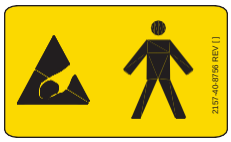
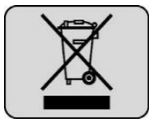
Table 2-1 List of Labels and Symbols

Label/Symbol	Description
	**CAUTION:** Consult accompanying documents.
	U.S. patents that may cover the laser system.
	**WARNING: CONSULT SERVICE MANUAL FOR FUSE REPLACEMENT. REPLACE ONLY WITH ORIGINAL TYPE AND RATING.**
	**CAUTION: Tip hazard when transporting the laser system.**
	Laser emission characteristics and classification per the IEC/EN standards.

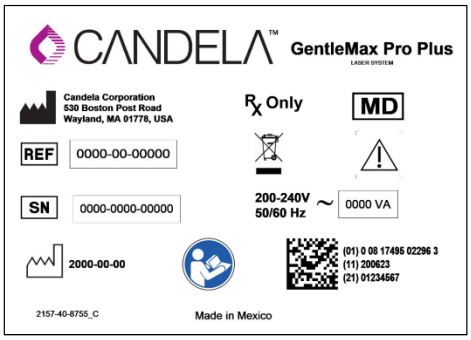
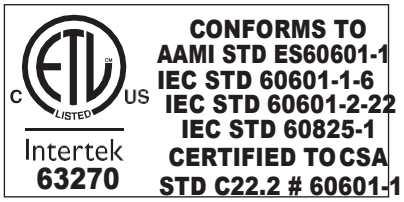
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Label/Symbol	Description
	Location of the footswitch control hose connection on the rear of the laser system.
	**WARNING: HIGH VOLTAGE**
	Location of the remote interlock circuit that connects to the laser treatment room door switch to shutdown the laser system should a person enter the laser treatment room during laser emission.
	**CAUTION: Class 4 visible and invisible radiation when open. Avoid eye or skin exposure to direct or scattered radiation.** Protective panel encloses a Class 4 laser light.
	Location of the USB software upgrade port.
	Selected requirements under CDRH 21 CFR 1040.10 & 1040.11 were waived for comparable IEC requirements as allowed by Laser Notice 50.
	Reservoir is filled with distilled or deionized water and should be kept full.

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Label/Symbol	Description
	Hand - the delivery system is "electrostatic-sensitive" Man - the delivery system is equipped with a "Type B" applied part in accordance with IEC/EN 60601-1.
	The laser system emits laser energy.
	**CAUTION: To reduce the risk of shock, do not remove covers. Refer servicing to qualified service personnel.**
	Hot surface when laser system is on. Do not touch.
	Refer to the system Operator's Manual for complete information on safe operation.
	System weight in Lbs. and Kg.
	Waste Electrical and Electronic Equipment (WEEE) Directive Label - the laser system and its components cannot be disposed of as regular trash. Contact Candela for disposal information.

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Label/Symbol	Description
	VA rating, model number, serial number, and date and place of manufacture.
	The laser system is approved to ETL standards.
	Laser Aperture label on the delivery system.

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Chapter 3 Touch-Screen

Overview of the Touch-Screen

The touch-screen features a smart user interface that allows the operator to access and monitor the laser system operation functions. Figure 3-1 shows the Alex DCD main screen, Figure 3-2 shows the Nd:YAG DCD main screen, and Figure 3-3 shows the ACC main screen. Choosing from the buttons, menus, and sub-menus, the operator sets the desired parameters to perform patient treatments.

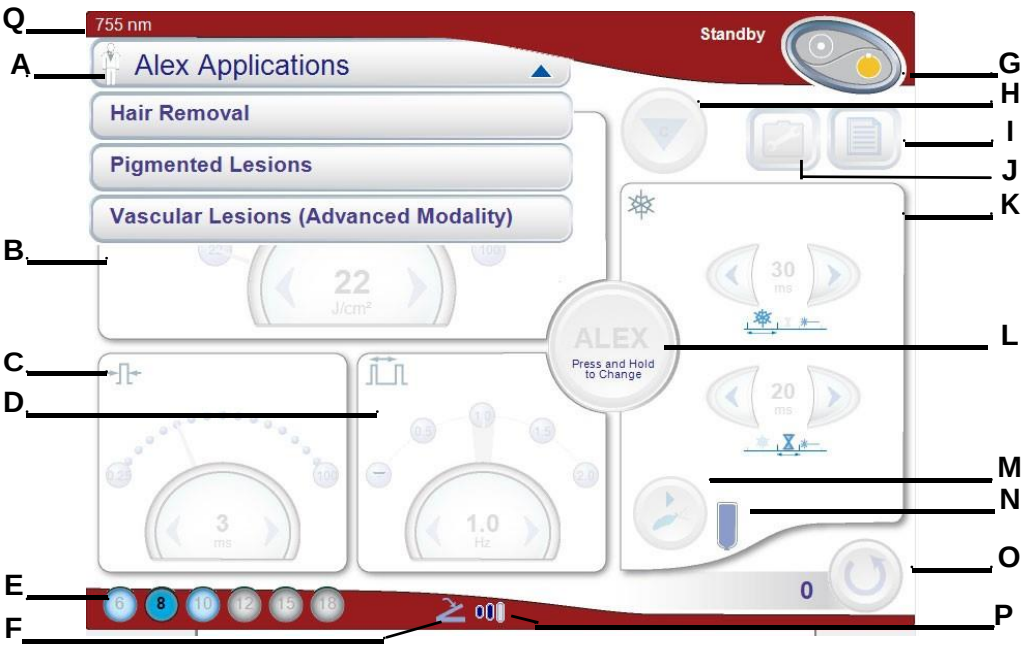


Figure 3-1 Touch-Screen - Alex DCD Main Screen

A	Applications Menu Bar
B	Fluence
C	Pulse Duration
D	Repetition Rate
E	Spot Size Identifier Bar
F	Trigger Select Indicator (fingerswitch or footswitch)
G	System Status Bar and Standby/Ready Button
H	Calibration Button
I	Treatment Summary Button
J	System Settings and Maintenance Mode Button
K	DCD Spray and Delay Duration Area
L	Laser (Wavelength) Selection Button

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M	Purge Button
N	DCD Status (see "DCD Status" on page 73)
O	Treatment Pulse Count and Reset Button
P	Aiming Beam Indicator
Q	Laser Wavelength

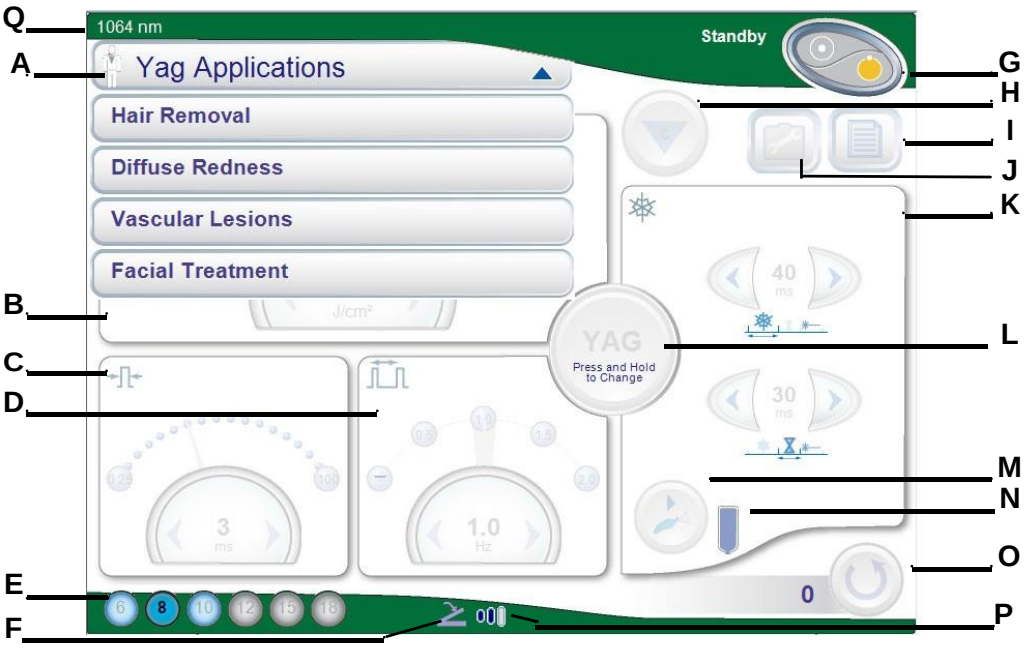


Figure 3-2 Touch-Screen - Nd:YAG DCD Main Screen

A	Applications Menu Bar
B	Fluence
C	Pulse Duration
D	Repetition Rate
E	Spot Size Identifier Bar
F	Trigger Select Indicator (fingerswitch or footswitch)
G	System Status Bar and Standby/Ready Button
H	Calibration Button
I	Treatment Summary Button
J	System Settings and Maintenance Mode Button
K	DCD Spray and Delay Duration Area
L	Laser (Wavelength) Selection Button
M	Purge Button
N	DCD Status (see "DCD Status" on page 73)

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O	Treatment Pulse Count and Reset Button
P	Aiming Beam Indicator
Q	Laser Wavelength

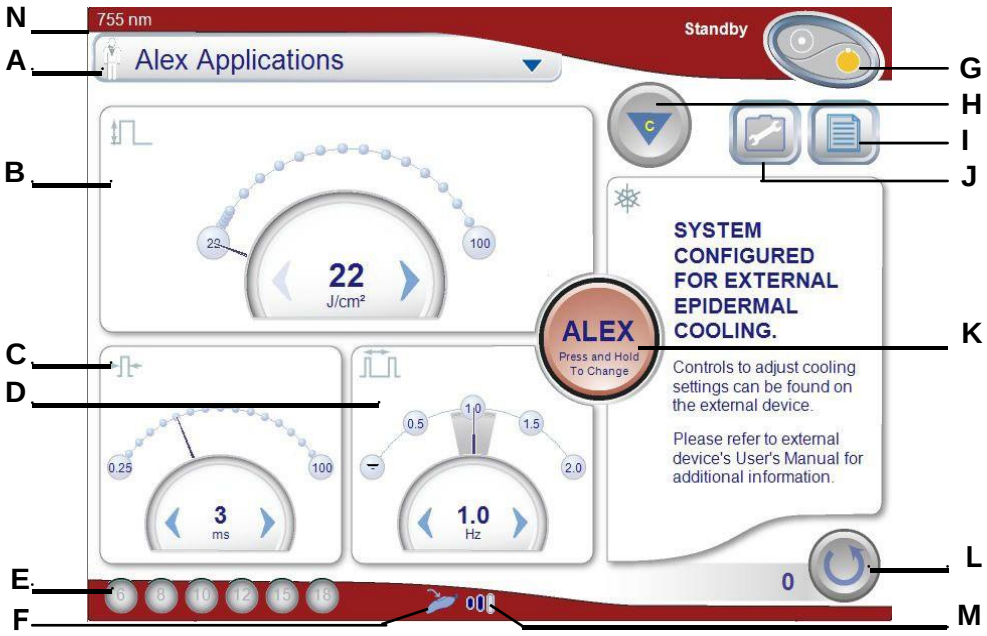


Figure 3-3 Touch-Screen - ACC Main Screen

A	Applications Menu Bar
B	Fluence
C	Pulse Duration
D	Repetition Rate
E	Spot Size Identifier Bar
F	Trigger Select Indicator (fingerswitch or footswitch)
G	System Status Bar and Standby/Ready Button
H	Calibration Button
I	Treatment Summary Button
J	System Settings and Maintenance Mode Button
K	Laser (Wavelength) Selection Button
L	Treatment Pulse Count and Reset Button
M	Aiming Beam Indicator
N	Laser Wavelength

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Main Screen Buttons

Calibration Button

The calibration button or the **Standby/Ready** button initiate the laser system calibration procedure. To calibrate, insert the delivery system handpiece into the calport and follow the instructions on page 84.

NOTE: The system initiates the calibration procedure automatically when a calibration is required and the operator selects the **Standby/Ready** button. The laser system calibration can be canceled at anytime by selecting the cancel button.

Treatment Pulse Counter and Reset Button

The treatment pulse counter and reset button indicates the number of times the laser has been pulsed. This counter keeps track of the total number of laser pulses used in a treatment session.

The pulse count is reset to zero by selecting and holding the treatment pulse reset button for approximately 1 second or longer until it clears.

Treatments Summary Button

The treatments summary button displays the treatments summary report. This report records the number of laser pulses and the operating parameters (fluence, pulse duration, spot size, repetition rate, and DCD settings) used for recent parameter changes. Selecting the reset button on the report screen for approximately 1 second clears all of the treatment data from the table memory.

Laser (Wavelength) Selection Button

The laser or wavelength button toggles between the ALEX laser to provide a 755 nm wavelength and Nd:YAG laser to provide a 1064 nm wavelength. To select a different laser and wavelength, press and hold the button for approximately 1 second.

System Status Bar

The system status bar contains the **Standby/Ready** button. The laser system operates in one of two modes: **Standby** or **Ready**. When the desired mode is selected, the system status bar displays the mode of the laser system in colors and words.

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Table 3-1 Standby/Ready Button Status

Button Color	Description
	**Warming Up** The laser system is warming up. The percentage shows the total warm-up time completed. Allow 8 minutes or longer to complete the warm up.
	**Standby** When the standby button is yellow, the system is in **Standby** mode. The laser emission is disabled.
	**Ready** When the ready button is green, the laser system is in **Ready** mode. The laser emission is enabled. Always put on protective eye wear before selecting the **Standby/Ready** button.
	**Lasing** When the **Standby/Ready** button displays the lasing symbol, the laser is pulsing. Always wear protective eye wear when lasing.

Standby Mode

The operator selects **Standby** mode by pressing and holding the **Standby/Ready** button. The standby symbol on the **Standby/Ready** button changes to yellow and "**Standby**" displays on the system status bar.

The GentleMax Pro Plus laser system automatically enters **Standby** mode during and following the initial warm up period, which occurs when the laser system is first powered up. If the laser system is not pulsed for two minutes, or if a fault condition is detected, the laser system automatically reverts to **Standby** mode.

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Ready Mode

WARNING

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

NOTE: Anytime the laser system is in **Ready** mode, an internal test pulse with no energy occurs.

The operator selects **Ready** mode by pressing the **Standby/Ready** button. The ready symbol on the **Standby/Ready** button changes to green and "**Ready**" displays on the system status bar. As a safety precaution, there is a delay of two seconds before the system enters **Ready** mode and the laser emission is enabled. An additional **Standby/Ready** button illuminates on the handpiece to indicate that the laser system is in **Ready** mode.

While entering **Ready** mode, the touch screen displays a message instructing the operator to wait for the audible beep, which indicates when the laser system is in **Ready** mode.

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Operating Parameters

The operating parameters that are configurable for laser treatments are the wavelength, fluence, pulse duration, repetition rate, DCD spray and delay duration settings. The operating parameters are set individually by the operator or selected from a list of Candela preset parameters under the applications menu (see page 81).

To change the setting of an operating parameter, use the arrows ❮ ❯ to set the desired value.

Fluence (J/cm^2)

The fluence parameter is the amount of energy in Joules (J) delivered to the treatment spot size (in cm^2). The adjustable fluence setting is dependent on the spot size, wavelength, and pulse duration. For each spot size, Table 3-2 lists the available ALEX fluence settings and Table 3-3 lists the available Nd:YAG fluence settings. If the spot size for either type of laser is changed, the laser system automatically selects the lowest possible fluence for the new spot size.

Table 3-2 ALEX Fluence Table

Spot Size (mm)	Fluence (J/cm^2)
3 *	40 - 400
3 x 10 *	10 - 200
6	6 - 150
5 *	9 - 40
8	6 -100
10	6 - 60
12	4 - 40

Spot Size (mm)	Fluence (J/cm^2)
15	2.5 - 30
18	1.75 - 20
20 *	5 - 21.5
22 *	4 - 18
24 *	3 - 15
26 *	5 - 12.5

(*) Optional spot sizes

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Table 3-3 Nd:YAG Fluence Table

Spot Size (mm)	Fluence (J/cm^2)
1.5 *	300 - 520
3 *	130 - 400
3 x 10 *	80 - 300
6	6 - 200
5 *	9 - 55
8	6 - 150
10	6 - 100
12	4 - 70
15	3 - 50
18	3 - 35
20 *	5 - 28
22 *	4 - 23
24 *	3 - 20
26 *	5 - 17

(*) Optional spot sizes

Pulse Duration

The pulse duration parameter is the duration of the pulse delivered to the patient in milliseconds (ms). It is configured when a treatment application is selected using the applications menu (see page 81), or adjusted manually by the operator on the main screen. Depending on the spot size selected (see Spot Size Identification Bar), the available pulse duration settings are from 0.25 ms to 100 ms.

To ensure that the selected pulse duration is delivered, the laser system automatically determines whether a calibration procedure (see page 84) is needed anytime the pulse duration parameter is adjusted.

Repetition Rate

The repetition rate parameter is the rate of the pulses delivered to the patient in hertz (Hz). It is configured when a treatment application is selected using the applications menu (see page 81) or adjusted manually by the operator on the main screen. The available repetition rate settings depend on the selected wavelength, spot size and pulse duration. The repetition rate can be single pulse or, in Hz: 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 5.0, 7.0 or 10.0. The actual pulse rate may vary by up to 20% from the selected rate (as indicated by the shaded area). After a few pulses the actual pulse rate is indicated by the needle in the display. In single pulse mode, each pulse must be triggered by pressing and releasing the fingerswitch trigger or footswitch trigger.

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Spot Size Identification Bar

When the silver slider is attached, the spot size identification bar  displays the available spot sizes in mm: 5, 6, 8, 10, 12, 15 & 18. When the correct slider attachment is installed and a spot size is selected with the slider, the spot size selection appears blue on the bar .

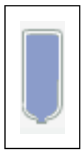
When the green slider is attached, the spot size identification bar  displays the available spot sizes in mm: 20, 22, 24 & 26. When the correct slider attachment is installed and a spot size is selected with the slider, the spot size selection appears blue on the bar .

Make sure to use the appropriate 1.5, 3 or 5 mm slider attachment to select the corresponding 1.5, 3 or 5 mm spot sizes, the 6/8/10 slider attachment to select 6 mm, 8 mm, or 10 mm spot sizes, and the 12/15/18 slider attachment to select 12 mm, 15 mm, or 18 mm spot sizes.

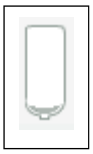
DCD Status

There are five possible DCD Cryogen canister states (refer to arrow # 1 in Figure 1 on page 79):

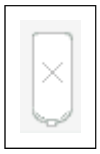
- Canister full:



- Canister empty:



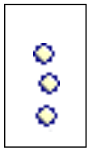
- Canister missing



- Canister warming up



- Bubbles present in the handpiece require a purge.



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DCD Spray and Delay Duration Area

The DCD spray and delay duration parameter area is configured when a treatment application is selected using the applications menu (see page 81) or adjusted manually by the operator on the main screen.

DCD Spray Duration

The DCD spray duration parameter controls the duration of the Cryogen spray applied to the patient before the laser pulse. The available DCD spray duration settings are 0 ms (off), or from 10 ms to 100 ms.

CAUTION

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

DCD Delay Duration

The DCD delay duration parameter controls the duration of the time between the DCD Cryogen spray and the laser pulse. The available DCD delay duration settings are from 10 ms to 100 ms, in increments of 10 ms.

DCD Post-Spray Duration

The DCD post-spray duration parameter controls the duration of the Cryogen spray applied to the patient after the laser pulse. The available DCD post-spray duration settings are 0 ms (off), or from 10 ms to 20 ms.

NOTE: The DCD post-spray duration is normally hidden from the main screen and must be enabled through the system settings button in order to be used (see "System Settings and Maintenance Mode" on page 76).

DCD Purge Button

The purge button removes air bubbles from the DCD Cryogen line when a new canister is placed in the system or a handpiece is installed. This action must be done with the handpiece removed from the calibration port and pointed in a safe direction. When the purge button is selected, the handpiece disperses Cryogen spray for the selected pre-spray duration. If the purge button is selected and held for longer than 1 second, a cycle of a short spray of Cryogen is followed by a pause and then a longer spray of Cryogen (up to 3 seconds), which disperses Cryogen and purges air bubbles.

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NOTE: The GentleMax Pro Plus laser system has been configured for a genuine Candela DCD canister. Only install the appropriate size Candela canister.

CAUTION

- **Failure to install the appropriate size canister for the laser system or failure to replace it when prompted by the laser system can lead to adverse patient treatment results, including burns. These adverse results may occur as a result of the following:**
  - **Significantly reduced cooling of the epidermis for a given laser energy**
  - **Inadequate pressure to fill a spot size area with Cryogen**
- **Always replace the canister when the system indicates "Replace Canister".**

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System Settings and Maintenance Mode

The system settings and maintenance mode button opens a pop-up window that contains two tabs, one for system configuration tools, the other for language selection.



Figure 3-4 System Settings Menu - Tab 1



Figure 3-5 System Settings Menu - Tab 2

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Trigger Source Button

The trigger source button toggles between the fingerswitch and footswitch, where the laser emission is initiated.

Aiming Beam Intensity Button

The aiming beam intensity button allows the operator to select from three aiming beam intensity levels or to turn off the aiming beam. The aiming beam, which is only visible in **Ready** mode, serves as a treatment area target as well as an emissions warning indicator.

NOTE: To allow the user to see the intensity level being set, the aiming beam is turned during the selection process.

Spray Button

The spray button allows the operator to select whether the DCD post-spray setting and buttons display or do not display on the main screen (see "DCD Post-Spray Duration" on page 74). Since most applications do not use post-spray, it is normally not displayed on the touch screen; however, it can be shown at any time.

Cryogen Level Indicator Button

When the Cryogen level indicator button is active, the main treatment screen will display an estimated level of Cryogen remaining in the currently installed DCD canister (refer to "Cryogen Level Indicator" on page 78).

Lock Button

The lock button protects the system settings from unauthorized changes. The passwords are 1234 or 5277

Touch Screen Calibration Button

The touch screen calibration button calibrates the touch screen. Contact a Candela Service Representative for instructions.

Laser Variable Mode Screen Button

The laser variable mode (LVM) button is used by a Candela Service Representative to diagnose problems or obtain laser system operating information.

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Language Tab and Flag Buttons

The language tab with the flag buttons allows the operator to select which language the touch screen displays.

Save Button

The save button saves/confirms the changes made on a screen.

Cancel Button

The cancel button closes a screen without saving the changes.

Cryogen Level Indicator

The Cryogen level indicator is a feature that assists the user by displaying the level of Cryogen remaining in the currently installed DCD canister. Press the button to toggle the feature on, press it again to toggle it off. Once activated, it will remain so until it is deactivated by the user.

NOTE: The Cryogen level indicator only displays an estimated level of Cryogen in the DCD canister.



Inactive Mode Active Mode

Figure 3-6 Cryogen Level Indicator Button: Active & Inactive Modes

When active, the Cryogen level indicator shows three additional DCD canister states on the main treatment screen. Each mode represents an estimate of the level of Cryogen left in the canister, including three quarters, half, and one quarter. These are in addition to the existing two states of full and empty, as well as the warm-up mode and "canister not installed" indicator.

The estimated amount of Cryogen in a canister is based on the assumption that a full canister is installed following the removal of a canister. If you have purposefully installed a partially full canister, you can manually modify the indicator based on your estimate of the level. This is accomplished by pressing and holding the canister icon on the main treatment screen until the level estimate screen is shown. In this case, the estimated canister level is full.

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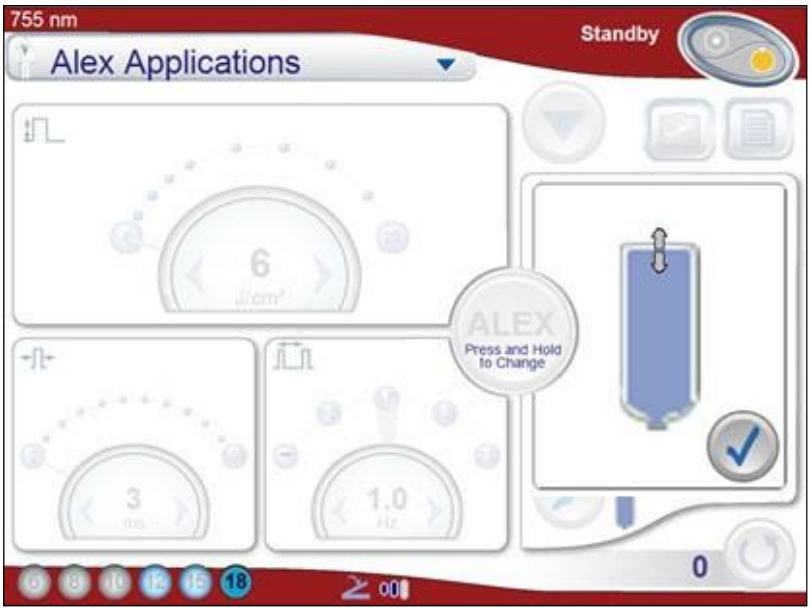


Figure 3-7 Cryogen Level Indicator: Estimated Full Canister

Hold and drag the arrows to select an estimate of full (100%), three quarters (75%), half (50%), one quarter full (25%) or empty (0%). Click the check box to confirm selected estimated level of Cryogen.

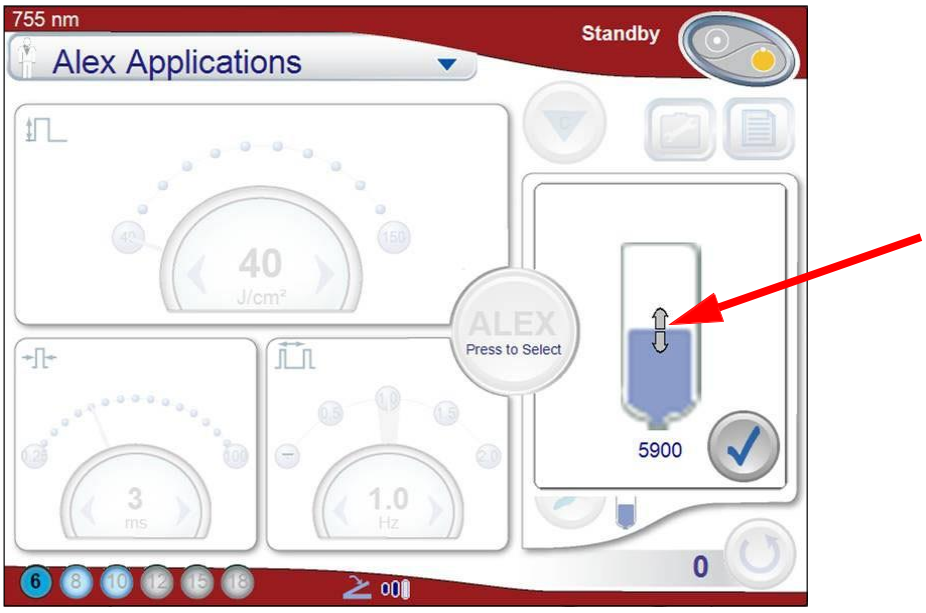


Figure 3-8 Cryogen Level Indicator: Estimated Half Canister

1. The system will then operate under the assumption the canister is half full, as reflected on the main treatment screen.

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2. This number represents the estimated remaining number of DCD spray pulses in the canister, rounded to the nearest 100. It is visible for about 5 seconds and then disappears.



Figure 3-9 Estimated Cryogen Level Indicator on Main Treatment Screen

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Applications Menu (Types of Treatments)

The applications drop-down menu 

provides a list of available treatment applications. When a treatment application is selected, the **Treatment Application - Select Parameters** screen appears.



Figure 3-10 Treatment Application Example: Hair Removal - Select Parameters

After selecting the desired parameters and selecting the next button to save and close the screen, the **Treatment Application - Common Settings** screen appears. This screen displays the common settings for the distance gauge installed. Figure 3-11 shows the DCD Treatment Application Guided Mode screen, and Figure 3-12 shows the **ACC Treatment Application Guided Mode** screen.

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Figure 3-11 DCD Treatment Application Example: Hair Removal - Common Settings



Figure 3-12 ACC Treatment Application Example: Hair Removal - Common Settings

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Treatment Application Options

The application options are limited to the spot sizes available for the laser system configuration and each treatment application. The laser system does not permit operators to use a treatment application without a supported spot size selected. Only use spot sizes that are supported by the desired treatment application.

Refer to the Candela Clinical Treatment Guidelines (Candela Document Part Number 8502-00-0924) to get the recommended preset treatment parameters and the spot sizes for the desired treatment applications. For instructions on performing a laser treatment, see "Preparing for the Laser Treatment" on page 90.

WARNING

THE PRESET TREATMENT PARAMETERS AND OPERATOR'S MANUAL DO NOT TAKE THE PLACE OF THE CANDELA CLINICAL GUIDELINES. FAILURE TO USE THE LASER SYSTEM IN ACCORDANCE WITH SUCH PROCEDURES AND INSTRUCTIONS COULD RESULT IN SERIOUS INJURY TO THE OPERATOR, PATIENT, AND OTHERS, AS WELL AS DAMAGE TO THE LASER SYSTEM.

CAUTION

For air cooling, set the epidermal protection according to the instructions provided by the manufacturer of the cooling system.

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Chapter 4 Performing a Calibration

Calibrating the Laser System

WARNING

- **ALL PERSONNEL IN THE VICINITY OF THE LASER MUST KEEP EYEWEAR ON AT ALL TIMES DURING CALIBRATION PROCEDURE.**
- **AFTER A CALIBRATION, PERFORM THE USER VERIFICATION TESTS ON PAGE 139. ALWAYS PERFORM THE USER VERIFICATION TESTS TO CHECK THE DELIVERY SYSTEM AND HANDPIECE FOR PROPER OPERATION AT THE BEGINNING OF EACH TREATMENT DAY OR EACH TIME IT IS REPLACED ON THE LASER SYSTEM.**

CAUTION

Failure to perform a calibration procedure after a handpiece window or slider attachment window has been cleaned or replaced can result in delivery of fluences greater than is specified on the control panel.

The GentleMax Pro Plus laser system requires that the laser be calibrated prior to each patient treatment. Before calibration, the handpiece must be cleaned and dried before being placed in the calport. During calibration, the handpiece, with appropriate spot size selection, must be inserted into the calport, allowing an internal energy meter to measure the laser output parameters delivered at the handpiece. The system adjusts itself until the desired output is obtained.

1. Put on the appropriate laser safety eyewear.
2. Select the appropriate wavelength and slider attachment, as described in "Performing the Laser Treatment" on page 92.
3. Verify that the handpiece window and slider attachment window are clean. For information on cleaning these windows, see "Cleaning the Handpiece Window" on page 122 and "Cleaning the Slider Attachment Window" on page 132, respectively.

WARNING

ALWAYS PLACE THE LASER SYSTEM INTO STANDBY OR "OFF" BEFORE ATTEMPTING TO CHECK, CLEAN, OR REPLACE THE DELIVERY SYSTEM, SLIDER, SLIDER ATTACHMENT, DISTANCE GAUGE, HANDPIECE WINDOW, OR SLIDER ATTACHMENT WINDOW.

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WARNING

Always recalibrate the laser system after fixing, cleaning, or replacing the delivery system, slider attachment, handpiece window, and slider attachment window. Failure to initiate a calibration after cleaning or replacing the windows, slider attachment, or delivery system may result in the delivery of excessive laser energy.

4. Insert the slider attachment (**B**) into the slider (**A**).

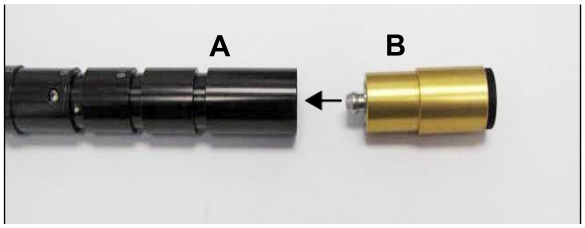


Figure 4-1 Inserting the Slider Attachment into the Slider

5. Press and hold the slider lock button (**D** in Figure 4-2) on the handpiece and insert the fiber cable, with the slider attachment, into the slider tube at the back end of the handpiece.



Figure 4-2 Inserting the Fiber Cable into the Handpiece (DCD shown; same for ACC)

- The slider has three circumferential grooves. Each groove is marked for use in combination with the corresponding slider attachment to determine the treatment spot size:
  - The "**A**" groove is marked "6/12" for the 6 mm and 12 mm spot sizes.
  - The "**B**" groove is marked "SS/8/15" for the small spot (SS) sizes of 1.5 mm and 3 mm and for the 8 and 15 mm spot sizes.
  - The "**C**" groove is marked "10/18" for the 10 mm and 18 mm spot sizes.

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- The 5 mm slider attachment has two black grooves. When the slider attachment is inserted together with fiber into the handpiece, the A/B/C grooves will stay outside the handpiece but the 5 mm slider attachment will be in place and locked.

6. Insert the slider attachment (**B**) into the slider (**A**).



Figure 4-3 Inserting the Slider Attachment into the Slider

7. Press and hold the slider lock button on the handpiece (**A** in Figure 4-4) and insert the fiber cable, with the slider attachment, into the slider tube at the back end of the handpiece.



Figure 4-4 Inserting the Fiber Cable into the Handpiece (DCD shown; same for ACC)

- The green slider attachment provides 20 mm or 26 mm (groove "A"), 22 mm (groove "B") or 24 mm (groove "C") treatment spot sizes in the Large Spot Delivery System.
- The "A" groove is marked "20/26" for the 20 mm and 26 mm spot sizes.

NOTE: Before calibrating the laser system with the 26 mm Slider Attachment, the laser MUST be calibrated with the 20mm Slider Attachment first.

NOTE: The 20 - 24 mm and 26 mm slider attachments can only be used with the green slider and the Large Spot DCD and ACC Delivery Systems

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The slider locks into place when properly positioned and the slider lock button (**D**) is released.

1. Remove the distance gauge.
2. Fully insert the handpiece into the calport.



Figure 4-5 ACC or DCD Handpiece Fully Inserted Into Calport

3. Select the operating parameters for the treatment application. To set individual operating parameters, see "Operating Parameters" on page 71, or to use pre-set operating parameters, see "Applications Menu (Types of Treatments)" on page 81.

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

4. Select the calibration button and follow the instructions on the touch screen.

NOTE: If the wavelength was changed prior to pressing the calibration button, the laser may make an audible "pop" sound as the system adjusts to the new wavelength when the calibration button is pressed.

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NOTE: The laser system calibration can be canceled at anytime by selecting the cancel button ⊘. If this occurs, restart the calibration procedure.

5. Remove the handpiece from the calport.
6. Put the distance gauge back on.

NOTE: After a calibration is completed, the laser system remains in **Standby** mode.

7. Press the **Standby/Ready** button on the touch screen and wait for the beep to sound before proceeding. DO NOT press the fingerswitch or the footswitch to pulse the laser until the beep has sounded.

NOTE: When the laser system enters **Ready** mode, it produces an internal test pulse, but with no energy.

8. Place the handpiece distance gauge on a white piece of paper and inspect the laser aiming beam for circular uniformity and clarity. If the aiming beam spot is uniform and clear, continue with the next step.

   If the aiming beam spot is not uniform, select the **Standby/Ready** button to put the laser system in **Standby** mode. Verify proper operation of the delivery system, as described in "Fiber Cable" on page 137.

CAUTION

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

9. Perform the laser treatment (see "Preparing for the Laser Treatment" on page 90).

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NOTE:

- The laser system does not allow treatment pulses until a calibration has been performed after any one of the following conditions:
  - Laser system is turned on
  - Delivery system changed
  - Slider attachment is changed
  - Specific faults occur
  - In **Standby** mode for more than 30 minutes
  - There is a change in wavelength
- The operator must initiate a calibration after cleaning or replacing the handpiece or slider attachment windows in the handpiece or slider.

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Chapter 5 Performing a Laser Treatment

Preparing for the Laser Treatment

WARNING

ALL PERSONNEL IN THE VICINITY OF THE LASER MUST KEEP EYEWEAR ON AT ALL TIMES DURING TREATMENT PROCEDURE.

WARNING

- **COVER TREATMENT ROOM WINDOWS WITH AN OPAQUE MATERIAL TO PREVENT UNINTENDED VIEWING.**
- **POST LASER WARNING SIGNS AT EACH ENTRANCE TO THE LASER TREATMENT ROOM.**
- **ENSURE AN ADEQUATE NUMBER OF PROTECTIVE EYEWEAR IS AVAILABLE.**

Before performing a laser treatment, read the "Safety" chapter starting on page 11.

The GentleMax Pro Plus laser system requires the laser to be calibrated prior to patient treatment. For instructions, see page 84.

NOTE: A swipe clean cycle must be performed on the distance gauge every 50 laser pulses. For instructions, see page 118.

CAUTION

Use only safety eyewear with an optical density of ≥ 5.8 for 755 nm and eyewear with an optical density of ≥ 6.3 for 1064 nm. Safety eyewear that is designed for use with other laser systems may not provide adequate protection. Please use the dual wavelength eyewear supplied with the system.

1. Plug the laser system into the correct electrical outlet. Ensure that the mains power switch (see page 59) on the rear panel is in the **ON** position.
2. Ensure that the handpiece and fiber cable connections are tight and secure to the front of the laser system.
3. Attach the delivery system cables onto the fiber pole. For instructions, see page 51.
4. Verify that the handpiece window and slider attachment window are clean. For instructions, see page 120 and page 130, respectively.

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WARNING

- **ALWAYS PLACE THE LASER SYSTEM IN STANDBY MODE OR OFF BEFORE ATTEMPTING TO CHECK, CLEAN, OR REPLACE THE DELIVERY SYSTEM, SLIDER, SLIDER ATTACHMENT, DISTANCE GAUGE, HANDPIECE WINDOW, OR SLIDER ATTACHMENT WINDOW.**
- **ALWAYS RECALIBRATE THE LASER SYSTEM AFTER ADJUSTING, CLEANING, OR REPLACING THE DELIVERY SYSTEM, SLIDER ATTACHMENT, HANDPIECE WINDOW, AND SLIDER ATTACHMENT WINDOW. FAILURE TO INITIATE A CALIBRATION AFTER CLEANING OR REPLACING THESE COMPONENTS MAY RESULT IN THE DELIVERY OF EXCESSIVE LASER ENERGY.**

Starting Up the Laser System

WARNING

ALL PERSONNEL IN THE VICINITY OF THE LASER MUST KEEP EYEWEAR ON AT ALL TIMES DURING TREATMENT PROCEDURE.

1. Turn the key-lock switch from the **OFF** to the **START** position.

   There may be a delay of several seconds before the system initializes; this is normal. When the main screen becomes visible, a warning appears on the touch screen to remind the operator to perform the user verification checks on page 139 before using the laser system. The system enters the warm-up mode. After the warm up is complete, the system enters **Standby** mode.

2. Configure the preferred system settings by selecting the system settings button and by doing the following:

   a. Select the preferred language (see page 78).

   b. Select fingerswitch or footswitch trigger (see page 77).

   c. Select aiming beam intensity level (see page 77).

3. Save the system settings by selecting the save button.

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Performing the Laser Treatment

Determine the appropriate treatment spot size. Then, set up the equipment as follows.

The slider is the long tube with three grooves that is attached to the fiber. Select the appropriate slider (see Figure 5-1):

- The silver slider is used with the Medium Spot Standard DCD and ACC delivery system handpieces and the 1.5/3/5/3x10 mm Small Spot Delivery System handpiece.
- The green slider is only used with the Large Spot DCD and ACC delivery systems.

1. Select the appropriate slider attachment (see Figure 5-1):

- The long, gold slider attachment with one black groove in the middle provides a 1.5 mm treatment spot size.
- The long, silver slider attachment with one black groove in the middle provides a 3 mm treatment spot size.
- The long, silver slider attachment with the two black grooves in the middle provides a 3x10 mm elliptical treatment spot size.
- The long, blue and silver slider attachment with the two black grooves in the middle provides a 5 mm treatment spot size.
- The short, gold slider attachment provides 6 mm, 8 mm or 10 mm treatment spot sizes.
- The short, silver slider attachment provides 12 mm, 15 mm or 18 mm treatment spot sizes.
- The slider has three circumferential grooves, each marked for use in combination with the corresponding slider attachment to determine the treatment spot size: The "A" groove is marked "6/12" for the 6 mm and 12 mm spot sizes.
- The "B" groove is marked "SS/8/15" for the Small Spot (SS) sizes of 1.5 mm, 3 mm, and 3x10 mm and for the 8 mm and 15 mm spot sizes.
- The "C" groove is marked "10/18" for the 10 mm and 18 mm spot sizes.
- The green slider attachment provides 20 mm (groove "A"), 22 mm (groove "B") or 24 mm (groove "C") treatment spot sizes in the Large Spot Delivery System.
- The "A" groove is marked "20/26" for the 20 mm and 26 mm spot sizes.

NOTE: The 1.5 mm, 3 mm, 3x10 mm and 5 mm slider attachments can only be used with the Small Spot DCD handpiece. The 6 - 18 mm slider attachments can only be used with the Medium Spot Standard DCD handpiece.

NOTE: The 20- 24 mm and 26 mm slider attachments can only be used with the green slider and the Large Spot DCD and ACC Delivery Systems.

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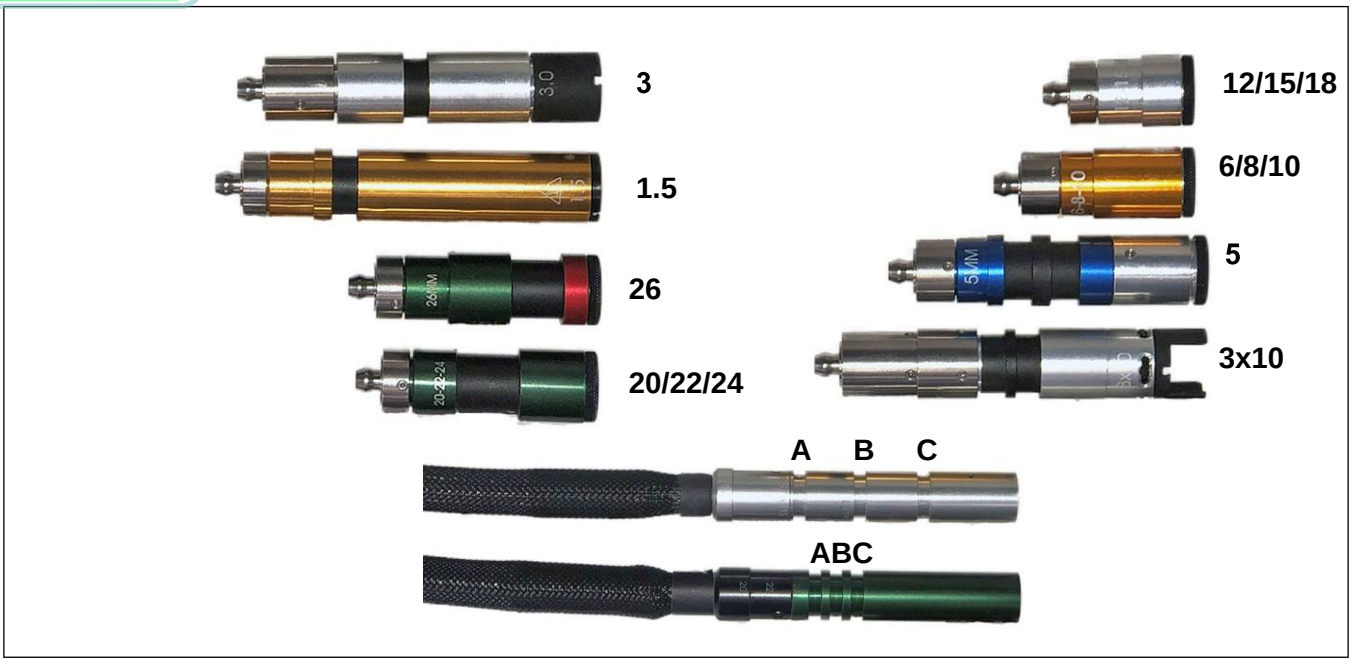


Figure 5-1 The Slider and Slider Attachments

2. Push the slider attachment (B in Figure 5-2) into the slider (A) until fully seated.

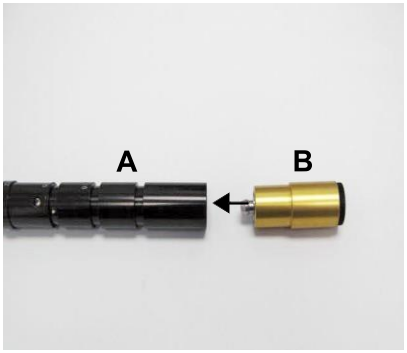


Figure 5-2 Attaching the Slider Attachment

3. Insert the fiber cable assembly into the handpiece to achieve the desired spot size:

a. Press and hold in the slider lock button (**D** in Figure 5-3).

b. While holding in the lock button, insert the fiber cable with the slider attachment into the slider tube at the back end of the handpiece until the desired spot size marked on the slide is adjacent to the handpiece.

c. Release the lock button to lock the slider in place. Gently tug on the slider attachment to verify that it is locked in place.

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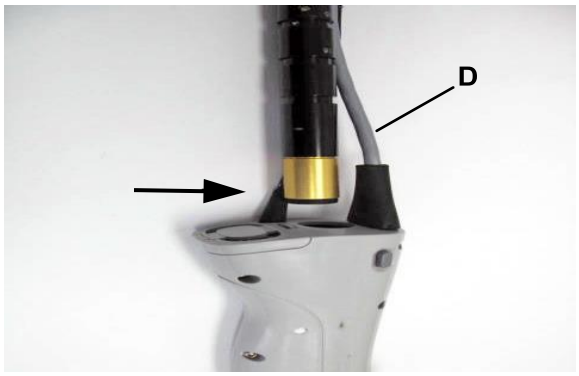


Figure 5-3 Inserting the Fiber Cable Assembly into the Handpiece

d. Confirm that the selected spot size is displayed on the lower left corner of the screen.

4. Select the desired operating parameters by choosing either step a or step b:

a. To use pre-set operating parameters:

i. Press and hold the central "ALEX" or "YAG" Laser (Wavelength) Selection button until the wavelength changes (approximately 1 second).

ii. Select the appropriate treatment application, that supports the selected spot size, from the applications menu (see "Applications Menu (Types of Treatments)" on page 81).

iii. Select the application parameters from the **Treatment Application - Select Parameters** screen and select the next button.

iv. Confirm the application parameters on the **Treatment Application - Common Settings** screen by selecting the save button. If you do not want to save the settings, select the cancel button.

v. If needed, manually adjust the settings of the operating parameters by using the arrows (see page 71).

b. To manually set individual operating parameters, use the arrows to:

i. Press and hold the central "ALEX" or "YAG" Laser (Wavelength) Selection button until the wavelength changes (approximately 1 second).

ii. Adjust the fluence setting (spot size dependent) (see page 71).

iii. Adjust the pulse duration setting (see page 72).

iv. Adjust the repetition rate setting (see page 72).

v. If applicable, adjust the DCD spray duration and delay duration settings (treatment dependent) (see page 74).

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CAUTION

For air cooling, set the epidermal protection according to the instructions provided by the manufacturer of the cooling system.

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

5. Perform a laser system calibration. For instructions, see page 84.

NOTE: The laser system calibration can be canceled at anytime by selecting the cancel button. If this occurs, see "Calibrating the Laser System" on page 84.

NOTE: After a calibration is completed, the laser system remains in **Standby** mode.

6. Insert the corresponding distance gauge (DG) into the front of the handpiece. The 6 mm and 8 mm share the same distance gauge. The 1.5 mm and 3 mm also share the same distance gauge. Adistance gauge marked with a spot size equal to or greater than the selected spot size can be used, except for the Small spot sizes of 1.5 mm, 3 mm, 3x10 mm and 5 mm.

The distance gauge is keyed for proper orientation, so the Cryogen spray does not hit the side of the distance gauge. To install the distance gauge, push while rotating (either direction) the distance gauge until its body is flush with the handpiece. The distance gauge legs will be aligned with the sides of the handpiece (see Figure 5-4, view **D**).

The 3x10 mm distance gauge has two keys. The first key aligns the long axis of the elliptical beam to the two notches in the ring of the distance gauge. The second is identical to the key in the other distance gauges, aligning the distance gauge legs with the sides of the handpiece. The procedure for installing the 3x10 mm distance gauge is the same as the procedure for installing the other distance gauges: push while rotating the distance gauge until its body is flush with the handpiece (see Figure 5-4).

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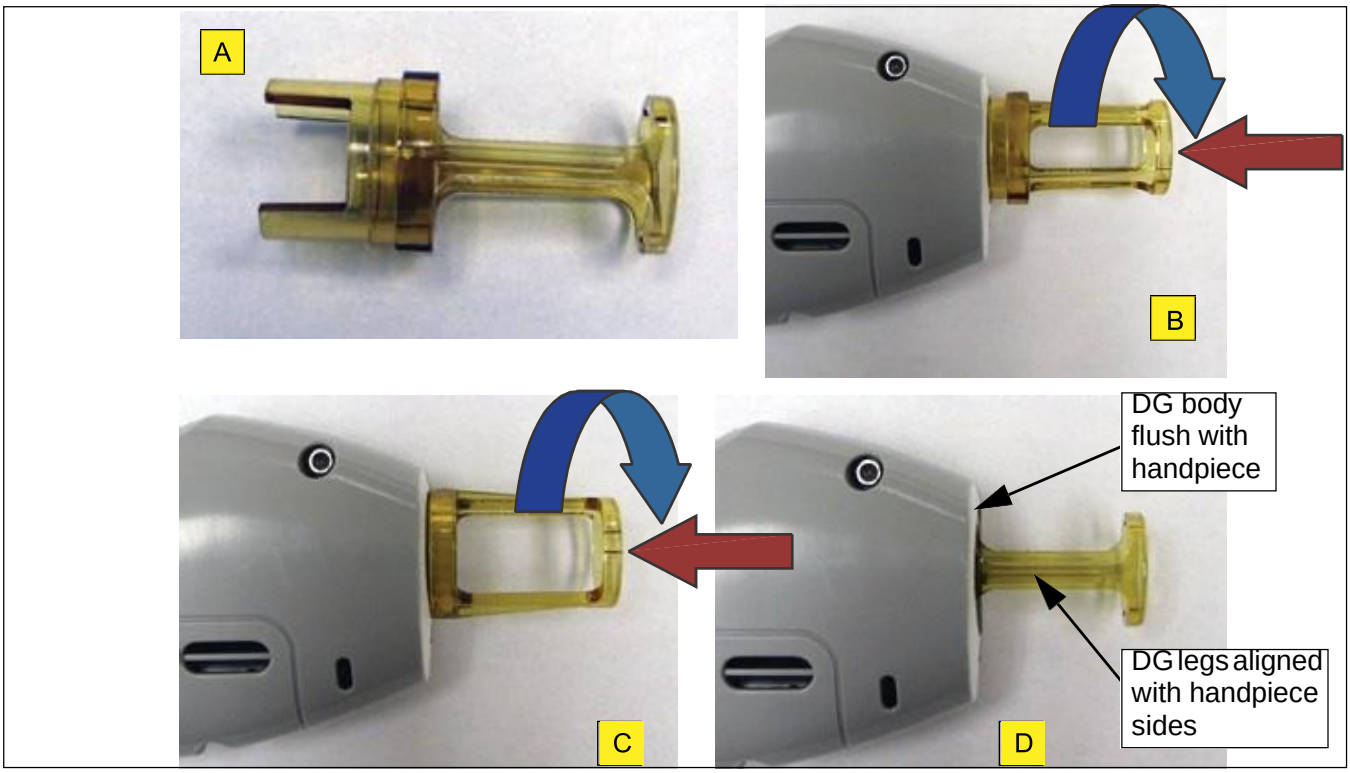


Figure 5-4 Insertion of Distance Gauges

View A:	3x10 Distance Gauge (DG)
View B:	Initial Insertion of 3x10 DG
View C:	First Position, 3x10 DG
View D:	Final Insertion of All DG's

7. Press the **Standby/Ready** button on the touch screen and wait for the beep to sound before proceeding. DO NOT press the fingerswitch or the footswitch to pulse the laser until the beep has sounded.

NOTE: When the laser system enters **Ready** mode, it produces an internal test pulse, but with no energy.

8. Reset the treatment pulse counter to zero by pressing and holding the treatment pulse reset button for greater than 1 second.

9. Perform the laser treatment.

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NOTE: A swipe clean cycle must be performed on the distance gauge every 50 laser pulses. For instructions, see page 118.

10. Place the laser system into **Standby** mode when the treatment is complete.
11. Place the handpiece in the handpiece holder, or remove the distance gauge and insert the handpiece into the calport.
12. Document laser system use. See "Treatments Summary Button" on page 68.
13. Adjust the laser system output parameters, as needed, before starting the next treatment.
14. Even if it is not required, a calibration should be initiated before each patient treatment. This allows the system to check the condition of the windows.

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Chapter 6 Troubleshooting

Overview of Troubleshooting

Review all instructions and procedures in this operator manual before attempting any of these general troubleshooting and fault message solutions.

General Troubleshooting

Table 6-1 General Troubleshooting Solutions

Situation/Symptom	Probable Cause or Fault Message	Solution
Aiming beam appears dim.	• The aiming beam intensity is set too low. • The slider attachment window is dirty. • The handpiece window is dirty or damaged.	• Set the aiming beam intensity (see page 77). • Clean (see page 132) or replace (see page 150) the slider attachment window. • Clean (see page 122) or replace (see page 147) the handpiece window. • Contact a Candela Service Representative.
Aiming beam appears non-uniform.	• The handpiece window is dirty or damaged. • The slider attachment window is dirty or damaged. • The fiber cable is damaged or broken.	• Clean (see page 122) or replace (see page 147) the handpiece window. • Clean (see page 132) or replace (see page 150) the slider attachment window. • Replace the fiber cable (see "Replacing the Fiber Cable" on page 150).

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Situation/Symptom	Probable Cause or Fault Message	Solution
Aiming beam is missing in **Ready** mode.	• The fiber cable is damaged or broken. • The aiming beam or driver circuit is bad. • The aiming beam is turned off.	• Replace the fiber cable (see "Replacing the Fiber Cable" on page 150). • Contact a Candela Service Representative. • Set the aiming beam intensity (see "Aiming Beam Intensity Button" on page 77).
Animated bubbles symbol: 	• Bubbles are detected in the Cryogen line.	• A purge is required. Remove the handpiece from calport, pointing it away from yourself, and select the purge button until the problem resolves. • If the problem persists, contact a Candela Service Representative.
Cryogen leak	• There are breaks in the delivery system tubing.	• Remove the Cryogen canister or disconnect the delivery system from the laser system. • Contact a Candela Service Representative.
Ineffective fluence response	• Delivery system cables or fiber cable is degraded. • Incorrect wavelength selected.	• Calibrate the laser system (see page 84). • Select correct wavelength. • If the problem persists, contact a Candela Service Representative.
Laser pulses but Cryogen is not delivered.	• The DCD spray settings are set to zero (0).	• Increase the DCD spray settings (see page 74).

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Situation/Symptom	Probable Cause or Fault Message	Solution
Laser system cannot be turned on.	• The mains power switch of the laser system is **Off**. • The key-lock switch is not fully engaged. • The power is not connected properly.	• Turn the mains power switch **On** (see page 59). • Fully engage the key-lock (see page 58). • Reseat the power cable and check the circuit breaker.
Laser system does not enter **Ready** mode.	• The trigger switch is depressed too early.	• Release the trigger switch, wait until the laser system is in **Ready** mode, and try again.
Replace Canister message appears.	• There is insufficient Cryogen in the canister.	• Replace the Cryogen canister with a new canister supplied by Candela (see page 153).
The Interlock is open.	• The CDRH plug is not installed.	• Ensure the CDRH plug is installed (see page 60). • Contact a Candela Service Representative.

Fault Messages

When a system malfunction occurs, the laser system enters a fault condition. The laser system beeps and displays a fault message. It continues to beep every 10 seconds until the fault is cleared.

Sometimes clearing the fault and retrying the previous operation corrects the fault condition. If the fault message persists, contact a Candela Service Representative and report the fault number.

NOTE: Fault processing automatically places the laser system into **Standby** mode.

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Table 6-2 Fault and Warning Messages and Solutions

Fault #	Situation/Symptom	Problem	Solution
F1.1	Handpiece Bubble Circuit	• Handpiece bubble circuit test did not detect a change in the signal.	• If problem persists, contact a Candela Service Representative for system servicing.
F1.2	Canister Bubble Circuit	• Canister bubble circuit test did not detect a change in the signal.	• If problem persists, contact a Candela Service Representative for system servicing.
F3.1	Shutter	• Shutter is not in the correct mode when checked. It does not respond to actuation to the correct mode.	• Turn off the laser system for 30 seconds and then restart the laser system (see page 59). • If problem persists, contact a Candela Service Representative for system servicing.
F4.2	Power Supply Communication	• High voltage power supply communications time-out.	
F5.1	Power Supply Tolerance	• High voltage power supply tolerance fault.	
F5.2	Power Supply Charge	• High voltage power supply charge time-out.	
F5.3	Discharge Error	• High voltage dump circuit test failed.	
F6.1	Calibration	Laser system failed to find threshold HD energy within normal voltage or laser system failed to find Max HD energy within 60 pulses. It may be caused by: • Laser system mobility shocks may have shifted the laser head out of alignment. • Aging laser head or laser head components.	• Calibrate the laser system (see page 84). • If problem persists, contact a Candela Service Representative for system servicing.

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Fault #	Situation/Symptom	Problem	Solution
F6.5	Calport Switch	• Calport redundant switches indicate different modes for longer than 1 second.	• Reinsert handpiece in calport. • If problem persists, contact a Candela Service Representative for system servicing.
F7.1	Fluid Low Temperature	• Distilled or DI water is under temperature.	• Put the laser system in **Standby** mode (see page 69) and allow sufficient time for the laser system to warm-up. • Verify the laser room environment and temperature meet the specifications provided in Appendix A, "Specifications." • Verify the water level is correct (see page 60). • Turn off the laser system for 30 seconds and then restart the laser system (see page 59). • If problem persists, contact a Candela Service Representative for system servicing.

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Fault #	Situation/Symptom	Problem	Solution
F7.2	Fluid High Temperature	• Distilled or DI water is over temperature.	• Turn off the laser system (see page 59) and allow sufficient time for the laser system to cool down. • Check the Distilled or DI water level (the reservoir should be filled with Distilled or DI water). Refill reservoir if needed (see page 60). • Verify the laser room environment and temperature meet the specifications provided in Appendix A, "Specifications." • Verify the laser system is more than 12 inches (305 mm) from the wall. • Turn off the laser system for 30 seconds and then restart the laser system (see page 59). • If problem persists, contact a Candela Service Representative for system servicing.

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Fault #	Situation/Symptom	Problem	Solution
F7.3	Fluid Flow	• Distilled or DI water pump pressure fault. • Low or no Distilled or DI water pressure and/or flow. • Distilled or DI water system pressure switch does not change when the power is turned on. • Distilled or DI water pump is not "On" or DI pressure switch is not actuated. • Distilled or DI water level is low and/or there are air bubbles flowing through the fluid system.	• Turn off the laser system (see page 59). • Check the Distilled or DI water level (the reservoir should be filled with Distilled or DI water). Refill reservoir if needed (see page 60). • Check for Distilled or DI water leaks underneath the laser system. If water leak is present, contact a Candela Service Representative for system servicing. • Restart and turn off (see page 59) the laser system 2 to 3 times to allow fluid system to pump water and flush out air bubbles. • If problem persists, contact a Candela Service Representative for system servicing.
F7.4	Fluid Temperature Sensor	• Temperature sensor fault (sensor circuit open or shorted).	
F7.5	Fluid Level Low	• Distilled or DI water level is low.	• Fill the reservoir with Distilled or DI water.
F8.2	DCD Canister High Pressure	• Faulty pressure sensor. • Overheated DCD canister.	• Check DCD canister level. If the canister is empty, replace it. ⚠ **CAUTION** **Canister may be HOT!**
F8.3	Handpiece DCD Valve	• DCD valve fault.	• Replace the delivery system (see page 150). • If problem persists, contact a Candela Service Representative for system servicing.

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Fault #	Situation/Symptom	Problem	Solution
F8.4	DCD Canister Temperature Sensor	• DCD temperature sensor.	• Turn off the laser system, allow it to cool down, and then restart the laser system (see page 59). • If problem persists, contact a Candela Service Representative for system servicing.
F9.1	Fluid Warm Up	• DI temperature is not in normal range after 60 minutes.	• Turn off the laser system for 30 seconds and then restart the laser system (see page 59). • If problem persists, contact a Candela Service Representative for system servicing.
F9.2	DCD Canister Warm Up	• DCD pressure is not in normal range after 60 minutes.	• Turn off the laser system for 30 seconds and then restart the laser system (see page 59). • If problem persists, contact a Candela Service Representative for system servicing.
F10.1	Slider Attachment Not Recognized.	• There is an unrecognized slider attachment while in **Ready** mode.	Slider attachment is not installed or detected; do the following: • Reinstall the slider attachment or insert a different size slider attachment (see page 133). • Calibrate the laser system (see page 84).
F12.1	Low Energy	• Laser head energy of last treatment pulse is low.	• Calibrate the laser system (see page 84). • If problem persists, contact a Candela Service Representative for system servicing.
F12.2	High Energy	• Laser head energy of last treatment pulse is high.	

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Fault #	Situation/Symptom	Problem	Solution
F12.3	Max Energy Exceeded.	• Laser head energy of last treatment pulse is greater than the maximum allowed.	• Clean (see page 122) or replace (see page 147) the handpiece window. • Clean (see page 132) or replace (see page 150) the slider attachment window.
F12.4	Energy Not Balanced.	• Laser head energy is not balanced between each sub-pulse.	• Calibrate the laser system (see page 84). • If problem persists, contact a Candela Service Representative for system servicing.
F12.6	Pulse Width Inconsistent.	• Total pulse width is not within +20 % of nominal.	
F13.1	Fingerswitch	• Redundant finger-switches indicate different modes for greater than 1 second.	• Change to footswitch (see page 77). • Change delivery system (see page 150).
F13.2	Footswitch	• Redundant footswitches indicate different modes for greater than 1 second.	• Make sure the footswitch cable is not compressed. • Change to the fingerswitch (see page 77). • If problem persists, contact a Candela Service Representative for system servicing.
F13.3	Fingerswitch	• Fingerswitch is stuck "On" while going into **Ready** mode for longer than 10 seconds.	• Change to the footswitch (see page 77). • Change delivery system (see page 150).
F13.4	Footswitch	• Footswitch is stuck "On" while going into **Ready** mode for longer than 10 seconds.	• Make sure the footswitch cable is not compressed. • Change to the fingerswitch (see page 77). • If problem persists, contact a Candela Service Representative for system servicing.

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Fault #	Situation/Symptom	Problem	Solution
F14.1	755 nm Simmer Fault	• Simmer circuit fault.	• Calibrate the laser system (see page 84). • If problem persists, contact a Candela Service Representative for system servicing.
F14.2	1064 nm Simmer Fault	• Simmer circuit fault.	• Calibrate the laser system (see page 84). • If problem persists, contact a Candela Service Representative for system servicing.
F15.1	Delivery System Transmission Low.	Low transmission; it may be caused by the following: • Dirty or damaged slider attachment window or handpiece window. • Incorrect windows are installed. • Delivery system is worn. • A slider attachment is not installed.	Calibrate the laser system (see page 84) after trying each of the following solutions: • Clean (see page 122) or replace (see page 147) the handpiece window. • Clean (see page 132) or replace (see page 150) the slider attachment window. • Try another slider attachment (the same size, if available). If this slider attachment works, contact a Candela Service Representative to replace the faulty slider attachment. • Replace the fiber cable (see page 150). • If problem persists, contact a Candela Service Representative for system servicing.

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Fault #	Situation/Symptom	Problem	Solution
F15.2	Delivery System Transmission High.	• High transmission.	• Calibrate the laser system (see page 84). • If problem persists, contact a Candela Service Representative for system servicing.
F18.1	Energy Circuit	• Energy circuit calibration fault.	• Contact a Candela Service Representative for system servicing.
F18.2	Fluid Circuit	• DI circuit calibration fault.	
F18.3	DCD Circuit	• DCD circuit calibration fault.	
F19.1	Laser Trigger	• Laser trigger fault.	
F19.3	Laser Power	• Laser power fault.	
F19.4	Laser Head Power	• Lasing head power fault. • Software detected head power present before/ after pulse. • Hardware detected pulse fault (Over Energy).	• Calibrate the laser system (see page 84). • If problem persists, contact a Candela Service Representative for system servicing.
F19.5	Discharge Error	• High voltage dump circuit test failed.	• Turn off the laser system for 30 seconds and then restart the laser system (see page 59). • If problem persists, contact a Candela Service Representative for system servicing.
F21	Software Update	• Code update did not complete properly.	• Contact a Candela Service Representative for system servicing.
F23	One Wire Communications	• One wire network fault.	• Turn off the laser system for 30 seconds and then restart the laser system (see page 59). • If problem persists, contact a Candela Service Representative for system servicing.
F24	Internal Communications Fault	• GUI communications fault.	

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Fault #	Situation/Symptom	Problem	Solution
F26.1	Internal Software Fault	• An internal software fault occurred.	Contact a Candela Service Representative for system servicing.
F26.2	Internal Software Fault	• An internal software fault occurred.	Contact a Candela Service Representative for system servicing.

Warning Messages

Table 6-3 Warning Messages and Solutions

Situation/Symptom	Warning #	Problem	Solution
Delivery System Not Connected.	10.2	• The delivery system is disconnected while in **Ready** mode.	• Disconnect and reinstall the electrical cable of the delivery system (see page 57). • Replace the delivery system (see page 150). • If problem persists, contact a Candela Service Representative for system servicing.
Slider Removed In Ready.	10.3	• The slider attachment is removed while in **Ready** mode.	• Reinstall the slider attachment (see page 133) and calibrate the laser system (see page 84).
Fiber Not Connected.	10.4	• Fiber is not detected while in **Ready** mode.	• Disconnect fiber cable from the laser system (see page 57) and reinstall. • Replace the fiber cable (see page 150). • If problem persists, contact a Candela Service Representative for system servicing.

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Situation/Symptom	Warning #	Problem	Solution
Warning - Handpiece Bubble	17	• Bubbles are detected in the handpiece. • Bubbles need to be purged out of the Cryogen fluid lines. • Cryogen canister is empty or lines obstructed.	• Press and hold the purge button to purge bubbles out of the Cryogen line. • Check the canister level to see if it is empty. Replace the canister if needed. • If the canister is full, remove it and then reinstall it. Select the purge button to ensure flow of Cryogen from the handpiece. • Handpiece may be overheated. Allow 10 minutes to cool, then select the purge button and try again. • If problem persists, contact a Candela Service Representative for system servicing.

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Appendix A Specifications

Laser System Specifications

Table A-1 GentleMax Pro Plus Laser System Specifications

Laser System Specifications	
Laser Type	Flashlamp-excited, pulsed Solid State Alexandrite and/or Nd:YAG.
Dimensions (H x W x D)	42 in (1067 mm) X 18 in (457 mm) X 27 in (686 mm)
Weight	260 lbs (118 kg)
Wavelength	755 nm and 1064 nm
Method of Optical Output	Lens-coupled optical fiber with user selectable spot sizes.
Maximum Delivered Energy	68 Joules (J) ALEX; 90 J Nd:YAG
Accuracy of Output Energy	±20%
Pulse Repetition Rate	Up to 10 Hz repetitive pulsing.
Pulse Duration	0.25 to 100 ms
Beam Spot Sizes	1.5 mm*, 3 mm*, 3x10 mm*, 5 mm, 6 mm, 8 mm, 10 mm, 12 mm, 15 mm, 18 mm, 20 mm*, 22 mm*, 24 mm* & 26 mm.
Laser Cooling Method	Ambient air
Aiming Device	520 nm to 550 nm, less than 8 mW.
Cryogen	HFC 134a
Wi-Fi	2.4/5 GHz IEEE 802.11a/b/g/n
Voltage and Power (30A configuration)	200 to 240 V~, 50/60 Hz, single phase, 4,600 VA or 20 A at 230 V~.
Voltage and Power (20A configuration)	200 to 240 V~, 50/60 Hz, single phase, 3,600 VA or 16 A at 230 V~.

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Environmental Specifications	
Humidity (non condensing)	Operating and Storage: 20% to 80% Transport: 5 % to 85%
Ambient Temperature	Operating: 65 to 85°F (18 to 29°C) Storage: 40 to 110°F (5 to 43°C) Transport: -20 to 140°F (-29 to 60°C) **WARNING** **Do not expose the laser system to temperatures below 40°F (5°C) because freezing damage may occur. If the laser system is exposed to temperature below 40°F (5°C), contact a Candela service representative prior to use.**

(*) Optional spot sizes

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Electromagnetic Compatibility (EMC)

Table A-2 Safety Compliance per IEC/EN60601-1

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

Regulatory Classifications

The GentleMax Pro Plus laser system is classified as a Class II medical device per FDA 21 CFR 878.4810, and a Class IIb (Rule 9), non-invasive, active device according to Annex IX of the European Medical Device Directive (MDD) 93/42/EEC. The device classification of the GentleMax Pro Plus laser system by Health Canada is Class 3. The GentleMax Pro Plus laser system is classified as a Class 4 laser per standard EN 60825-1.

NOTE: The Candela Family of Pulsed Lasers complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

NOTE: The Candela Family of Pulsed Lasers should be installed and operated according to CAN/CSA-Z386-08: Laser safety in health care facilities.

Electrical Requirements

The electrical requirements for the GentleMax Pro Plus laser system are listed in Table A-3.

WARNING

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

CAUTION

If a plug or line cable 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.

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For United States installations, the laser system is shipped with a 12 ft (3.7 m) power cable terminated with a locking NEMA L6-30P plug. The installation site requires a mating NEMA L6-30R power receptacle located within 10 ft (3 m) of the intended laser system location.

For International installations, the power connections should be made with a grounded 2-conductor plug and receptacle pair. The plug and receptacle must be rated for the service line voltage at a minimum and capable of handling 4,600 VA (for detailed ratings, see Table A-3). A plug meeting these requirements must be installed onto the laser system line cable. Alternately, the entire line cable may be replaced with one which is terminated with the appropriate plug.

For international installations with limited power connections, the laser system can be configured by authorized installation personnel to operate with reduced capabilities to allow connection to a lower size branch circuit. In this configuration, the branch circuit, plug and cable connection should be suitable to supply a 3,600 VA load.

Installation Site Electrical Service Requirements

Table A-3 Site Electrical Service Requirements

United States	200 V - 240 V~ (± 10%), 60 Hz, single phase, 30 Amp dedicated branch circuit with earth ground conductor.
Worldwide	200 V - 240 V~ (± 10%), 50/60 Hz, single phase, dedicated branch circuit with earth ground conductor capable of delivering 4600 VA of power in accordance with the local electrical code. Or, when configured for lower power operation: 200 V - 240 V~ (± 10%), 50/60 Hz, single phase, dedicated branch circuit with earth ground conductor capable of delivering 3600 VA of power in accordance with the local electrical code.

Operation of the GentleMax Pro Plus laser system on a power line that is not consistently within these specifications may damage the system and will void the warranty.

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Appendix B Maintenance

Overview of Maintenance

WARNING

NO UNAUTHORIZED MODIFICATION OF THIS PRODUCT IS ALLOWED.

The laser system requires routine care of some of its components for proper performance, reliability, and lifetime. These components are:

- Air filter
- Delivery system components:
  - Distance gauges
  - Handpiece body, fan filter, and window.
  - Slider attachment and slider attachment window.
  - Fiber cable
- Laser system exterior
- Cryogen canister
- Water cooling system
- Touch screen

There are two user verification tests that verify proper operation of the delivery system, if its operation is ever questionable, such as after it is accidentally dropped. These are in "User Verification Tests" on page 139.

All other maintenance and service must be performed by a qualified service representative. Routine preventive maintenance of the laser system should be performed by a qualified service representative periodically.

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Air Filter

There is a user serviceable air filter on the right side of the rear panel of the laser system. It is recommended that you clean the air filter on a monthly basis.

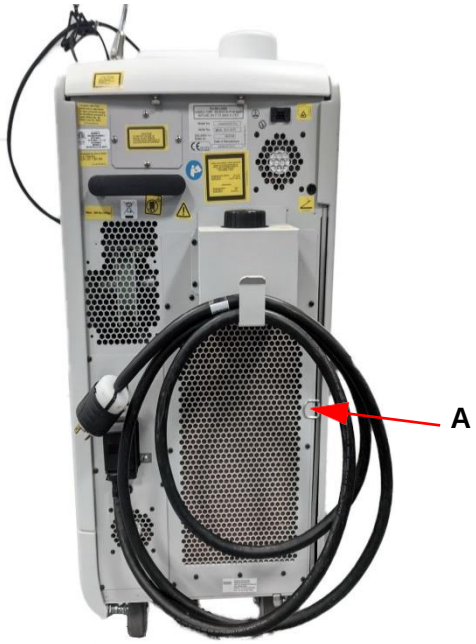


Figure B-1 Location of the Air Filter (Rear Panel View)

Removing, Cleaning, and Replacing the Air Filter

1. Remove the air filter (**A**) by pulling on the ring attached to the filter on right side of the rear panel of the laser system.
2. Vacuum the air filter on the grill side of the filter.

   The air filter can also be cleaned by running water through it from the foam side of the filter.
3. Let the air filter "air dry".
4. Insert the air filter, with the grill side on the left, into the slot and push it all the way in.

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Delivery System

The delivery system consists of a number of components that require routine maintenance for proper system performance. These components are:

- Distance gauges
- Handpiece components:
  - Handpiece window
  - Handpiece window holder
  - Handpiece body
  - Handpiece fan filter
- Slider attachment window
- Fiber cable

WARNING

- **ALWAYS PUT THE LASER SYSTEM INTO STANDBY MODE OR OFF AND REMOVE THE SLIDER ATTACHMENT FROM THE HANDPIECE WHEN CHECKING, CLEANING, OR REPLACING THE DELIVERY SYSTEM, SLIDER ATTACHMENT, DISTANCE GAUGE, HANDPIECE WINDOW, OR SLIDER ATTACHMENT WINDOW.**
- **ALWAYS CALIBRATE THE LASER SYSTEM AFTER FIXING, CLEANING, OR REPLACING THE DELIVERY SYSTEM, HANDPIECE WINDOW, OR SLIDER ATTACHMENT WINDOW. FAILURE TO INITIATE A CALIBRATION AFTER CLEANING OR REPLACING THE PARTS MAY RESULT IN DELIVERY OF EXCESSIVE LASER ENERGY.**
- **ALWAYS PERFORM THE USER VERIFICATION TESTS ON PAGE 139 TO CHECK THE DELIVERY SYSTEM FOR PROPER OPERATION AT THE BEGINNING OF EACH TREATMENT DAY. IN ADDITION, USE THE USER VERIFICATION TESTS TO CHECK THE DELIVERY SYSTEM IF THERE IS AN UNEXPLAINED TREATMENT RESPONSE NOTED OR THE DELIVERY SYSTEM HAS BEEN DROPPED. DISCONTINUE USE OF THE DELIVERY SYSTEM IF YOU SUSPECT A PROBLEM.**

Distance Gauges

When a distance gauge becomes dirty with debris, a bright flash of white light may appear. As the debris continues to build-up, the white light becomes larger and brighter.

Follow these instructions to maximize the length of use of the distance gauges. It may make the difference between using the distance gauges for a few hundred pulses or for several months.

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Reducing Debris Build-up

- Shave the treatment area clean just prior to initiating the procedure. There should be no stubble. **Dry shaving is recommended.** Burnt hair is the number one contributor to debris build-up on the distance gauges and handpiece window. If you use a topical anesthetic, remove it completely by washing with soap and water or witch hazel. The skin must be completely degreased. Perform a "swipe clean cycle" every 50 laser pulses (see Cleaning the Distance Gauges Using a Swipe Clean Cycle). It is easier to prevent debris build-up by consistently wiping clean the distance gauge during a procedure than it is to remove the debris once it is burnt on.
- At the end of each patient procedure, put that distance gauge aside for a "full clean cycle" overnight.

Cleaning the Distance Gauges Using a Swipe Clean Cycle

Perform a swipe clean cycle every 40-50 laser pulses or sooner if you detect significant flashing or if you note additional debris build-up. This procedure takes minimal time to perform.

1. Swipe a paper towel or piece of gauze moistened with warm water across the patient contact surface of the distance gauge tip or ring.
2. As the towel passes across the surface, allow your index finger to push into the ring slightly and rotate. You are cleaning a portion of the inner surface of the ring.
3. Continue the treatment.

Cleaning the Distance Gauges Using a Full Cycle

Perform a full cycle clean after each individual patient treatment.

1. Prepare a soaking container with chlorine bleach, suitable for disinfecting and cleaning. The bleach should not contain any other chemicals or softeners. Add tap water (distilled water is not necessary) to make a solution.

   A 10% bleach solution can be prepared by mixing one (1) part bleach to nine (9) parts water.
2. Place the distance gauges into a container and soak overnight.
3. Scrub all surfaces of the distance gauge body with a toothbrush and rinse with clean water.
4. Let the distance gauge "air dry".

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Handpiece

Thoroughly clean the handpiece, its components, and the slider attachment (see Cleaning the Slider Attachment) and slider attachment window (see Cleaning the Slider Attachment Window) after each patient is treated.

- Handpiece Window (see "Cleaning the Handpiece Window" on page 122)
- Handpiece Window Holder (see "Cleaning the Handpiece Window Holder" on page 122)
- Handpiece Body (see "Cleaning the Handpiece Body" on page 124)
- Handpiece Fan Filter (see "Cleaning the Handpiece Fan Filter" on page 127)

NOTE: These procedures are the same for the DCD and ACC handpieces.

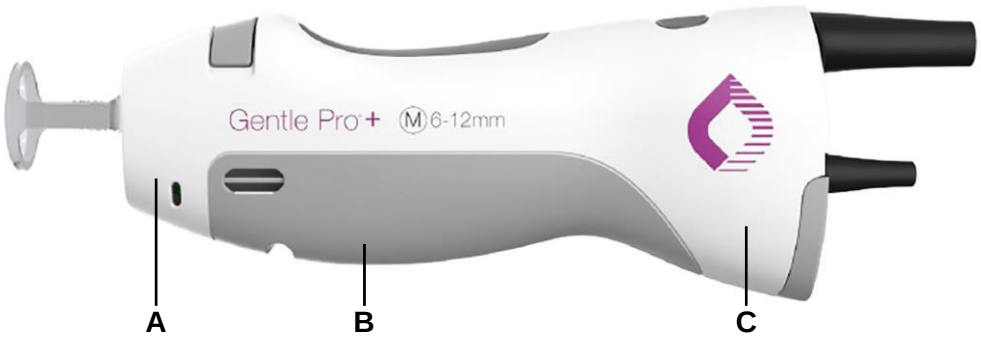


Figure B-2 Standard DCD Handpiece Components

A	Standard DCD Handpiece Window Holder
B	Standard DCD Handpiece Body
C	Standard DCD Handpiece Fan Filter Holder

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Standard DCD and ACC Handpiece Windows

WARNING

FAILURE TO RE-INSTALL WINDOWS PROPERLY AFTER CLEANING OR IMPROPER WINDOW INSERTION CAN RESULT IN FAILURE OF THE WINDOW AND MAY CAUSE PATIENT BURNS.

WHEN REMOVING A WINDOW FOR CLEANING, CAREFULLY NOTE THE WINDOW SURFACE THAT WAS EXPOSED TO DEBRIS AND THE DIRECTION IN WHICH THE WINDOW SURFACE FACES. WHEN RE-INSERTING THE WINDOW, ENSURE THAT THE WINDOW SURFACE THAT WAS EXPOSED TO DEBRIS FACES THE SAME DIRECTION AS IT DID PRIOR TO REMOVAL.

NOTE: The Small-Spot DCD Handpiece does not have a window.

The handpiece window holder (**A** in Figure B-3) holds the handpiece window. Remove and clean the Standard DCD or ACC handpiece window between treatments, as described below; replace the handpiece window when there is excessive debris build-up. The laser system displays a message when the handpiece window needs to be cleaned or replaced.

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Removing the Handpiece Window

1. Verify the laser system is in **Standby** mode or **OFF**.
2. Place a clean piece of tissue or paper on a flat surface.
3. Point the handpiece down.
4. Refer to Figure B-3: gently pull out the window holder from the handpiece body, ensuring that the handpiece window falls onto the tissue or paper.

   If the handpiece has the new yellow window holder that retains the window, the window may not fall out of the holder. The window can be cleaned while it is in the holder or gently pushed out of the holder for cleaning or replacement (see "Cleaning the Handpiece Window" on page 122).



Figure B-3 Removing the Standard Handpiece Window Holder

NOTE: Never touch the surface of the handpiece window; only hold it by its edges. Even if you are wearing dustless or plastic gloves, do not touch the surface of the handpiece window, as some gloves leave a residue.

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Cleaning the Handpiece Window

1. Wear dustless or plastic gloves or finger cots to prevent the natural oils on your skin from contaminating the handpiece window.
2. Using a gauze pad or towelette soaked with 70% to 100% isopropyl solution or a 10% bleach solution, clean both surfaces of the handpiece window. Remove any debris from the handpiece window surfaces by gently swiping across the surface. Use one swab per pass across the optic to avoid spreading debris.
3. Wipe the handpiece window dry with a lint-free lens paper, tissue, or equivalent.

NOTE: If the laser system gives warning messages about cleaning the handpiece window after it has been cleaned, replace the handpiece window.

Cleaning the Handpiece Window Holder

1. Remove the handpiece window as described in Removing the Handpiece Window.
2. After removing the window:
   a. Use a clean cloth, moistened with either 70% to 100% Isopropyl or a 10% bleach solution, to wipe clean the inside and outside edges of the window holder.
   b. Use a cotton-tipped swab moistened with either 70% to 100% Isopropyl or a 10% bleach solution to wipe clean the inner edge upon which the window sits.

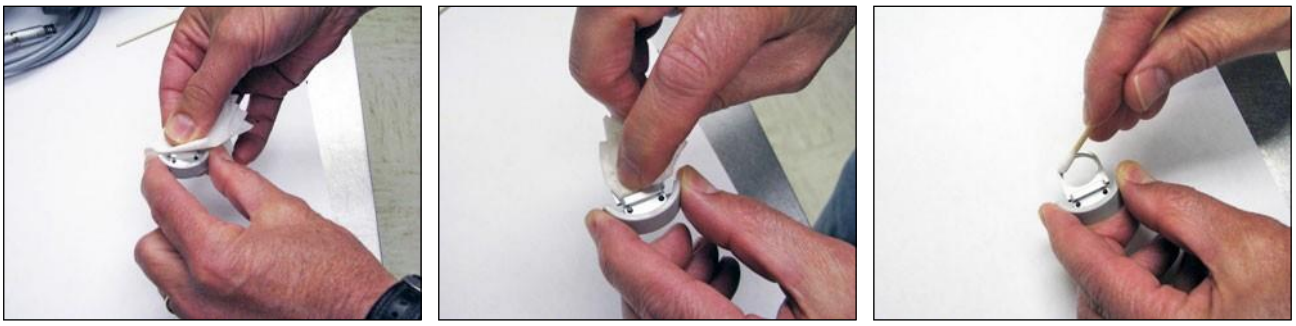


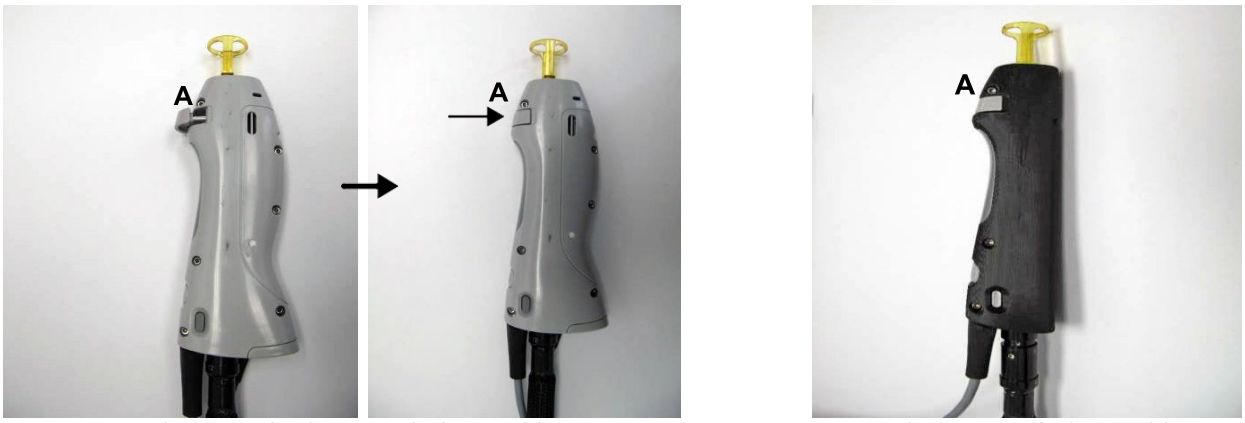
Figure B-4 Cleaning the Handpiece Window Holder

3. Replace the handpiece window as described in Inserting the Handpiece Window and Window Holder.

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Inserting the Handpiece Window and Window Holder

1. Hold the handpiece window by its edges and drop it into the window holder. The handpiece window must sit flush in the window holder to ensure that it correctly fits in the handpiece.
2. While pointing the handpiece up, slide the window holder (**A**) into the handpiece until it the window holder is flush with the top of the handpiece.



Inserting Standard DCD Window Holder

Inserting ACC Window Holder

Figure B-5 Inserting the Window Holder into the Standard DCD and ACC Handpieces

3. Newer handpieces will have a yellow window tray (holder) that retains the window. To insert the window into the tray:
   - Refer to Figure B-6: place the window into the window tray, distal end in first. The large rib on the tray faces up.

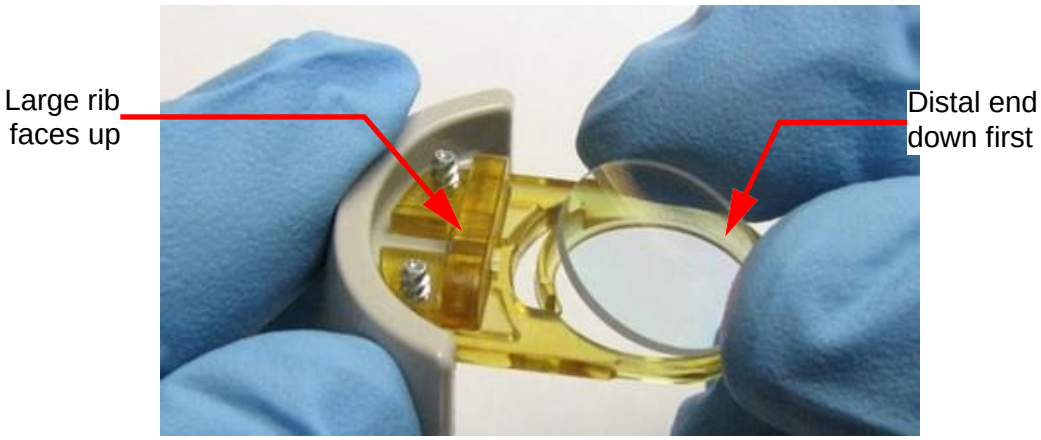


Figure B-6 Inserting the Window in the Window Tray (1)

   - Refer to Figure B-7: gently press the window into place with a dry, clean, lint-free lens tissue, or similar product.

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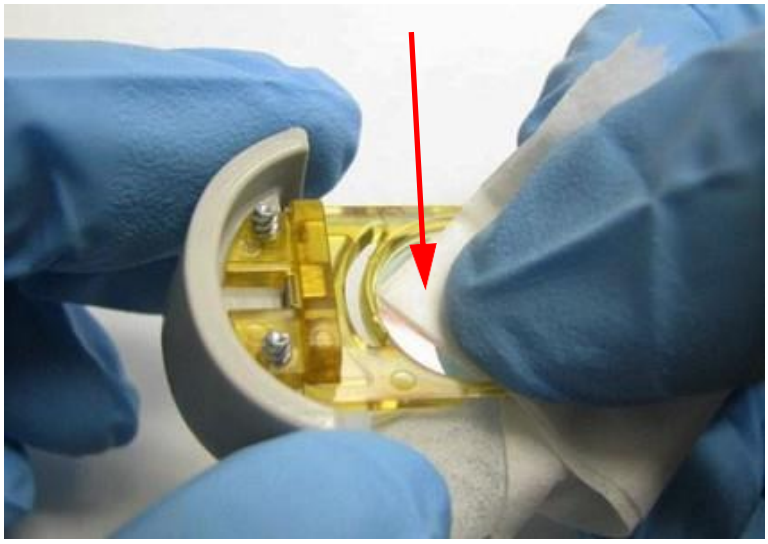


Figure B-7 Inserting the Window in the Window Tray (2)

4. The window is properly installed when its edges do not protrude outside of the tray and it does not fall out of the tray.
5. The window can be cleaned while it is in the tray.
6. Calibrate the laser system. For instructions, see page 84.

Handpiece Body

Cleaning the Handpiece Body

1. After each treatment session, immediately put the laser system in **Standby** mode and wipe the exterior surface of the handpiece body with a gauze pad or towelette moistened with 70% to 100% isopropyl solution or a 10% bleach solution. Take care to avoid contaminating the internal optical surfaces of the handpiece.
2. If a disinfectant is used, remove any residual disinfectant by wiping the handpiece body with a gauze pad or towelette moistened with 70% to 100% isopropyl solution or a 10% bleach solution.
3. After cleaning the handpiece body, dry the area thoroughly before beginning a laser treatment.
4. Periodically clean the inside of the handpiece using the following procedure. Daily cleaning is recommended for heavy hair removal usage.
   - Remove the window and window holder (see Figure B-3).
   - Refer to Figure B-8: use 70% to 100% isopropanol wipes (**A**) or paper towel wetted with isopropanol (**B**) to wipe the inside tube of the handpiece. Long forceps (**C** - supplied in the Accessory Kit) will help facilitate this cleaning.

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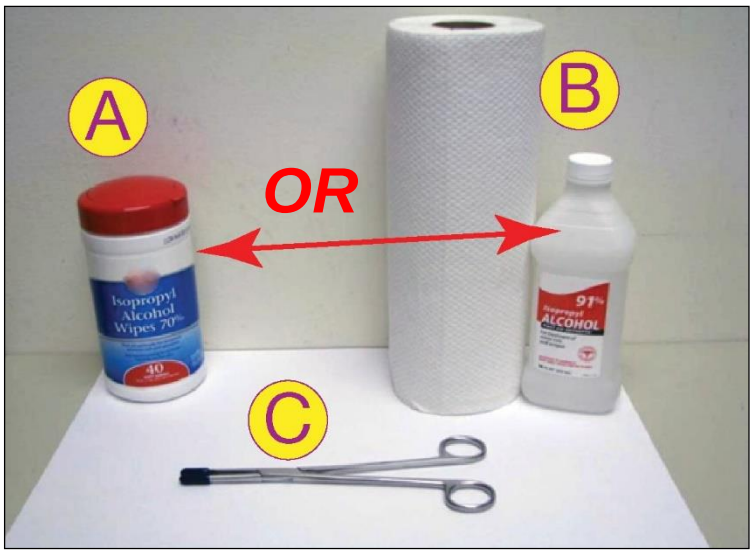


Figure B-8 Handpiece Cleaning Components

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- Refer to Figure B-9: Clean the back and the front tube of the handpiece.

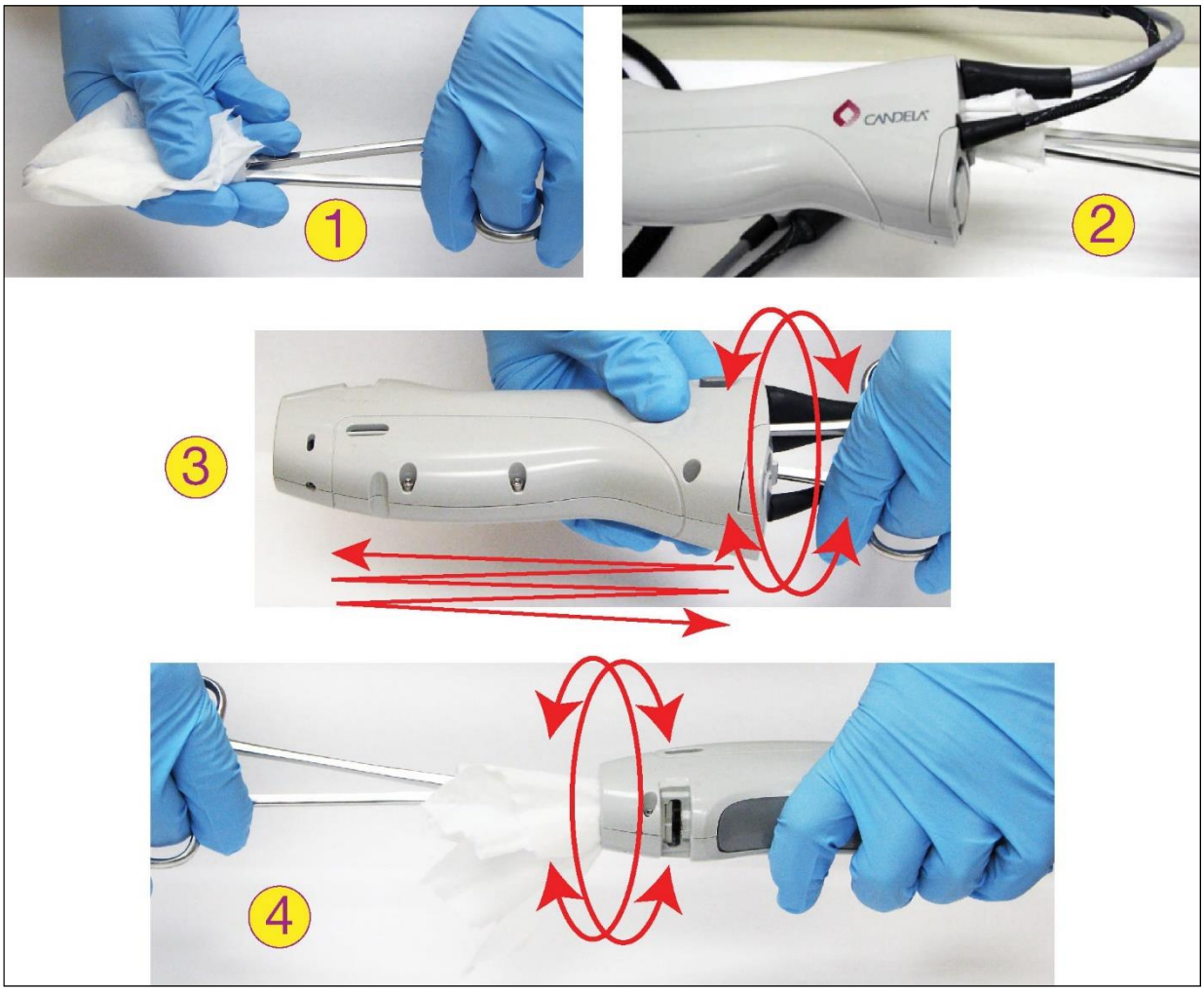


Figure B-9 Cleaning the Handpiece Internal Tube

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Cleaning the ACC Air Cooling Aperture

Use a cotton-tipped swab moistened with either 70% to 100% Isopropyl or a 10% bleach solution to clean the ACC air cooling aperture.



Figure B-10 Cleaning the ACC Air Cooling Aperture

Handpiece Fan Filter

The handpiece fan filter holder (**C**) holds the fan filter, which cools the handpiece. Clean the fan filter periodically and when a handpiece bubble message appears.

Cleaning the Handpiece Fan Filter

1. Push down on the small clasp at the top of the handpiece fan filter cover (**A**) and pull the fan filter cover off.

TIP: Removing the slider tube from the handpiece may make this easier.

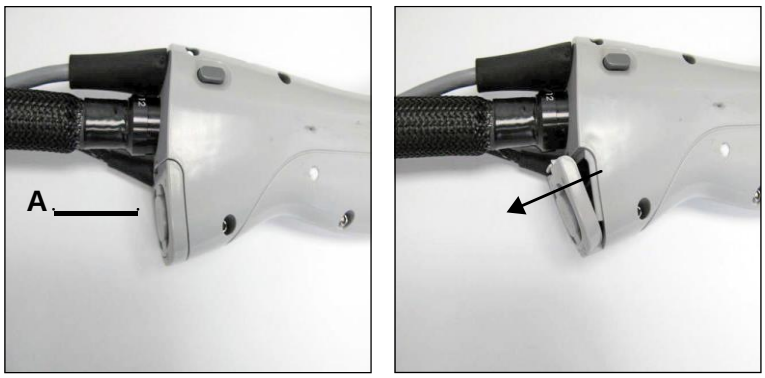


Figure B-11 Removing the DCD Handpiece Fan Filter Cover

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2. Remove the fan filter (**C**) from the cover by pulling the filter off the Velcro square (**B**).

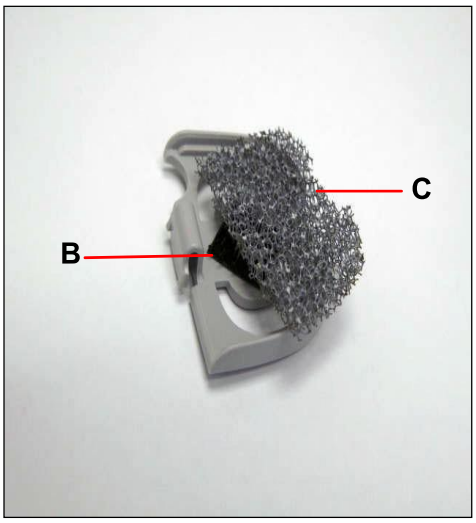


Figure B-12 Removing the Handpiece Fan Filter

3. Remove the fan filter from the cover.
4. Run water through the filter to clean it.
5. Let the filter "air dry".
6. Once dry, press the filter onto the back of the handpiece filter cover (**C**), and reattach the cover.

Slider Attachment

CAUTION

- **Do not use heat, steam, or autoclaves to sterilize the slider attachment.**
- **Do not completely submerge the slider attachment in cleaning solutions or water.**

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Cleaning the Slider Attachment

1. Verify the laser system is in **Standby** mode or **OFF**.
2. Remove the slider (**A**) by pressing and holding the slider lock button (**B**) and gently pulling the slider all the way out of the handpiece.

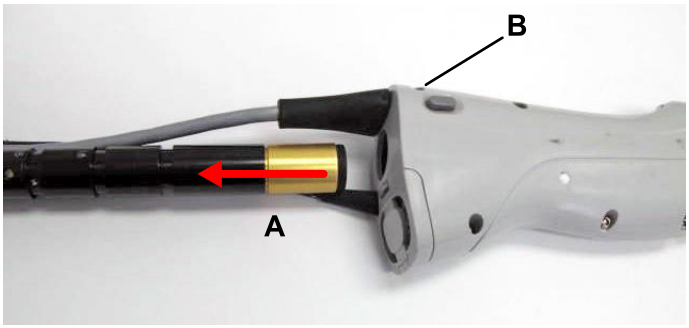


Figure B-13 Removing the Slider from the Handpiece

3. Remove the slider attachment (**C**) from the slider (**A**).

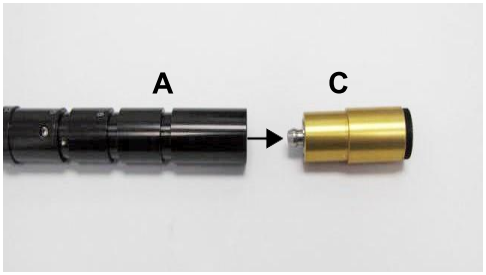


Figure B-14 Removing the Slider Attachment from the Slider

4. Wipe the slider attachment with a gauze pad or towelette moistened with 70% to 100% isopropyl solution or a 10% bleach solution.
5. Let the slider attachment "air dry".
6. Reattach the slider attachment by reversing step 2 and then step 1.

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Slider Attachment Window

WARNING

- **FAILURE TO RE-INSTALL WINDOWS PROPERLY AFTER CLEANING OR IMPROPER WINDOW INSERTION CAN RESULT IN FAILURE OF THE WINDOW AND MAY CAUSE PATIENT BURNS.**
- **WHEN REMOVING A WINDOW FOR CLEANING, CAREFULLY NOTE THE WINDOW SURFACE THAT WAS EXPOSED TO DEBRIS AND THE DIRECTION IN WHICH SUCH WINDOW SURFACE FACES. WHEN RE-INSERTING THE WINDOW, ENSURE THAT THE WINDOW SURFACE THAT WAS EXPOSED TO DEBRIS FACES THE SAME DIRECTION AS IT DID PRIOR TO REMOVAL.**

CAUTION

- **Only use GentleMax Pro Plus replacement windows in the slider attachment or permanent damage may occur.**
- **Do not disassemble the slider attachment to perform repairs. Only clean or replace the slider attachment window.**

The slider attachment contains a window to protect its internal lenses. The slider attachment window does not get as dirty as the handpiece window because the slider attachment window is further from the treatment area. Although the slider attachment window does not have to be checked as often as the handpiece window, it should be checked periodically to maintain proper system performance.

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Removing the Slider Attachment Window [6/8/10, 12/15/18, 20/22/24 & 26 Slider Attachments Only]

1. Verify the laser system is in **Standby** mode or **OFF**.
2. Remove the slider (**A**) by pressing and holding the slider lock button (**B**) and gently pulling the slider all the way out of the handpiece.

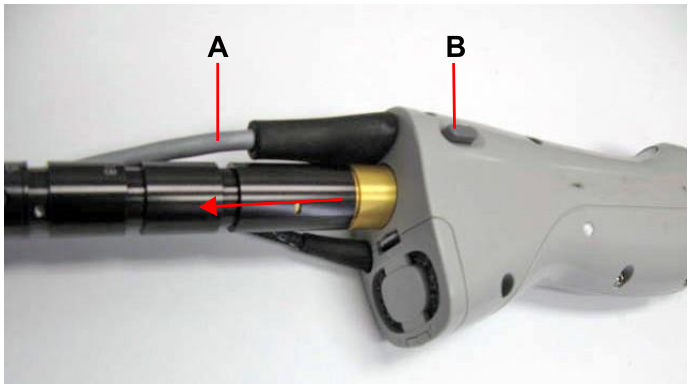


Figure B-15 Removing the Slider from the Handpiece

3. Remove the slider attachment (**C**) from the slider (**A**).

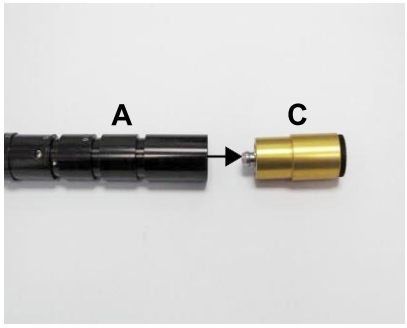


Figure B-16 Removing the Slider Attachment from the Slider

4. Completely remove the slider attachment window retainer (**D** in Figure B-17) from the slider attachment. Depending on the slider attachment, either unscrew the retainer counterclockwise (no tools needed) or pull it off.

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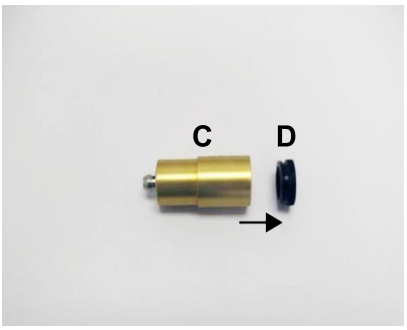


Figure B-17 Removing the Window Retainer from the Slider Attachment

5. Turn the slider attachment (**C**) upside down over a clean piece of tissue or paper so that the slider attachment window (**E**) falls out.

NOTE: Never touch the surface of the window; only hold it by its edges. Even if you are wearing dustless or plastic gloves, do not touch the surface of the window, as some gloves leave a residue.

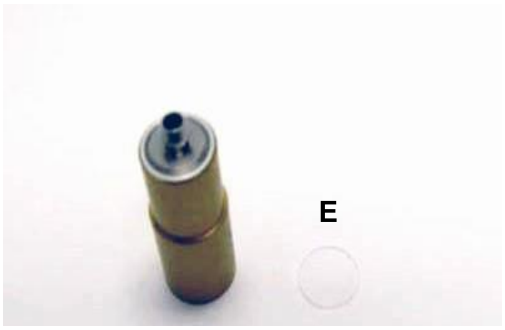


Figure B-18 Removing the Window from the Slider Attachment

Cleaning the Slider Attachment Window

1. Wear dustless or plastic gloves or finger cots to prevent the natural oils on your skin from contaminating the window.

2. Using a gauze pad or towelette soaked with 70% to 100% isopropyl solution or a 10% bleach solution, clean both surfaces of the window. Remove any debris from the window surfaces by gently swiping across the surface. Use one swab per pass across the optic to avoid spreading debris.

3. Wipe the window dry with a lint-free lens paper, tissue, or equivalent.

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Installing the Slider Attachment Window [5 mm, 6/8/10 and 12/15/18 Slider Attachments Only]

With the slider attachment vertical, hold the slider attachment window (**E** in Figure B-19) by its edges and carefully drop it into the slider attachment (**C** in Figure B-19). The slider attachment window must sit flat (**F** in Figure B-19) in the slider attachment to ensure that it does not break when installing the window retainer.

NOTE: Never touch the surface of the window; only hold it by its edges. Even if you are wearing dustless or plastic gloves, do not touch the surface of the window, as some gloves leave a residue.

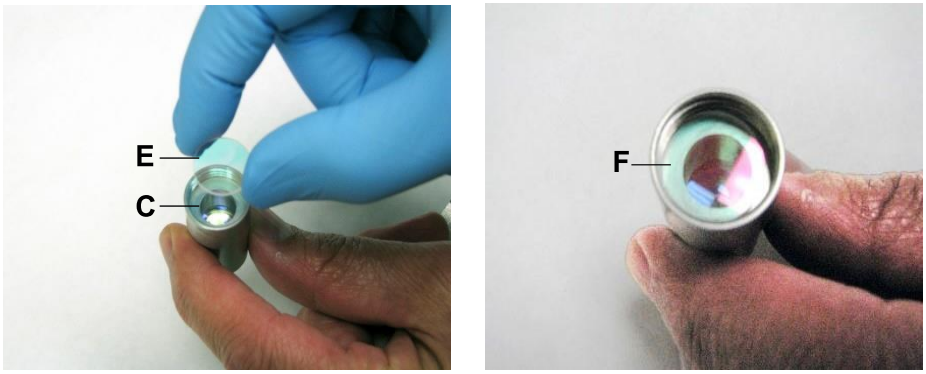


Figure B-19 Drop Window Into Slider Attachment

4. With the slider attachment vertical, insert and, depending on the slider attachment, either push on the window retainer (**D**) or hand screw it on clockwise until tight. Shake the slider attachment. If the window rattles, the retainer is not tight enough, so carefully tighten it and shake it again. If needed, continue to tighten and shake it until it no longer rattles.

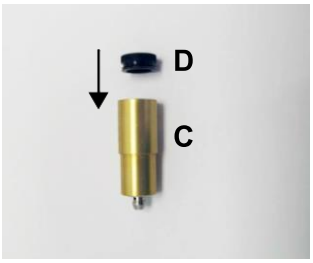


Figure B-20 Attaching the Window Retainer to the Slider Attachment

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5. Reattach the slider attachment (**C**) into slider (**A**).

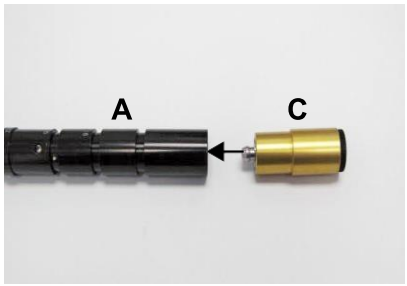


Figure B-21 Reattaching the Slider Attachment into the Slider

6. Reinsert the slider (**A**) by pressing and holding the slider lock button (**B**), gently pushing the slider into the handpiece to the desired spot size and releasing the slider lock button.

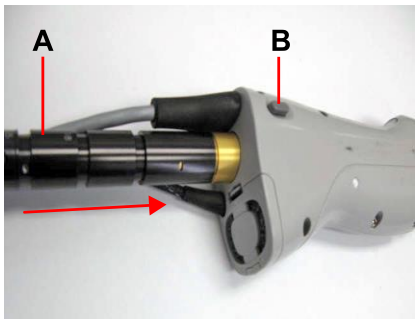


Figure B-22 Reinserting the Slider into the Handpiece

7. Calibrate the laser system. For information on calibrating, see page 84.

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Removing the Slider Attachment Window [1.5 mm, 3 mm, and 3x10 mm Slider Attachments Only]

1. Refer to Figure B-23: remove the O-ring that is retaining the window by inserting a small clean object into the notch at the end of the slider attachment and pushing out the O-ring. The images shown are of the 1.5 mm, but the same procedure is also used for the 3 mm and 3x10 mm.

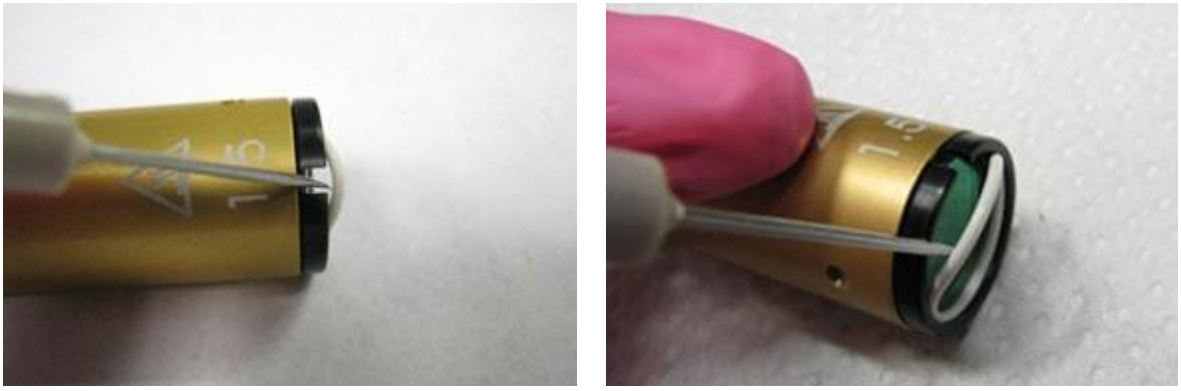


Figure B-23 Removing the O-Ring

2. Refer to Figure B-24: allow the window and O-ring to fall out. The slider attachment may have to be held upside down.

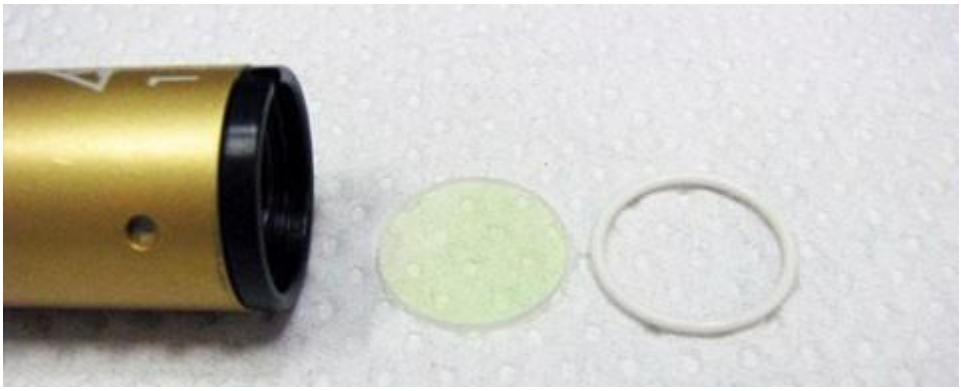


Figure B-24 O-Ring and Window Removed

3. Clean the window as described previously.

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Installing the Slider Attachment Window [1.5 mm, 3 mm, and 3x10 mm Slider Attachments Only]

1. Refer to Figure B-25: with the slider attachment vertical drop the window into the slider attachment.



Figure B-25 Window Installed in Slider Attachment

2. Refer to Figure B-26: install one edge of the O-ring into the groove above the window. Press the remainder of the O-ring into the groove.



Figure B-26 Installing the O-Ring

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Fiber Cable

Check the fiber cable in the delivery system before each procedure by observing the aiming beam quality.

Checking the Fiber Cable

1. Wear protective eyewear.
2. Press the aiming beam intensity button to turn on the aiming beam. If the aiming beam turns off, press the button again.
3. Point the aiming beam at a white sheet of paper. The beam should be a uniform and well defined circumference. If the aiming beam is non-existent, verify that it is fully on.
4. If it still cannot be seen, try another slider attachment.
5. If the aiming beam again cannot be seen, verify that both the handpiece and the slider attachment windows are clean. If they are and the beam is still missing or very dim, discontinue use. The fiber cable must be replaced. Contact Candela to order a new fiber cable.

CAUTION

Using a damaged fiber cable is dangerous and must be avoided. If damage is suspected, discontinue use immediately.

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

Laser System Exterior

Clean the exterior of the laser system weekly.

1. Wipe the exterior of the laser system with a soft cloth slightly moistened with hospital-grade disinfectant, 70% to 100% isopropyl solution or a 10% bleach solution, or a solution of mild soap and water. Do not use harsh detergents.
2. If disinfectant is used, remove any residual disinfectant by wiping the handpiece body with a 70% to 100% isopropyl solution or a 10% bleach solution.

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Water Cooling System

CAUTION

The cooling water is heated to 149°F (65°C). Do not insert fingers into the water tank. Avoid splashing of heated water.

The system is cooled with deionized (DI) or distilled water. Check the water level monthly if the system is used daily, every 6 months if the system is used weekly, or if a fault message with a fault code preceded by a "7" display.

Checking the Water Level

1. Turn off the laser system and allow it to cool down.
2. Turn the water reservoir fill cap, located on the rear panel of the laser system, counter-clockwise to remove it.
3. Inspect the water level by looking into the reservoir.
4. Fill with DI or distilled water until the water fills up to within ½ to 1 inch from the top of the reservoir and reattach the water reservoir fill cap.
5. Turn on the laser system and allow operation for 15 seconds then turn the laser system off.
6. Remove the filler cap to check the water level and refill with more water if needed.
7. Repeat the procedure until the water reservoir is filled within ½ to 1 inch from the top of the reservoir.
8. After the reservoir is completely refilled, restart the laser system and allow the system to warm up.

Touch-Screen Care and Cleaning

Always handle the touch-screen with care. It is recommended that you periodically clean the glass touch screen.

1. Only use a dedicated LCD cleaning solution, available in all computer supply stores.
2. Apply the cleaner with a soft cloth. Avoid using gritty cloths.
3. Always dampen the cloth and then clean the touch-screen.

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User Verification Tests

WARNING

- **ALWAYS PERFORM USER VERIFICATION TESTS AT THE START OF EACH TREATMENT DAY AND WHEN THE HANDPIECE IS CHANGED.**
- **CHECK THE DELIVERY SYSTEM FOR ANY DAMAGE (FOR EXAMPLE, WHEN THE HANDPIECE IS DROPPED).**
- **DISCONTINUE USE OF THE DELIVERY SYSTEM IF YOU SUSPECT A PROBLEM.**

There are 2 user verification tests:

- **Cryogen and Air Cooling Coverage**—Verifies that the Cryogen spray nozzle is properly aligned with the distance gauge ring and the spray duration required to fill the distance gauge ring.
- **Beam Alignment**—Verifies that the laser and aiming beam are in alignment with the distance gauge.

Items Needed for the User Verification Tests

The following supplies are needed to perform the user verification tests:

- Laser safety glasses.
- Thermochromic ink paper, Candela Part Number 1630-00-0431 (included in the accessory kit supplied with the laser system).
- GentleMax Pro Plus laser system 12/15/18 mm slider attachment and 10 and 18 mm distance gauges.
- White paper

Cryogen and Air Cooling Coverage Tests

The Cryogen coverage test verifies the Cryogen spray nozzle is properly aligned with the distance gauge ring and the proper spray duration required to fill the distance gauge ring.

NOTE: This test should be performed with a ring-style distance gauge.

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Performing the Cryogen and Air Cooling Coverage Tests

- Distance gauge ring is larger than the spot size marking.
- 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 operator to help identify changes in the handpiece operation.

1. Wear protective eyewear.
2. Put the laser system into **Standby** mode.

CAUTION

Laser system should remain in Standby mode for the duration of the test.

3. Install the 18 mm distance gauge:
   a. 18 mm distance gauge for the Standard DCD, Standard ACC, and Small Spot DCD handpieces.
   b. Large Spot distance gauge for the Large Spot DCD and ACC handpieces.

NOTE: For the Small-Spot DCD handpiece, the fiber and slider attachment must be removed from the handpiece in order to attach the 18 mm distance gauge.

4. Using the cooling selection buttons:
   a. For Cryogen, set the pre-spray to 40 ms, delay to 20 ms, and the post-spray to 0 ms.
   b. For air cooling, set the chiller to 9.
5. Hold the handpiece perpendicular to a Thermochromic ink paper, Candela Part Number 1630-00-0431, and place the distance gauge on the paper.
   a. For Cryogen, press and release the purge button to expel the Cryogen.
   b. For air, if not already done, securely attach the air clip to the ACC handpiece, then turn the chiller on and set the chiller at a high flow rate.

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Cryogen or Air Cooling Coverage Test Result

The paper turns color where the Cryogen sprayed or where the air cooled.

Acceptable:

- **Standard Medium-Spot DCD:** The spray must be centered and fill the 18 mm distance gauge ring. Small (<1 mm) white sections at the ring are acceptable.
- **Large-Spot DCD:** The spray must be centered and fill the Large Spot distance gauge ring. Small (<1 mm) white sections at the ring are acceptable.
- **Small-Spot DCD:** The spray may not fill the 18 mm distance gauge ring, but the spray must be centered within it.
- **Standard ACC:** The air must fill the 18 mm distance gauge ring.
- **Large Spot ACC:** The air must fill the Large Spot distance gauge ring.

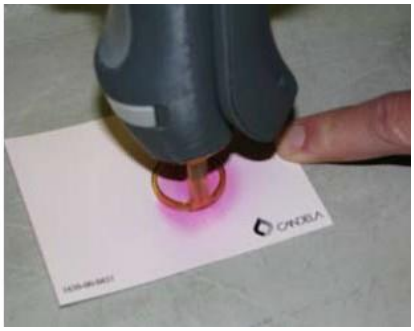
NOTE: Spray or air outside of the ring is acceptable for the Standard DCD and ACC handpieces.



Standard DCD Spray



Small-Spot DCD Spray
(distortion due to photo angle)



Air Cooled

Figure B-27 Acceptable Cooling Test Results

- Unacceptable:
  - Standard DCD handpiece spray or ACC handpiece air does not fill the ring.
  - Spray is not centered (Small-Spot DCD handpiece).
  - For the DCD handpieces, incorrect alignment shows as a white build-up of frost on the distance gauge ring.
  - Cryogen leak noted.
- If any results are unacceptable, replace the handpiece assembly or contact a Candela Service Representative.

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Beam Alignment Test

WARNING

ALL PERSONNEL IN THE VICINITY OF THE LASER MUST KEEP EYEWEAR ON AT ALL TIMES DURING TREATMENT PROCEDURE.

The beam alignment test verifies that the laser and aiming beam are in alignment with the distance gauge.

Performing the Beam Alignment Test

CAUTION

Laser system should remain in Standby mode for the duration of the test.

1. Install the desired slider attachment and distance gauge spot size for the laser treatment.
2. Press the aiming beam intensity button to turn on the aiming beam. If the aiming beam turns off, press the button again.

CAUTION

DO NOT press the fingerswitch or the footswitch to pulse the laser.

3. Aim the handpiece at a white piece of paper and inspect the aiming laser beam for circular uniformity and clarity.
4. If the aiming beam spot is not uniform, check for distance gauge interference, and clean the distance gauge (see page 117).
5. Check that the handpiece window (Standard DCD and ACC handpieces only) and slider attachment window are clean. For instructions on cleaning the windows, see page 122 and page 130.
6. Repeat the beam alignment test until satisfactory results are achieved. If satisfactory results cannot be achieved, contact a Candela Service Representative.

NOTE: Always repeat this procedure for each distance gauge prior to beginning a treatment.

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CAUTION

Discontinue use of the laser system if the aiming beam is not present! This may be an indication of a broken fiber cable. Replace the fiber cable (see "Replacing the Fiber Cable" on page 150) and perform the beam alignment test to see if this corrects the problem. If this does not fix the problem, contact a Candela Service Representative.

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Appendix C Accessories

Configurations

The GentleMax Pro Plus laser family consists of three systems:

- Base Laser:
  - GentleMax Pro Plus (755 and 1064 nm).
- Supporting System Accessories.
- Accessory Kit
- Delivery Systems:
  - Medium Spot DCD.
  - Medium Spot ACC (optional).
  - Small Spot DCD (optional).
  - Large Spot DCD (optional).
  - Large Spot ACC (optional).

Base Laser with DCD or ACC Option Support

The accessories listed in the following tables are available for each of the products described in this manual.

Table C-1 GentleMax Pro Plus with DCD or ACC Support Option

Description	Quantity	Part Number
GentleMax Pro Plus Base Laser System	1	9914-CE-9036
Supporting System Accessories, which includes:	1	7123-00-0641
• Footswitch	1	5103-00-0030
• Fiber Pole	1	7122-00-9435
• DCD Cap	1	1303-00-1219
Accessory Kit, which includes:	**1**	**7123-00-0642**
• USB Operator's Manual and Treatment Guidelines	1	4805-00-0108
• 18 mm Distance Gauge Kit	1	7122-00-9424
• 15 mm Distance Gauge Kit	1	7122-00-9418
• 12 mm Distance Gauge Kit	1	7122-00-9521
• 10 mm Distance Gauge Kit	1	7122-00-9522

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Description	Quantity	Part Number
6/8 mm Distance Gauge Kit	1	7122-00-9523
Replacement Window Kit	1	7122-00-9655
Physician Safety Eyewear	2	8095-00-0476
Metal Opaque Shield (Patient Eyewear)	1	8095-00-0470
Key Ring with Candela Fob	1	1301-00-3409
Canister Empty Valve	1	3430-02-0010
Laser Warning Sign	1	2157-40-8754
Service Information Label	1	2157-27-0100
Standard Medium Spot DCD Delivery System Accessories, which include:		
• Handpiece/Electrical/Standard Medium Spot DCD Delivery System Assembly.	1	7123-CE-0632
• Fiber Assembly	1	7123-CE-0658
• 12/15/18 mm Slider Attachment Assembly	1	7122-00-9552
• 6/8/10 mm Slider Attachment Assembly	1	7122-00-9551
• Velcro Strap Kit	1	7122-00-9527
• ULTEM Window Holder	1	7122-00-9657
Small Spot DCD Delivery System Option [7123-CE-0650], which include:		
• Handpiece/Electrical/Standard Small Spot DCD Delivery System Assembly.	1	7123-CE-0633
• Fiber Assembly	1	7123-CE-0658
• 1.5 mm Slider Attachment Assembly	1	7122-00-9560
• 3 mm Slider Attachment Assembly	1	7122-00-9561
• 3x10 mm Slider Attachment Assembly	1	7122-00-9610
• 5 mm Slider Attachment Assembly	1	7122-00-9753
• Velcro Strap Kit	1	7122-00-9527
Medium Spot ACC Delivery System Accessories [7123-CE-0648], which include:		
• Handpiece/Electrical/ACC Delivery System Assembly	1	7123-CE-0629
• Fiber Assembly	1	7123-CE-0658
• 12/15/18 Slider Attachment Assembly	1	7122-00-9552
• 6/8/10 Slider Attachment Assembly	1	7122-00-9551
• Air Clip	1	7122-00-9420
• ACC Velcro Strap Kit	1	7122-00-9586

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Description	Quantity	Part Number
Large Spot DCD Delivery System Option [7123-CE-0652], which include:		
Handpiece/Electrical/Large Spot DCD Delivery System Assembly	1	7123-CE-0631
Large-Spot Fiber Assembly	1	7123-CE-0635
20/22/24 Slider Attachment Assembly	1	7122-00-9747
20, 22, 24mm Distance Gauge Kit	1	7122-00-9758
26 Slider Attachment Assembly	1	7123-00-0609
26mm Distance Gauge Kit	1	7123-00-0665
Large Spot ACC Delivery System Option [7123-CE-0653], which include:		
Handpiece/Electrical/ACC Delivery System Assembly	1	7123-CE-0628
Large-Spot Fiber Assembly	1	7123-CE-0635
20/22/24 Slider Attachment Assembly	1	7122-00-9747
20, 22, 24mm Distance Gauge Kit	1	7122-00-9758
26 Slider Attachment Assembly	1	7123-00-0609
26mm Distance Gauge Kit	1	7123-00-0665

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Appendix D Replacing Parts

Overview of Replacing Parts

The following parts can be replaced on the GentleMax Pro Plus laser system:

- Air filter.
- Handpiece window (DCD and ACC handpieces).
- Handpiece fan filter (DCD handpiece only).
- Slider attachment window.
- Delivery system cables (fiber or handpiece assembly).
- Cryogen canister.

Air Filter

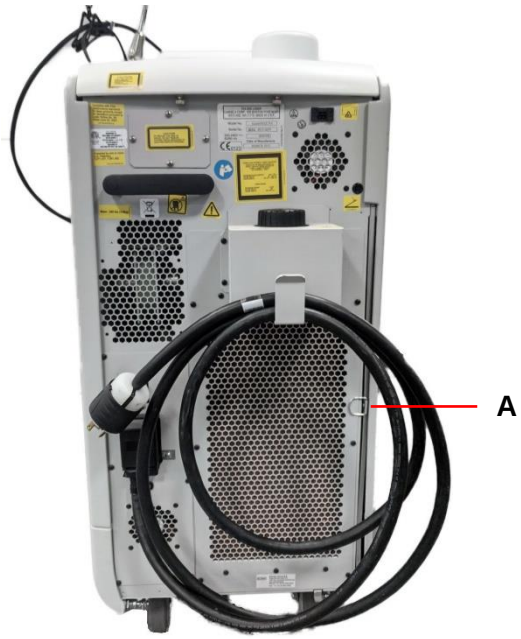


Figure D-1 Location of the Air Filter (Rear Panel View)

Replacing the Air Filter

1. Remove the air filter (**A**) by pulling on the ring attached to the filter on the right side of the rear panel of the laser system.
2. Insert the new air filter into the slot and push it in all the way.

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DCD Handpiece Replacement Parts

The DCD handpiece has two parts that can be replaced:

- Handpiece window
- Fan filter

Replacing the DCD Handpiece Window

CAUTION

- **Only use GentleMax Pro Plus laser system replacement windows in the handpiece or permanent damage may occur.**
- **Only disassemble the handpiece to clean or replace the handpiece window.**

To replace the DCD handpiece window, follow the instructions given in "Removing the Handpiece Window" on page 121 and "Inserting the Handpiece Window and Window Holder" on page 123.

Replacing the DCD Handpiece Fan Filter

1. Push down on the small clasp at the top of the handpiece fan filter cover (**A**) and pull the fan filter cover off.

   TIP: Removing the slider tube from the handpiece may make this easier.

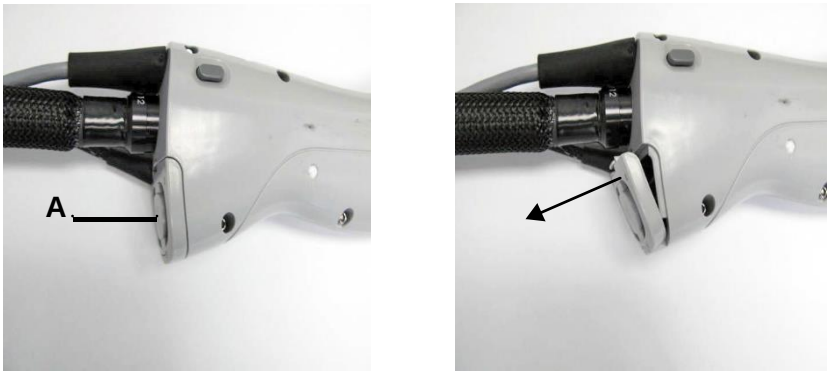


Figure D-2 Removing the DCD Handpiece Fan Filter Cover

2. Remove the fan filter (**C** in Figure D-3**)** from the cover by pulling the filter off the Velcro square (**B**).

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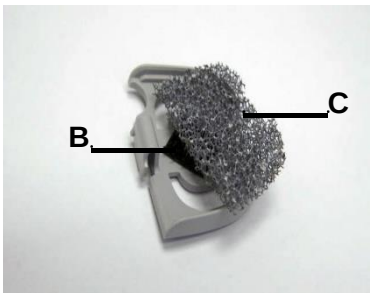


Figure D-3 Removing the Handpiece Fan Filter

3. Place the new fan filter (**C**) onto the cover and press the filter onto the Velcro square.

ACC Handpiece Replacement Part

The ACC handpiece has only one part that can be replaced, the handpiece window.

Replacing the ACC Handpiece Window

To replace the ACC handpiece window, follow the instructions given in "Removing the Handpiece Window" on page 121 and "Inserting the Handpiece Window and Window Holder" on page 123.

Slider Attachment Window

The slider attachment has a window that can be replaced.

CAUTION

- **Only use GentleMax Pro Plus replacement windows in the slider attachment or permanent damage may occur.**
- **Do not disassemble the slider attachment to perform repairs. Only disassemble the slider attachment to clean or replace the slider attachment window.**

WARNING

FAILURE TO RE-INSTALL WINDOWS PROPERLY OR IMPROPER WINDOW INSERTION CAN RESULT IN FAILURE OF THE WINDOW AND MAY CAUSE PATIENT BURNS.

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Replacing the Slider Attachment Windows

Replacing the Slider Attachment Window [6/8/10 and 12/15/18 Slider Attachments Only]

To replace the slider attachment window:

a. Follow the instructions given in "Removing the Slider Attachment Window [6/8/10, 12/15/18, 20/22/24 & 26 Slider Attachments Only]" on page 131, then:

b. Follow the instructions given in "Installing the Slider Attachment Window [5 mm, 6/8/10 and 12/15/18 Slider Attachments Only]" on page 133.

Replacing the Slider Attachment Window [1.5 mm, 3 mm, and 3x10 mm Slider Attachments Only]

To replace the slider attachment window:

a. Follow the instructions given in "Removing the Slider Attachment Window [1.5 mm, 3 mm, and 3x10 mm Slider Attachments Only]" on page 135, then:

b. Follow the instructions given in "Installing the Slider Attachment Window [1.5 mm, 3 mm, and 3x10 mm Slider Attachments Only]" on page 136.

Delivery System Replacement

The delivery system has two parts that can be replaced:

- Fiber cable
- Handpiece assembly

Replacing the Fiber Cable

NOTE: For illustration purposes, the DCD handpiece is shown. Your handpiece may differ.

1. Verify the laser system is in **Standby** mode or **OFF**.
2. Remove the Velcro straps that hold the fiber cable and the handpiece assembly cable together.

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Figure D-4 Removing the Velcro Straps

3. Remove the slider (**A**) by pressing and holding the slider lock button (**B**), and gently pulling the slider all the way out of the handpiece.

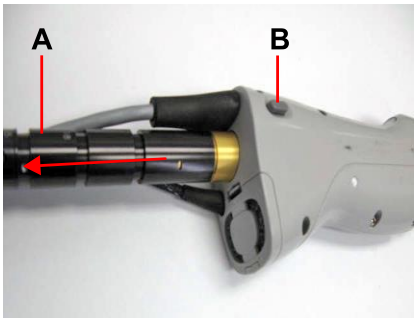


Figure D-5 Removing the Slider from the Handpiece

4. Remove the proximal connector of the fiber cable from the front panel of the laser system.
5. Replace the fiber cable by inserting the proximal connector into the laser system, and the slider end, with a slider attachment, into the handpiece.
6. Reattach the Velcro straps to the fiber cable and handpiece assembly cable.
7. Perform a delivery system calibration starting on page 84 and the user verification tests starting on page 139.

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Replacing the Handpiece Assembly (DCD or ACC)

1. Verify the laser system is in **Standby** mode or **OFF**.
2. Remove the Velcro straps that hold the fiber cable and the handpiece assembly cables together.



Figure D-6 Removing the Velcro Straps

3. Remove the slider (**A**) by pressing and holding the slider lock button (**B**), and gently pulling the slider all the way out of the handpiece.

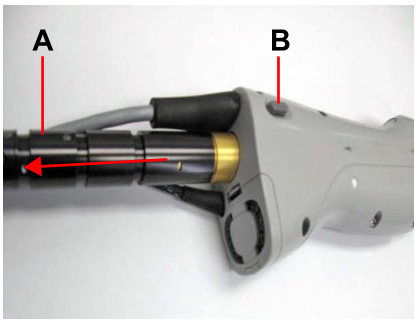


Figure D-7 Removing the Slider from the Handpiece

4. Remove the DCD/Cryogen connection (on DCD handpiece only) and electrical connection cables of the handpiece assembly from the front panel of the laser system.
5. Insert the electrical connection cable of the handpiece assembly into the front panel of the laser system. If installing the DCD handpiece assembly, also connect the DCD/ Cryogen connector to the front panel.
6. Reinsert the slider (**A**) into the handpiece by pressing and holding the slider lock button (**B**), gently pushing the slider into the handpiece to the desired spot size, and releasing the slider lock button.

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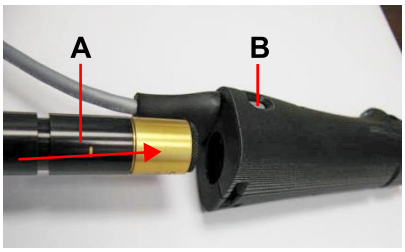


Figure D-8 Inserting the Slider into the ACC Handpiece

7. Reattach the Velcro straps to the fiber cable and handpiece assembly cables.
8. Perform a delivery system calibration starting on page 84 and the user verification tests starting on page 139.

Cryogen Canister Replacement

CAUTION

The contents of the Cryogen canister are under pressure. Before handling, read the MSDS Candela Part Number 8501-00-1701 and the label on the canister.

Replacing the DCD Canister

1. Remove the DCD cover (**A**) on top of the laser system.



Figure D-9 Removing the DCD Cover

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2. Slightly pull the two retention brackets apart that hold the empty DCD canister and pull out the DCD canister from the laser system. A small amount of Cryogen may release when the canister is removed.
3. Install the new DCD canister by placing it into the DCD receptacle and gently pushing it down into place. The retention brackets lightly snap into place over the canister end.
4. Replace the DCD cover (**A**).

Canister Disposal

The canister can be disposed of by a waste disposal company or in the trash if it is completely emptied (as per the instructions enclosed with each canister).

Purge Tool

Be sure to work in an open air or well ventilated area. You will need the venting valve found in the accessory kit.

CAUTION

Large amounts of Cryogen need to be evacuated in a well-ventilated area. Canisters with more than a residual amount remaining must be disposed of by a hazardous material disposal company.

Emptying a Cryogen Canister with the Purge Tool

1. Turn the venting valve handle completely clockwise to close the valve.

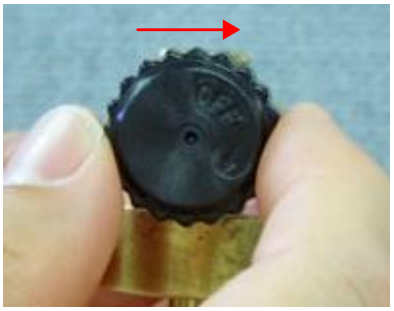


Figure D-10 Turing the Venting Valve Handle

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2. Attach the venting valve to the canister by turning the venting valve clockwise onto the threaded portion of the canister.



Figure D-11 Putting the Venting Valve on the Canister

3. Position the canister so that the venting valve is at the top and pointed in a safe direction away from you or other personnel.

4. Open the venting valve by turning the venting valve handle completely counter-clockwise.

   The residual Cryogen vents into the air. Set the canister down and allow it to empty completely. Once canister appears to be empty, shake to be sure there are no remaining contents.

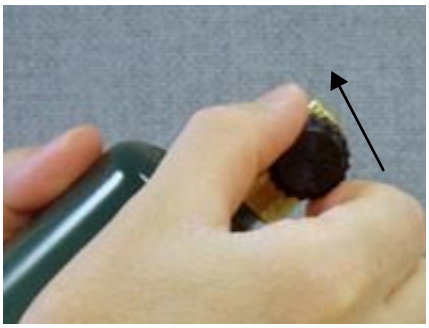


Figure D-12 Purging the Cryogen Canister

5. Remove the venting valve from the canister by turning it counter-clockwise.

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6. Remove the venting valve from the canister by turning the venting valve counter-clockwise off the threaded portion of the canister.



Figure D-13 Putting the Venting Valve on the Canister

7. Store the venting valve for future use.

8. Dispose of the empty canister as nonhazardous material.