GentleMAX™
Operator's Manual

GentleMax

CE 0123

PN 8501-00-1810 Revision 06
June 2007
Candela Corporation

Copyright and Disclaimer

Copyright © 2007 Candela Corporation. All rights reserved.

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

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

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

Contact Information

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

Candela Corporation
530 Boston Post Road
Wayland, MA 01778-1886
Telephone (508) 358-7400
Toll Free (800) 733-8550 (Technical Assistance)
Toll Free (800) 73-LASER (Customer Service)
Website: www.candelalaser.com

Trademarks

All brand names and product names used in this manual are trademarks, registered trademarks or trade names of their respective holders.

Limit of Liability

The publisher has used their best efforts in preparing this manual. Candela Corporation makes no representation or warranty with respect to the accuracy or completeness of the contents of this manual and specifically disclaims any implied warranties of merchantability or fitness for any particular purpose and shall in no event be liable for any loss of profit or any other commercial damage including but not limited to special, incidental, consequential, or other damages.

The information in this manual is subject to change without notice at the discretion of Candela Corporation.

Table of Contents

Chapter 2: Understanding the Laser

Appendix A: Cleaning the Distance Gauge

Appendix B: Electromagnetic Compatibility

Index

Preface

Welcome to the Candela Corporation's *GentleMAX Operator's Manual*.

Book Conventions

This guide contains the following information highlights and cross-references:

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.

▸▸ Cross references indicate the location of additional information regarding the chosen topic. References may include either headings on specific pages or entire chapters.

Intended Audience

This guide is intended for use by physicians.

General Safety Statements and Guidelines

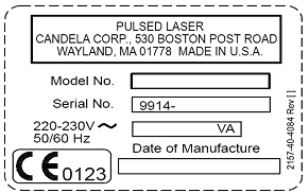
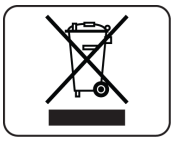
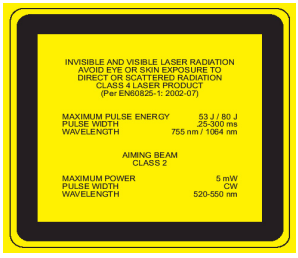
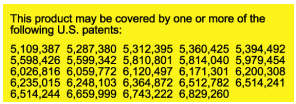
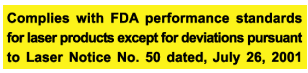
Routine Maintenance

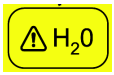
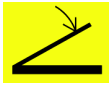
Only qualified personnel who are fully informed of the system's safety hazards should operate, maintain, and troubleshoot this equipment.

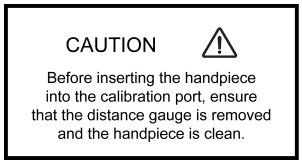
Definitions of Symbols (Labeling on the Equipment and Location)

This section details the meaning, intent, and location of the labels (containing symbols) that appear on the GentleMAX Laser System.

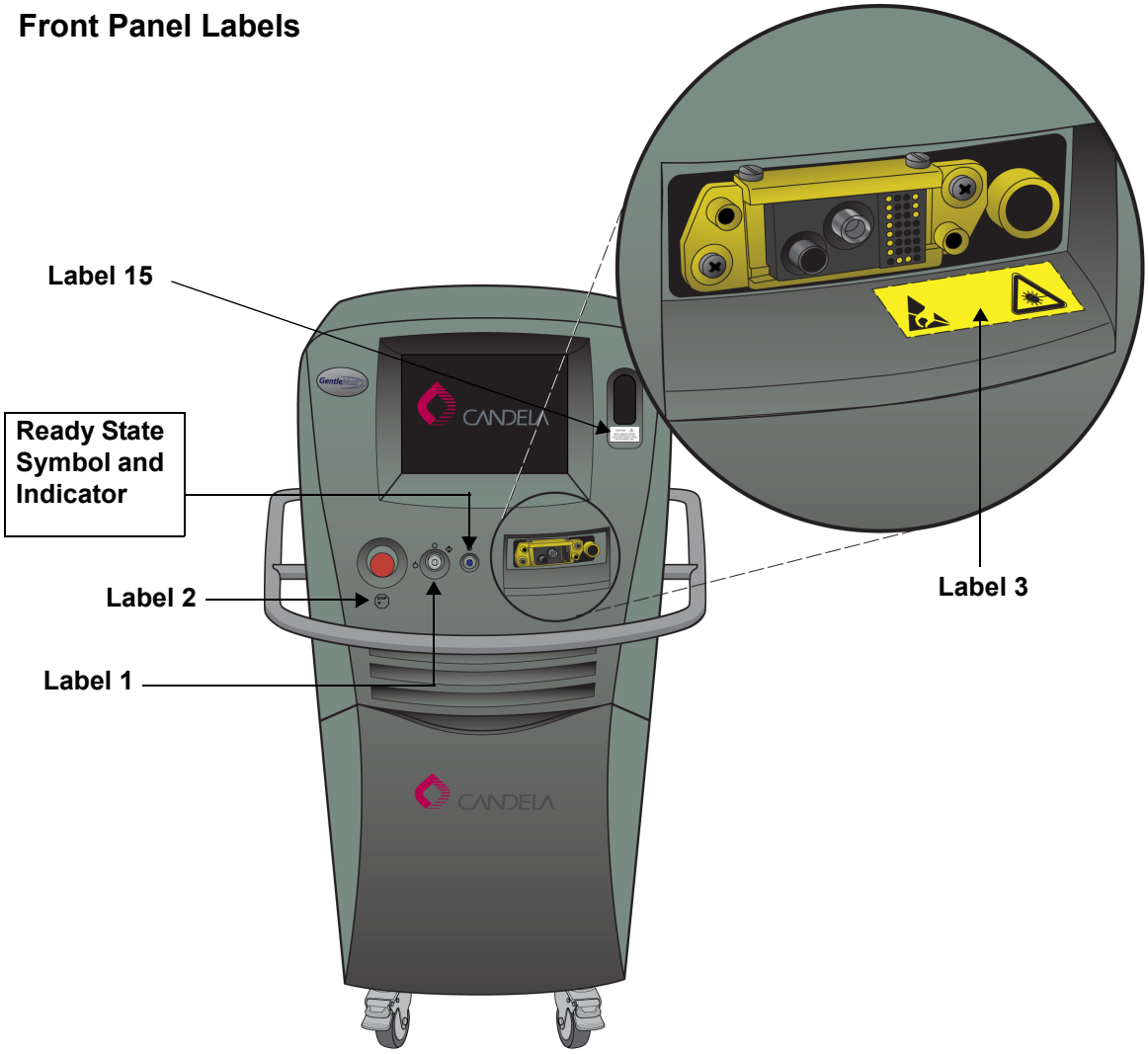
Label	Description
	**Label 1:** Keylock Switch - OFF position. When the switch is in the OFF position, all circuits, except the Keylock Switch circuit, have been de-energized.
	**Label 1:** Keylock Switch - ON position. When the switch is in the ON position, all circuits are energized and the laser system is fully functional.
	**Label 1:** Keylock Switch - START position. This is a spring-loaded keylock switch used to start system operation. This position does not start the release of energy.
	**Label 2:** Emergency Laser Stop. Pushing the Laser Stop button will stop the laser immediately.
	**Label 3:** Electrostatic Sensitive. Indicates that the nearby Delivery System is “electrostatic sensitive.” This label is required by agencies to indicate static sensitive connections, where electrostatic discharge could potentially damage components of a labeled connection. Take anti-static precautions prior to accessing this connection. Such precautions include simply discharging one’s body to a known grounded point prior to making a connection to the delivery system connector. A good grounding point is the fiber receptacle.
	**Label 3 and 11:** Indicates laser radiation is being emitted from this device.
	**Label 4:** This label indicates that the protective panel encloses a Class 4 laser radiation.

Label	Description
	**Label 5:** ETL present, indicates the laser is approved to UL or ETL standards.
	**Label 6:** Identification Label indicates manufacturer's information, date of manufacture and power requirements of the device.
	**Label 7:** Waste Electrical and Electronic Equipment symbol. Indicates that the GentleMAX laser system and its components cannot be disposed of as regular trash. Contact Candela for disposal information.
	**Label 8:** Indicates laser emission characteristics and classification per the IEC/EN standards.
	**Label 8:** Indicates U.S. patents that may be covered on this laser system.
	**Label 8:** Indicates that selected requirements under CDRH 21 CFR 1040.10 & 1040.11 were waived for comparable IEC requirements as allowed by Laser Notice 50.
	**Label 8:** This label indicates that a tip hazard may exist while transporting the laser system. To avoid a tip hazard, move the laser at a normal to slow pace, do not make sudden turns, and use caution when traversing the system across slopes or ramps.
	**Label 9:** Indicates the location of the primary safety ground. The screw adjacent to this symbol should never be tampered with or removed.
O	**Label 10:** Main Power Switch - OFF position.
|	**Label 10:** Main Power Switch - ON position.

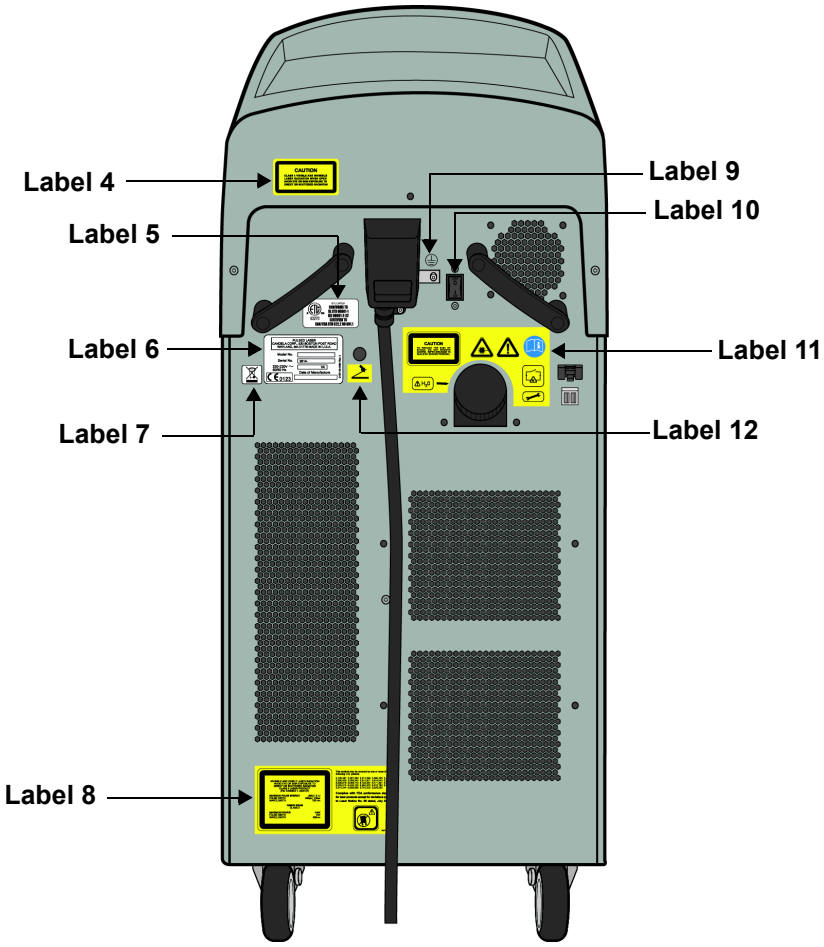
Label	Description
	**Label 11: CAUTION**: Risk of electrical shock if laser covers are removed or serviced by unauthorized persons. There are lethal voltages inside the system enclosure.
	**Label 11**: Water reservoir. Indicates that the reservoir should be filled with deionized or distilled water. The reservoir should be filled approximately once a week and should be kept full up to 1-2 inches above the base of the filler neck with deionized or distilled water.
	**Label 11: Warning** - Main Power Switch. This label draws attention to the main power switch. The switch should be placed in the OFF position when the system is not being used. When the system is being used, the switch should be placed in the ON position.
	**Label 11**: Refer to the Operator's Manual for the safe use of this device.
	**Label 11**: Remote interlock circuit for door switch. Indicates the location of the remote interlock circuit that can be connected to a door switch to shut down the laser if the door is opened during laser emission. The symbol illustrates that an open connection will inhibit the lasing function.
	**Label 11:** USB Software Upgrade Port. Indicates the location of the USB port on the rear of the laser system. Contact Candela Clinical Sales or Service for the latest software upgrades. **CAUTION:** The Software Upgrade Port is not a standard USB port. Do not connect any devices to this port unless instructed by a Candela Support Representative. Never connect powered devices to this port.
	**Label 12:** Footswitch Connection. Indicates the location of the Footswitch connection on the rear of the laser system.

Label	Description
	**Label 13:** Provides delivery system information. The icon of a man indicates that the Delivery System is equipped with a “Type B” applied part in accordance with IEC/EN 60601-1 Laser aperture is at the end of the fiber applicator.
	**Label 14:** Hot Surface
	**Label 15:** 2157-40-2180 Clean Handpiece label.

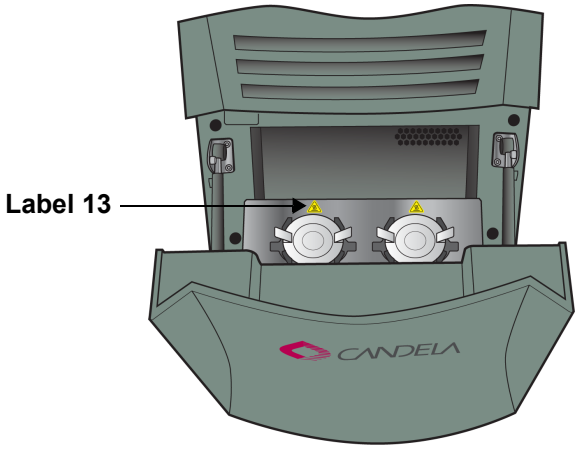
Front Panel Labels



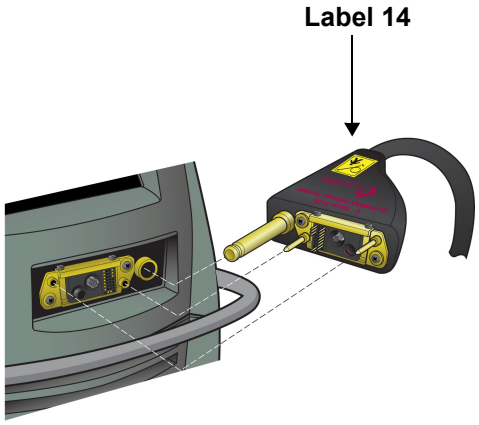
Rear Panel Labels



DCD Labels Inside DCD Storage Compartment



Delivery System Label



Using this Manual

This manual is divided into the following sections:

- **Chapter 1: Getting Started**
  This chapter provides warnings and cautions, adverse events descriptions, indications for use, and contraindications.

- **Chapter 2: Understanding the Laser**
  This chapter provides a brief description of all system components and functionality.

- **Chapter 3: Using the Laser**
  The instructions in this section describe how to perform a laser treatment.

- **Chapter 4: Maintaining the Laser**
  This chapter describes how to clean and maintain the laser system.

- **Chapter 5: Troubleshooting the Laser**
  This chapter describes how to troubleshoot the laser, if necessary.

- **Chapter 6: Specifications**
  This chapter provides general system specifications.

- **Chapter 7: Laser System Packing Lists, Accessories, and Replacement Parts**
  This chapter details Accessories and provides a packing list.

- **Chapter 8: Service Internal Calibration Procedure**
  This chapter details the internal calibration process.

- **Appendix A: Cleaning the Distance Gauge**
  This section provides detailed descriptions for properly maintaining the Distance Gauges.

- **Appendix B: Electromagnetic Compatibility**
  This section describes the EMC compliance.

- **Index**
  The Index will help you locate sections in the manual.

Chapter 1: Getting Started

Topics described in this chapter include:

Overview

This chapter provides a a brief introduction to the Candela GentleMAX Laser system. This chapter provides information on the application for which the system was designed, and a brief description of the laser system's major components and their function. It also provides information on the safety warnings and precautions for GentleMAX.

Laser for Dermatologic Applications and Hair Removal

The GentleMAX Laser System may be used for hair removal, to treat dermatological vascular lesions and other indicated dermatological applications. This unique Laser System contains two separate laser heads, an Alexandrite and ND:YAG (Neodymium-doped Yttrium Aluminum Garnet); which when pulsed produces laser light energy emitted at a nominal wavelength of 755 nanometers (nm) and 1064 (nm) respectively. The outputs of each laser head 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.

At these wavelengths, the Candela GentleMAX Laser System causes maximum energy absorption by targeting specific chromophores in tissue. In addition, the laser pulse duration is controlled to be equal to or shorter than the thermal relaxation time of the target, to minimize heat transfer to surrounding tissues.

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

This Operator's Manual provides operation instructions for the GentleMAX Laser system with all available spot sizes. The spot sizes included in your laser system depend on which options were purchased. **Table 1-1** lists all the available spot sizes for the GentleMAX Laser system.

Table 1-1: GentleMAX Laser System Configurations

Laser System Configuration	**Description and Spot Sizes (mm)**
755nm/1064nm with DCD	DCD Laser system w/YAG and Alex laser heads ● 1.5/3 mm Delivery System w/DCD ● 6-18 mm Delivery System w/DCD ● Lens Cartridge and Distance Gauge Kits ● Includes 8 spots (1.5, 3, 6, 8, 10, 12, 15, 18)
1064nm with DCD	DCD Laser system w/YAG laser head ● 1.5/3 mm Delivery System w/DCD ● 6-18 mm Delivery System w/DCD ● Lens Cartridge and Distance Gauge Kits ● Includes 8 spots (1.5, 3, 6, 8, 10, 12, 15, 18)
755nm with DCD	DCD Laser system w/MGL laser head ● 1.5/3 mm Delivery System w/DCD ● 6-18 mm Delivery System w/DCD ● Lens Cartridge and Distance Gauge Kits ● Includes 8 spots (1.5, 3, 6, 8, 10, 12, 15, 18)
755nm/1064nm LE with DCD	DCD Laser system w/YAG and Alex laser heads ● 1.5/3 mm Delivery System w/DCD ● 6-18 mm Delivery System w/DCD ● Lens Cartridge and Distance Gauge Kits ● Includes 6 spots (3, 6, 8, 10, 12, 15)
755nm/1064nm with DCD & Zimmer Air-Cooling	DCD/Air-Cooling Laser system w/YAG and Alex laser heads ● 1.5-18 mm Delivery System w/o DCD ● 1.5/3 mm Delivery System w/DCD ● 6-18 mm Delivery System w/DCD ● Lens Cartridge and Distance Gauge Kits ● Includes 8 spots (1.5, 3, 6, 8, 10, 12, 15, 18)
755nm/1064nm with Zimmer Air-Cooling No DCD	Air-Cooled (No DCD) Laser system w/YAG and Alex laser heads ● 1.5-18 mm Delivery System w/o DCD ● Lens Cartridge and Distance Gauge Kits ● Includes 8 spots (1.5, 3, 6, 8, 10, 12, 15, 18)

Table 1-1: GentleMAX Laser System Configurations

Laser System Configuration	Description and Spot Sizes (mm)
1064nm with Zimmer Air-Cooling No DCD	Air-Cooled Laser system w/YAG laser head ● 1.5-18 mm Delivery System w/o DCD ● Lens Cartridge and Distance Gauge Kits ● Includes 8 spots (1.5, 3, 6, 8, 10, 12, 15, 18)
755nm with Zimmer Air-Cooling No DCD	Air-Cooled Laser system w/MGL laser head ● 1.5-18 mm Delivery System w/o DCD ● Lens Cartridge and Distance Gauge Kits ● Includes 8 spots (1.5, 3, 6, 8, 10, 12, 15, 18)
755/1064 LE Laser System w/Air-Cooling w/Zimmer unit	Air-Cooled Laser system w/MGL laser head ● 1.5-18 mm Delivery System w/o DCD ● Lens Cartridge and Distance Gauge Kits ● Includes 6 spots (3, 6, 8, 10, 12, 15)
755nm/1064nm with DCD & Air-Cooling No Zimmer unit	Air-Cooled Laser system w/YAG and Alex laser heads ● 1.5-18 mm Delivery System w/o DCD ● 1.5/3 mm Delivery System w/DCD ● 6-18 mm Delivery System w/DCD ● Lens Cartridge and Distance Gauge Kits ● Includes 8 spots (1.5, 3, 6, 8, 10, 12, 15, 18)

Indications for Use

The GentleMAX Laser System may be used for hair removal, to treat dermatological vascular lesions and other indicated dermatological applications. The decision to treat with laser therapy should be based upon appropriate diagnostic evaluation and consideration of all patient factors.

For instructions on the specific applications and treatment parameters for each indication, refer to the Candela Treatment Guidelines for the GentleMAX Laser System (Candela Document Part Number (P/N) 8502-00-0907).

Contraindications

Laser therapy is contraindicated for those patients:

- With a personal history of skin cancer, such as melanoma.
- With infected "target" tattoo site or adjacent areas.
- With photosensitivity in the 755 nanometer region.
- Using medication for which infra-red light is a contraindication.

Patient Selection

Candela's GentleMAX Laser is intended for hair removal and the treatment of dermatological vascular lesions and other indicated dermatological applications.

Hair Removal

The removal of unwanted hair.

Dermatological Vascular Lesions

Vascular tissue exhibiting altoreal pathology.

Warnings, Cautions, and Precautions

Observe the following warnings and cautions when using the Candela Corporation GentleMAX Laser system.

Warnings and Cautions

General Hazards

- **WARNING!** The electrical and laser radiation hazards present during servicing of the GentleMAX Laser can be extremely dangerous if proper safety precautions are not taken. Consequently, the GentleMAX Laser is to be serviced only by those qualified technicians who have received appropriate training on the GentleMAX Laser from Candela, and who are familiar with the safety considerations discussed in this section.
- **WARNING!** The GentleMAX Laser system has been designed for the safest possible operation and maintenance. However, any laser system can cause injury if it is not properly installed, operated, moved or serviced, and the GentleMAX Laser is no exception. The potential hazards associated with the GentleMAX Laser are: ocular (vision) damage resulting from exposure to direct or reflected laser radiation, electrical shock from contact with electrical components inside the system, and physical injury incurred while moving the system.
- **WARNING!** Invisible and visible laser radiation. Avoid eye or skin exposure to direct or scattered radiation. Class 4 laser product (Per EN60825-1: 2002-07)
- **WARNING!** The Preset Treatment Parameters and Clinical Treatment Guidelines do not take the place of the procedures and instructions found in the Operator's Manual. Failure to use the laser in accordance with such procedures and instructions could result in serious injury to the operator, the patient, and others, as well as damage to the laser system.
  - Follow OSHA and ANSI standards for laser safety. Protective eyewear must be worn by all persons in the treatment room during laser operation.
  - Check the delivery system for any damage (i.e. dropped).
  - Discontinue use of your laser delivery system if you suspect a problem.
- **WARNING!** Always put the laser system into Standby or turn it off before attempting to check, clean, and/or replace the Delivery System, Handpiece, Lens Cartridge, or Distance Gauge.
- **WARNING!** Always recalibrate the laser after fixing, cleaning, or replacing the Delivery System, Handpiece, or Lens Cartridge and/or Windows. Failure to initiate a calibration after cleaning/replacing the Handpiece, Lens Cartridge, Windows, and/or Delivery System may result in the delivery of excessive laser energy.
- **WARNING!** Ensure that the spot size on the Lens Cartridge and Distance Gauge matches the spot size displayed in the spot size field on the control panel. Failure to do so can result in the delivery of improper energy to the patient.
- **WARNING!** Do not operate the laser if the aiming beam is on but not present when it is turned on! This may be an indication of a broken fiber optic. If the aiming beam is on but is not present, replace the Delivery System. If this does not correct the problem, call Technical Support.
- **Caution!** Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

- **Caution!** Federal (USA) law restricts this device to sale by or on the order of a physician.
- **Caution!** Do not enter the Ready state without a Delivery System installed and without having the proper protective eyewear on.
- **Caution!** Before the laser system is turned on, a Lens Cartridge must be installed in the Handpiece.
- **Caution!** Handpiece lens and the tips of the laser fiber may be damaged from exposure to dust particles or any other foreign particles that may deposit on their surfaces. Particles on these surfaces will burn and leave a deposit when exposed to laser energy. This may lead to lower fiber or Handpiece transmission and/or failure of the assembly. In order to reduce the probability of mechanical damage please observe the following guidelines.
  - **Caution!** To reduce the risk of personal injury and damage to the Delivery System cable, use the Fiber Pole to support the delivery system at all times. When not in use, insert the Handpiece in the Calibration Port. This removes excess slack from the Delivery System cable and reduces the possibility of damage to property and/or personal injury from stepping on or tripping on the cable or running the wheels over it.
  - **Caution!** When using the Fiber Pole to support the Delivery System, make sure there are no sharp bends in the Delivery System cable. The laser system can be damaged if the cable is subjected to excessive bending. To prevent damage, never pulse the laser system if the Delivery System cable bend radius is less than six inches.

Optical Hazards

- **WARNING!** The laser operates at 755 and 1064 nm, which lies in the invisible, near-infrared region of the electromagnetic spectrum. The laser beam emitted by the GentleMAX is capable of causing loss of vision. Energy emitted by the GentleMAX 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 scotoma (vision absence in an isolated area), long term photophobia (sensitivity to light) and/or loss of vision.
- **WARNING!** Use only safety eyewear that is known to have an optical density (O.D.) of 5.8 or more for 755 nm and eyewear with an optical density of 6.3 or more for 1064 nm. Safety eyewear that is designed for use with other laser systems may not provide adequate protection.
- **WARNING!** Nominal Ocular Hazard Distance (NOHD). The laser aperture of the GentleMAX 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 distance along with the full angle beam divergence for each Handpiece is shown in **Table 1-2**.

Table 1-2: Vision Hazards for GentleMAX Laser NOHD Zone

Spot Diameter (mm)	Beam Divergence Full Angle (radians)		NOHD (meters)	
	755nm	1064nm	755nm	1064nm
1.5	0.410	0.404	29.2	15.0
3	0.250	0.245	83.6	43.4
6	0.168	0.164	255.8	132.9
8	0.130	0.126	360.0	189.0
10	0.106	0.101	427.8	228.8
12	0.109	0.108	294.6	199.6
15	0.138	0.137	250.1	155.5
18	0.168	0.165	201.6	127.5

- **WARNING!** To avoid vision hazards, everyone (including service personnel) within the NOHD where the laser is operating must wear appropriate eye protection available from Candela. Such eyewear provides adequate protection against reflected or scattered laser radiation, or inadvertent brief exposure to the laser beam. Laser safety eyewear should be stored away from direct sunlight at temperatures of 65°F - 75°F or 18° - 24°C.

- **WARNING!** During laser procedures, the patient's eyes must be protected. The opaque patient goggles provided by Candela are appropriate for most patients. It is recommended to place gauze sponges under the opaque patient goggles to ensure that the patient's eyes remain closed. In addition, the opaque goggles do not fit well if used on infants or small children. Gauze sponges moistened with water and taped over the eyelids, or a moistened facecloth held over the eyes are recommended. If the patient is asleep, the eyes should be taped closed and covered with moistened gauze sponges.
- **WARNING!** Even when wearing protective eyewear, looking directly into the path of the laser beam may cause permanent eye damage.
- **Caution!** The laser beam emitted by the GentleMAX Laser System should never be directed at any part of the body other than the intended site of treatment or testing.
- **Caution!** Removal of any of the exterior panels could allow access to hazardous levels of laser radiation. For this reason, these panels are designed not to be easily removable; they must not be removed except by authorized trained service personnel.

Electrical and Mechanical Hazards

- **WARNING!** The GentleMAX Laser converts and amplifies the AC line voltage to produce extremely high voltages inside the laser system which are very dangerous, even 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 Laser has been disconnected from the line voltage. Therefore, no part of the exterior housing should be displaced, except by a trained and authorized technician.
- **WARNING!** The GentleMAX Laser System laser delivery system utilizes fiber optics that can be damaged if installed or subjected to excessive bending. To avoid damage to the optical fiber, limit bends to a radius of 6 inches (15 cm) or greater. Failure to follow recommended procedures may lead to damage to the fiber or delivery system and/or harm to the patient or user. When damaged, the fiber or delivery system becomes a potential fire hazard (see **"Fire Hazards" on page 1-13**).
- **WARNING!** Although the GentleMAX Laser System is well balanced, it weighs more than 300 pounds (almost 150 kg) and may cause injury if proper care is not used when moving it. The system should always be moved carefully and slowly.
- **Caution!** To prevent the laser from moving, both front wheels must be locked. To lock the wheels, step down on the tabs on the front of the wheels. To unlock, step down on the top (smaller) tabs.

Chemical Hazards

There are no known chemical hazards associated with the GentleMAX 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.** Ingestion is not considered a potential route of exposure.
- **WARNING! IMPORTANT NOTE TO PHYSICIANS**
  Because of possible disturbance of cardiac rhythm, catecholamine drugs such as epinephrine should only be used with special caution in situations, when performing emergency life support. See MSDS sheet, Candela P/N 8501-00-1701.

Guidelines for Cryogen Treatment Areas

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

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

General Treatment Area Guidelines

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

Frostbite Risks

Treatment areas should have sufficient free floor space to allow a patient or user the ability to move away from unanticipated spray of cryogen. **Table 1-3** provides exposure guidelines:

Table 1-3: Frostbite Prevention in Treatment Areas

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

For specific customer situations, contact Candela Technical Support.

Flash Fire Hazards

- **WARNING!** Extreme caution must be used whenever oxygen is present during the laser procedure. The presence of oxygen greatly accelerates combustion of any flammable material. Failure to follow adequate precautions could result in a fire and possible injury to the patient or staff.
- **WARNING!** Hair, gauze, masks, cannula and airway materials can be ignited by laser energy in an oxygen enriched atmosphere. Even if thoroughly soaked with saline, flammable materials can be ignited by laser energy in the presence of oxygen. The following sequence can lead to a flash fire during laser treatment:

    - Oxygen (with or without other gases) is administered via a mask, endotracheal tube, or nasal cannula. Leakage of oxygen generally occurs near the eye region where a tight seal of the mask is difficult to maintain, near the nasal area when a nasal cannula is used, or near the mouth area when an endotracheal tube is used.
    - An oxygen-rich atmosphere is created beyond the oxygen delivery device and dissipates over the facial area. Transient local concentrations of oxygen can occur sufficient to greatly accelerate combustion.
    - During treatment, the laser pulse strikes combustible material which absorbs the laser energy, resulting in the heating of the material beyond the combustion point. This can be as simple as the singeing of the tip of a single hair at the hairline, eyebrow, or eye lash.
    - 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 towards the most oxygen enriched zone. This is generally the oxygen source (mask, cannula, endotracheal tube).
    - Since the flash fire represents combustion and oxygen itself is not combustible, other combustible substances are involved as a secondary effect of the initial ignition. These combustible substances may be related to hair, gauze, oxygen delivery devices, anesthesia gases, or byproducts of anesthesia in the oxygen enriched atmosphere.
    - A burn may then occur where this secondary effect is present. This accounts for the situation of a burn occurring in an area not being directly treated by the laser.

- **Caution!** The electrical and laser radiation hazards present during servicing of the GentleMAX Laser System can be extremely dangerous. The system should be serviced only by those qualified technicians who have received appropriate training on the GentleMAX Laser System from Candela.

Fire Hazards

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

- Treatment Area
  Never use any flammable substance, such as alcohol or acetone in the preparation of the skin for treatment. Use soap and water if necessary.
- Anesthetics
  Anesthetics administered either by inhalation or topically must be approved as non-flammable.
- Instruments
  Since laser beams are reflected by most shiny surfaces, all instruments used in laser procedures should have brushed, burnished, or blackened, non-reflective surfaces.
- Laser Fiber Fire Hazard
  The GentleMAX Laser System fibers carry significant laser energy. If the fiber were to break during laser pulsing, a sudden flash or flame may be observed at the break point. This flash or flame with each pulse will continue until pulsing is stopped. Individuals in contact with this flash or flame could receive a burn. Ignition of combustible materials (including clothing) in the proximity of the fiber break could also occur.
  - If a break or sudden flash or flame is observed in the fiber, discontinue pulsing immediately.
  - Because a break could occur suddenly, always position the fiber during each use such that it is in full view. For example, do not drape the fiber over the shoulder or around the back, leaving a portion of the fiber out of view during use.
  - Do not lay the fiber across combustible materials during use.
  - Do not drape the fiber over the shoulder or back or place it on combustible material.

Laser Generated Air Contaminants (LGAC)

- **Caution!** Laser plume may contain viable tissue particulate.
  - Please reference the American National Standard for Safe Use of Lasers (ANSI A136.3.-2005), section 7.3 Laser Generated Air Contaminants (LGAC).
  - It is recommended that some mechanism for decreasing LGACs be used. Based on the type of condition being treated by the laser, there may be a higher incidence of LGAC.
- **Caution!** NIOSH Hazard Controls.
  - Reference the NIOSH Hazard Controls: Control of Smoke from Laser/Electrical Surgical Procedures bulletin (HC11) – US Department of Health and Human Services, Public Health Service: National Institute for Occupational Safety and Health, September 1996.
  - NIOSH has shown that airborne contaminants generated by laser use can be effectively controlled by proper ventilation and work practices. (The thermal destruction of tissue creates smoke byproduct, which can contain a variety of gases, vapors, dead and live cellular material, including blood fragments).

Electromagnetic Interference

- For information on Electromagnetic Compatibility specifications, see **"Electromagnetic Compatibility" on page B-1**.
  - **WARNING!** The GentleMAX Laser System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.
  - **WARNING!** When treating patients with this laser and using the Dynamic Cooling Device (DCD) feature in conjunction with an ECG monitoring device attached to the patient, interference with the ECG monitoring device may result.

Delivery System Warnings

- Use of a Delivery System/Handpiece or Lens Cartridge with problems could result in adverse effects such as burns, scarring (hyper-tropic and / or atrophic) and / or hyper pigmentation / hypo pigmentation.
- Do not use a dropped Delivery System/Handpiece or Lens Cartridge until after testing.
- Dropping the Delivery System can result in damage and can affect the life of the Delivery System, Calibration, Cryogen Spray Alignment, or Bubble Sense Detection resulting in possible patient burns. If the Delivery System is dropped the user tests must be performed before use.

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

- Do not use a Handpiece if cryogen is not aligned with the delivered energy spot / aiming beam or the cryogen spray pattern is unusual. If cryogen is not aligned, contact Candela Technical Support and discontinue use of the Handpiece.
- Do not use a Handpiece if cryogen is found to be leaking from the Handpiece nozzle tip or there is a reduced cryogen flow. Discontinue use until the cause is determined and eliminated. Purge the lines in order to flush the valve. If problem persists, do not use. Contact Candela Technical Support.

Treatment Related Warnings

- Tilting the Distance Gauge can result in an elliptical energy spot verses a circular spot and affect the distribution pattern of the cryogen. The Distance Gauge must be held perpendicular to the treatment spot. Crescent burns on the patient may occur.
- 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 fiber tips and Lens Cartridge optics free of dust and debris can lead to possible patient burns.
  Laser energy striking dust and debris on optics including fiber tips will damage the optics, and could lead to possible patient burns. When components of the Delivery System are not attached to the laser system, such as the proximal end connector, cover to prevent dust and debris from collecting on optics and exposed fiber tips.
- Failure to keep windows at optimum may result in patient burns. Clean the Delivery System as described in **“Cleaning the Delivery System Handpiece” on page 4-9**. Replace/clean windows as described in **“Cleaning the Delivery System Handpiece” on page 4-9**.
- Failure to re-install windows properly after cleaning can result in failure of the lens or window and may cause patient burns. Improper window insertion could result in lens or window failure and cause burns.
  When removing a window for cleaning, carefully note the window surface that was exposed to debris and the direction in which such window surface faces. When re-inserting the window, ensure that the window surface that was exposed to debris faces the same direction as it did prior to removal.

Precautions

General Precautions

To reduce the risk of shock, do not remove covers. Service must be performed by qualified service personnel.

- In the United States, the facility operating a Candela laser system should follow OSHA guidelines and applicable ANSI standards for the safe use of lasers.
- In Canada, Candela laser systems should be installed and operated in accordance with CAN/CSA -Z386-92: Laser Safety in Health Care Facilities.
- In Australia and New Zealand, the facility operating a Candela laser system should be aware of the requirements of AS/NZS 2211.1, "Laser Safety, Part 1: Equipment Classification and User's Guide", designed to protect persons from laser radiation affecting the eye status of users by implementing a thorough system of examination and reporting.

Laser Room Precautions

- Identify the laser room clearly. Post appropriate warning signs in prominent locations at all entrances to the laser room.
- Cover all windows, portholes, etc. with opaque material to prevent unintended viewing or laser light escaping from the laser room.
- When the GentleMAX Laser System is in operation, restrict entry and limit access to the laser room only to personnel that are both essential to the procedure and well trained in laser safety precautions.
- Make sure that all laser room personnel are familiar with the laser system controls and know how to shut down the laser system instantly in an emergency.
- **Caution!** The use of flammable anesthetics or oxidizing gases such as nitrous oxide and oxygen should be avoided. The high temperature produced during normal use of the laser equipment may ignite some materials, for example cotton or gauze pads when saturated with oxygen. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. Attention should also be drawn to the danger of ignition of endogenous gases.

Optical Precautions

- Appoint one person to be responsible for the laser system controls during the procedure.
- Ensure that all personnel wear appropriate safety eyewear whenever the laser system is on.
- Avoid accidental exposure to the laser beam either directly, or reflected from a surface, by ensuring that all personnel wear appropriate safety eyewear whenever the laser system is on. Verify that the protective eyewear used is known to protect against the wavelengths emitted by the GentleMAX Laser.
- Never look directly into the laser beam coming from the laser system, or reflected from a surface, even when wearing protective eyewear.
- Never allow the laser beam to be directed at anything other than the targeted area, the calibration port or a safe beam stop.
- Never permit reflective objects such as jewelry, watches, instruments or mirrors to intercept the laser beam.
- When the laser system is not actually being used, place the GentleMAX Laser in the Standby state. This will prevent accidental pulsing of the laser should anyone inadvertently depress the Trigger Switch.
- Never leave the key in an unattended laser system or use the Screen Lock to prevent unauthorized use.

Oxygen (with or without other gases)

- Never direct oxygen (with or without other gases) toward or over the laser field.
- Select the appropriate size mask for patient. Masks with soft or filled cushions help to minimize leakage.
- An oxygen analyzer may be used to check concentrations around the oxygen source (mask, cannula or airway).

Hair

- Whenever treating near the hairline, eyebrows or any other facial or body hair, the hair must be kept moist with water or saline.
- Consider shaving hair-bearing areas (beards, mustaches, arm or leg hair, etc.) prior to laser treatment to reduce the risk of igniting hair.

Gauze, Drapes, and Clothing

- Avoid combustible materials such as gauze, drapes and clothing in the treatment area.
- When the use of gauze or drapes is required, all combustible materials must be kept moist with water or saline.
- Saline soaked Telfa pads rather than gauze should be used to protect the eyes.

Masks, Cannula and Airway Materials

- Avoid the use of colored masks, cannula or airway materials.

Treatment Area Preparation

- Never use any flammable substance, such as alcohol or acetone, in the preparation of the skin for treatment. Use soap and water, if necessary.
- When alcohol is used to clean and disinfect any part of the Handpiece, it must be allowed to dry before the laser is pulsed.

Anesthetics

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

Instruments

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

Extinguishing Fires

Simple and effective means of quickly extinguishing a small fire should be kept on hand during each procedure. A small basin of water and a fire extinguisher are recommended.

Safety Features

The GentleMAX Laser system has the following safety features to assist you in operating the system safely.

On/Off Keylock Switch

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

▸▸ For more information, see **"On/Off Keylock Switch" on page 2-8**.

Emergency Laser Stop Button

When the red Laser Emergency Stop button (located on the lower left side of the control panel) is pressed, the GentleMAX laser is shut down immediately.

▸▸ For more information, see **"Emergency Laser Stop" on page 2-7**.

Screen Lock

When the key is turned all the way to the left the screen will prompt the user to remove the key to lock the laser and prevent it from being used. To use the laser again, simply install the key and turn it 90 degrees to the right and the main screen will appear.

▸▸ For more information, see **"On/Off Keylock Switch" on page 2-8**.

PFN (Pulse Forming Network) Beep Sound Alert

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

Lasing Beep Sound Alert

An audible beep sounds and the Status Area on the front panel will change from the Standby/Ready button to a lasing symbol to indicate that the laser is releasing laser energy.

Ready Indicator

The green lamp mounted on the control panel, next to the key-lock switch, is illuminated when the laser is in the Ready state (Figure 3.1). This indicator illuminates at the same time as the Ready Indicator on the Handpiece.

▸▸ For more information, see **"Ready Indicator" on page 2-6**.

Delivery System Cable Indicator

There is an Indicator on the Distal end of the Delivery System Cable that illuminates when the laser is in Ready State. This Indicator illuminates at the same time as the Ready Indicator on the front panel.

▸▸ For more information, see **“Delivery System Cable” on page 2-14**.

Standby and Ready Operating Modes

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

In the Standby state, laser emission is disabled. You must put the system into the Ready state in order to enable laser emission.

In the Ready state, laser pulses are generated by depressing the Footswitch or Fingerswitch. As a safety precaution, there is a delay of two seconds from the time that the system enters the Ready state to the time that the laser emission is enabled.

When the laser system is not being used, it should be returned to the Standby state. The laser will automatically revert back to the Standby state after two minutes of inactivity in the Ready state.

You select the operating state via the Touch Screen/Display Panel. System state information is displayed on the Status Area of the Touch Screen/Display Panel. When the system is in the Ready state, the Ready Indicator on the front panel and the Delivery System Cable Indicator are also illuminated.

▸▸ For more information, see **“System Status Bar and Standby/Ready Button” on page 2-29**.

Remote Interlock

An external connector for a remote interlock switch is provided on the rear panel of the system. This interlock switch can be connected to the doors of the laser room. If the door is opened while the laser is in the Ready state, the laser will return immediately to the Standby state where the laser beam is extinguished.

▸▸ For more information, on installation of a remote interlock, call Candela Technical Support. Also see **“Remote (CDRH) Interlock” on page 2-12**.

Environmental Protection: Disposal Hazards and Guidance

- **Used Delivery System Accessories**
  Residues that accumulate on the Delivery System windows and Distance Gauge during normal use may contain infectious viable tissue particulate. Under certain conditions, contact with viable tissue particulate can put a user at risk for contracting disease. Therefore at the end of its useful life, the Distance Gauge, Windows and cleaning materials should be disposed of in a way that minimizes risk of exposure.

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

- **Laser System Components and Accessories**
  The Waste Electrical and Electronic Equipment (WEEE) Directive Label on the rear of the laser system indicates that the GentleMAX Laser System and its components cannot be disposed of as regular trash (see **Figure 1-1**). Contact Candela for disposal instructions.

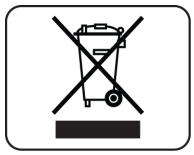


Figure 1-1: WEEE Symbol

Environmental Information

- The equipment that you bought has required the extraction and use of natural resources for its production. It may contain hazardous substances that could impact health and the environment.
- In order to avoid the dissemination of those substances in our environment and to diminish the pressure on the natural resources, we encourage you to use the appropriate take-back systems. Those systems will reuse or recycle most of the materials of your end life equipment in a sound way.
- The crossed-out wheeled bin symbol invites you to use those systems.
- If you need more information on the collection, reuse and recycling systems, please contact your local or regional waste administration.
- You can also contact us for more information on the environmental performances of our products.

Hazardous Material and Hazardous Waste

The DCD GentleCOOL™ cryogen canister is classified as “hazardous”. **Table 1-4** provides more information on disposal of hazardous material.

Table 1-4: Disposal of Hazardous Material

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

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

Warning: Proper disposal of the laser system, its components, accessories, and hazardous materials/waste specified in this manual and the referenced documents is required. Read all labels, procedures, and the referenced documents for additional information.

Chapter 2: Understanding the Laser

Topics described in this chapter include:

Introduction

This chapter provides detailed reference-based descriptions of all the panels, controls, and screens for the GentleMAX Laser system. It includes detailed illustrations of the unit.

Laser System Description

Figure 2-1 shows the GentleMAX Laser system.

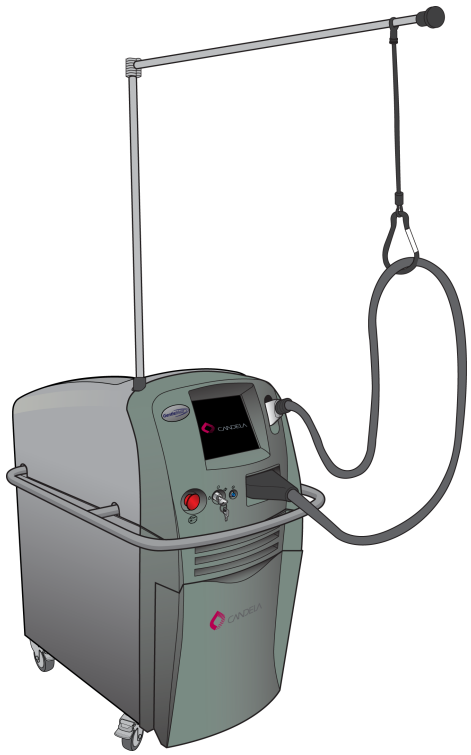


Figure 2-1: Candela GentleMAX Laser System

The GentleMAX Pulsed Laser System is a pulsed, flashlamp-excited Alexandrite and Nd:YAG medical laser controlled by two separate processors. One processor is used to control the Graphical User Interface (GUI) and the other is used to control the laser I/O functionality. The user interface is an LCD panel with a touch screen overlay that allows you to select the laser operating parameters, initiate an automatic calibration procedure, and select DCD parameters.

The Laser System

The GentleMAX Laser System consists of an Alexandrite laser head and a Nd:YAG laser head, a power supply, and a coolant water circulator. The laser heads contain the cavity mirrors, solid-state laser medium rod, and two high-intensity xenon flashlamps that excite the laser medium. A Calibration Port with an internal energy meter is located centrally on the front of the laser. This port is used to calibrate the output of the Handpiece at selected fluence levels. The circulation of coolant water at a controlled temperature regulates the temperature of the laser head.

A microprocessor based system controller monitors and directs all system functions. You select parameters and monitor operation via electronic controls and a display panel. A computer terminal gives the service technician access to the system controller, both to obtain information and to control system functions, for maintenance and for troubleshooting.

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

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

The output of the laser is delivered through an optical fiber coupled to a removable Lens Cartridge. The Lens Cartridge contains the internal focal lenses and a removable Distance Gauge ring. The Distance Gauge ring is placed against the skin to ensure proper focusing and spot placement on the treatment area. A Trigger Switch (Fingerswitch or Footswitch) controls the delivery of the pulses.

You select the desired energy density (fluence) level and enable or disable the laser at the control panel or from the Handpiece. The laser delivers pulses at a repetition rate of up to 10 pulses per second depending on the fluence, pulse duration and spot size setting.

The laser system is equipped with interlocks that 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 enters the Ready State.

The GentleMAX can be configured with the DCD (Dynamic Cooling Device) skin cooling device (used during treatments) which is internal to the system; but an external cooling device can be used with the laser system.

Front Panel

Figure 2-2 shows the front view of the GentleMAX Laser System.

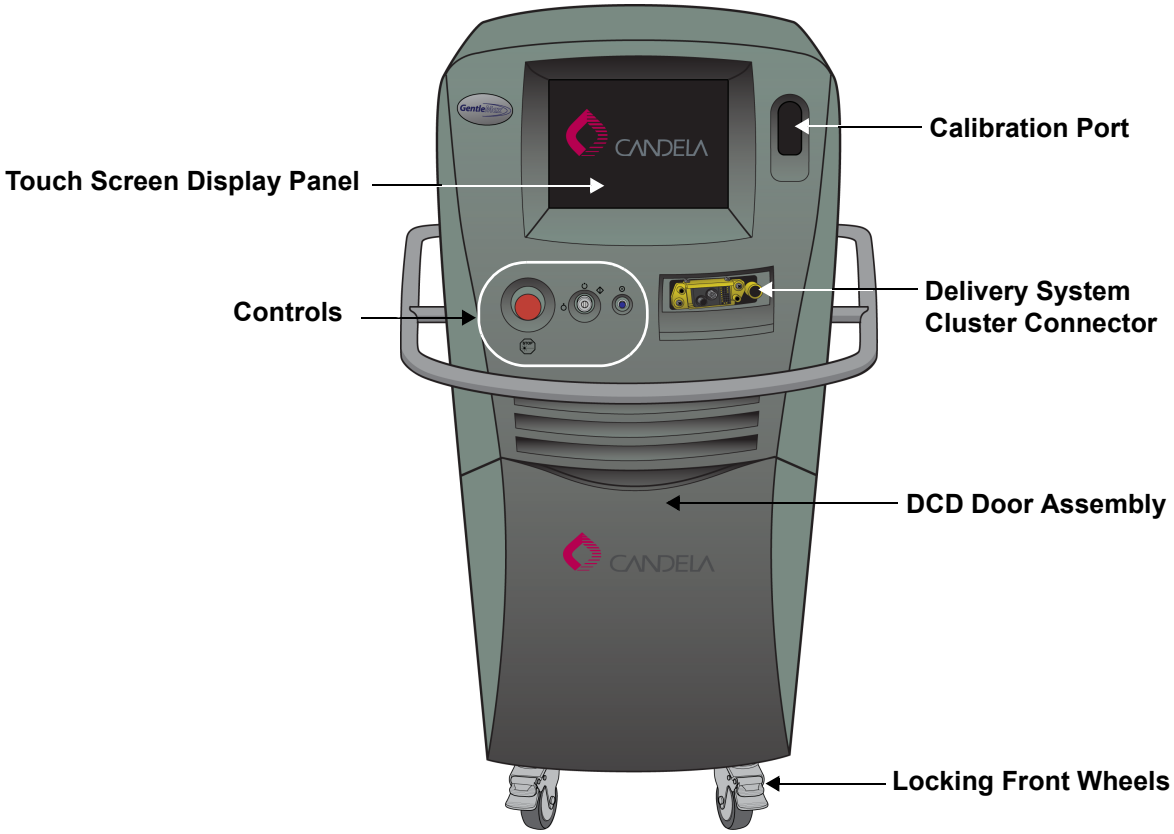


Figure 2-2: Front View of Laser System

The following sections provide a brief description of the front panel components.

Touch Screen/Display Panel

The Touch Screen/Display Panel provides a simple graphical user interface (GUI) from which you can set the operating mode, laser parameters DCD parameters, and output energy calibration. All system status is also displayed on this panel.

▸▸ For complete details on the Touch Screen/Display Panel, see **“Touch Screen/Display Panel” on page 2-23**.

Controls

Figure 2-3 shows a detailed view of the controls on the front of the GentleMAX Laser System.

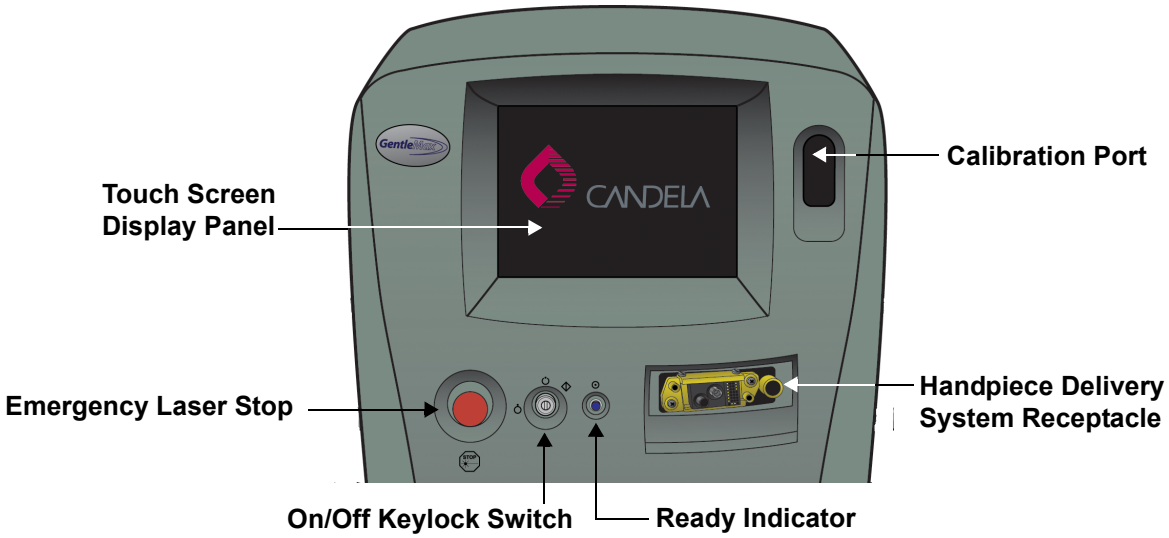


Figure 2-3: Controls and Connectors on the Front Panel

The GentleMAX Laser System controls are located on the Front Display Bezel of the laser system. The controls include an On/Off Key-lock switch, an Emergency Laser Stop push-button switch, and a Ready Indicator Lamp.

Ready Indicator

This indicator shows that the laser has been calibrated and is “ready” to pulse. The laser remains in Standby (no energy will be released) until you press the Ready button and then press the Trigger Switch. See **Figure 2-4** for a detailed view of the indicator.

Emergency Laser Stop

There is a red emergency stop button. When this button is pressed, the GentleMAX laser is shut down immediately. This button is also used to turn off power to the laser after you have turned the Keylock Switch to the Off position. See **Figure 2-4** for a detailed view of the button.

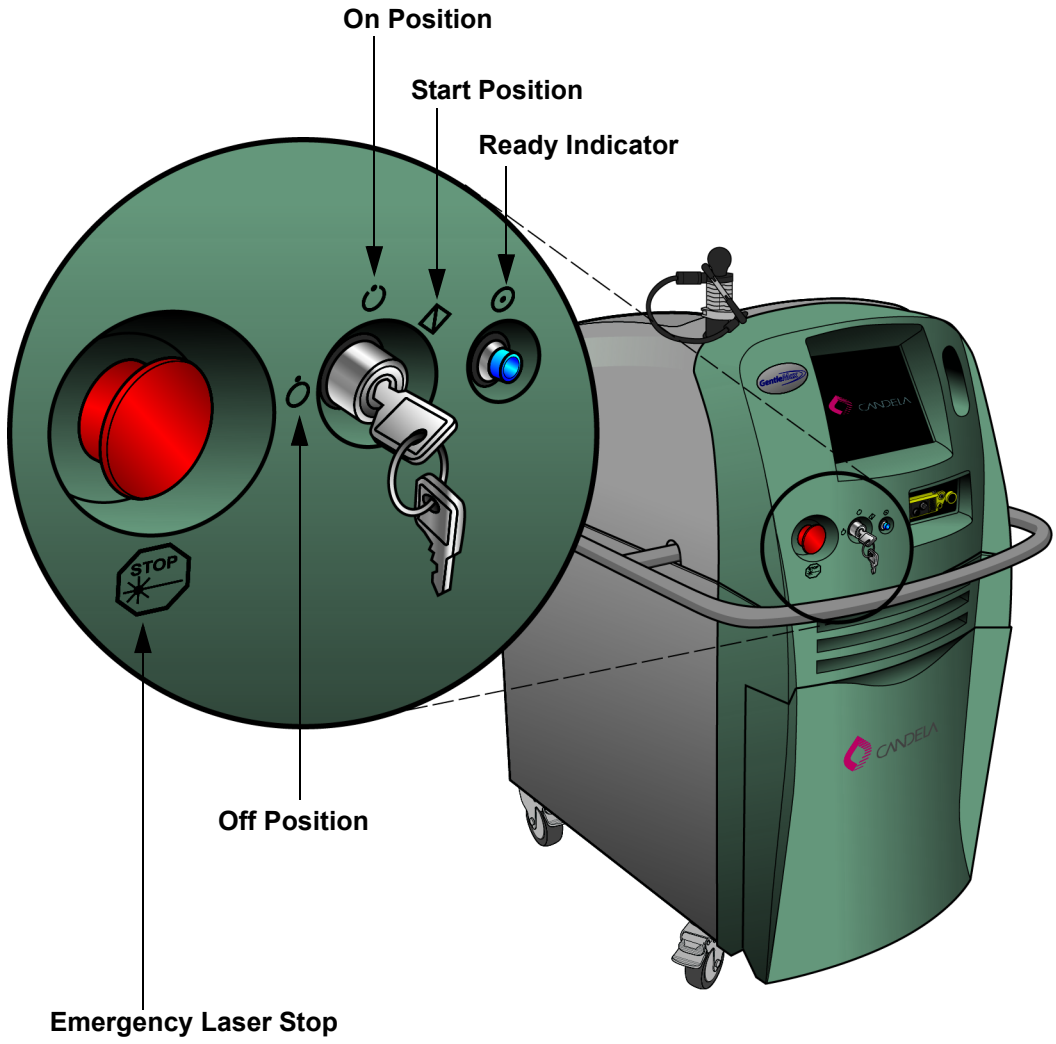


Figure 2-4: Keylock Switch Positions

To restart the laser system after an emergency stop, turn the Keylock switch to the Start position and release.

On/Off Keylock Switch

The electrical power to the laser system is controlled via a key-operated switch. The laser system can only be operated using the key provided by Candela Corporation.

The Keylock Switch is spring-loaded. To turn on the system, move the switch to the Start position and release it. It automatically springs back to the On position.

Caution: The key should be removed from the Keylock Switch and stored in a safe place when the laser is not in use.

The Keylock Switch has three positions as shown in **Figure 2-4** and described in **Table 2-1**:

Table 2-1: Keylock Switch Positions

Keylock Position	Description
Off/Screen Lock 	To turn off the laser system, turn the key in the Keylock switch to the Off position and then press the red Emergency Stop Button. This de-energizes all circuits, except the Keylock switch circuit itself. If you turn the key to the Off position and remove the key (without pressing the Emergency Stop Button), the laser is left idling and the screen is locked so it cannot be used. A message displays on the screen indicating the laser cannot be used until the key is re-inserted and turned to the On position.
On 	When the Keylock switch is in the On position, all circuits are energized. The laser becomes fully functional when the Keylock switch is turned past On to the Start position.
Start 	Start is a spring-loaded keylock position used to start system operation. The key must be turned past the On position to the Start position to start the system. Once the Keylock switch has been turned to Start, it springs back to the On position. Turning the Keylock Switch to the Start position does not start the release of laser energy.

Calibration Port

The Calibration Port (sometimes referred to as the Cal Port) is used to measure the laser output energy. The Handpiece on the Distal end of the Delivery System cable is inserted into the Calibration Port to start this procedure. You also insert the Handpiece into the Calibration Port when the treatment is complete.

The Handpiece must be clean and dry before being placed in the Calibration Port.

When not in use, the Handpiece can be stored in the Calibration Port with the Lens Cartridge installed. The Distance Gauge must be removed prior to performing laser calibrations and stored in a separate clean storage space. The Calibration Port, Handpiece, Lens Cartridge, Distance Gauge, and the Windows must be kept clean at all times to maintain optimal laser performance.

▸▸ For more information on the Handpiece, Lens Cartridge, and Distance Gauge, see **“Delivery System” on page 2-13**.

Handpiece Delivery System Receptacle

The Fiber Optic, Cryogen Line, and Handpiece Electrical connections are used to connect the Handpiece Delivery System cable assembly to the laser.

For more information on the Delivery System cable, see **“Delivery System” on page 2-13**.

Dynamic Cooling Device (DCD™) Door Assembly

The laser system comes with a skin cooling device called the Dynamic Cooling Device (DCD). This device is located inside the DCD Door Assembly, where there are compartments for two Cryogen canisters (Canister A and Canister B). See **Figure 2-5**.

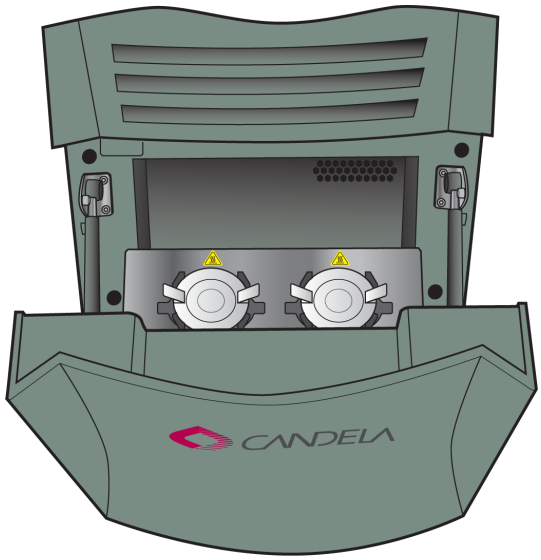


Figure 2-5: Cryogen Canisters Inside the DCD Door Assembly

One canister is for treatment and the other is a backup in case one canister is emptied. This makes the treatment interruption very minimal as there is only a short pause (with message) when the canisters are switching from an empty to a full one. The DCD was FDA cleared under K001589. The DCD consists of an electrically controlled spray nozzle located at the treatment end of the Handpiece, a cryogen reservoir canister and the associated electronic control circuitry located inside the system enclosure.

The cryogen, GentleCool^{TM} is stored under pressure in the reservoir canister(s) and delivered to the solenoid valve via tubing. When the DCD system is on, depressing the Fingerswitch or the Footswitch (whichever is selected) will cause a burst of cryogen spray to be applied to the skin prior to the laser pulse. Controls are provided on the laser touch screen to adjust of the spray burst duration and the time delay between the spray burst and the laser pulse.

- For information on installation and removal of the cryogen canister, see **"Replacing the Cryogen Canister" on page 4-19**.
- For information on setting the cooling parameters, see **"Cooling" on page 2-34**.

Locking Wheels

The GentleMAX system is equipped with wheels. The two front wheels can swivel to allow for maneuverability. The rear wheels are fixed and do not swivel.

The front swivel wheels contain levers which stop the wheels from rotating. To prevent the laser from moving, the front wheels must be locked. To lock the front wheels, use your foot to press down on the locking lever over each of the front wheels. To release the wheel lock, either press on the Off lever or put your foot under the On lever and press up. There are no levers in place for the rear wheels (see **Figure 2-6**).

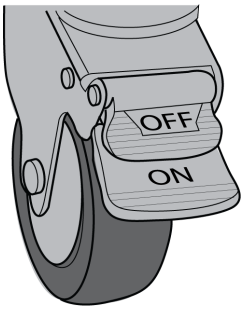


Figure 2-6: Front Wheel Locks

Rear Panel

Figure 2-7 shows the rear view of the GentleMAX Laser System.

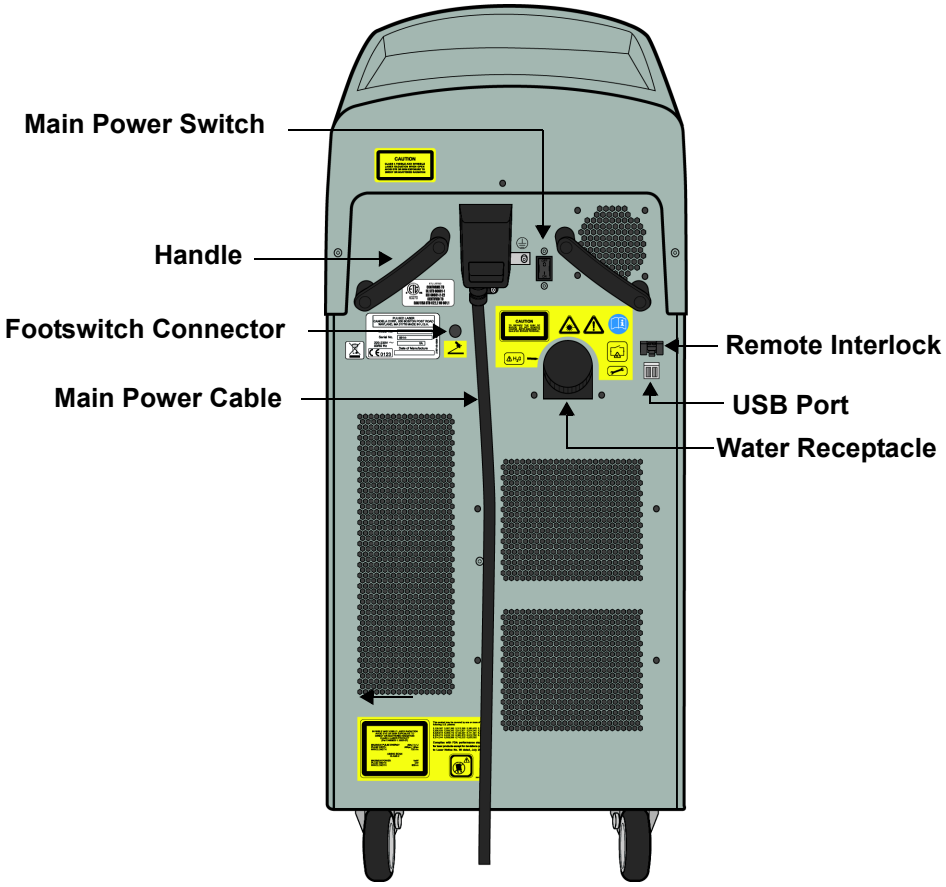


Figure 2-7: Rear View of Laser System

The following sections provide a brief description of the rear panel components.

Main Power Switch and Power Cord

The main power switch (also referred to as the Mains Switch or circuit breaker) and power cord for the laser system are located on the rear of the GentleMAX Laser system. The power switch must be in the ON position for the laser system to operate.

Always place the On/Off Main Switch in the OFF position when the laser is not in use.

Remote (CDRH) Interlock

This connector allows for a remote interlock for safety. This interlock may be connected to one or more switches on the laser room door(s). If the door is opened when the laser is in the Ready State, the interlock causes the laser to revert to the Standby state. The switch must be connected so that with the door closed, the switch contacts are closed. When the door is opened, the switch contacts must open.

When the remote interlock is not in use, the supplied jumper must be plugged into the interlock connector.

Footswitch Connector

The Footswitch is connected into the Footswitch Connector, located on the back of the laser system. Use the Footswitch to deliver energy from the laser to the treatment area.

▸▸ For more information on the Footswitch, see **“Fingerswitch and Footswitch” on page 2-18**.

Water Receptacle

The GentleMAX Laser System is cooled with distilled water. The water tank is located inside the laser and is connected to a reservoir filler bottleneck protruding from the rear of the laser. The water cooling system holds 2.8 liters of DI water.

Handle

There are two handles on the rear panel of the laser system to help you easily roll the system around on its wheels.

Caution: The handles are not intended to be used to lift the laser system.

Delivery System

The Delivery System consists of a Delivery System cable, a Handpiece Assembly, a Lens Cartridge, a Distance Gauge, and a Fiber Pole. Each spot size requires a separate Lens Cartridge with its matching Distance Gauge to be installed in the Handpiece.

The GentleMAX laser system with DCD includes two Delivery Systems (1.5/3 mm and 6-18 mm). Both Delivery Systems operate in the same manner.

Note: Only the Delivery System for the larger spot sizes (6-18 mm) require the use of a Window Tube inside the Lens Cartridge.

Figure 2-8 shows the Delivery System connected to the Laser System.

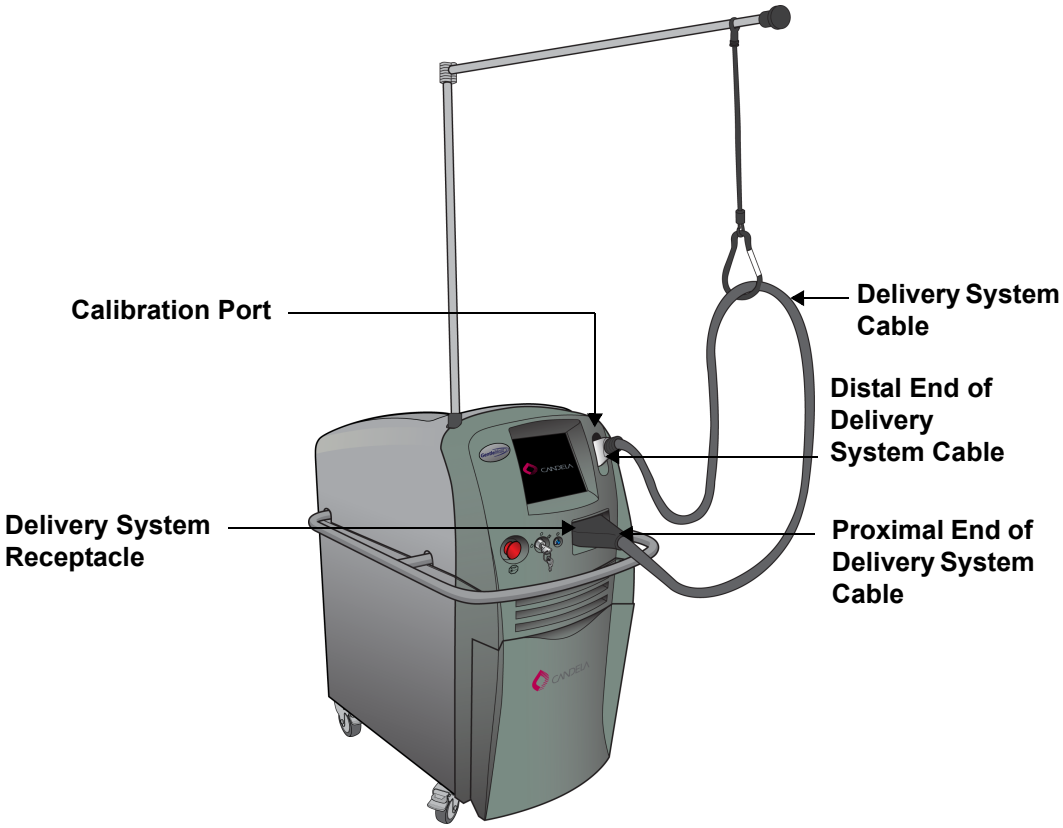


Figure 2-8: Delivery System

Delivery System Cable

The Cable Assembly contains the fiber optic, cryogen input line, air cooling line, and valve control wires. The Handpiece Assembly is on the distal end of the Delivery System cable. It is placed in the Calibration Port before laser treatments. The proximal end of the Delivery System cable connects to the Delivery System Receptacle.

Figure 2-9 and **Figure 2-10** show the connectors on each end of the Delivery System Cable. **Figure 2-10** also shows the Lens Cartridge and the Distance Gauges connected to the distal end of the cable.

Proximal End of Delivery System Cable
(connects to the Delivery System Receptacle)

Figure 2-9: Proximal End of Delivery System Cable

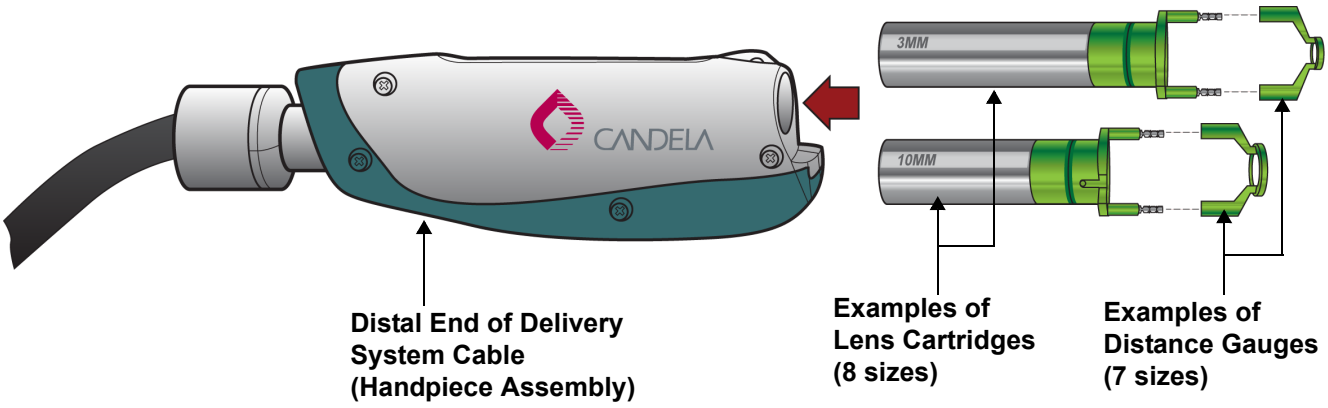


Figure 2-10: Distal End of Delivery System Cable

Handpiece Assembly

The Handpiece Assembly on the distal end of the Delivery System cable contains the DCD Spray Nozzle, the Trigger Switch (Fingerswitch) and the safety and detection electronics. The laser aperture is located at the distal end of the Handpiece where the Lens Cartridge is inserted.

Each laser configuration comes with its own Delivery System(s), Lens Cartridge, and Distance Gauge Kit. Each spot size requires a separate Lens Cartridge and its matching Distance Gauge to be installed in the Handpiece. The color bands on the legs of the Lens Cartridges and Distance Gauges are color-coded to match for each spot size.

The Lens Cartridge and Distance Gauge are installed into the Handpiece Assembly. The Spray Nozzle is located near the Distance Gauge at the treatment end of the Handpiece. The Fingerswitch is located on the Handpiece. An alternate Standby/Ready button with indicator is also located on top of the handpiece.The Handpiece Assembly also has an alternate Standby/Ready button with a Ready Indicator that is illuminated with the system is ready to deliver energy to treat a patient on the top of the Handpiece. See **Figure 2-11**.

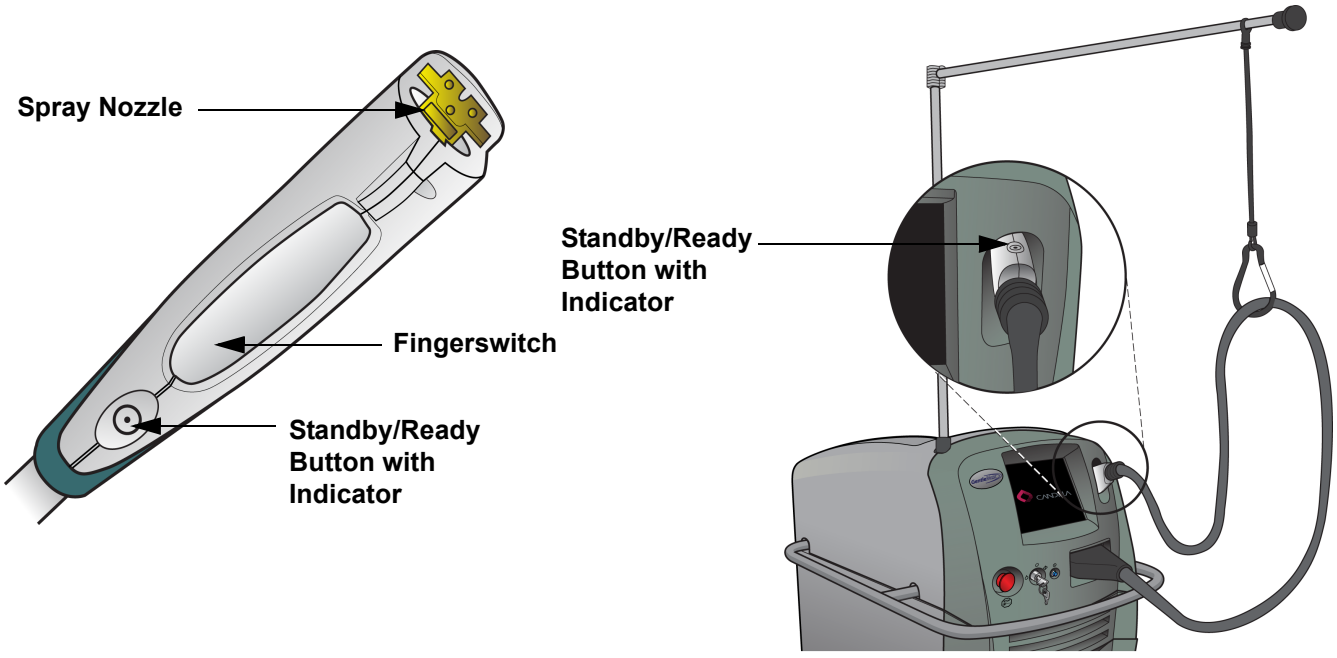


Figure 2-11: Detailed View of Handpiece Assembly

Use the Treatment Guidelines to determine the Delivery System, Lens Cartridge, and Distance Gauge to be used for a specific treatment. The correct Lens Cartridge is then installed into the Handpiece Assembly.

The Handpiece Assembly, without the Distance Gauge, is inserted into the Calibration Port to calibrate the laser before treatment. When the laser is successfully calibrated, the Handpiece Assembly is removed from the Calibration Port and the matching Distance Gauge for the treatment is installed. After treatment, remove the Distance Gauge and return the Handpiece to the Calibration Port.

The Handpiece has an internal window that is removable with a tool supplied with the system called the Window Removal Tool. See

- For information on removing and cleaning the Handpiece window, **see "Cleaning the Delivery System Handpiece" on page 4-9.**

Lens Cartridges

There are eight Lens Cartridges included with the GentleMAX laser system. The Lens Cartridge contains internal focusing lenses and input/output windows to protect the lenses from dust and debris. The output window is contained in a removable Window Tube in the 6-18mm Lens Cartridges.

The Lens Cartridges come in eight sizes for the following spot sizes: 1.5, 3, 6, 8, 10, 12, 15. and 18 mm (see **Figure 2-10** for examples of the Lens Cartridge). The Lens Cartridges have color bands on the legs that are color-coded to match the Distance Gauges.

- For information on removing and cleaning the windows of the Lens Cartridge, see **"Cleaning the Lens Cartridge and Distance Gauge" on page 4-12**.

Distance Gauge

There are seven removable Distance Gauge sizes included with the GentleMAX laser system. The Distance Gauge is the only part of the laser system that comes in contact with the patient. It is mounted on the Lens Cartridge (see **Figure 2-10** for examples of the Distance Gauges).

The Distance Gauge contains a Distance Gauge Ring. It 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.

Distance Gauges come in seven sizes for the following spot sizes: the 1.5/3mm in one size and the 6, 8, 10, 12, 15, and 18mm. The color bands on the legs are color-coded to match the Lens Cartridges: Grey (1.5/3mm), Black (6mm), Blue (8mm), Purple (10mm), Red (12mm), Green (15mm)and Yellow (18mm).

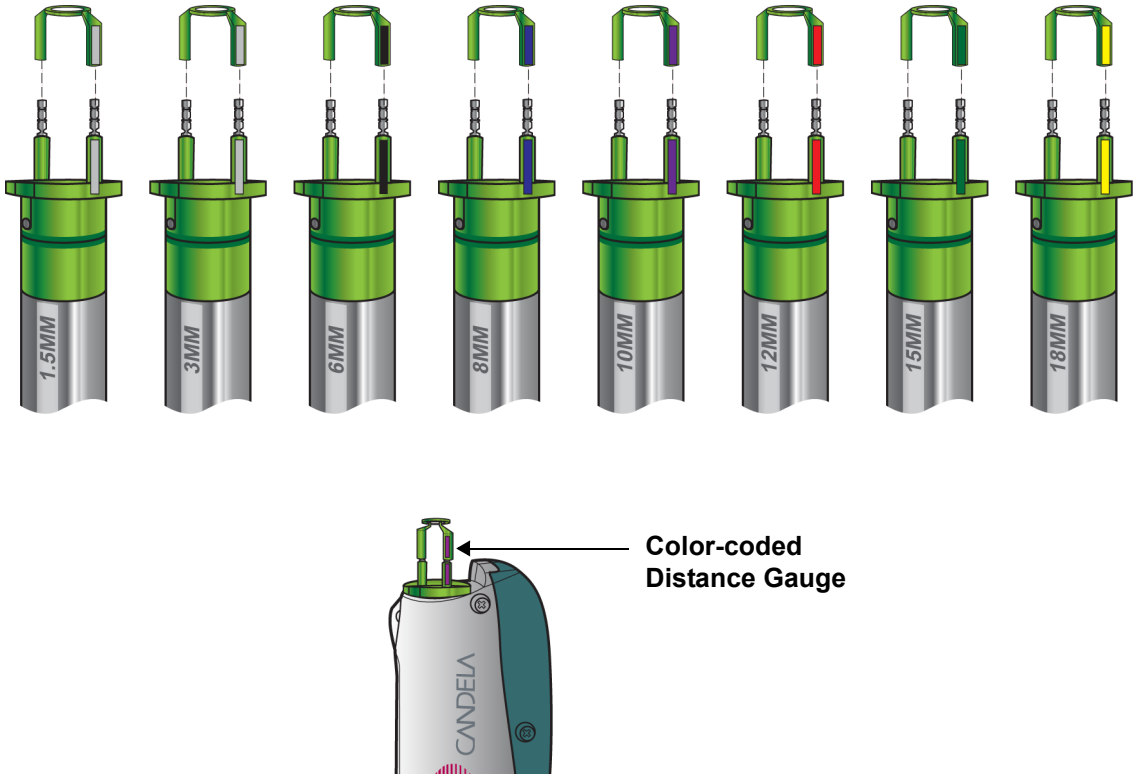
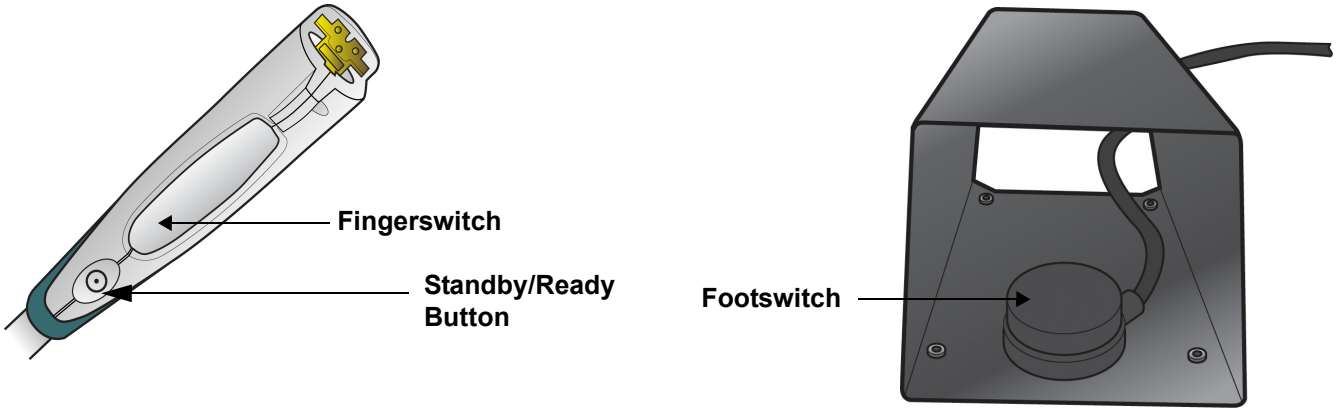


Figure 2-12: Example: Color-Coded Gauge

Fingerswitch and Footswitch

The energy is delivered through the laser when the Fingerswitch or Footswitch is depressed (depending on the Trigger Source you selected during setup). The amount of energy delivered and the length and number of pulses delivered depends on the settings selected during setup. The Fingerswitch is located on the Handpiece (see **Figure 2-13**). The Footswitch is connected to the Footswitch connector on the rear of the system (see **Figure 2-13**).



The Fingerswitch is located on the Handpiece.

The Footswitch is connected to the rear of the Laser System.

Figure 2-13: Fingerswitch and Footswitch

Fiber Pole

The adjustable Fiber Pole supports the Delivery System cable as shown in **Figure 2-14**. This device keeps the cable suspended and reduces the weight of the delivery system during use.

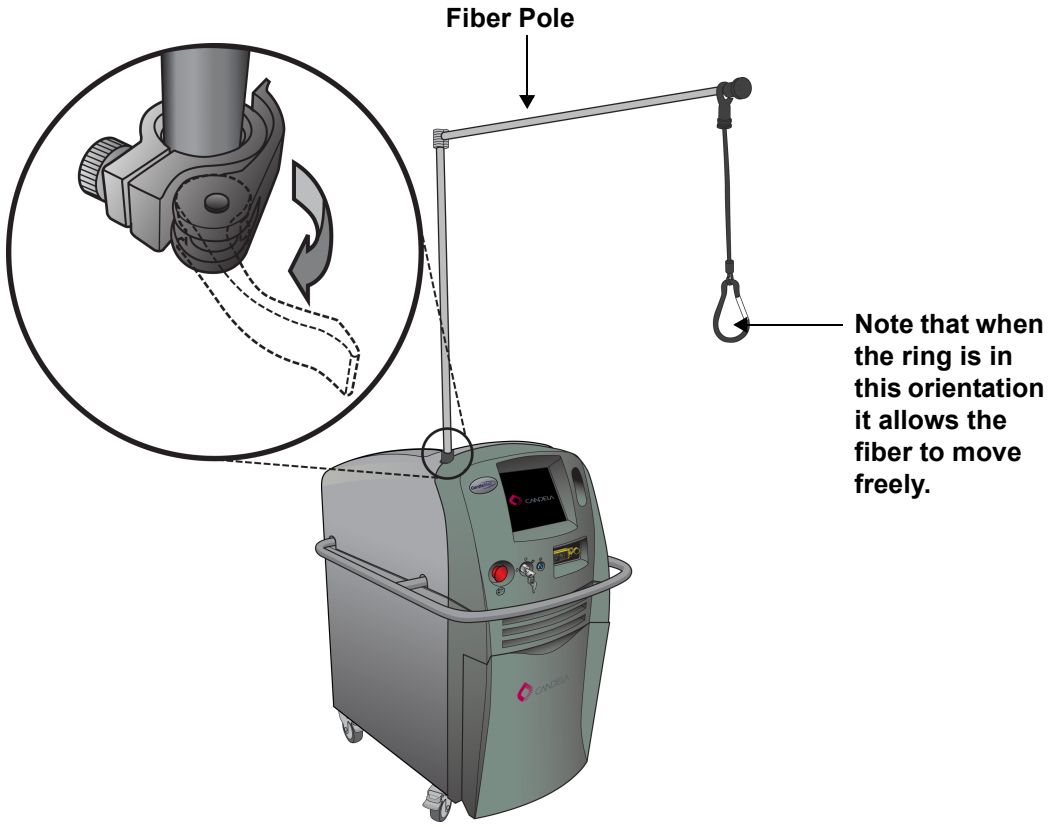


Figure 2-14: Fiber Pole Configuration 1

The Fiber Pole height is adjustable via the locking clip at its base at the top of the laser system (see **Figure 2-14**). Once extended, the top part of the Fiber Pole bends at 90 degrees and can be moved in a 360 degree motion. There is a bearing with a ring at the end for the fiber. This bearing will traverse the now horizontal part of the Fiber Pole allowing free range of movement. When not in use, the Fiber Pole can be folded and retracted back into the system for storage.

There are two configurations for the ring at the end of the pole for the fiber. Configuration 1 allows the delivery system cable to slide freely through the ring (see **Figure 2-14**). Configuration 2 locks the delivery cable in place so that the handpiece is supported (see **Figure 2-15**.)

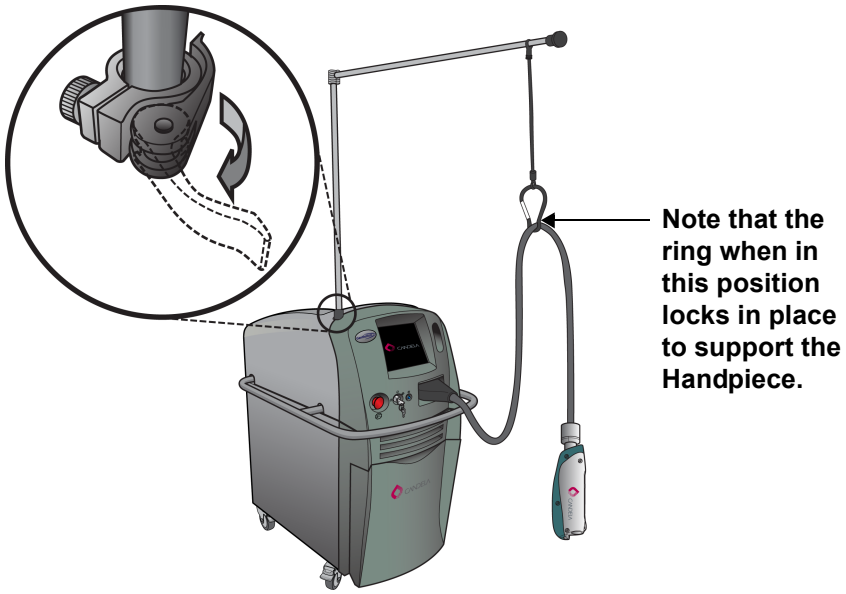


Figure 2-15: Fiber Pole Configuration 2

Caution: To reduce the risk of personal injury and damage to the Delivery System cable, use the Fiber Pole to support the Delivery System at all times. When not in use, insert the Handpiece in the Calibration Port. This removes excess slack from the Delivery System cable and reduces the possibility of damage to property and/or personal injury from stepping on or tripping on the cable or running the wheels over it.

Caution: When using the Fiber Pole to support the Delivery System, make sure there are no sharp bends in the Delivery System cable. The laser system can be damaged if the cable is subjected to excessive bending. To prevent damage, never pulse the laser system if the Delivery System cable bend radius is less than six inches.

Connecting the Lens Cartridge and the Distance Gauge to the Handpiece

Before you can use the laser, you must install the Lens Cartridge in to the Handpiece and install the Distance Gauge.

To install the Lens Cartridge into the Handpiece and install the Distance Gauge:

1. Select the Lens Cartridge and Distance Gauge to be used in the treatment.

2. Align the flat on the Lens Cartridge with the flat protrusion on the Handpiece Assembly (see **Figure 2-17**) and then gently push the Lens Cartridge into place (see **Figure 2-17**).

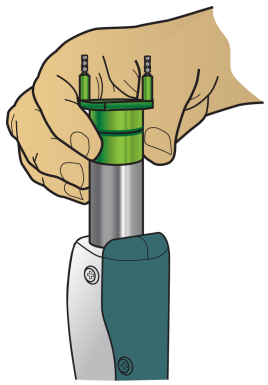


Figure 2-16: Insert Lens Cartridge into Handpiece Assembly

3. Install the Distance Gauge on the top of the Lens Cartridge (see **Figure 2-17**).

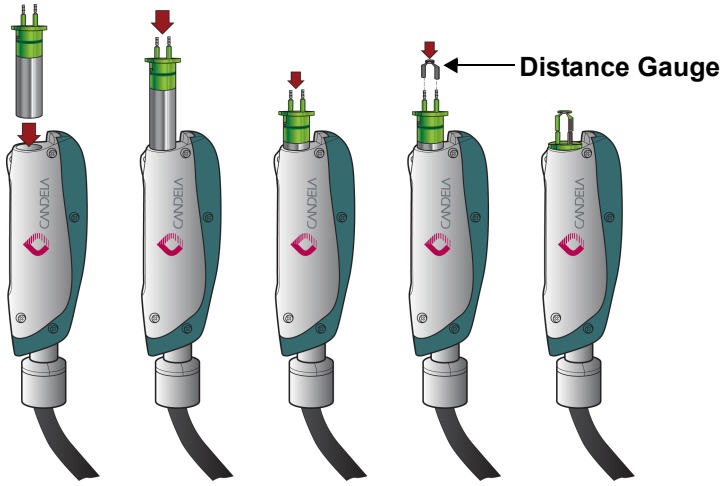


Figure 2-17: Install Lens Cartridge into Handpiece Assembly and Install Distance Gauge

Connecting the Delivery System Cable

Figure 2-18 shows how to connect the two ends of the Delivery System Cable to the front of the laser system. Both connectors are keyed and have orientation marks to ensure they are connected correctly.

Before you connect the Delivery System Cable, the Lens Cartridge should be installed on the distal end of the Delivery System Cable.

1. Insert the proximal end of the Delivery System cable into the Delivery System Receptacle (see **Figure 2-18**).

2. Insert the distal end Handpiece of the Delivery System cable into the Calibration Port (see **Figure 2-18**).

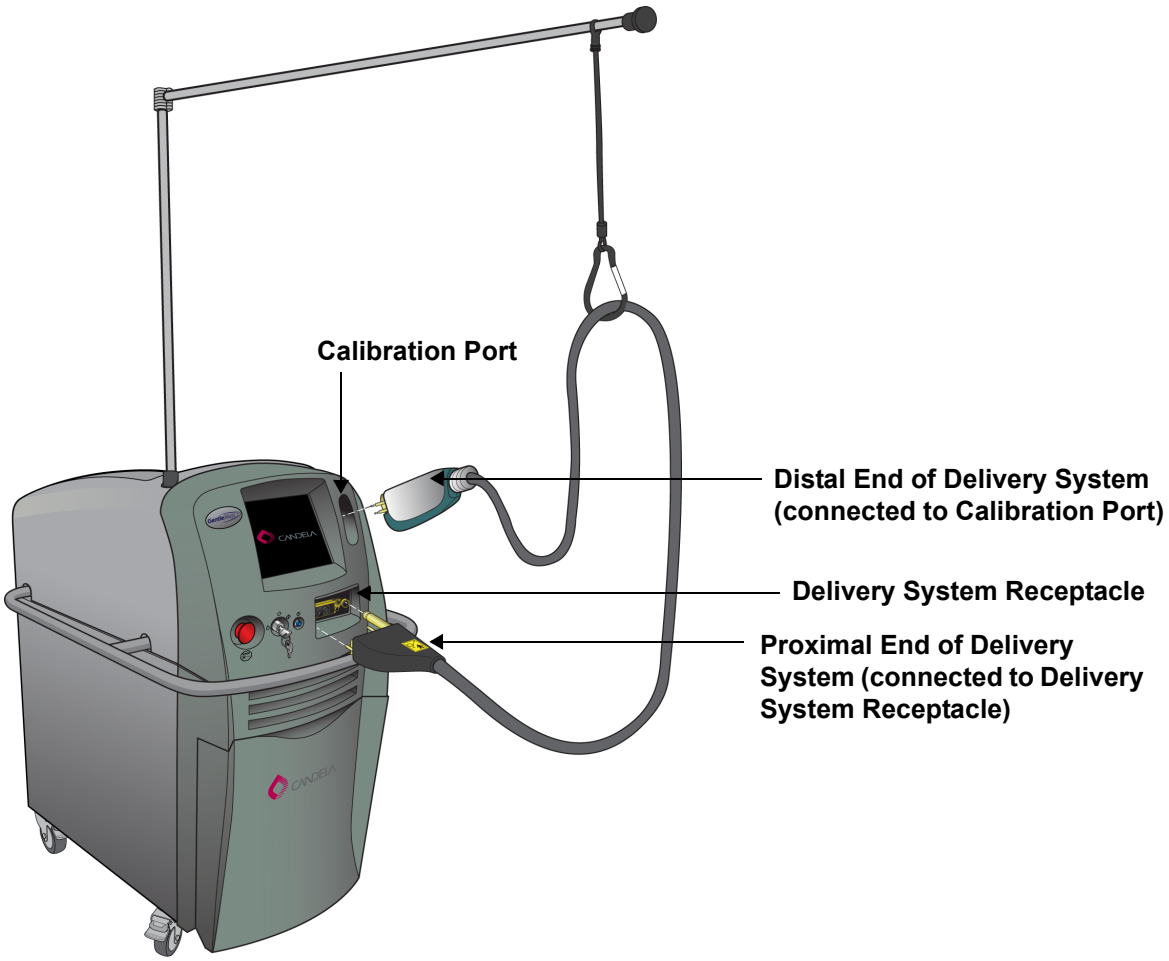


Figure 2-18: Install Delivery System Cable into the Laser System

When the system is turned on, the range for the Fluence parameter will be set up automatically based on the Lens Cartridge spot size that is installed.

Touch Screen/Display Panel

This section provides an overview of the graphical user interface provided on the Touch Screen/Display Panel. The Touch Screen/Display Panel features a Smart User Interface, easily allowing you to access and monitor the laser system operation functions. Choosing from the menus and submenus, you can select the desired parameters to perform patient treatments.

Figure 2-19 shows the main display screen:

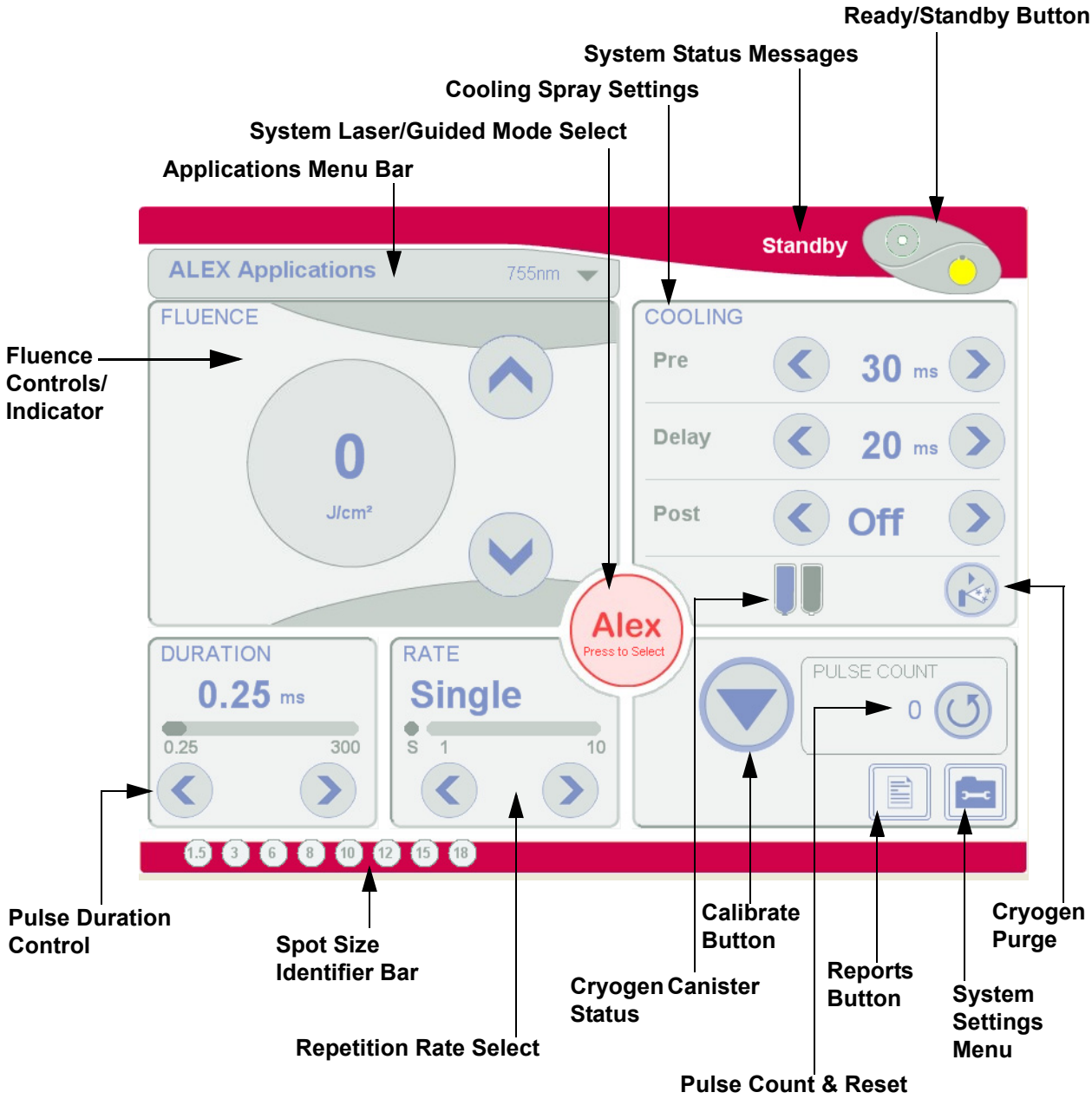


Figure 2-19: Touch Screen/Control Panel Main Screen

Applications Menu Bar

Touching the Applications Menu bar on the Main Screen displays a list of available applications. When a treatment application is selected in the Applications Menu, the selected application bar will turn blue and a submenu will appear (see **Figure 2-20** for the available Alex and YAG applications).

ALEX Applications **YAG Applications**

Figure 2-20: Applications Drop Down Menu

If you have selected ALEX applications, then the ALEX Applications bar displays when you select ALEX Applications and the background for the screens is red. If you selected YAG applications, then the YAG Applications bar displays when you select YAG Applications and the background for the screens is green.

- For information on selecting ALEX or YAG applications, see **"Laser System/Guided Mode Select" on page 2-27**.

Treatment Parameters

When a treatment application is selected from one of the drop down menus, the Select Parameters screen displays for that specific selected application. For example, if you select Hair Removal from the ALEX Applications, the Hair Removal Select Parameters screen displays (see **Figure 2-21**). Use this screen to select the desired parameters.

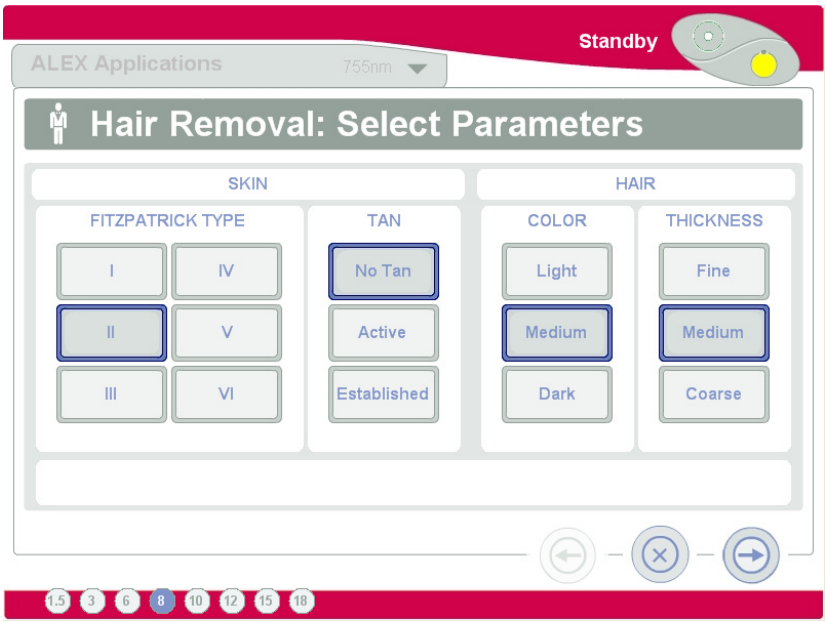


Figure 2-21: Example of Select Parameters Screen for Hair Removal

Select the arrow pointing right  to accept the selected parameters:

The Common Settings screen appears. This screen shows you the common settings for the Lens Cartridge/Distance Gauge that has been installed. Continuing with the example above, **Figure 2-22** shows an example of the Common Setting screen.

Figure 2-22: Example of the Common Setting for Hair Removal

Press the checkmark  to accept the settings and have the main screen auto-set to the suggested parameters (see **Figure 2-23**).

Figure 2-23: Example of Auto-Set Parameters to the Suggested Parameters

To exit any of these screens, select the X button or select the Applications Menu Bar.

Refer to the Candela Clinical Treatment Guidelines (see **"Candela Clinical Treatment Guidelines" on page 2-29**) for the recommended preset treatment parameters and the spot sizes for the desired treatment applications. See **"Performing a Laser Treatment" on page 3-2** for instructions on performing patient treatments. Read and follow all the instructions, procedures, and messages provided in this manual, on the Touch Panel/Display Panel, and all referenced documents.

Laser System/Guided Mode Select

The Laser System/Guided Mode Select button in the center of the screen allows you to switch between the ALEX and YAG lasers. It also allows you to choose to use a guided mode.

If you select the red and pink button from the center of the screen (see **Figure 2-19**), it expands to allow you to choose the mode to use (see **Figure 2-24**).

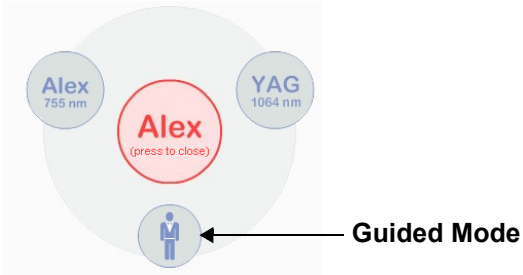


Figure 2-24: Select Laser System or Guided Mode

To use the Alex laser, select the Alex button in the upper left. To use the YAG laser, select the YAG button in the upper right. To use Guided mode, touch the button with the icon of a man in the lower center.

If you select either of the two lasers, only parameters for the selected laser display.

If you select Guided Mode, you are prompted to enter a set of parameters. Once you enter those parameters, the system shows the common settings based on your selections. This function helps guide you to the most commonly used parameters for certain skin types.

Guided Mode: Treatment Parameters

When you select Guided Mode (see **Figure 2-24**), the Guided Mode menu displays (see **Figure 2-25**).

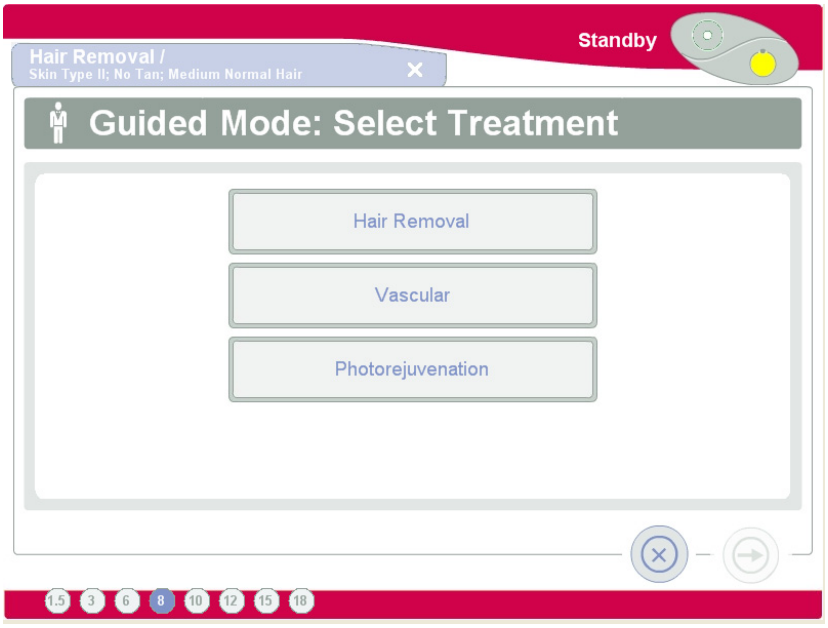


Figure 2-25: Guided Mode Menu

When you make a selection from this menu, the Guided Mode allows you to enter parameters and have the laser system guide you to the commonly used settings (similar to pressing the Applications Menu).

Treatment Application Options

The Application options are limited to the spot sizes available for the laser system configuration (see **Table 1-1**) and each treatment application. The laser system will not permit you to use a treatment application with an unsupported Lens Cartridge/Distance Gauge spot size installed. Only use Lens Cartridge/Distance Gauge spot sizes that are supported by the desired treatment application.

Refer to the Candela Clinical Treatment Guidelines (see **"Candela Clinical Treatment Guidelines" on page 2-29**) to get the recommended pre-set treatment parameters and the supported Lens Cartridge/Distance Gauge spot sizes for the desired treatment applications.

- See **"Performing a Laser Treatment" on page 3-2** for step by step instructions for performing patient laser treatments. Read and follow all the instructions, procedures and messages provided in this Manual, on the laser screen and all referenced documents.

Candela Clinical Treatment Guidelines

Warning: The Preset Treatment Parameters and Clinical Treatment Guidelines do not take the place of the procedures and instructions found in the Operator's Manual.

Failure to use the laser in accordance with such procedures and instructions could result in serious injury to the operator, the patient and others, as well as damage to the laser system.

Follow OSHA and ANSI standards for laser safety. Protective eyewear must be worn by all persons in the treatment room during laser operation.

Check the Delivery System for any damage (i.e. dropped).

Discontinue use of your laser Delivery System if you suspect a problem.

The Candela Clinical Treatment Guidelines were developed from clinical experience for applications specific to the GentleMAX laser. Each treatment application has its own set of starting operating parameters. If needed, each operating parameter can be adjusted by pressing the up and down buttons to adjust the value to the desired setting.

- If questions arise or additional information about a treatment application is needed, refer to the Candela Clinical Treatment Guidelines available on www.MyCandela.com or contact Clinical Support.
- For step by step instructions for performing patient laser treatments, see **"Performing a Laser Treatment" on page 3-2**. Read and follow all the instructions, procedures and messages provided in this Manual, on the laser screen and all referenced documents.

Note: The Candela Preset Treatment Parameters and Clinical Treatment Guidelines were developed from clinical experience and are subject to change as additional experience is gained. Be sure to inquire with your Candela Sales Representative, Clinical Consultant or visit MyCandela.com regularly for the latest updates, laser system software upgrades and a comprehensive bibliography list of references/published articles.

System Status Bar and Standby/Ready Button

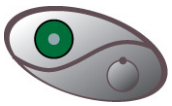
The System Status Bar is located in the upper right side of the Main Screen display and contains the Ready and Standby Buttons (see **Figure 2-19**). The system operates in one of two states: STANDBY and READY.

When the desired state is selected, the System Status Bar displays the System Status in symbols and its operating state in words. **Table 2-2** describes the meaning of the System Status Bar and Button symbols.

Standby/Ready Button

Table 2-2 describes the function of the Standby/Ready button. The Standby/Ready button toggles between the Standby state and the Ready state. This area is also used to show the status of the system (see **“Status Area” on page 2-31**).

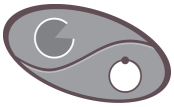
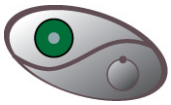
Table 2-2: Standby/Ready Button Functions

Button	Description
Ready 	**Caution:** Do not enter the Ready state without a delivery system installed and having the proper protective eyewear on. When in Ready, laser emission is enabled. Select the Ready button (the upper left button with the dot in the center) to put the system into the Ready state. In Ready state the laser is armed and ready to use for treatment. A two second delay is implemented before laser emission is enabled when the system state changes from Standby to Ready. When the system enters the Ready state, the Ready button displays in green, the word “READY” appears in the Status Area beside the button, and the Ready Indicators on the front panel and on the Handpiece Assembly are illuminated. **NOTE:** If the laser remains idle (unused) for more than two minutes in the Ready state, it will automatically revert back to the Standby state.
Standby 	When in Standby, the laser emission is disabled. Select the Standby button (the lower right button) to place the system in Standby. When you select Standby, the Standby button displays in yellow and the word “STANDBY” displays in the Status Area beside the button. The GentleMAX Laser System automatically enters Standby state during and following the initial warm-up period which occurs when the laser system is first powered up. The system automatically reverts to Standby when the laser remains idle in the Ready state for more than 2 minutes or when a fault condition is detected. Select the Standby button when a treatment session is complete and before you return the Handpiece to the Calibration Port.

Status Area

Table 2-3 describes the status of the system based on the color of the Standby/Ready button and the symbols displayed in that area. This area is also used to toggle the system between the Ready and Standby states (see **“Standby/Ready Button” on page 2-30**).

Table 2-3: System Area Indicators

Indicator	Description
Standby 	When the Standby button is yellow, the system is in the Standby state. When in Standby, the laser is disabled. The word “STANDBY” displays next to the symbol. The laser automatically enters Standby during and following initial warm up, which occurs when the laser is first powered on. It also automatically enters Standby if the laser is idle for more than 2 minutes while in the Ready state.
Warming Up 	The Warm Up icon displays while the system is warming up. Allow 15 minutes for the system to complete the warm up cycle. The percentage of the total warm up time completed is displayed next to the symbol. For example, if the warm up is 45% complete, the message, “Warming Up 45%” displays next to the symbol.
Ready 	When the Ready button is green, the system is in the Ready state. The word “READY” displays next to they symbol. When Ready, the laser is armed and ready for use. Laser energy will not be emitted until you press the Trigger Switch while the system is in the Ready state. The Ready Indicator on the front panel and the Indicator on the Handpiece Assembly in the Calibration Port are also illuminated when the system status is Ready.
Lasing 	The Standby/Ready button displays the Laser symbol when the laser is pulsing. The word “LASING” displays next to the symbol. Always wear protective eyewear when lasing. This symbol appears when you press the Trigger Switch to begin laser treatment. The symbol displays while the Trigger Switch (Fingerswitch or Footswitch) is depressed. When the Trigger Switch is released, the system reverts back to the Ready state and the Standby/Ready button is green.

Operating Parameters

You can adjust the following operating parameters for laser treatments: Fluence, Cooling (DCD Spray and DCD Delay Duration), Pulse Duration, Repetition Rate, and Spot Size.

You can set the parameters individually by the operator or they can be selected from a list of Candela Preset Treatment Parameters under the Applications Menu Bar. The Laser Start-up and Calibration Procedures in **"Performing a Laser Treatment" on page 3-2** and **"Calibration Procedure" on page 4-22** have step-by-step instructions for setting up the operating parameters.

To change a parameter, press the appropriate button or menu bar to make the selection and use the arrows to adjust the value to the desired setting.

Fluence Controls and Indicators

The Fluence parameter specifies the amount of energy density (in Joules/cm^2) delivered to the treatment spot size (in cm). See **Figure 2-26**.

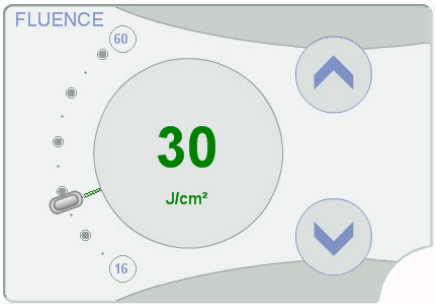


Figure 2-26: Fluence Control

The Fluence setting is adjustable in increments of 1, 2, 5, 10, and 20 J/cm^2 between the lower and upper Fluence values depending on the settings for spot size and pulse duration.

Table 2-4 shows the Alexandrite Fluence table which shows the ranges for the available fluence settings for 6, 8, 10, 12, 15, and 18 mm spot sizes. **Table 2-5** shows the YAG Fluence table which shows the ranges for the available fluence settings for 1.5, 3, 6, 8, 10, 12, 15, and 18 mm spot sizes. The settings vary depending on the spot size and pulse duration.

Warning: There are no currently approved indications for the 1.5 mm and 3 mm spot sizes at 755 nm. Use caution when treating the 1.5 mm and 3.0 mm spots at 755 nm.

Table 2-4: Alexandrite Fluence Table

Spot Diameter (mm)	Pulse Durations		
	0.25 - 0.50 ms	3 - 300 ms	10 - 300 ms
6 mm	6 - 30 J/cm^2	35 - 150 J/cm^2	
8 mm	6 - 20 J/cm^2	20 - 100 J/cm^2	
10 mm	6 - 12 J/cm^2	20 - 60 J/cm^2	
12 mm		10 - 40 J/cm^2	
15 mm		6 - 30 J/cm^2	
18 mm		6 - 20 J/cm^2	

Table 2-5: ND:YAG Fluence Table

Spot Diameter (mm)	Pulse Durations		
	0.25 - 0.50 ms	3 - 300 ms	10 - 300 ms
1.5 mm			200 - 600 J/cm^2
3 mm			50 - 460 J/cm^2
6 mm	6 - 30 J/cm^2	35 - 200 J/cm^2	
8 mm	6 - 20 J/cm^2	20 - 150 J/cm^2	
10 mm	6 - 12 J/cm^2	20 - 100 J/cm^2	
12 mm		10 - 70 J/cm^2	
15 mm		6 - 44 J/cm^2	
18 mm		6 - 30 J/cm^2	

To change the Fluence setting, select the up and down arrows (see **Figure 2-26**).

If the spot size is changed, the laser will automatically select the lowest possible fluence for the new spot size and a calibration will be automatically required.

Cooling

The Cooling menu allows for adjustments to the DCD Cooling system (see **Figure 2-19**). When you make a selection anywhere in the Cooling menu, left and right arrows appear to allow you to manually adjust the settings (see **Figure 2-27**).

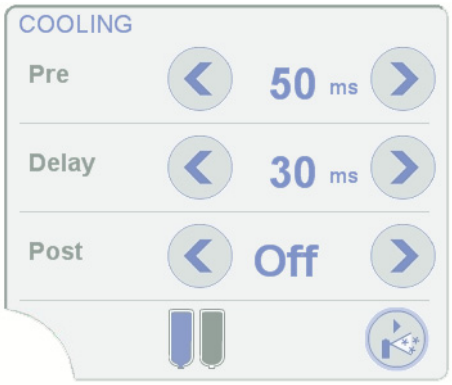


Figure 2-27: Cooling Menu

The DCD Pre-Spray and Post-Spray Duration parameters and the DCD Delay Duration parameter can be set to preprogrammed settings by the laser or can be adjusted manually. When a treatment application is selected in the Applications Menu, the computer will set the laser system to the preprogrammed DCD Spray and Delay duration settings. The DCD Spray and Delay parameter can be adjusted manually to non-standard settings from the Cooling Menu.

The menu offers the option to manually adjust the DCD Pre-Spray Duration, DCD Post-Spray Duration, DCD Delay Duration parameters. It also allows you to purge the system to remove cryogen air bubbles and shows the level of the cryogen canisters.

The following section describe the selections on the Cooling menu.

DCD Pre-Spray Duration

This parameter controls the duration of the cryogen spray that is applied before the laser pulse. The DCD spray can be turned off (set to 0 ms), or the duration can be in the range of 10 to 100 ms. This parameter is used in conjunction with DCD Delay Duration.

Change the DCD Pre-Spray using the right and left arrow buttons.

DCD Delay Duration

The DCD Delay parameter adjusts the duration of the time between the DCD cryogen spray and the laser pulse. The delay can be set in the range of 3 to 150 ms. The delay duration works with the Pre-Spray Duration to delay the last 5 ms of the Pre-Spray set duration, for the amount of time that is set for this Delay parameter.

For example, if Pre-Spray Duration is set to 40 ms and Delay Duration is set to 20 ms, when the Finger Switch or Foot Switch is depressed, the laser will spray 35 ms of cryogen, pause (or delay) for 20 ms, then spray 5 ms of cryogen. Then the laser will pulse.

Change the DCD Delay Duration using the right and left arrow buttons.

DCD Post-Spray Duration

This parameter controls the duration of the cryogen spray that is applied after the laser pulses. The DCD spray can be turned off (set to 0 ms), or the duration can be in the range of 10 to 50 ms.

Change the DCD Post-Spray Duration using the right and left arrow buttons for each parameter.

Purge Button

The Purge Button (see **Figure 2-28**) is used to remove air bubbles from the DCD cryogen line when a new canister is placed in the system or a Handpiece is installed.

Figure 2-28: Purge Button

The Handpiece must be removed from the Calibration Port and pointed in a safe direction when you press the Purge button.

When the button is pressed, the Handpiece disperses cryogen spray for the selected Pre-Spray duration. If the button is held for longer than one second, a short spray and then a longer spray of cryogen (up to three seconds) will be dispersed.

Note: The GentleMAX laser system has been configured for the following GentleCool™ canister. Do not install any other type of canister in the system.

GentleMAX Laser System Cryogen Canister
Candela Part Number: 1600-00-021-
Laser Type: GentleMAX Laser System
Canister Size: GentleCool™ 1000 grams

Warning: Failure to install the appropriate sized canister 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".

Status of Cryogen Canisters

Figure 2-29 shows an example of the cryogen canisters status displayed on the Main Screen.

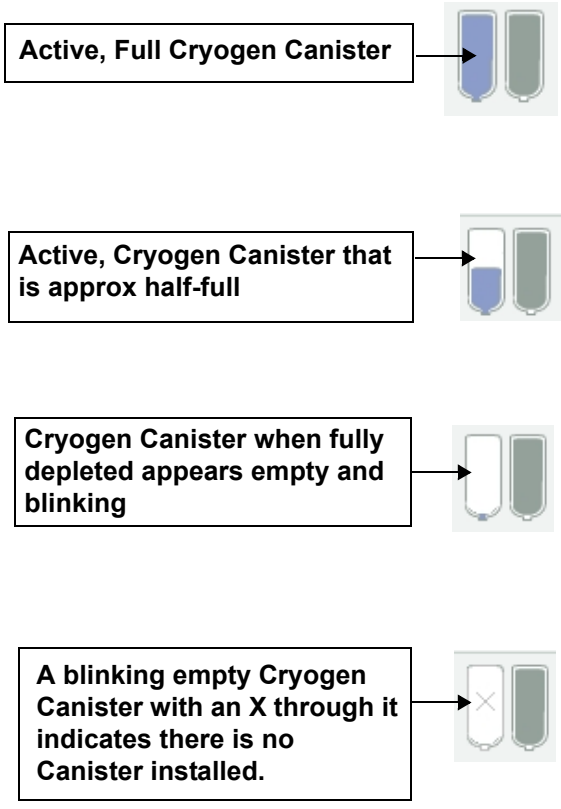


Figure 2-29: Status of Cryogen Canisters

A canister filled with blue indicates the canister is active and full. Partially filled canisters have blue on the bottom and white on the top. The percentage of the canister filled with blue indicates the percentage of cryogen remaining in the canister. When a canister is fully depleted, it appears empty and blinking. If one of the canisters is not installed, the canister appears empty, is blinking, and there is an X over the canister icon.

Note: The DCD level is ONLY an estimate of the amount of cryogen in the canister. If the system prompts you to “Replace Canister”, then the canister must be replaced regardless of the DCD count.

- For detailed information on replacing the cryogen canister, see **“Replacing the Cryogen Canister” on page 4-19**.

Pulse Duration Control

The Pulse Duration parameter is the duration of the pulse delivered to the patient. It can be set to between 0.25 and 300 milliseconds (see **Figure 2-30**) depending on the spot size.

To change the Pulse Duration setting, select the left and right arrows.

Figure 2-30: Pulse Duration Control

Repetition Rate Select

The Repetition Rate (or Pulse Rate) selection controls the number of times the laser will be pulsed each time the Trigger Switch is pressed.

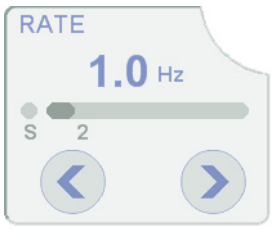


Figure 2-31: Pulse Rate Control

In Single Pulse Mode, the laser pulses once for each depression of the Trigger Switch (Fingerswitch or Footswitch). In Multi-Pulse Mode, the laser will pulse at a steady rate as long as the Trigger Switch is depressed.

Set the Repetition Rate to different repetition rates from single, 0.5 to 10 Hz (depending on the selected spot size and Pulse Duration) using the left and right arrows.

Spot Size Identifier Bar

A bar on the bottom left side of the main screen displays the spot sizes available (sizes are in mm) for your laser configuration or the treatment application selected in the Application submenu (see **Figure 2-32**).

Figure 2-32: Spot Size Identifier Bar

When a Lens Cartridge/Distance Gauge spot size is selected and installed in the Handpiece, the spot size selection is highlighted in blue on the Spot Size identification Bar. The submenus for all Treatment Applications also display the selection in blue to show the available treatment application option for the spot size selected.

Other Controls

The following sections describe additional controls provided on the GentleMAX laser system Main screen.

Calibration Button

The Calibration button is used to begin the calibration process (see **Figure 2-33**).

Figure 2-33: Calibration Button

The laser calibration procedure is initiated by pressing the Calibrate Button (inverted triangle). To calibrate, insert the Delivery System Handpiece into the Calibration Port and calibrate the laser per the instructions provided in **"Calibration Procedure" on page 4-22**. Pop-up windows appear on the screen providing instructions and information about the system.

Note: The system automatically initiates the calibration procedure if the system enters the READY state and a calibration is required. The laser calibration can be cancelled at anytime by pressing the Cancel Button (X) on the screen.

After calibration, the system returns to Standby.

Caution: Do not enter the Ready state without a fiber installed and without having the proper protective eyewear on.

You must perform a calibration when you start the system and anytime you change the Handpiece and/or Lens Cartridge spot size. If you select the Calibration button, and the system was already calibrated, the system stays in the Standby state, rather than entering the Ready state. If you select the Calibration button and the system has not been calibrated, you are prompted to start the calibration. You are also prompted to calibrate the system if you change the Handpiece and/or Lens Cartridge spot size.

Pulse Count and Pulse Count Reset Button

The Treatment Pulse Counter parameter indicates the number of times the laser has been pulsed during a treatment session. The number of pules delivered displays beside the Pulse Count Reset button (see **Figure 2-34**). In this example, no pulses have been delivered.

Figure 2-34: Pulse Count and Reset Button

The Pulse Count is automatically reset to zero at system startup (when the Keylock Switch is turned on). The Pulse Count can also be reset to zero by pressing and holding the Reset button beside the counter for at least two seconds. The system responds by setting the Pulse Count value displayed back to zero.

Reports Page Button

The Reports Page button provides access to the Reports screen. From this screen, you can select any of he following tabs:

- Treatment Tab
- Last Faults Tab
- Operating Tab
- Software Tab

To display the Reports page, select the Reports Page button (see **Figure 2-35**).

Figure 2-35: Reports Page Button

When you select this button, the Reports Page screen displays. The following sections describe each of the tabs available from the Reports Page Screen.

Treatments Tab

The Treatments Tab records the number of laser pulses and the operating parameters (Fluence, pulse duration, spot size, repetition rate and DCD settings) used for the last eight parameter changes (see **Figure 2-36**).

Figure 2-36: Reports Page - Treatment Tab Screen

Press the Reset button (see the button with the circular arrow) from the Treatments screen for approximately two seconds or longer to clear all of the treatment data from the table memory.

Last Faults Tab

The Last Faults Tab shows the fault data for any faults that might occur during usage. It records the Time, Pulse Number, Fault Number and additional data (see **Figure 2-37**).

Figure 2-37: Reports Page - Faults Tab Screen

Press the Reset button (see the button with the circular arrow) from the Last Faults screen for approximately two seconds or longer to clear all of the data from the table memory.

Operating Tab

The Operating Tab shows the laser systems status such as DI water level and temperature; DCD A and B levels, temperature and pressure; Power (voltage); and Delivery System Handpiece that is installed (see **Figure 2-38**).

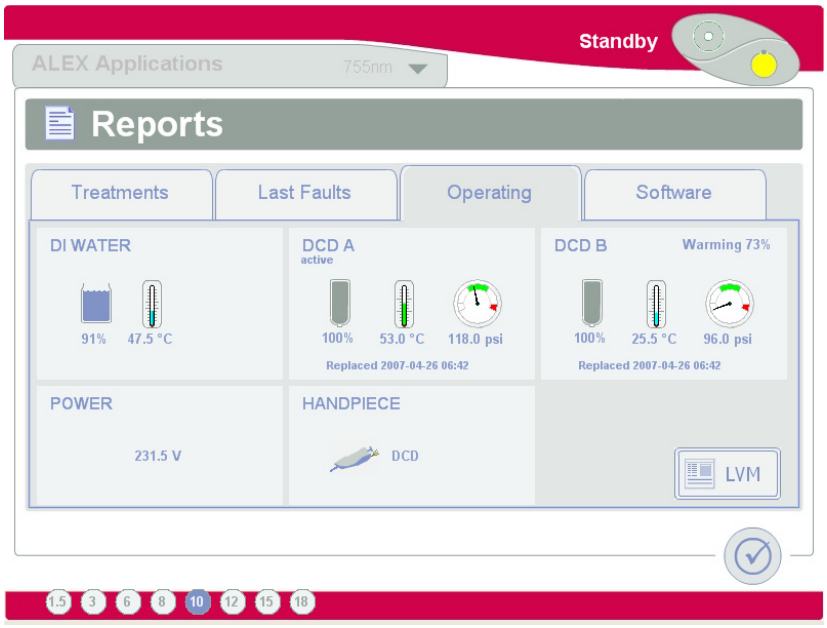


Figure 2-38: Reports Page - Operating Tab Screen

There is a Laser Variable Mode (LVM) Screen Button on the lower right side of this tab (see **Figure 2-38**). Pressing this button displays the Laser Variable Mode screen, which contains information about the laser including the number of pulses and energy calculations (see **Figure 2-39**).

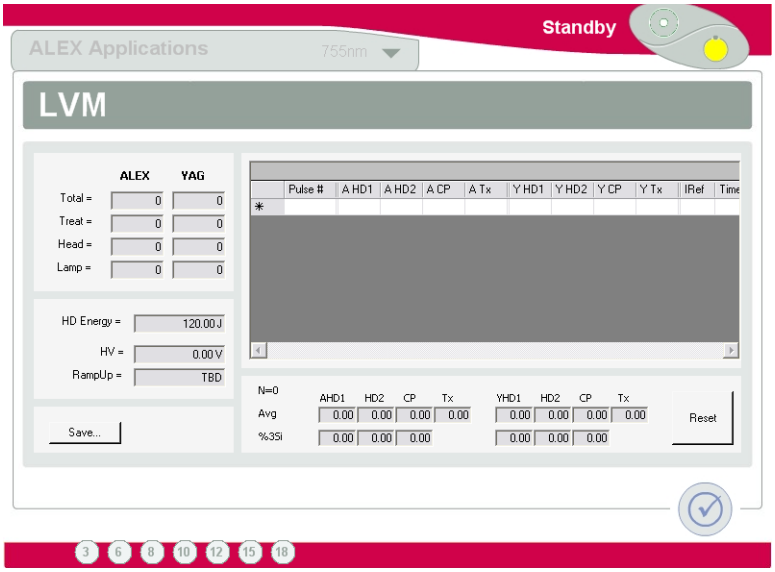


Figure 2-39: Reports Page - Operating Tab (LVM Page)

The Laser Variable Mode is used by Candela Field Service to diagnose problems or obtain laser operating information.

Note: The GentleMAX Laser cannot be used for patient treatments while the Laser Variable Mode page is displayed.

Software Tab

The Software Tab shows the current revisions of all software installed on the laser system (see **Figure 2-40**).

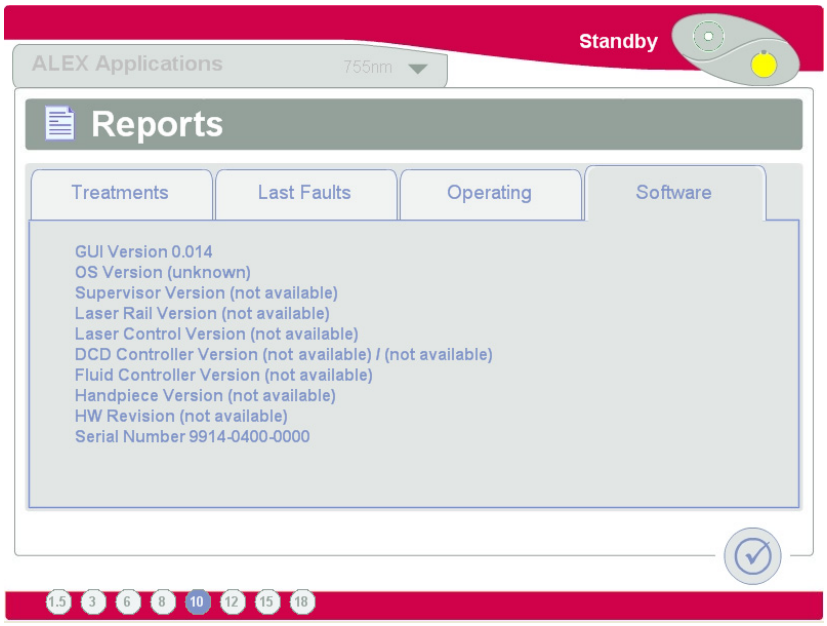


Figure 2-40: Reports Page - Software Tab Screen

System Setting Menu Button

The System Menu button is represented by a wrench (see **Figure 2-41**).

Figure 2-41: System Settings Menu Button

Selecting this button displays the Settings screen (see **Figure 2-42**).

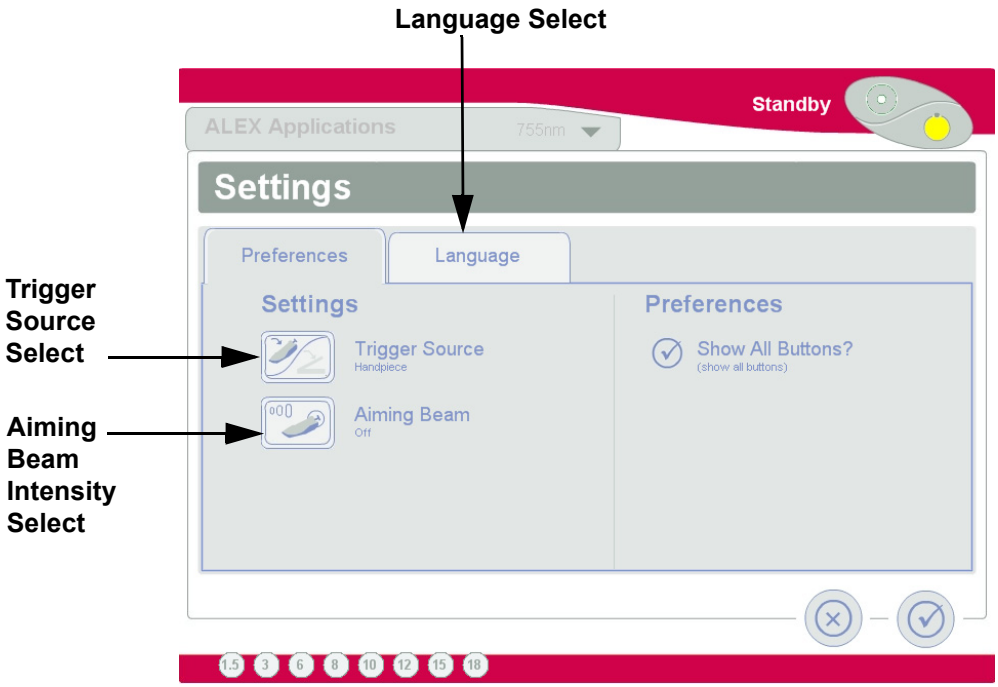


Figure 2-42: System Settings Screen

These settings are described in **Table 2-6**.

Table 2-6: System Configuration Parameters

Configuration Parameter	Description
Language Select 	Use the Language Select button to select the language shown on the display. When you select the button, the available languages display. The choices are: English, German, Spanish and French as shown in this table. The selected language is highlighted with a white check mark in a blue circle next to it
Trigger Source Select 	Laser emission is generated by either the Fingerswitch (located on the Handpiece) or the Footswitch (attached to the rear panel of the laser system). Use this button to choose the switch you will use. Selecting this button toggles between the two choices. The Trigger Source button shown in this table indicates that the Fingerswitch option has been selected.
Aiming Beam Intensity Select 	Use this button to select from three green aiming beam intensity levels and off. The button toggles through the different levels available.

Chapter 3: Using the Laser

Topics described in this chapter include:

Introduction

This chapter describes how to use the GentleMAX Laser system to treat patients.

Caution: Before starting up the laser system for any reason, you must ensure that all personnel in the area are familiar with the safety concerns outlined in **"Warnings, Cautions, and Precautions" on page 1-6**, and that they are equipped with the correct safety eyewear.

Caution: Before the laser system is turned on, a Lens Cartridge must be installed in the Handpiece.

Performing a Laser Treatment

Before You Begin

Perform the following tasks before you begin your laser treatment:

- Cover the treatment room windows with an opaque material to prevent unintended viewing.
- Post a laser warning sign at each entrance to the laser treatment room.
- Ensure that protective eyewear is available for everyone in the treatment room.
  - For 755 nm, proper eyewear must filter light at a wavelength of more than 755 nm with an O.D. of 5.8 or greater.
  - For 1064 nm, proper eyewear must filter light at a wavelength of more than 1064 nm with an O.D. of 6.3 or greater.
- Plug the laser into the correct electrical outlet. Ensure that the power switch on the rear panel is in the ON position.
- To prevent the laser system from moving inadvertently, lock each front wheel.
- Verify that the Handpiece, Distance Gauges and the Windows (Internal Handpiece Window and Input and Output Lens Cartridge windows) which will be used during this procedure, are clean.
- Consult the Candela Treatment Guidelines for information on selecting the spot size and operating parameters.

Warning: Always put the laser system into Standby or turn it off and remove the Lens Cartridge from the Handpiece before attempting to check, clean, and/or replace the Delivery System, Lens Cartridge, Distance Gauge, and/or Window(s).

Warning: Always recalibrate the laser after fixing, cleaning, or replacing the Delivery System, Lens Cartridge, and/or Window(s). Failure to initiate a calibration after cleaning/replacing the Window(s) or Delivery System may result in the delivery of excessive laser energy.

User Verification Test

Perform this test at any time.

Warning: Always perform User Verification tests as outlined in this section at the start of each treatment day and when the Handpiece is changed. Check the Delivery System(s) and Lens Cartridges for any damage (for example, was it dropped). Discontinue use of your laser delivery system(s) and/or Lens Cartridges if you suspect a problem.

Warning: The fact that your laser Delivery System passes the applicable User Verification Tests does not guarantee that your laser Delivery System is problem-free. Discontinue use of your laser Delivery System if you suspect a problem with it. See "Delivery System Warnings" on page 1-14.

Overview of Tests

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

You will need the following supplies to perform these tests:

- Laser Safety Glasses.
- Cryogen Coverage Template, Candela P/N 1301-00-8291 (included in the accessory kit supplied with the laser).
- GentleMAX Laser Delivery System Handpiece that needs to be tested.
- GentleMAX Laser (3 mm and 12 mm) Lens Cartridge and Distance Gauge.
- White paper.

The following tests are described in this section:

- Cryogen Alignment: Verifies the cryogen spray nozzle is properly aligned with the Distance Gauge ring.
- Cryogen Coverage: Verifies the spray duration required to fill the Distance Gauge ring.
- Cryogen Bubble Detection: Verifies that bubbles in the cryogen line are detected.
- Beam Alignment: Verifies that the laser and aiming beam are in alignment with the Distance Gauge.

Test 1: Cryogen Alignment

To verify the cryogen spray nozzle is properly aligned with the Distance Gauge ring:

1. Put the laser with the Delivery System installed into the Standby state.

Caution: The laser should remain in the Standby mode for the duration of the test.

2. Using the Cooling Selection buttons, set the Pre-Spray to 30 ms, the Delay to 10 ms, and the Post-Spray to 0 ms.

   Install the GentleMAX Laser (3 mm or 12 mm depending on the Delivery System selected to be tested) Lens Cartridge.

3. Install the GentleMAX 12 mm Distance Gauge (this Distance Gauge spot size will be used to check the cryogen alignment on both 1.5/3 mm and 6-18 mm Delivery Systems).

4. Point the Handpiece away from objects and personnel (toward the floor). View the contact ring of the Distance Gauge, looking from the Handpiece.

5. Press and release the Purge button.
   DCD spray should flow completely through the contact ring. There may be a minimal spray mist seen hitting the contact ring. No spray should be spraying beyond outside of the contact ring. Incorrect alignment will be shown as a white build-up of cryogen on the distance gauge ring.

Results

- Acceptable alignment – No further action needed.
- Unacceptable alignment – Repeat the test with a different 10 mm distance gauge.

Repeat Test Results

- If the tests show acceptable alignment with the new Distance Gauge, contact Candela Technical Support to review results. See **Figure 3-1**.
- If the result is still “unacceptable”, try a different Handpiece (if available) or contact Candela Technical Support.

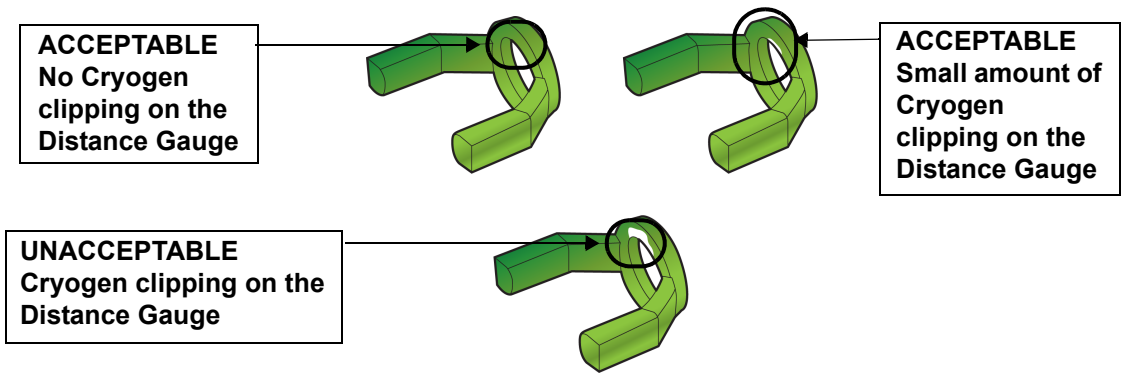


Figure 3-1: Cryogen Results: Acceptable and Unacceptable

Test 2: Cryogen Coverage

Note: Distance gauge ring is larger than the spot size marking.

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

To verify the proper spray duration required to fill the Distance Gauge ring:

1. Put on appropriate laser safety glasses.
2. Put the laser in Standby.

Caution: The laser should remain in the Standby mode for the duration of the test.

3. Install appropriate distance gauge from **Table 3-1 on page 3-6**.
4. Select Pre-Spray Duration shown in **Table 3-1 on page 3-6**, Delay at 10 ms and Post-Spray at 0ms. Place Handpiece Distance Gauge over desired distance gauge spots on the template (1301-00-8291). For 6 mm to 18 mm spot sizes, use the 8 mm to 18 mm spots on the template in the area listed for GL/GYAG Family Spot Sizes. For the 1.5 mm and 3mm spot sizes, use the distance gauges with the small treatment ring. Place the distance gauge over the 5 mm spot on the template in the area listed as Vbeam Spot Sizes.
5. Press and release the Purge button
6. Remove the Handpiece QUICKLY from template.
7. THE DCD Spray should completely fill the inner spot.

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

Table 3-1: Spray Settings for Fill Test

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

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

Test 3: Cryogen Bubble Detection

To ensure that bubbles in the cryogen line are detected.

1. Ensure that at least one installed DCD canister is partially full and the laser "WARM UP" is completed.
2. Put on appropriate laser safety glasses.
3. Ensure that the delivery system to be used is installed.
4. Using the Cooling Selection buttons, set the Pre-Spray to 100 ms, the Delay to 10 ms, and the Post-Spray to 50 ms.
5. Remove the Handpiece from the Calport and aim it at the floor away from objects or personnel (toward the floor).
6. Press the purge button 10 times to ensure that cryogen line is filled.
7. Remove all of the cryogen canisters from the system.
8. Press and hold the Cryogen Purge button. The cryogen will spray (100ms) once then will spray again for 2 seconds. Once this happens; lift finger and then press and hold the button again to repeat the purge sequence. Continue repeating this sequence until the bubble indicator appears on the main screen, in the DCD section.
9. If after pressing the button the cryogen purging out of the delivery system is gone but the screen does not indicate a bubble; install a different delivery system and repeat steps 6-8.

Table 3-2: Diagnostics

Results	Comments	Action
If a bubble is indicated on the main screen	This particular Delivery System passed the test	You may continue use of this Delivery System.
If a bubble was not indicated on the main screen	This particular Delivery System failed the test	**Discontinue use of this Delivery System and contact Candela Technical Support.**
If the screen constantly indicates a bubble is present	The cryogen canisters may be empty; there are air bubbles in the canisters or they have defected valve(s). The cryogen line may be blocked or the Delivery System may need to be replaced.	Try reinstalling the canisters and pressing the Purge Button several times. If this does not work, try replacing the canisters. If the problem persists, try a new Delivery system. If you continue to see the problem, contact Candela Technical Support.

10. If there are no problems with the Delivery System, reinstall the cryogen canister(s) back into compartments Canister A and/or B.
11. Press the Purge Button until the cryogen line is refilled and there are no fault messages appearing on the screen.

Test 4: Beam Alignment

This procedure is designed to help identify a misalignment on your Delivery System.This test also verifies that the aiming laser beam is working properly.

To verify beam alignment:

1. Put on appropriate laser safety glasses.

Warning: The laser will enter Ready mode for the duration of the test.

2. Install the desired Lens Cartridge and Distance Gauge spot size for your laser treatment.

3. Enter READY. A calibration may be required.

4. Set the Aiming Beam at the lowest setting.

5. Do NOT press the Fingerswitch or the Footswitch to pulse the laser. Aim the Handpiece at a white piece of paper and inspect the aiming laser beam for circular uniformity and clarity. If the aiming beam spot is not uniform, press the Standby Button to put the laser in Standby mode. Check for Distance Gauge interference or dirty window(s). Replace the Distance Gauge or clean/replace the window(s) as described in **"Cleaning the Lens Cartridge and Distance Gauge" on page 4-12** if correct results cannot be achieved. If the problem persists, try a different size Lens Cartridge and Distance Gauge. Repeat this Beam Alignment test until satisfactory results are achieved. If you continue to see problems, Contact Candela Technical Support.

Note: Always repeat this procedure for each Lens Cartridge/Distance Gauge prior to use.

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

Treatment Procedure

1. Locate the Delivery System, the Lens Cartridge, and Distance Gauge to be used for the treatment and install as follows:
2. Align the flat on the Lens Cartridge with the flat protrusion on the Handpiece Assembly (see **Figure 3-2**) and then gently push the Lens Cartridge into place.

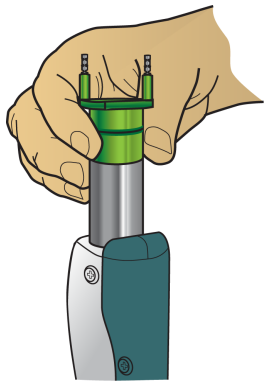


Figure 3-2: Insert Lens Cartridge into Handpiece Assembly

3. Install the Distance Gauge on the top of the Lens Cartridge (see **Figure 3-3**).

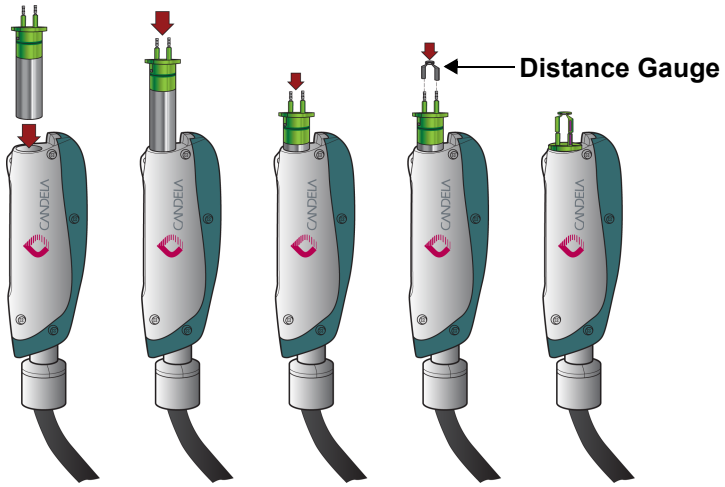


Figure 3-3: Install Lens Cartridge into Handpiece Assembly and Install Distance Gauge

4. Insert the proximal end of the Delivery System cable into the Delivery System Receptacle. Verify that the cluster connector is tight and secure. Insert the distal end of the Delivery System cable (the Handpiece Assembly with the Lens Cartridge and Distance Gauge installed) into the Calibration Port (see **Figure 3-4**).

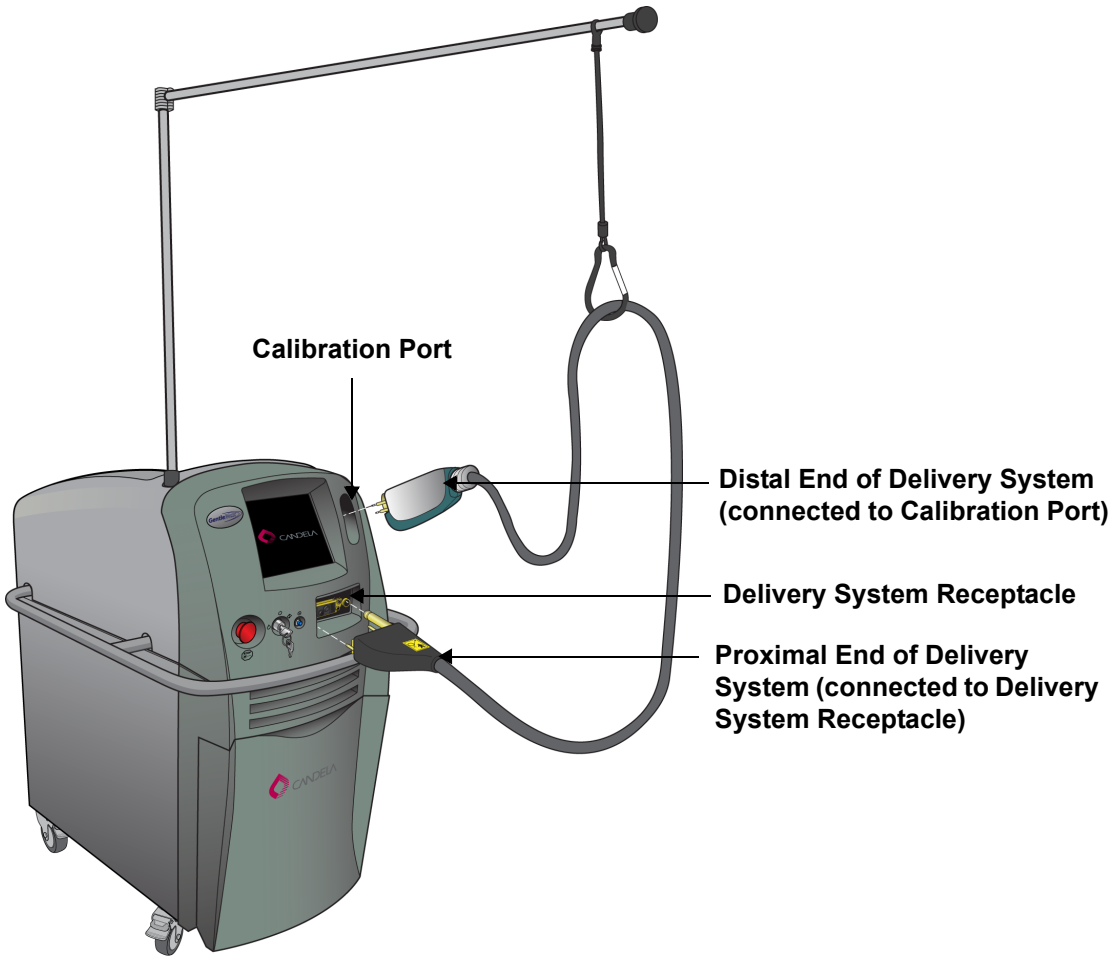


Figure 3-4: Install Delivery System Cable into the Laser System

When the system is turned on, the range for the Fluence parameter will be set up automatically based on the Lens Cartridge that is installed. The setting defaults to the lowest fluence setting.

5. Set up the Delivery System on the Fiber Pole. There are two configurations, one for locking the delivery system cable in the ring and one for it to slide freely through the ring (**see "Fiber Pole" on page 2-19.**)
6. Turn the Keylock Switch from Off to the Start position. The key will automatically spring back to the On position.

   There may be a delay of several seconds before the system initializes. This is normal. The system will enter a brief warm up state (approximately 20 minutes) during which the water begins circulating and warms up.

Note: Be sure to check the water level as needed. For more information, see **"Maintaining the Water Cooling System" on page 4-5**.

During warm up, the Standby/Ready button displays the Warm Up icon and a Warming Up counter displays percentage complete (see **Figure 3-5**).

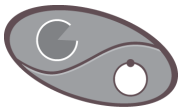


Figure 3-5: System is Warming Up

After warm-up is complete, the system enters Standby state and a message displays reminding you to perform user checks before using the laser (**see Chapter 4**). The Standby/Ready button is yellow, indicating the system is in Standby (see **Figure 3-6**).

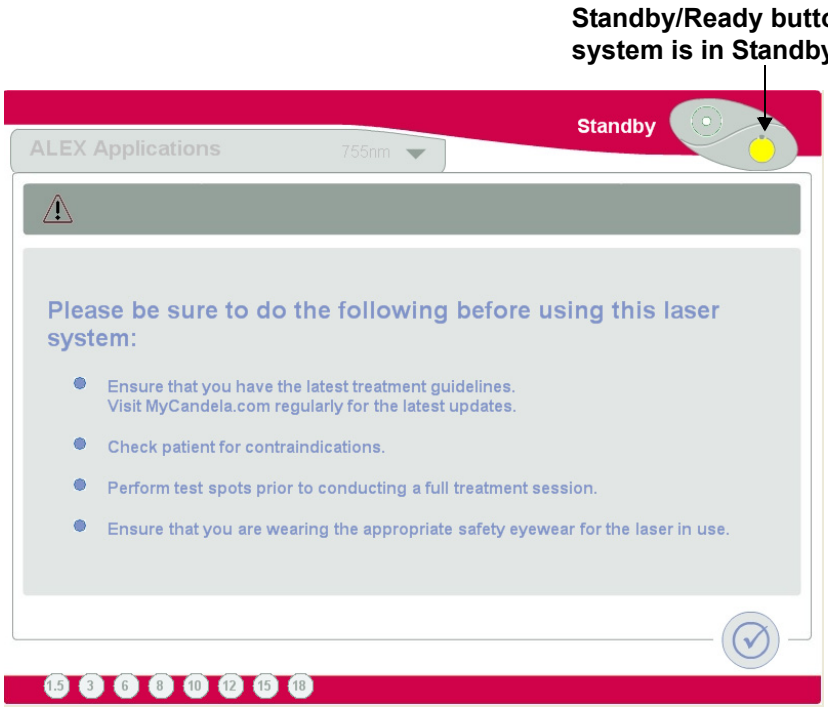


Figure 3-6: System is in Standby After Warm Up is Complete

When all checks have been complete, press the checkmark  to continue. The Main Screen displays (see **Figure 3-7**).

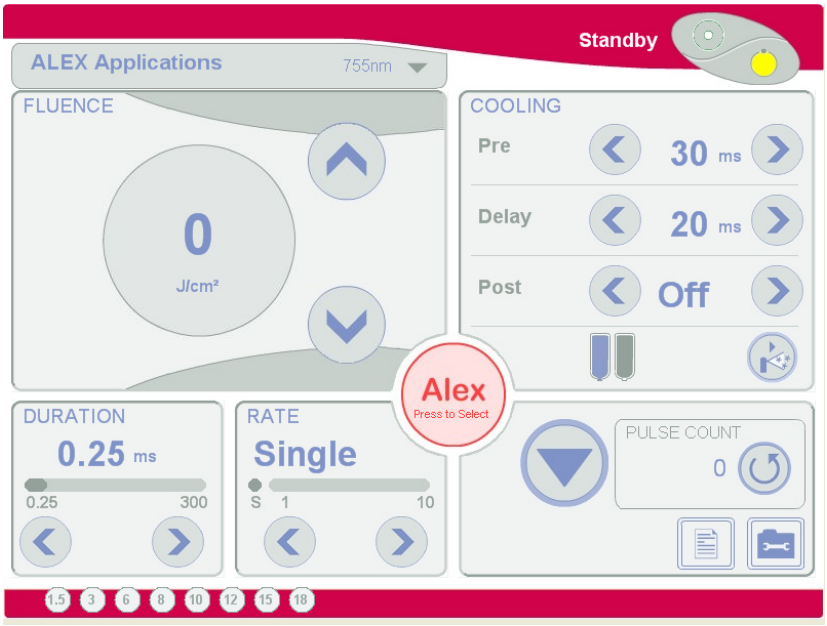


Figure 3-7: Main Screen

7. Put on protective eyewear.

8. From the Main Screen (see **Figure 3-7**), select the System Settings Menu button (see **Figure 3-8**).

Figure 3-8: System Settings Menu Button

9. Choose the preferred settings for the following parameters on the System Settings screen (see **Figure 3-9**):

- Preferred Language
- Trigger Source
- Aiming Beam Intensity Level

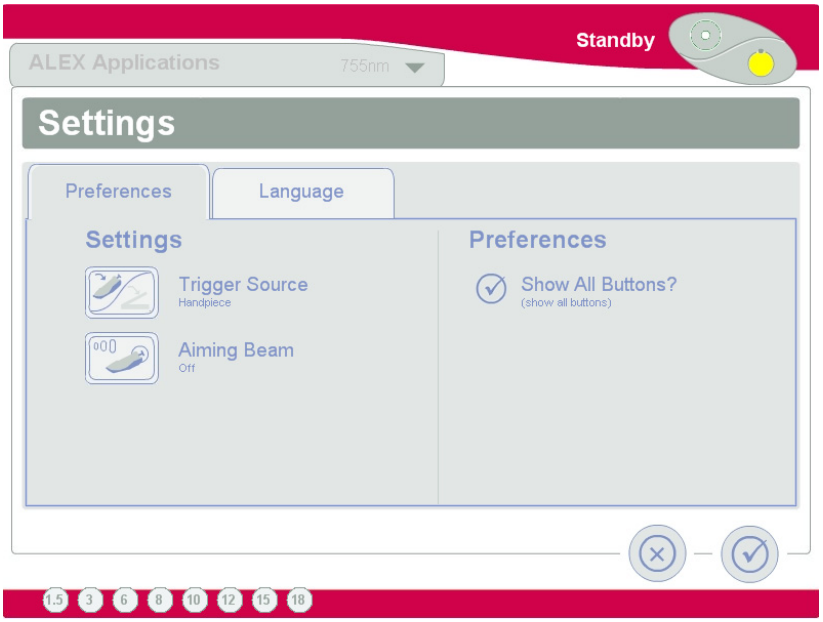


Figure 3-9: System Settings Screen

These settings are described in **Table 3-3**.

Table 3-3: System Configuration Parameters

Configuration Parameter	Description
Language Select 	Use the Language Select button to select the language shown on the display. When you select the button, the available languages display. The choices are: English, German, Spanish and French as shown in this table. The selected language is highlighted with a white check mark in a blue circle next to it
Trigger Source Select 	Laser emission is generated by either the Fingerswitch (located on the Handpiece) or the Footswitch (attached to the rear panel of the laser system). Use this button to choose the switch you will use. Selecting this button toggles between the two choices. The Trigger Source button shown in this table indicates that the Fingerswitch option has been selected.
Aiming Beam Intensity Select 	Use this button to select from three green aiming beam intensity levels and Off. The button toggles through the different levels available. The green aiming beam, which is visible only in the Ready state, serves as a treatment area target.

10. Close the System Settings screen by selecting the checkmark  to save the current settings.

11. Perform the User Verification Tests.

Warning: Always perform the User Verification Tests to check the Delivery System and Lens Cartridge for proper operation at the beginning of each treatment day or each time it is replaced on the laser system. In addition, use the User Verification Tests to check the Delivery System and/or Lens Cartridge if there is an unexplained treatment response noted or the Delivery System and/or Lens Cartridge have been dropped. Discontinue use of your laser Delivery System or Lens Cartridge if you suspect a problem.

12. Install the appropriate Lens Cartridge and Distance Gauge for the selected spot size onto the Handpiece.
   ▸ ▸ For information in installing the Lens Cartridge and the Distance Gauge, see Step 1.

13. Verify that the desired Lens Cartridge and Distance Gauges spot size is available on the Spot Size Identification Bar on the Main Screen (see **Figure 3-7**). The installed cartridge is highlighted in blue on the Main Screen.

14. Select the desired laser operating parameters as described in the following steps. (Alternately, you can manually select the operating parameters as described in Step 17.)

15. Select the available treatment application that supports the Lens Cartridge and Distance Gauge spot size installed in Step 11 from the Applications Menu Bar (see **Figure 3-7**).
Table 3-4 lists the available applications.

Table 3-4: Select Application

Setting	Description
Alex Applications	Select the Alex application from the Alex drop down menu. The choices are: ● Hair Removal ● Vascular ● Photorejuvenation
YAG Applications	Select the YAG application fro the YAG drop down menu. The choices are: ● Hair Removal ● Vascular ● Photorejuvenation

When you select the application, the Select Parameters screen displays for the selected application.

16. Select the parameters from the Select Parameters screen. When you are done, select the right arrow button to continue. **Figure 3-10** shows an example of the Select Parameters screen. **Table 3-5** lists the parameters to be configured for each application.

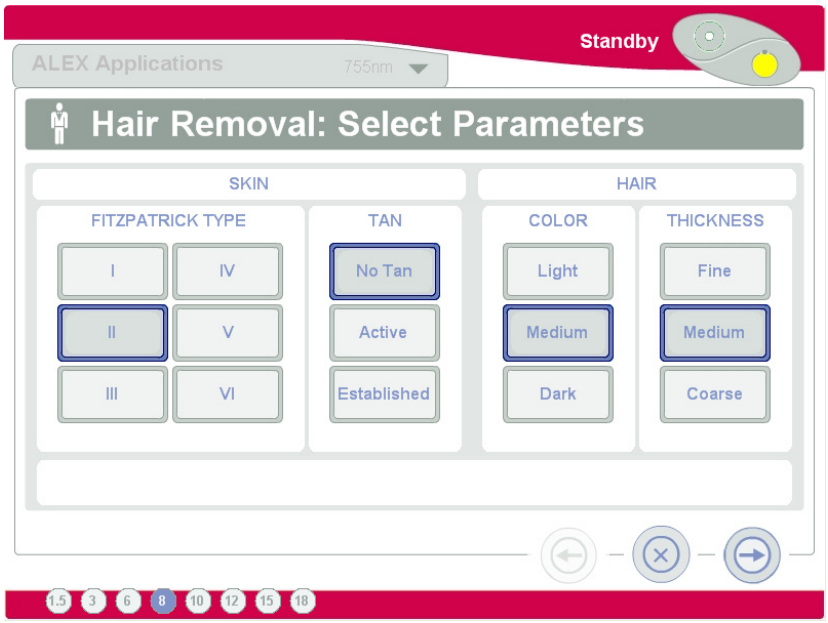


Figure 3-10: Example of Select Parameters Screen for Hair Removal

Table 3-5: Parameters for the Selected Application

Application	Parameters for the Selected Application
Alex Applications	
• Hair Removal	Skin (Fitzpatrick Type, Tan) Hair (Color, Thickness)
• Vascular	Skin (Fitzpatrick Type) Vessel (Type, Size)
• Photorejuventation	Skin (Fitzpatrick Type) Treatment (Type)
YAG Applications	
• Hair Removal	Skin (Fitzpatrick Type, Tan) Hair (Color, Thickness)
• Vascular	Skin (Fitzpatrick Type) Vessel (Type, Size)
• Photorejuvenation	Skin (Fitzpatrick Type) Treatment (Location)

When you select the right arrow button, the Common Parameters screen displays for the selected parameters (see **Figure 3-11**).

Figure 3-11: Example of the Common Setting for Hair Removal

17. Confirm the suggested parameters on the Common Parameters screen. When you are done, select the checkmark button.

The Main Screen displays the common operating parameters (see **Figure 3-12**). The selected application and the parameters for the patient appear in the Application Menu bar for reference.

Figure 3-12: Example of Auto-Set Parameters to the Suggested Parameters

18. If needed, adjust the operating parameters by pressing the arrows (up and down or left and right) to change the settings (see **Table 3-6**). Always consult the Candela Treatment Guidelines when adjusting operating parameters.

Table 3-6: Operating Settings

Setting	Description
Fluence	Select the amount of energy delivered based on the spot size. The range of setting available is determined by the spot size selected. The default is set to the lowest value in the range based on the treatment guidelines that are stored in the system. Increase or decrease the fluence as needed within the specified range by selecting the up and down arrows.
Pulse Duration	Pulse Duration .25 - 300 milliseconds
Repetition Rate	Select the frequency (n Hz) of the pulses delivered with each depression of the Trigger Switch. The choices are: ● Single - one pulse delivered every time you depress the Trigger Switch. ● 0.5 - 10 Hz (depending on selected spot size and Pulse Duration).
DCD Pre-Spray and Post Spray Duration	Select the duration of the cryogen spray applied before and after the laser pulse. The choices are: ● 0 ms ● Pre-Spray: 0 ms, 10-100 ms ● Post-Spray: 0 ms, 10-50 ms
DCD Delay Duration	Select the duration of the delay between the cryogen spray and the laser pulse. ● 3-150 ms

Note: If you are experiencing difficulty setting the operating parameters, check the ensure the settings are allowed for the selected Lens Cartridge and Distance Gauge spot size.

19. If you performed Steps 13-16, skip this step. This step provides a method to manually set the operating parameters without selecting an application. Always consult the Candela Treatment Guidelines when setting the parameters.

Refer to **Table 3-6** to manually set the following operating parameters:

- Fluence
- Pulse Duration
- Repetition Rate
- Pre-Spray and Post-Spray Delay Duration
- DCD Delay Duration

Note: If you are experiencing difficulty setting the operating parameters, check the ensure the settings are allowed for the selected Lens Cartridge and Distance Gauge spot size.

Figure 3-13: Calibration Button (Calibration Required)

20. Insert the Handpiece into the Calibration Port (see **Figure 3-4**).

Note: Do not install the Distance Gauge at this point.

21. Select the Calibration button on the Main Screen (see **Figure 3-13**).

The Calibrating screen displays (see **Figure 3-14**).

Figure 3-14: Confirm Calibration Parameters

This screen asks you to confirm the Calibration parameters and provides information about the calibration process. Select the checkmark button to confirm that calibration parameters and the system enters READY. If the settings are not correct, select the X to cancel.

22. Follow the instructions on the screen. You are first instructed to place the Handpiece into the Calibration Port (see **Figure 3-4**). Perform this step if the Handpiece is not already in the Calibration Port. Note that if the Fingerswitch is set, the screen will prompt you to press a button that will be displayed to begin calibration. If Footswitch is selected, the screen will prompt you to “Depress Footswtich.” Press and hold the Footswitch.

A message displays indicating the system is calibrating. When the calibration is complete, a Calibration Complete message displays (see **Figure 3-15**).

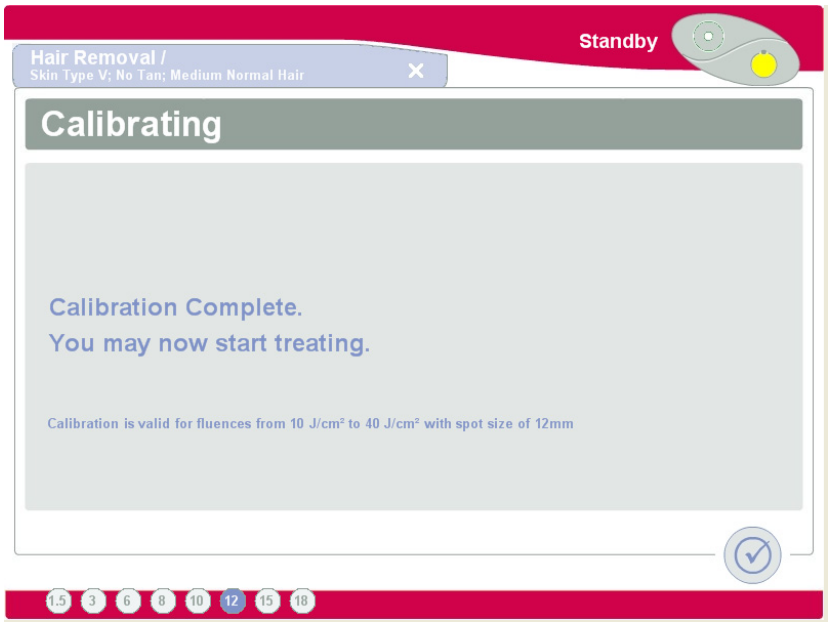


Figure 3-15: Calibration Complete Screen

23. When the Calibration is complete, remove the Handpiece from the Calibration Port.

Note: When the calibration is complete, the laser goes to STANDBY.

24. Install the Distance Gauge.

25. Press the Ready button on the Main screen or on the Handpiece. Do not press the selected Trigger Switch to pulse the laser. Instead, aim the Handpiece at a white piece of paper and inspect the aiming laser beam for circular uniformity and clarity. If the aiming beam spot is not uniform, press the Standby Button to put the laser in the Standby mode. Check for Distance Gauge interference and dirty or damaged Handpiece or Lens Cartridge windows (**see Chapter 4** for cleaning or replacing windows.)

Warning: Always recalibrate the laser after fixing, cleaning or replacing the Delivery system, Lens Cartridge, Distance Gauge, and/or Window(s). Failure to initiate a calibration after cleaning/replacing the parts may result in the delivery of excessive laser energy.

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

The laser is now armed and ready to use. The Ready indicator on the front panel and the Indicator on the Handpiece are illuminated, but no energy is being delivered yet (see **Figure 3-16**).

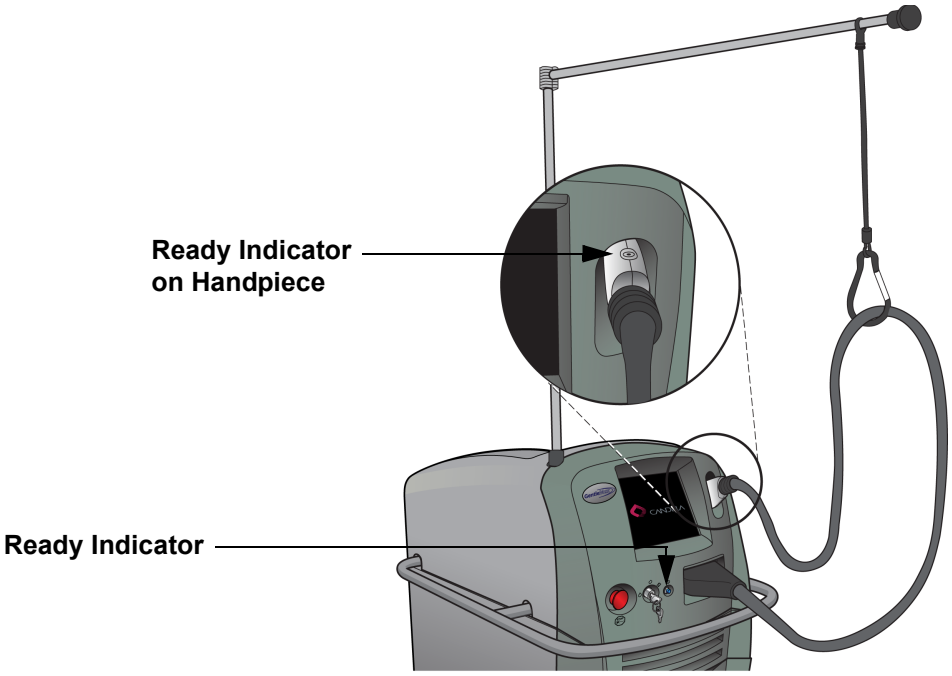


Figure 3-16: Ready Indicator on Handpiece and Laser System

- Before treatment, read **Appendix C** and clean per procedure every 40-50 pulses.

26. Perform the laser treatment using the Fingerswitch or the Footswitch.

- For information on Treatment Related Warnings, see **"Treatment Related Warnings" on page 1-15**.

When the Fingerswitch or Footswitch is depressed, laser energy is released and the Ready/Status button displays the Lasing symbol (see **Figure 3-17**).

Figure 3-17: The Laser is Being Used for Treatment

When the Fingerswitch or Footswitch is released, the Lasing symbol is replaced with the Ready state in the Status Area.

Note: If the laser remains idle (unused) for more than 2 minutes while in Ready state, the system automatically reverts to the Standby state.

Note: If you choose to change the Fluence setting during the treatment by selecting the up and down arrow buttons, a confirmation message displays before the new settings take effect. Select the checkmark to confirm the new setting.

27. When the treatment is complete, select the Standby button to place the system in Standby. The Standby/Ready button turns yellow (see **Figure 3-18**).

Figure 3-18: System is in Standby

28. Insert the Handpiece in the Calibration Port. Document the laser use. When in Standby state, you can then adjust the laser output parameters as needed.

Notes:

- To return the Pulse Counter to zero, press the Pulse Count Reset button on the Main screen for at least two seconds.
- The laser system will not allow treatment pulses until a calibration has been performed after any one of the following conditions:
  - Laser is turned on.
  - Fluence is change to outside of the yellow lines.
  - Pulse Duration parameter is changed.
  - Delivery System is changed.
  - The Lens Cartridge was changed or became disconnected from the Handpiece.
  - Specific faults occurred.
  - The laser system was in Standby for more than 30 minutes.
- The user must initiate a calibration after cleaning or replacing the window(s) in the Handpiece and/or Lens Cartridge.
- If the desired Fluence cannot be reached, a message appears indicating that the system may need a new fiber or laser head. Call Candela Customer Service. If a higher Fluence is desired immediately, reduce the spot size.

Chapter 4: Maintaining the Laser

Topics described in this chapter include:

General Information

In general, the laser system requires no special maintenance. Routine care of the Handpieces, cleaning and disinfecting of the exterior of the system are covered in this chapter. During normal operation, you are required to calibrate the energy output of the laser system, as discussed in **“Calibration Procedure” on page 4-22**. You are also required to perform user verifications tests as described in **“” on page 4-25**.

Solutions to the most common operating problems are provided in**“Troubleshooting” on page 5-2**. The fault messages that appear on the front panel display described in **“Fault Messages” on page 5-4**.

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 at least every 18 months. At each of these preventive maintenance visits, the service representative will check and adjust the functioning of the system.

Caution: The electrical and laser radiation hazards present while servicing the GentleMAX laser system can be extremely dangerous if proper safety precautions are not taken.

The GentleMAX laser system is to be installed and serviced only by a qualified and authorized technicians who have received appropriate training from Candela. Any attempt by an unauthorized person to perform any service procedure may result in a personal injury and will void any warranty on the laser system.

Laser Software and System Upgrades

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

The Laser System Software Upgrade USB Port and Memory Stick

Minor laser system software upgrades can be performed at the convenience of the authorized user(s) without the presence of a Candela Service Representative. The laser system software upgrades will be shipped in USB Memory Sticks with instructions. The instructions will provide simple steps and procedures to verify that the upgrade is completed successfully. The USB Port is located on the rear of the laser system (see **Figure 2-7**). Follow the instructions and procedures provided with each software upgrade.

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

Maintaining the Fiber Optic Delivery System

Warning: Always put the laser system into Standby or Off and remove the Lens Cartridge from the Handpiece when checking, cleaning, and/or replacing the Delivery System, Lens Cartridge, and/or Windows.

The GentleMAX Laser Delivery System utilizes fiber optics that can be damaged if subjected to excessive bending. To avoid damage to the optical fiber, limit bends to a radius of 6 inches (15 cm) or greater.

The Delivery System should be checked before each procedure by observing aiming beam quality. The beam as viewed against a white sheet of paper should have intensity, homogeneous distribution and a well defined circumference.

If the aiming beam is turned on but non-existent, discontinue use immediately as the fiber may be broken. A dim aiming beam may also indicate a broken fiber or dirty or damaged windows. Clean or replace the Lens Cartridge and/or Handpiece window(s) before repeating this test.

Use of a damaged fiber optic delivery system is dangerous and must be avoided. If damage is suspected, discontinue use immediately.

Warning: Always recalibrate the laser after fixing, cleaning or replacing the Delivery system, Lens Cartridge, and/or Window(s). Failure to initiate a calibration after cleaning/replacing the parts may result in the delivery of excessive laser energy.

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

Maintaining the Air Intake

The air intake is located on the bottom of the laser system.

On a monthly basis you should inspect the laser bottom, where cooling air intake is located, and clean off any accumulated dust.

Maintaining the Water Cooling System

Caution: The cooling water is heated to 65°C. Do not put your fingers into the water tank. Avoid splashing the heated water.

The system is cooled with distilled or deionized (DI). The water level should be checked monthly if the system is used daily or every six months if the system is used weekly. You should also check the level if you receive a fault message preceded by a “7”, which indicates a fault in the DI system.

The water tank is located inside the laser and is connected to a reservoir filler bottleneck protruding from the rear of the laser. The water cooling system holds approximately 2.8 liters of DI water.

To check the water level:

1. Turn off the laser and allow it to cool down.
2. Turn the filler cap counter-clockwise to remove.
3. Inspect the water level by looking into the reservoir filler bottleneck.
4. Fill with DI water until the water is within ½ to 1 inch from the top of the spout.
5. Replace the filler cap and tighten.
6. After the reservoir is completely refilled, start the laser system and allow the system to operate for 15 seconds and then turn the system off.
7. Remove the filler cap to check the water level and refill with more DI water, if needed.
8. Replace the filler cap and tighten.
9. Repeat Steps 6-8 until the water reservoir is filled within ½ to 1 inch from the top of the bottleneck.
10. After the reservoir is completely refilled, restart the laser system and allow it to warm up.

Maintaining Handpiece and Lens Cartridge Windows

Warning: Always put the laser system into Standby or Off and remove the Lens Cartridge from the Handpiece when checking, cleaning, and/or replacing the Delivery System, Distance Gauge, Lens Cartridge, and/or Windows.

Due to the nature of some procedures, the Windows will require frequent cleaning and/or replacement to maintain proper system performance. These components should be maintained in accordance with the cleaning and disinfection procedures in **"Cleaning and Disinfecting" on page 4-8**. Diagrams and procedures specific to the GentleMAX Laser delivery systems are included in this section.

Each Lens Cartridge assembly contains two removable windows to protect the Delivery System optics and its internal lenses. All Lens Cartridge windows are secured inside the Lens Cartridges by removable o-rings. The Lens Cartridges for the 6-18mm spot sizes contain a removable Window Tube with a window on one end and a hole that is keyed to align with the air blower inside the 6-18mm Delivery System intended to reduce the amount of debris entering the handpiece and the internal cartridge areas. The Window Tube has a pin that fits into a slot on the cartridge. The Lens Cartridges and the Window Tube have notched access openings to make it easy to pull out the o-rings to clean or replace the window(s) (see **Figure 4-1** and **Figure 4-2**).

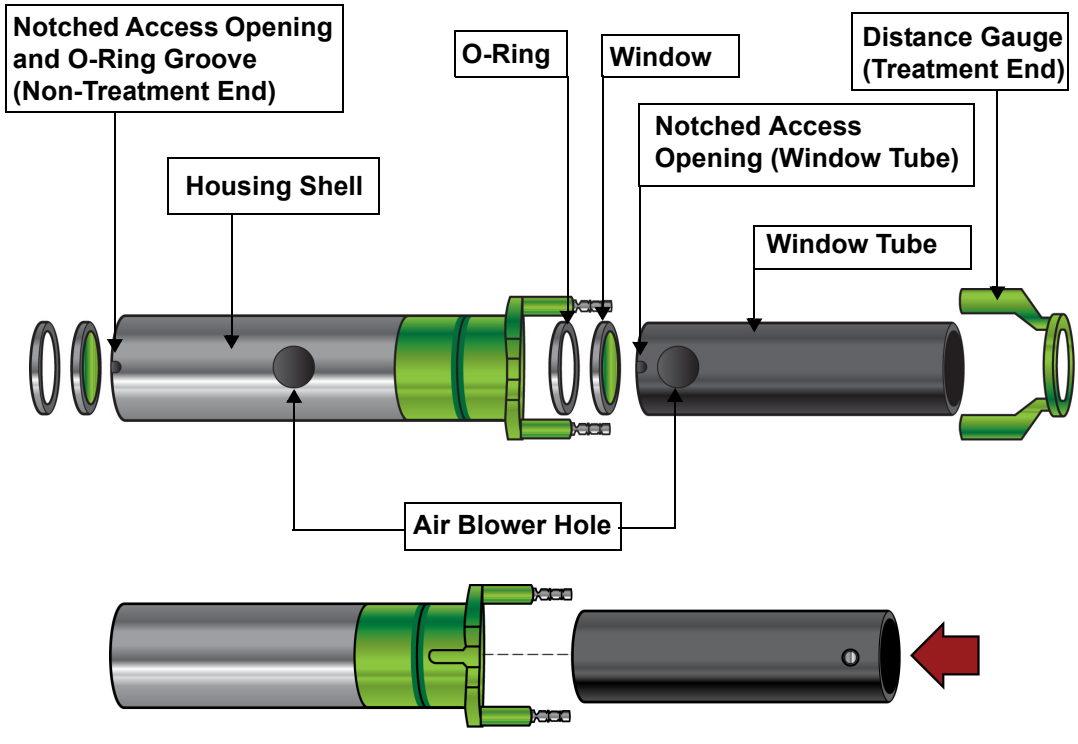


Figure 4-1: 6-18mm Lens Cartridge

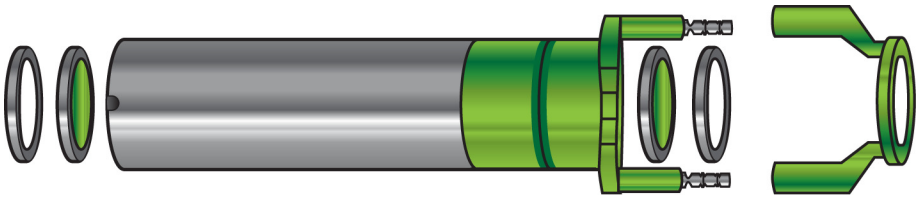


Figure 4-2: 1.5-3mm Lens Cartridge Design

The Handpiece contains one internal Handpiece window that can be installed or removed easily using the Window Removal Tool supplied with each laser.

Cleaning and Disinfecting

This section describes how to clean and disinfect the components of the laser system.

Warning: Always put the laser system into Standby or Off and remove the Lens Cartridge from the Handpiece when checking, cleaning, and/or replacing the Delivery System, Distance Gauge, and/or Windows.

Warning: Always recalibrate the laser after fixing, cleaning or replacing the Delivery system, Lens Cartridge, and/or Window(s). Failure to initiate a calibration after cleaning/replacing the Window(s), Lens Cartridge, and/or Delivery System may result in the delivery of excessive laser energy.

Warning: Always perform the User Verification Tests (see "User Verification Test" on page 3-3) to check the Delivery System and Lens Cartridge for proper operation at the beginning of each treatment day or each time it is replaced on the laser system. In addition, use the User Verification Tests to check the Delivery System and/or Lens Cartridge if there is an unexplained treatment response noted or the Delivery System and/or Lens Cartridge has been dropped. Discontinue use of your laser Delivery System or Lens Cartridge if you suspect a problem.

Caution: Handpiece lens and the tips of the laser fiber may be damaged from exposure to dust particles or any other foreign particles that may deposit on their surfaces.

Particles on these surfaces will burn and leave a deposit when exposed to laser energy. This may lead to lower fiber or Handpiece transmission and/or failure of the assembly.

In order to reduce the probability of damage please observe the cleaning guidelines and cover the proximal end of the fiber when it is not installed in the laser.

Cleaning the Exterior of the Laser System

The exterior of the laser system may be cleaned weekly using a soft cloth moistened with a solution of mild soap and water. Harsh detergents should not be used. If it becomes necessary to disinfect the exterior of the laser system, a soft cloth moistened with isopropyl alcohol may be used.

Cleaning the Delivery System Handpiece

The outer shell and internal window of the Delivery System Handpiece need to be kept clean and free of residue. The procedures below describe proper cleaning and disinfection of the outer shell and internal window of the Delivery System Handpiece.

To clean and disinfect the Handpiece immediately after each treatment session:

1. Put the laser in Standby and wipe the exterior surface of the Handpiece body with a gauze pad or towelette moistened with hospital grade disinfectant solution or alcohol solution.

   Take care to avoid contaminating the internal optical surfaces of the Handpiece.

2. After cleaning the Handpiece, dry the area thoroughly prior to the beginning of a laser procedure.

To clean or replace the Handpiece Window:

This procedure requires the use of the Handpiece Window Removal Tool (Candela P/N 7122-00-9006). **Figure 4-3** shows how to use the Window Removal Tool for removing and inserting the Handpiece Window.

1. Turn off the laser system.

2. Remove any Lens Cartridge that may be inserted in the Handpiece and set aside.

3. Wear dustless gloves to prevent smudges or fingerprints on the Handpiece window.

4. Fully slide the Handpiece Window Removal Tool in the Handpiece port with the “Out” arrow pointing in the opposite direction away from the laser aperture.

Note: The “Out” arrow indicates the direction in which the Handpiece internal window will be removed.

5. Slowly rotate the Window Removal Tool to make a ¼ turn in a counterclockwise or clockwise direction. This will exert a magnetic pull on the Handpiece internal window causing it to attach itself to the Window Tool.

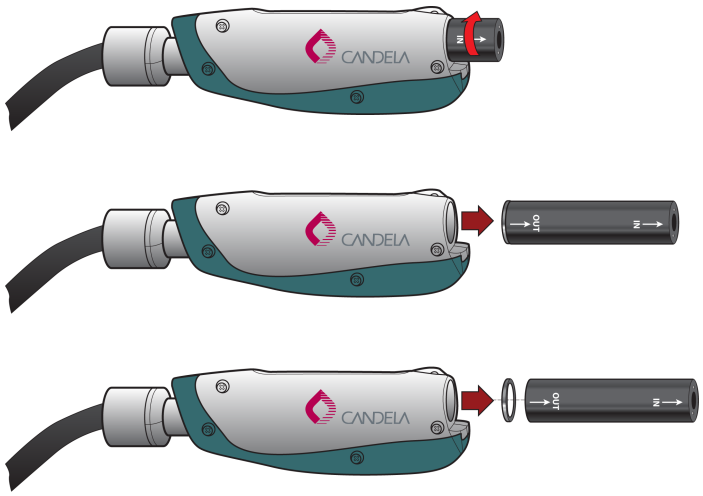


Figure 4-3: Window Removal Tool (Removing)

6. Slowly pull the Window Removal Tool out in the direction of the “Out” arrow. The Handpiece window should be magnetically attached to the proximal end of this tool.

7. Remove the Handpiece window from the tool to clean as follows:

   - Clean the window with a lint free tissue or towelette moistened with clean isopropyl alcohol. Wipe only once with each tissue.
   - Re-inspect the window and compare to the Window Acceptability Chart (see **Figure 4-4**). If the window does not match an acceptable example in the chart, discard the window and replace it with a new one.

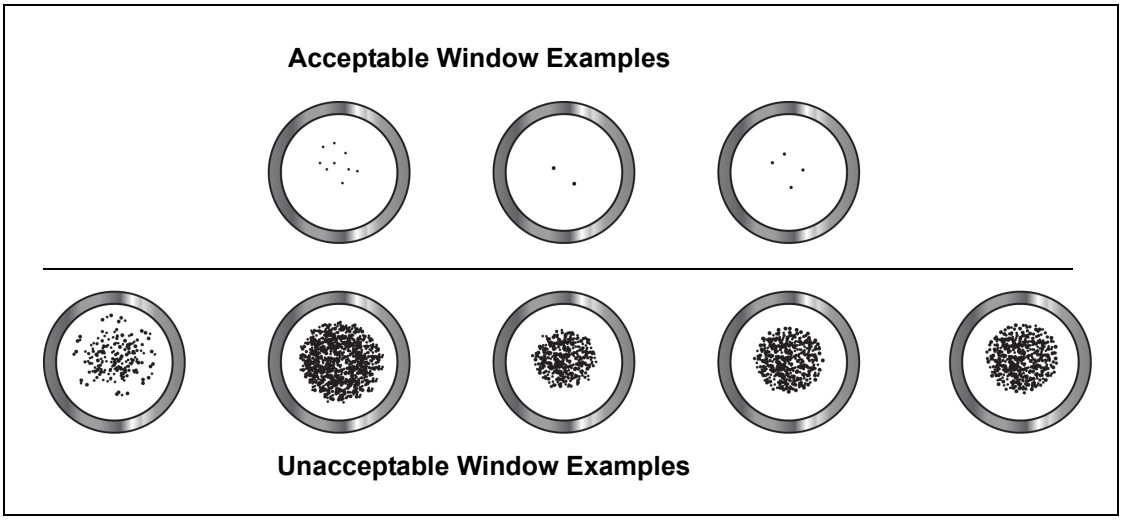


Figure 4-4: Window Acceptability Chart

8. Grasp the clean or new window by the edges and magnetically attach it to the other end of the Window Tool where the “In” arrow is located (the orientation of the window does not matter). See **Figure 4-5**.
9. Carefully slide the Window Removal Tool in the direction of the “In” arrow back in the Handpiece port until it comes to a full stop.

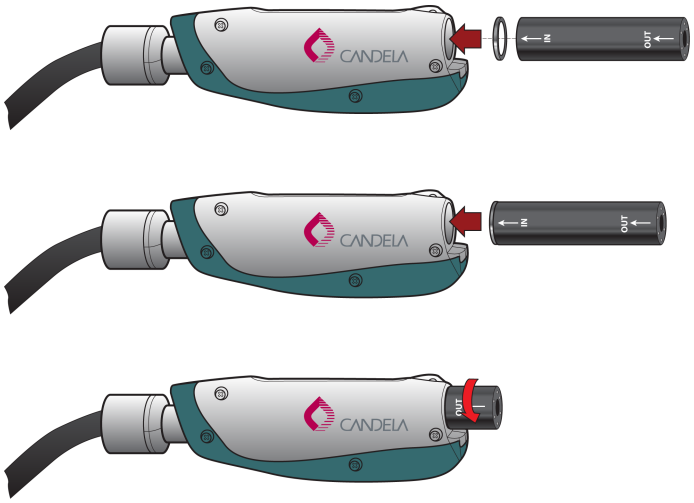


Figure 4-5: Window Removal Tool (Replacing)

10. Slowly rotate the Window Removal Tool to make a ¼ turn in a counterclockwise or clockwise direction. This will release the Handpiece window from the Window Removal Tool.
11. Slowly pull the Window Removal Tool out. Verify that the Handpiece window is no longer attached to the tool and that it attached itself inside the Handpiece.
12. Hold the handpiece under a bright light to verify that the Handpiece window is fully magnetically connected to the bottom surface (flat) of the Handpiece port and that the window fully covers the internal Delivery System optics.
13. Reinsert the Lens Cartridge with its matching Distance Gauge attached into the Handpiece.The Lens Cartridge should be able to slide in without any obstacles. If you are unable to insert the Lens Cartridge, the Handpiece window may not be properly seated. Repeat Steps 2-12 until the Handpiece window can be properly set in place.

Warning: Always verify that the Handpiece window is properly set in its place.

14. Turn on the laser and allow it to warm-up.
15. Calibrate the laser.
    ▸▸ For more information, see **“Calibration Procedure” on page 4-22**.

Warning: Always perform a laser calibration after replacing/cleaning a dirty or burnt window.

Cleaning the Lens Cartridge and Distance Gauge

The Distance Gauge is the only part of the Handpiece that comes in contact with the patient. This customer replaceable and consumable item should be replaced when signs of degradation, breakages, or difficultly in cleaning occur. Proper care will result in improved laser performance.

Cleaning the Distance Gauge

Appendix C details the procedure for cleaning the Distance Gauges.

After approximately 40-50 pulses (sooner if you detect significant flashing), or if you note additional debris buildup, swipe a paper towel or piece of gauze moistened with warm water across the patient contact surface of the Distance Gauge tip or ring. As the towel passes across the surface, allow your index finger to push into the ring slightly and rotate. You will be cleaning a portion of the inner surface of the ring. Continue the treatment. This step takes about one second and represents minimal interruption to your treatment routine.

For more detailed instructions on performing a **full cycle clean**, refer to **Appendix C**.

Warning: Always put the laser system into Standby or Off and remove the Lens Cartridge from the Handpiece when checking, cleaning, and/or replacing the Delivery System, Lens Cartridge, Distance Gauge and/or Windows.

Warning: Always perform the User Verification Tests (see “” on page 4-25) to check the Delivery System and Lens Cartridge for proper operation at the beginning of each treatment day or each time it is replaced on the laser system. In addition, use the User Verification Tests to check the Delivery System and/or Lens Cartridge if there is an unexplained treatment response noted or the Delivery System and/or Lens Cartridge has been dropped. Discontinue use of your laser Delivery System or Lens Cartridge if you suspect a problem.

Warning: Always recalibrate the laser after fixing, cleaning or replacing the Delivery system, Lens Cartridge, Window(s). Failure to initiate a calibration after cleaning/replacing the Window(s), Lens Cartridge, and/or Delivery System may result in the delivery of excessive laser energy.

Each Lens Cartridge assembly has an outer housing shell and two windows that need to be kept clean and free of residue build-up. The procedure below describe the proper cleaning and disinfection of the Lens Cartridges, Window Tube, and windows.

Clean/disinfect the Lens Cartridge posts, and exposed section of housing shell with a gauze pad moistened with clean isopropyl alcohol.

Caution:
Do not use heat, steam or autoclaves to sterilize the Lens Cartridge or do not completely submerge it in cleaning solutions or water. Use a pad moistened with clean isopropyl alcohol to wipe clean the Lens Cartridge as described in this manual.

Do not disassemble the Lens Cartridge to perform repairs. Only clean or replace the windows as instructed in this manual.

Only use GentleMAX laser replacement windows in the Lens Cartridge or permanent damage may occur.

The Lens Cartridge, its Windows, and the Lens may become soiled with normal usage. To ensure proper fluence delivery, it is important to inspect and clean the Lens Cartridge and its Windows frequently so debris does not get burned into the Window or Lens surface.

When the Lens Cartridge Windows or Lens become dirty or burnt, the amount of energy delivered to the patient may be reduced. Therefore, after replacing/cleaning a dirty or burnt Lens Cartridge Window, always recalibrate the laser.

To clean or replace the Lens Cartridges windows:

1. Wear dustless gloves to prevent smudges or fingerprints on the window(s).

2. Put the laser in Standby and remove the Lens Cartridge assembly from the Handpiece. Remove the Distance Gauge from the Lens Cartridge assembly.

   The windows are located on both ends of the 1.5 and 3mm Lens Cartridge (treatment and non-treatment end) and the bottom end (non-treatment end) of the 6-18mm Lens Cartridges. They are each held in grooves by O-rings. A notched access opening near the edge of the grooves on both ends allows easy removal of the O-rings (see **Figure 4-1** and **Figure 4-2**).

3. With the treatment end of the Distance Gauge pointing downwards, remove the O-ring from the non-treatment end with tweezers or poke a pointed object into the notch.

4. Gently pull the O-ring toward the center of the window to free the O-ring from the groove.

5. Turn the assembly upside down, allowing the window to fall out onto a clean surface.

6. Repeat Steps 3 – 5 to remove the second window from the treatment end of the Lens Cartridge (1.5 and 3mm Lens Cartridges only) starting with the non-treatment end of the Lens Cartridge facing downwards.

7. Clean the window as follows:
   - Clean the window with a lint free tissue or towelette moistened with clean isopropyl alcohol. Wipe only once with each tissue.
   - Re-inspect the window and compare to the Window and Lens Acceptability Chart (see **Figure 4-4**). If the window does not match an acceptable example in the chart, discard the window and replace it with a new one.

8. One window at a time, grasp the new or cleaned window by the edges and place it back into the Lens Cartridge so that it is resting flat on the ledge.

9. Reinsert the O-ring into the groove.

10. Use the tip of the tweezers or a pointed object to gently push the O-ring fully into the groove, being careful not to touch the window or the lens underneath.

11. Re-insert Distance Gauge back on the Lens Cartridge. Reinsert the Lens Cartridge back in the handpiece and insert into the Calibration Port.

12. Perform the Calibration Procedure.
▸ ▸ For more information, see **"Calibration Procedure" on page 4-22**.

Note: Only use GentleMAX laser replacement windows in the Lens Cartridge, or permanent damage may occur.

Warning: Always perform a laser calibration after replacing/cleaning a dirty or burnt Window or Lens.

Cleaning the Window Tube and Windows

This procedure describes how to clean the Window Tube and its window in the Lens Cartridge. The 1.5 mm and 3 mm Lens Cartridges do not use a WIndow Tube.

To clean the Window Tube and window:

1. Use your thumb to push the pin on the Window Tube out of the slot on the Lens Cartridge.

2. Push the tube all the way out of the Lens Cartridge.

3. Clean the window and tube as follows:

- Remove the window in the same fashion as done for the Lens Cartridge windows (**see "Cleaning the Lens Cartridge and Distance Gauge" on page 4-12.**) Clean the tube and window with a lint free tissue or towelette moistened with clean isopropyl alcohol. Wipe only once with each tissue.
- Re-inspect the window and compare to the Window Acceptability Chart (see **Figure 4-4**). If the window does not match an acceptable example in the chart, discard the window and replace it with a new one. Place the clean or new window back in the tube in the same fashion as done for the Lens Cartridge windows (**see "Cleaning the Lens Cartridge and Distance Gauge" on page 4-12.**)

4. To insert the tube into the Lens cartridge, align the small peg on the Window Tube with the notch in the Lens Cartridge (see **Figure 4-6**) and gently push the tube into the Lens Cartridge.

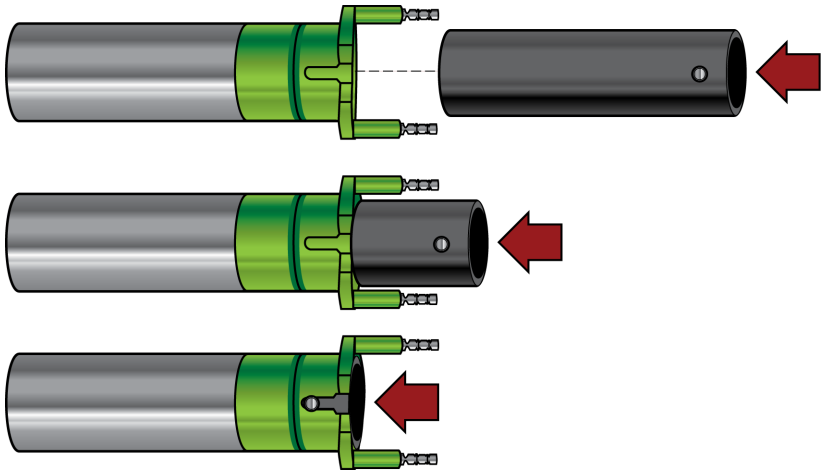


Figure 4-6: Install Window Tube

5. Re-insert the Distance Gauge back on the Lens Cartridge. Reinsert the Lens Cartridge back in the Handpiece and insert into the Calibration Port.
6. Perform the Calibration Procedure.
   ▸▸ For more information, **see "Calibration Procedure" on page 4-22.**

Note: Only use GentleMAX laser replacement windows in the Lens Cartridge, or permanent damage may occur.

Warning: Always perform a laser calibration after replacing/cleaning a dirty or burnt Window or Lens.

Cleaning the Touch Screen/Display Panel

Always handle the Touch Screen/Display Panel with care. It is recommended that you periodically clean the glass touch screen as follows:

- Use isopropyl alcohol or a non-abrasive glass cleaner. Avoid using cleaners other than glass cleaners.
- Apply the cleaner with a soft cloth. Avoid using gritty cloths.
- Always dampen the cloth and then clean the screen.

Replacing Parts

The following sections describe how to replace components of the GentleMAX laser system.

Replacing the Handpiece Delivery System

Turn off the laser system before replacing the Handpiece Delivery System. When not in use, the Delivery Systems should be stored in the supplied case with the plastic cap over the end of the fiber.

Removing the Delivery System

The black connector (the Cluster connector) that is plugged into the Cluster connector on the front of the laser (see **Figure 2-2**) contains all of the Delivery System connections.

To remove the Delivery System:

1. Turn the laser system OFF.
2. Grasp the Cluster connector and gently pull straight back to remove it. Do not pull the cable or its protective braid cover.
3. Place the Delivery System into supplied storage case with plastic end cap on the fiber for protection.

Connecting the Delivery System:

To connect the Delivery System:

1. Turn the laser system OFF.

2. Remove the Delivery System from the storage case and remove the plastic end cap on the fiber.

3. Grasp the Cluster connector (with the Candela logo facing up) and align the two pins as shown in **Figure 4-7** while gently pushing it straight into the Cluster connector receptacle on the front of the laser until it makes a clicking sound to indicate it is properly seated.

Figure 4-7: Proximal End of Delivery System Cable

4. Turn the laser system ON.

Caution: If the Fiber is not seated properly, damage may occur during use.

5. Perform the User Verification Tests as described in **Figure on page 3-3**.

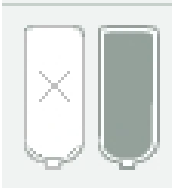
Replacing the Cryogen Canister

Caution: The contents of the Cryogen Canister(s) are under pressure. Read the MSDS Candela P/N 8501-00-1701 and the label on the canister before handling.

Replacing the Canister

The Main Screen (see **Figure 2-19**) has two icons depicting the two DCD canister slots available. As the DCD canisters installed into these slots are emptied, the icons will change in level to show an approximation of the amount of cryogen left in them. This two canister system allows you to install two full canisters and then run the laser continuously with a seamless transition between the two canisters when one runs empty.

When pulsing the laser with cryogen, the DCD canisters will automatically switch from an empty canister to the backup “full” canister. The empty canister can be identified on the Main Screen. The empty canister will be blinking. An X across the canister indicates there is no canister installed:



To replace a DCD canister:

1. Identify the empty canister on the main screen as described above. The empty canister will be blinking.

2. Open the front DCD door (see **Figure 4-8**) by grasping the indented handle on the front of the laser and pulling the door towards you to reveal the cryogen canisters (see **Figure 4-9**).

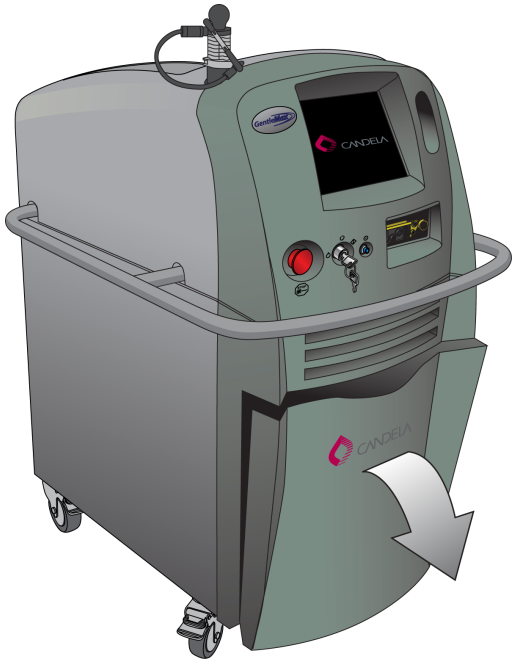


Figure 4-8: Open the DCD Door

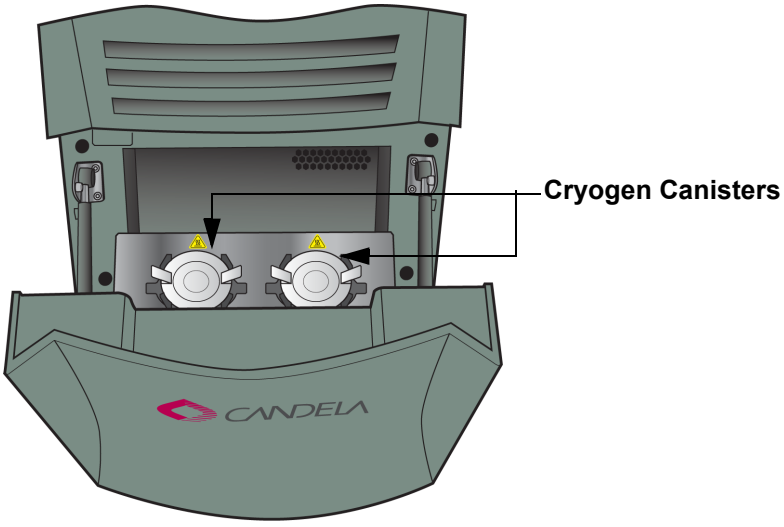


Figure 4-9: Cryogen Canisters Inside the DCD Drawer

3. Pull the empty canister out of the laser system.

4. Install the new canister by placing it into the DCD receptacle and gently pushing it into place until it the two retention brackets lightly snap into place.

Cryogen Safety Information

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

Disposing of Cryogen Canisters

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

▸▸ For more information, see **"Environmental Protection: Disposal Hazards and Guidance" on page 1-21**.

Calibration Procedure

Warning: Always recalibrate the laser after fixing, cleaning or replacing the Delivery system, Lens Cartridge, Window(s). Failure to initiate a calibration after cleaning/replacing the Window(s), Lens Cartridge, and/or Delivery System may result in the delivery of excessive laser energy.

The GentleMAX Laser System requires that the laser be calibrated prior to patient treatment. During calibration, the Handpiece with a Lens Cartridge must be inserted into the Calibration Port allowing an internal energy meter to measure the laser output parameters delivered at the Handpiece. The system adjusts itself until the desired output is obtained. Usually ~5-10 laser pulses are required before calibration is complete.

Note: Remove the Distance Gauge before calibration (and reinstall after calibration).

To calibrate the laser:

1. Put on safety eyewear.
2. Verify that the Handpiece and Lens Cartridge windows are clean (clean or replace as necessary as described in **“Cleaning the Delivery System Handpiece” on page 4-9** and **“Cleaning the Lens Cartridge and Distance Gauge” on page 4-12**).

Warning: Always place the laser system into Standby or Off and remove the Lens Cartridge from the Handpiece before checking, cleaning and/or replacing the Delivery System, Lens Cartridge, or Lens, Window(s).

Warning: Always perform the User Verification Tests (see “” on page 4-25) to check the Delivery System and Lens Cartridge for proper operation at the beginning of each treatment day or each time it is replaced on the laser system. In addition, use the User Verification Tests to check the Delivery System and/or Lens Cartridge if there is an unexplained treatment response noted or the Delivery System and/or Lens Cartridge has been dropped. Discontinue use of your laser Delivery System or Lens Cartridge if you suspect a problem.

3. Insert the desired Lens Cartridge spot size into the Handpiece Assembly.
4. Fully insert the Handpiece into the Calibration Port.
5. Select the desired laser operating parameters. (Alternately, you can manually select the operating parameters.)

6. Select the available treatment application that supports the Lens Cartridge spot size installed in Step 3 from the Applications Menu Bar (see **Figure 3-7**). **Table 3-4** lists the available applications.

   When you select the application, the Select Parameters screen displays for the selected application.

7. Select the parameters from the Select Parameters screen. When you are done, select the right arrow button to continue. **Figure 3-10** shows an example of the Select Parameters screen. **Table 3-5** lists the parameters to be configured for each application.

8. Confirm the suggested parameters on the Common Parameters screen are within the desired treatment parameters for the current patient treatment. When you are done, select the checkmark button.

9. If needed, adjust the operating parameters by pressing the arrows (up and down or left and right) to the desired settings (see **Table 3-6**).

Note: If you are experiencing difficulty setting the operating parameters, check to ensure the settings are allowed for the selected Lens Cartridge/Distance Gauge spot size.

Skip to Step 11.

10. If you performed Steps 6-9, skip this step. This step provides a method to manually set the operating parameters without selecting an application.

    Refer to **Table 3-6** to manually set the following operating parameters:

    - Fluence
    - Pulse Duration
    - Repetition Rate
    - Pre-Spray and Post-Spray Delay Duration
    - DCD Delay Duration

Note: If you are experiencing difficulty setting the operating parameters, check to ensure the settings are allowed for the selected Lens Cartridge/Distance Gauge spot size.

11. Select the Calibration button on the Main Screen (see **Figure 3-13**).

The Calibrating screen displays (see **Figure 3-14**).

This screen prompts you to confirm the Calibration parameters and provides information about the calibration process. Select the checkmark button to confirm the calibration parameters. The system will enter the READY state if the Handpiece is inside the Calport. If the settings are not correct, select the X to cancel.

12. If Footswitch is selected, A prompt indicates you should press and hold the Footswitch. Press the Footswitch to start the calibration. You must hold the Footswitch until the calibration is complete. If Fingerswitch is selected, a button will appear in the screen. Press and release this button to begin calibration.

A message displays indicating the system is calibrating. When the calibration is complete, a Calibration Complete message displays (see **Figure 3-15**).

13. The laser defaults to Standby after calibration. Install the matching Distance Gauge for the Lens Cartridge in the Handpiece.

14. Press the Ready button on the Main screen or on the Handpiece. Do not press the selected Trigger Switch to pulse the laser. Instead, aim the Handpiece at a white piece of paper and inspect the aiming laser beam for circular uniformity and clarity. If the aiming beam spot is not uniform, press the Standby Button to put the laser in the Standby mode. Check for Distance Gauge interference and dirty or damaged Handpiece or Lens Cartridge windows.

Warning: Always recalibrate the laser after fixing, cleaning or replacing the Delivery system, Lens Cartridge, Distance Gauge, and/or Window(s). Failure to initiate a calibration after cleaning/replacing the parts may result in the delivery of excessive laser energy.

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

The laser is now ready to use. The Ready indicator on the front panel and the Indicator on the Handpiece are illuminated, but no energy is being delivered yet (see **Figure 3-16**).

15. Perform the laser treatment using the Fingerswitch or the Footswitch.

- For information on Treatment Related Warnings, see **"Treatment Related Warnings" on page 1-15**.

When the Fingerswitch or Footswitch is depressed, laser energy is released and the Ready/Status button displays the Lasing symbol (see **Figure 3-17**).

When the Fingerswitch or Footswitch is released, the Lasing symbol is replaced with the Ready state in the Status Area.

Note: If the laser remains idle (unused) for more than 2 minutes while in Ready state, the system automatically reverts to the Standby state.

Note: If you choose to change the Fluence setting during the treatment by selecting the up and down arrow buttons, a confirmation message displays before the new settings take effect. Select the checkmark to confirm the new setting.

16. When the treatment is complete, select the Standby button on the Front Display or Handpiece to place the system in Standby. The Standby/Ready button turns yellow (see **Figure 4-10**).

Figure 4-10: System is in Standby

17. Remove the Distance Gauge and insert the Handpiece in the Calibration Port. Document the laser use. When in the Standby state, you can then adjust the laser output parameters as needed before restarting the treatment.

Notes:

- To return the Pulse Counter to zero, press the Pulse Count Reset button on the Main screen for at least two seconds.
- The laser system will not allow treatment pulses until a calibration has been performed after any one of the following conditions:
  - Laser is turned on.
  - Fluence is change to outside of the yellow lines.
  - Pulse Duration parameter is changed.
  - Delivery System is changed.
  - The Lens Cartridge position changed or became disconnected from the Handpiece.
  - Specific faults occurred.
  - The laser system was in Standby for more than 30 minutes.
- The user must initiate a calibration after cleaning or replacing the window(s) in the Handpiece, Lens Cartridges, and/or the Window Tube.
- If the desired Fluence cannot be reached, a message appears indicating that the system may need a new fiber or laser head. Call Candela Customer Service. If a higher Fluence is desired immediately, reduce the spot size.

Chapter 5: Troubleshooting the Laser

Topics described in this chapter include:

Introduction

This chapter provides troubleshooting and diagnostic information for the GentleMAX Laser System.

Troubleshooting

These troubleshooting procedures do not replace the instructions or procedures provided in this guide. Review all instructions and procedures in this guide before performing the following troubleshooting procedures.

Table 5-1 provides general troubleshooting information for the GentleMAX Laser system.

Table 5-1: General Troubleshooting Solutions for the GentleMAX Laser System

Situation/Symptom	Probable Cause or Fault Message	Solution
The system cannot be turned on properly.	The power is not connected properly.	• Reseat the power cable and check the facility circuit breaker. • Switch the circuit breaker to the "On" position. • Check the remote interlock connection. If it is connected to a door, make sure the door is closed.
	The laser system circuit breaker is in the "off" position.	
	The keylock switch was not fully engaged.	
	The external interlock is defeated.	
Laser pulses, but no cryogen is delivered	The DCD Spray settings are set to zero.	Select the DCD Spray up arrow button to increase the spray setting.
Cryogen Leak	There are breaks in the Delivery System tubing.	• Remove the Cryogen Canister or disconnect the Handpiece Assembly from the laser. • Contact Customer Service.
Warm-up Time has exceeded 60 minutes.	The water or cryogen temperature control circuitry failed.	Contact Customer Service.
Ineffective fluence response.	The system or the fiber has degraded.	• Perform a calibration procedure (see **“Calibration Procedure” on page 4-22**). • Contact Customer Service if problem persists.

Table 5-1: General Troubleshooting Solutions for the GentleMAX Laser System

Situation/Symptom	Probable Cause or Fault Message	Solution
The “Replace Canister” message displays.	There is insufficient cryogen in the canister.	• Replace the Cryogen Canister with a new canister supplied by Candela.
A Purge is required.	Bubbles have been detected in the cryogen line.	• Remove the Handpiece from the Calibration Port. • Press the Purge button until problem resolves. • If the problem persists, call Service.
The laser will not go into the Ready state.	The Trigger Switch is depressed.	De-activate the Trigger Switch.
The Aiming beam is missing in the READY state.	The Fiber is damaged or broken. The aiming beam laser or driver circuit is bad.	• Replace the Delivery System. • Contact Technical Support
The Aiming beam appears dim.	• The Intensity set too low • The Lens Cartridge windows are dirty. • The Lens Cartridge optics are dirty or damaged. • The aiming laser is failing.	• Set the aiming beam intensity using the button provided. • Clean or replace the windows. • Contact Technical Support.
The Aiming beam appears non-uniform.	• The Lens Cartridge windows are dirty. • The slider optics are dirty or damaged.	• Clean or replace the windows. • Replace the Lens Cartridge. • Replace the Delivery System.
CDRH Open	Interlock Open	• Ensure CDRH connector is installed. • Contact Technical Support.

Fault Messages

A fault message typically occurs due to a system malfunction. Sometimes clearing the fault and retrying the previous operation can be successfully accomplished without further faults occurring. If a fault message persists, call Candela Technical Support and report the Fault Number. Fault processing automatically places the system into the Standby state.

The following conditions occur outside of normal system operation. When the system enters a fault condition, it beeps and displays a fault message.

Table 5-2 lists the fault messages and possible solutions to resolve them. These solutions do not replace the instructions or procedures given in this guide. Review all instructions and procedures in this guide before performing the following troubleshooting solutions.

Table 5-2: Fault Message and Solutions for the GentleMAX Laser System

Situation/Symptom	Fault #	Reason	Solution
Fault 1 - Handpiece Bubble Circuit	1.1	HP Bubble Circuit Test did not detect a change in the signal.	• Replace the Delivery System. If problem persists, contact Candela Technical Support for system servicing.
Fault 1 - Canister A Bubble Circuit	1.2	Canister Bubble Circuit Test did not detect a change in the signal.	• Canister A malfunction. Only Canister B is available. If problem persists, contact Candela Technical Support for system servicing.
Fault 2	2.1	System H/W Test - ROM checksum failure.	• Turn system off for 5 seconds, and then restart the system. If problem persists, contact Candela Technical Support for system servicing.
Fault 2	2.2	System H/W Test - VRef Chk failure. Failure will specify module name and expected and actual measurements.	• Turn system off for 5 seconds, and then restart the system. If problem persists, contact Candela Technical Support for system servicing.
Fault 3 - Shutter	3.1	Shutter is not in the correct state when checked. It does not respond to actuation to the correct state.	• Turn system off for 5 seconds, and then restart the system. If problem persists, contact Candela Technical Support for system servicing.
Fault 4 - Power Supply Communication	4.2	High Voltage Power Supply Communications Time-out.	• Turn system off for 5 seconds, and then restart the system. If problem persists, contact Candela Technical Support.
Fault 5 - Power Supply Tolerance	5.1	High Voltage Power Supply Tolerance fault	• Turn system off for 5 seconds, and then restart the system. If problem persists, contact Candela Technical Support for system servicing.

Table 5-2: Fault Message and Solutions for the GentleMAX Laser System

Situation/Symptom	Fault #	Reason	Solution
Fault 5 - Power Supply Charge	5.2	High Voltage Power Supply charge time-out.	• Turn system off for 5 seconds, and then restart the system. If problem persists, contact Candela Technical Support for system servicing.
Fault 6 - Calibration Fault	6.2	Laser failed to Calibration to desired Fluence within 20 pulses. This could be caused by: • Damaged or dirty windows and/or lenses. • Laser mobility shocks may have shifted the laser head out of alignment. • Worn delivery system components. • Aging laser head, fluid system, and/or laser head components. • Low power input or output.	Recalibrate laser after each step in the order listed below until a successful calibration is achieved: • Put laser in Standby. • Check, clean and/or replace the Lens Cartridge windows. • Clean or replace the Handpiece Window • Change fluence by two settings up or down. • Try a different Lens Cartridge. • If available, install a spare Delivery System. If problem persists, contact Candela Technical Support.
Fault 6 - Rail Error	6.5	Calport redundant switches not same for longer than 1 second.	• Turn system off for 5 seconds, and then restart the system. If problem persists, contact Candela Technical Support for system servicing.

Table 5-2: Fault Message and Solutions for the GentleMAX Laser System

Situation/Symptom	Fault #	Reason	Solution
Fault 7 - Fluid Low Temperature	7.1	DI water is under temperature.	● Put laser in Standby and allow sufficient time for laser to warm-up. ● Verify that the laser room environment and temperature meet the specifications provided in **"Environmental Requirements" on page 6-5**. ● Verify that the water level is correct. ● Turn system off for 5 seconds, and then restart the system. If problem persists, contact Candela Technical Support for system servicing.
Fault 7 - Fluid High Temperature	7.2	DI water over temperature.	● Turn off laser and allow sufficient time for it to cool down. ● Verify that the laser room environment and temperature meet the specifications provided in **"Environmental Requirements" on page 6-5**. ● Verify that the system is more than 12" from the wall. ● Verify that the water level is correct. ● Turn the system off for 5 seconds, and then restart the system. If problem persists, contact Candela Technical Support for system servicing.

Table 5-2: Fault Message and Solutions for the GentleMAX Laser System

Situation/Symptom	Fault #	Reason	Solution
Fault 7 - Fluid Flow	7.3	DI Water Pump Pressure fault. Low or no DI water pressure and/or flow. Possible reasons are: ● DI water system pressure switch does not change when power is turned on. ● DI water pump is not ON or DI pressure switch is not actuated. ● DI water level is low and/or there are air bubbles flowing through the fluid system.	● Turn laser OFF. ● Check DI water level (the base of the reservoir filler bottleneck should be filled with DI water). ● Refill reservoir if needed. ● Check for DI water leaks underneath the laser. If water leak is present, call Service. ● Restart and turn off laser 2-3 times to allow fluid system to pump water and flush out air bubbles. If problem persists, contact Candela Technical Support for System Servicing.
Fault 7 - DI System Fault (Water)	7.4	Temperature Sensor Fault (sensor circuit is open or shorted).	● Turn laser OFF. ● Check the DI water level (the base of the reservoir filler bottleneck should be filled with DI water). ● Refill reservoir if needed. ● Check for DI water leaks underneath the laser. If water leak is present, call Service. ● Restart and turn off laser 2-3 times to allow fluid system to pump water and flush out air bubbles. If problem persists, contact Candela Technical Support for system servicing.

Table 5-2: Fault Message and Solutions for the GentleMAX Laser System

Situation/Symptom	Fault #	Reason	Solution
Fault 8 - DCD Canister A - Low Pressure	8.1	● Low DCD pressure. ● Cryogen Canister may be empty. ● Bubbles need to be purged out of new canister. ● Flow of cryogen may be obstructed. ● Overheated Delivery System or DCD canister ● DCD Settings may be out of range.	● Check DCD Canister level; replace if empty. **Caution!!** Canister may be HOT!
Fault 8 - DCD Canister B - Low Pressure	8.1	● Low DCD pressure. ● Cryogen Canister may be empty. ● Bubbles need to be purged out of new canister. ● Flow of cryogen may be obstructed. ● Overheated Delivery. System or DCD canister. ● DCD Settings may be out of range.	● Check DCD Canister level; replace if empty. **Caution!!** Canister may be HOT!
Fault 8 - DCD Canister A - High Pressure	8.2	● High DCD pressure. ● Bubbles need to be purged out of new canister. ● Flow of cryogen may be obstructed. ● Overheated Delivery System or DCD canister. ● DCD Settings may be out of range.	● Check DCD Canister level; replace if empty. **Caution!!** Canister may be HOT!
Fault 8 - DCD Canister B - High Pressure	8.2	● High DCD pressure. ● Bubbles need to be purged out of new canister. ● Flow of cryogen may be obstructed. ● Overheated Delivery System or DCD canister. ● DCD Settings may be out of range.	Check DCD Canister level; replace if empty. **Caution!!** Canister may be HOT!

Table 5-2: Fault Message and Solutions for the GentleMAX Laser System

Situation/Symptom	Fault #	Reason	Solution
Fault 8 - DCD Canister DCD HP Valve	8.3	DCD Valve Fault.	• Replace the Delivery System. If problem persists, contact Candela Technical Support for system servicing.
Fault 8 - DCD Canister A - Temperature Sensor	8.4	DCD Temperature Sensor.	• Turn laser off and allow to sit for 5 minutes before powering back on. If problem persists, contact Candela Technical Support for system servicing.
Fault 8 - DCD Canister B -Temperature Sensor	8.4	DCD Temperature Sensor.	• Turn laser off and allow to sit for 5 minutes before powering back on. If problem persists, contact Candela Technical Support for system servicing.
Fault 9 - Fluid Warm Up	9.1	DI temperature is not in normal range after 60 minutes.	• Turn system off for 5 seconds, and then restart the system. If problem persists, contact Candela Technical Support for system servicing.
Fault 9 - DCD Canister A (Canister B) Warm Up	9.2	DCD pressure is not in normal range after 60 minutes.	• Turn system off for 5 seconds, and then restart the system. If problem persists, contact Candela Technical Support for system servicing.
Fault 10 - Lens Cartridge Not Recognized	10.1	Unrecognized Lens Cartridge while in Ready state.	Lens Cartridge is not installed. • Reinstall Lens Cartridge or insert a different size Lens Cartridge. • Calibrate the laser.

Table 5-2: Fault Message and Solutions for the GentleMAX Laser System

Situation/Symptom	Fault #	Reason	Solution
Fault 10 - Delivery System Not Connected	10.2	Handpiece is disconnected while in Ready state.	Delivery System is not connected. ● Remove the Delivery System and reinstall. ● Calibrate the laser. ● Replace the Delivery System with a spare or new Delivery System. ● Calibrate the laser. If problem persists, contact Candela Technical Support for system servicing.
Fault 10 - Lens Cartridge Not Installed	10.3	The Lens Cartridge is disconnected while the system is in Ready state.	Lens Cartridge is not installed. ● Reinstall Lens Cartridge or insert a different size Lens Cartridge. ● Calibrate the laser.
Fault 10 - Delivery System Fiber Not Installed	10.4	Fiber is not detected while in Ready state.	● Remove the Delivery System and reinstall. ● Calibrate the laser. ● Replace the Delivery System with a spare or new Delivery System. ● Calibrate the laser. If problem persists, contact Candela Technical Support for system servicing.
Fault 10 - Lens Cartridge Not Correct	10.5	Lens Cartridge not supported.	The system or Handpiece does not support the installed Lens Cartridge.

Table 5-2: Fault Message and Solutions for the GentleMAX Laser System

Situation/Symptom	Fault #	Reason	Solution
Fault 10 - Delivery System	10.6	Delivery System not Supported	• Verify correct Delivery System is installed. • Turn system off for 5 seconds, and then restart system. If problem persists, contact Candela Technical Support
Fault 12 - Low Energy	12.1	Laser head energy of last treatment pulse was low.	• Recalibrate the laser system. If problem persists, contact Candela Technical Support for system servicing.
Fault 12 - High Energy	12.2	Laser head energy of last treatment pulse was high.	• Recalibrate the laser system. If problem persists, contact Contact Candela Technical Support for system servicing.
Fault 12 - MAX Energy Exceeded	12.3	Laser head energy of last treatment pulse was greater than maximum allowed.	Clean or replace both Lens Cartridge windows and/or Handpiece window.
Fault 12 - Energy Not Balanced	12.4	Laser head energy is not balanced.	• Recalibrate the laser system. If problem persists, contact Candela Technical Support for system servicing.
Fault 12.5 - LaserC	12.5	HD2 energy not within $\pm$20% of HDI energy.	• Recalibrate the laser system. If problem persists, contact Candela Technical Support for system servicing.
Fault 12.6 - LaserC	12.6	Total Pulse Width not within $\pm$20% of nominal.	• Recalibrate the laser system. If problem persists, contact Candela Technical Support for system servicing.
Fault 13 - Fingerswitch	13.1	Fingerswitch	Change to Footswitch or change Delivery System.
Fault 13 - Footswitch	13.2	Redundant Trigger Switch fault.	Change to Fingerswitch.

Table 5-2: Fault Message and Solutions for the GentleMAX Laser System

Situation/Symptom	Fault #	Reason	Solution
Fault 14 - 755 nm Simmer Fault	14	Simmer Circuit fault.	● Recalibrate the laser system. ● If problem persists; change to 1064 nm laser; if available.
Fault 14 -1064 nm Simmer Fault	14	Simmer Circuit fault.	● Recalibrate the laser system. ● If problem persists; change to 755 nm laser; if available.
Fault 15 - Delivery System Transmission Low	15.1	Low Transmission. It may be caused by: ● Dirty windows in Lens Cartridge and/or Handpiece. ● Damaged lenses in Lens Cartridge. ● Incorrect windows were installed. ● Worn Delivery System.	Recalibrate laser after each step in the order listed below until a successful calibration is achieved: ● Clean and/or replace windows in the Lens Cartridge and/or Handpiece ● Try another Lens Cartridge (the same size, if available). If this Lens Cartridge works, contact Customer Service to replace the bad Lens Cartridge. ● Verify that there is no flat on the window edge and/or replace the window (GentleMAX Laser windows only). ● Replace the Delivery System. If problem persists, contact Candela Technical Support for system servicing.

Table 5-2: Fault Message and Solutions for the GentleMAX Laser System

Situation/Symptom	Fault #	Reason	Solution
Fault 15 - Delivery System Transmission High	15.2	High Transmission. It may be caused by Windows missing.	Recalibrate laser after each step in the order given below until a successful calibration is achieved: ● Verify that the Lens Cartridge has both windows (input and output) and that the Handpiece has a window. If problem persists, contact Candela Technical Support for system servicing.
Fault 16 - DCD Canister Empty	16	This message displays if canister bubble is detected in the READY state and the DCD is enabled. ● Bubbles need to be purged out of new canister. ● Cryogen Canister may be empty. ● Flow of cryogen may be obstructed.	● Press Purge Button to purge bubbles out of cryogen line. ● Check canister to see if it is empty. Replace if needed. ● If the canister is full, take it out and reinstall, and then press Purge Button. If problem persists, contact Candela Technical Support for system servicing.
Fault 17 - HP Bubble	17	Bubbles detected in Handpiece. ● Air bubbles need to be purged out of cryogen fluid lines. ● Cryogen Canister may be empty. ● Cryogen line may be obstructed. ● The Delivery System is overheated.	● Press the Purge Button to purge bubbles out of cryogen line. ● Check the canister to see if it is empty. Replace if needed. ● If canister is full, remove it and reinstall, then press the Purge Button. If problem persists, contact Candela Technical Support for system servicing.
Fault 18 - Energy Circuit	18.1	Energy Circuit Calibration Fault.	Contact Candela Technical Support for system servicing.
Fault 18 - Fluid Circuit	18.2	DI Circuit Calibration Fault.	Contact Candela Technical Support for system servicing.
Fault 18 - DCD Circuit	18.3	DCD Circuit Calibration Fault.	Contact Candela Technical Support for system servicing.

Table 5-2: Fault Message and Solutions for the GentleMAX Laser System

Situation/Symptom	Fault #	Reason	Solution
Fault 18 - Blower Temperature Circuit	18.4	Blower Air too hot.	Contact Candela Technical Support for system servicing.
Fault 18 - CktCAL HP Bubble Fault	18.6	CktCAL HP Bubble Fault	Contact Candela Technical Support for system servicing.
Fault 18 - CktCAL CAN Bubble Fault	18.7	• CktCAL DCDA Bubble Fault • CktCAL DCDB Bubble Fault	Contact Candela Technical Support for system servicing.
Fault 18 - CktCAL AC Line Fault	18.8	CktCAL AC Line Fault	Contact Candela Technical Support for system servicing.
Fault 19 - Laser Trigger	19.1	Laser Trigger Fault.	Contact Candela Technical Support for system servicing.
Fault 19 - Laser Timer	19.2	Laser Timer Fault.	Contact Candela Technical Support for system servicing.
Fault 19 - Laser Power	19.3	Laser Power Fault.	Contact Candela Technical Support for system servicing.
Fault 19 - Laser	19.4	Lasing HD Power Fault: • Software detected head power present before/after pulse. • Hardware detected pulse fault (Over Energy, Over Current, No Current).	• Recalibrate the laser system. If problem persists, contact Candela Technical Support for system servicing.
Fault 19 - Laser	19.5	HV Dump Fault (HV smp > 150V after dump).	• Recalibrate the laser system. If problem persists, contact Candela Technical Support for system servicing.
Fault 21 - Software Update Fault	21	Code update did not complete properly.	Contact Candela Technical Support for system servicing.
Fault 22 - Software CAN	22		Contact Candela Technical Support for system servicing.
Fault 22 - CAN Communications Fault	22.1	CAN Communications Fault	• Turn system off for 5 seconds, and then restart the system. If problem persists, contact Candela Technical Support for system servicing.

Table 5-2: Fault Message and Solutions for the GentleMAX Laser System

Situation/Symptom	Fault #	Reason	Solution
Fault 22 - GUI Communications Fault (RS232)	22.2	GUI Communications Fault (RS232)	• Turn system off for 5 seconds, and then restart the system. If problem persists, contact Candela Technical Support for system servicing.
Fault 23 - One Wire Network Fault	23	One Wire Network Fault	• Turn system off for 5 seconds, and then restart the system. If problem persists, contact Candela Technical Support for system servicing.
Fault 21 - Software Update Fault	21	Code update did not complete properly.	Contact Candela Technical Support for system servicing.
Fault 22 - Software CAN	22		Contact Candela Technical Support for system servicing.

Chapter 6: Specifications

Topics described in this chapter include:

System Specifications

Table 6-1 lists the system specifications of the GentleMAX Laser System.

Table 6-1: GentleMAX System Specifications

Specification	Description
Laser Type:	Flashlamp-excited, pulsed Solid State Alexandrite and ND:YAG laser
Wavelength	755 nm and 1064 nm
Method of Optical Output:	Lens-coupled optical fiber with user selectable spot sizes
Maximum Delivered Energy:	53 joules (J) Alexandrite 79.2 joules (J) ND:YAG
Accuracy of Output Energy: Includes Cumulative Measurement Uncertainty	± 20%
Pulse Repetition Rate:	Up to 10 Hz repetitive pulsing
Pulse Duration (milliseconds):	0.35 - 300 milliseconds
Beam Spot Sizes:	1.5, 3, 6, 8, 10, 12, 15 and 18 mm diameter
Laser Cooling Method:	Ambient air
Dimension	42” H x 18” W x 27” D
Weight	300 lbs
Aiming Device	Class 2 Light (per EN 60825-1), 520-550 nm, 5.0mW
Cryogen	HFC 134a
Voltage and Power	220-230 V~, 50/60 Hz, single phase, 4000 VA or 17.4 A at 230 V~

Medical Electrical Equipment Standard Specifications and Classification

- For information on Electromagnetic Compatibility specifications, see **“Electromagnetic Compatibility” on page B-1**.

Electrical Requirements

In the US and Asia Pacific, a NEMA L6-30R receptacle, or equivalent, is required. For Europe, an IEC 309, Blue, 32 Amp receptacle or equivalent is required.

The power cord is a approximately 12-foot power cord 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 feet of the intended laser system location. See **Table 6-2** for electrical service requirements.

Warning: The power plug must be installed by a qualified person, in accordance with IEC requirements and the appropriate national electrical code.

For International installations, the power connections should be made with a grounded 2-conductor plug and receptacle pair. The plug and receptacle must be rated for the service line voltage at a minimum and capable of handling 4,000 VA (see **Table 6-2** for detailed ratings). A plug meeting these requirements must be installed onto the laser system line cord. Alternately, the entire line cord may be replaced with one which is terminated with the appropriate plug.

Table 6-2: Installation Site Electrical Service Requirements

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

The input power line should be free of transients (spikes, sags and/or surges). A dedicated branch circuit is recommended.

Operation of the GentleMAX Laser on a power line that is not consistently within the specification may cause damage to the system and may void the warranty.

Ground Continuity Tests

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

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

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

Environmental Requirements

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

Important Note: Installation of the laser must be performed by a Candela Service Representative. Following installation, a Candela Clinical Consultant must instruct designated personnel on the basic operation and care of the laser. An in-depth clinical training is required of a physician to become proficient in the use of the GentleMAX Pulsed Laser System.

Important Note: Treatment room areas associated with the use of cryogen require special precautions. Refer to the Chemical Hazards section in Chapter 1 of this manual and the Material Safety Data Sheet or MSDS sheet (Candela P/N 8501-00-1701) for General Treatment Area Guidelines and further information.

Space

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

Air Quality

- Ensure that the atmosphere is non-corrosive, with no salts or acids in suspension in the air. Acids, corrosives, and volatile materials are likely to attack electrical wiring and the surfaces of optical components.
- Keep air-borne dust particles to a minimum. Dust particles can cause permanent damage to optical surfaces. Metallic dust can be destructive to electrical equipment.

Humidity

20% to 80%, non-condensing.

Ambient Temperature

- Maintain the temperature in the laser room between 65° and 85°F (18° and 29°C).
- Avoid placing the laser system near heating outlets or other openings that might be the source of air currents that could cause uneven cooling in the laser system.
- The laser system must be stored at a temperature between 40° and 110° F (4.5° and 43°C).

Relocation

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

Warning: Do not use the Fiber Pole to lift or move the laser system. It was not designed to sustain the weight of the laser when it is being moved.

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

Mobile Use

The GentleMAX Laser System is not designed for mobile use.

Transport and Storage

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

Warning: Do not expose to temperatures below 5°C (40° F) or damage may occur. If the laser is exposed to temperatures below 5°C, contact Candela Technical Support prior to use.

Internal Cooling Water Requirements

Distilled Water: 2.8 liters provided by the customer (readily available at hospitals, where it is used for sterile water).

Using water that is not distilled or deionized will result in poor flashlamp performance, and may result in permanent flashlamp damage.

Chapter 7: Laser System Packing Lists, Accessories, and Replacement Parts

Topics described in this chapter include:

Packing List

The following items are included in the shipping package for all GentleMAX laser systems.

Table 7-1: Laser Accessories

Description	Quantity	Part Number
GentleMAX Accessory Kit	1	7122-00-9005
Footswitch	1	5103-00-0030
PF1 Fiber Pole Assembly	1	7122-00-9004
Ship Mtrl Crate PF1	1	6510-00-0261

Accessory Kit and Parts Included with All New GentleMAX Laser Systems

The following items are included in the shipping package for all GentleMAX laser systems. Each can also be ordered individually as replacement or spare parts.

Table 7-2: Laser Accessory Kit

Description	Quantity	Part Number
Laser Radiation Symbol Wall Sign	1	2157-40-5000
PF1 Eyewear 755/1064 OD7 CE	2	8095-00-0476
PF1 Operator's Manual	1	8501-00-1810
PF1 Treatment Guidelines	1	8502-00-0907
PF1 Software Treatment Guidelines Chart	-	8502-02-0907
PF1 HP Tool Window Extractor Tool	1	7122-00-9006
Cryogen Release Valve	1	3430-02-0010
Patient Goggles	1	8095-00-0470
Ship Material, Box, Acc. Lit, Sptl-1b	1	6510-01-0170
PF1 Window Assy	2	7122-00-3959
Warranty Registration Card	1	0920-25-0018
Laser Eyewear Selection Document	1	8502-00-0825
Candela Key Ring	1	1301-00-3409
Candela Service Information Label	1	2157-27-0100
Declaration of Conformity PF1	1	8501-00-1820
EC Certificate	1	8501-00-1521
My Candela Magnet	1	0920-25-0055
Candela Magazine Customer Letter	1	0920-25-0056
GMAX Laser Radation Wall Sign	1	2157-40-8148
Window Kit Assy	1	7122-00-1175

Table 7-2: Laser Accessory Kit

1.5/3 mm Distance Gauge Kit	5	7122-00-9045
6 mm Distance Gauge Kit	5	7122-00-9046
8 mm Distance Gauge Kit	5	7122-00-9047
10 mm Distance Gauge Kit	5	7122-00-9048
12 mm Distance Gauge Kit	5	7122-00-9049
15 mm Distance Gauge Kit	5	7122-00-9050
18 mm Distance Gauge Kit	5	7122-00-9051
Cryogen Coverage Template	1	1301-00-8291

Replacement or Spare Parts

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

Table 7-3: GentleMAX Laser Delivery System and Distance Gauge Kits

Designated Laser System	Description	Part Number
GentleMax	Two GentleMAX Laser Handpiece, Lens Cartridges, and matching Distance Gauges.	0800-00-1077
1.5 mm Lens Cartridge	1	7122-00-3947
3 mm Lens Cartridge	1	7122-00-3951
6 mm Lens Cartridge	1	7122-00-3948
8 mm Lens Cartridge	1	7122-00-3952
10 mm Lens Cartridge	1	7122-00-3949
12 mm Lens Cartridge	1	7122-00-3953
15 mm Lens Cartridge	1	7122-00-3950
18 mm Lens Cartridge	1	7122-00-3954
PF1 6-18 mm Delivery System	1	7122-00-3956
PF1 1.5/3 mm Delivery System	1	7122-00-4028

Table 7-4: Cryogen Packs

Description	Quantity	Part Number
Cryogen Canisters, 12 pack	1	1600-00-0212

Chapter 8: Service Internal Calibration Procedure

Topics described in this chapter include:

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

Warning: The electrical and laser radiation hazards present during servicing of the GentleMAX can be extremely dangerous if proper safety precautions are not taken. The GentleMAX is to be serviced only by qualified technicians who have received appropriate training from Candela. Any attempt by an unauthorized person to perform any service procedure will void any warranty on the laser system.

Calibration Schedule

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

Introduction

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

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

Parts List

The following parts are needed for the Calibration procedure.

1. Energy meter (OPHIR with L40 (150)A head).
2. Delivery System with known good transmission (85%).
3. 10mm Lens Cartridge with clean windows.

Warning: Make sure all personnel in the area are wearing safety eyewear appropriate for the GentleMAX Laser System.

Improper internal calibration of this laser system will cause delivery of lower or higher fluences and potential burning of patients. This procedure must be followed precisely for proper results. If the "Final verification of User Calibration Energy" section fails, contact Candela Technical Support for further information.

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

Internal Calibration

This section describes the internal calibration procedure.

Starting the Circuit Calibration Procedure

1. Install the delivery system with a 10 mm Lens Cartridge and Distance Gauge.

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

2. Go to the Main Screen. Set the DCD Spray to Off.

3. Press and hold the wrench/file icon for a few seconds until a keyboard shows up on the screen. Enter the code 882347 to go to the Circuit CAL screen. Note that other Maintenance Mode tab selections are grayed out providing no access to their functionality.

Laser Energy Circuit CAL

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

1. Put on GentleMAX laser safety eyewear.

Warning: The laser will enter the READY mode for the entire calibration procedure.

2. Press the **Cal ALEX** button to begin the Circuit CAL. A message will appear on the screen: "Are you sure you want to calibrate the Energy Circuits? All factors reset when initiated". Press "Yes" to initiate the Energy Circuit calibration and the laser will enter the READY State.

Warning: Once the calibration is initiated, the Laser Energy must be calibrated correctly and successfully completed in order to use the laser for treatments.

3. Carefully follow the prompts at the bottom of the screen.

   - There are two typical prompts displayed:
   - **Pulse HP in OPHIR. Pulse Laser and Enter Ophir Data**. This means you should aim the Handpiece (HP) to pulse the laser into the external Ophir meter head and then enter the Ophir energy using the keypad that will pop-up after the first laser pulse.
   - **Pulse HP in Calport**. This means you should insert the Handpiece in the Calibration Port and then pulse the laser.

   - Make sure that you wait sufficient time (at least 3-5 seconds) between pulses to allow the software to measure the energy properly.
   - The laser software will automatically set internal parameters and prompt the technician to pulse the laser while directing the Delivery System output into the Ophir meter or the Calibration Port as the calibration progresses. When pulsing into the Ophir, a keypad will pop up so that the technician can enter the Ophir reading (If the Ophir doesn't read any energy, then enter a "0".) All entries into the pop up keypad must be entered in Joules (J). The keypad has a fixed decimal point and accepts entries as follows:

   - **Example 1:** If the meter is reading 0.769 J, the technician will enter 769 into the keypad. This will appear as 0.769 on the keypad.
   - **Example 2:** If the meter is reading 4.35 J, the technician will enter 4350 (must add the "0" at the end to make it J). This will appear as 4.35 on the keypad.

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

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

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

6. Press CAL YAG and repeat Steps 2-4.

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

Final Verification of User Calibration Energy

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

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

2. Complete the appropriate Calibration Tables using the specified spot size, fluence, and pulse width (See **Table 8-1** and **Table 8-2**). After each Calibration, pulse 3 times into the Ophir meter. Record each Ophir energy reading.

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

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

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

Table 8-1: Calibration Table (Alex Laser Mode)

6mm, 20 J/cm^2, 0.35 ms Expected Energy = 5.7 J		**15mm, 30 J/cm^2, 20 ms Expected Energy = 53 J**	
Pulse #	**Ophir Energy (J)**	**Pulse #**	**Ophir Energy (J)**
1		1	
2		2	
3		3	
Average (J)		Average (J)	
Percent Difference (%)		Percent Difference (%)	

Table 8-2: Calibration Table (YAG Laser Mode)

6mm, 20 J/cm^2, 0.35 ms Expected Energy = 5.7 J		**15mm, 30 J/cm^2, 20 ms Expected Energy = 53 J**	
Pulse #	**Ophir Energy (J)**	**Pulse #**	**Ophir Energy (J)**
1		1	
2		2	
3		3	
Average (J)		Average (J)	
Percent Difference (%)		Percent Difference (%)	

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

Appendix A: Cleaning the Distance Gauge

Proper cleaning of the GentleMAX Distance Gauge is critical for the patient. This Appendix provides details for the proper cleaning and maintenance of Distance Gauges.

Cleaning the Distance Gauge

Laser energy is delivered to the treatment spot at the tip of the Distance Gauge. While the tissue absorbs most of this energy, a portion of it is reflected, like a mirror, back from the tissue to the Distance Gauge. This reflected energy will heat any treatment debris that can be found on the Distance Gauge itself. Continued absorption of laser energy by the debris will result in burning the debris onto the Distance Gauge and window, making it difficult to remove and shorten the life expectancy of the Distance Gauge and/or window. the Distance Gauge and window itself can also become hot, causing potential damage to the Distance Gauge, slider, fiber, and Handpiece assembly. In an extreme case, heat could result in burning the Distance Gauge.

Determining if Debris is Absorbing Energy?

Normal pulsing of a laser will result in a colored light being observed in the patient contact area and the area of the posts of the Distance Gauge. The light you see is not laser light; that is blocked from your view by the safety eyewear. The colored light you observe is the from the flash lamp within the laser and is a by-product of creating laser energy. When a Distance Gauge contains excessive debris build-up, a bright flashing may be encountered. This bright white light is the result of laser energy striking the debris and combusting. If the debris on the Distance Gauge is allowed to continue to build-up, the white light will become larger and brighter.

Reducing Debris Buildup

- You must 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 windows.
- If you use a topical anesthetic, remove it completely by washing with soap and water or witch hazel. The skin must be completely degreased.
- You must utilize a **“swipe clean cycle”** every 40-50 laser pulses. It is easier to prevent debris buildup by consistently wiping clean the Distance Gauge during a procedure than trying 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.

Performing the Swipe Clean Cycle

You must perform the “swipe clean cycle” every 40-50 laser pulses. When you become familiar with the process, it will become integrated into your normal laser pulsing routine and rhythm. It is not a timely interruption to your routine.

After approximately 40-50 pulses (sooner if you detect significant flashing), or if you note additional debris buildup, swipe a paper towel or piece of gauze moistened with warm water across the patient contact surface of the Distance Gauge tip or ring. As the towel passes across the surface, allow your index finger to push into the ring slightly and rotate. You will be cleaning a portion of the inner surface of the ring. Continue the treatment. This step takes about one second and represents minimal interruption to your treatment routine.

Performing a Full Cycle Clean

After each individual patient treatment, put the Distance Gauge aside for a full cycle clean as described in this section.

- Prepare a soaking container with chlorine bleach suitable for disinfecting and cleaning. Note that the BLEACH used 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 (1 part bleach, 9 parts water.)
- Put the complete Distance Gauges into the container with the bleach/water mix and soak overnight.
- Wearing gloves, scrub all surfaces of the Distance Gauge body with a toothbrush and rinse with clean water.
- Allow the Distance Gauge to air dry.

Following these instructions will maximize the life expectancy of your Distance Gauges. The care and precautions you take will mean the difference between using the Distance Gauges a few hundred pulses or for months of use. Refining and optimizing your techniques make the difference.

Reminders

- Always shave the treatment area - no stubble.
- Use the swipe clean cycle every 40-50 laser pulses.
- Use the Distance Gauge on a single patient followed by a full cycle clean.

Taking shortcuts in the above procedures will result in reduced efficacy and increased costs operating your hair removal laser.

Appendix B: Electromagnetic Compatibility

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

Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

For more information regarding the aforementioned notices, refer to the Declaration of Conformity and EMC Guidance (8501-00-1820) included in your accessory kit.

Warning: The use of accessories, transducers and/or cables other than those specified, with the exception of those sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity of the GentleMAX Laser System.

The GentleMAX Laser is EMC compliant with the following accessories:

- Optical delivery system
- Pneumatic footswitch

Warning: The GentleMAX Laser System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the GentleMAX Laser should be observed to verify normal operation in the configuration in which it will be used.

- The Candela SmoothPeel and Lightstation Products are designed to be stacked and operated on top of the GentleMAX.

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

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

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Accompanying Documents. Refer to accompanying Declaration and EMC Guidance Document (Candela Part Number 8501-00-1820) in the Accessory Kit shipped with the laser for additional information and guidance.

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

If interference from the GentleMAX 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 Laser System or the affected equipment into another room.

Table B-1 lists the system specifications of the GentleMAX Laser System.

Table B-1: Compliance per IEC/EN60601-1

Protection	**Specification**
Type of protection against electric shock	Class 1 equipment
Degree of protection against electric shock	Type “B”
Sterilization method	None required
Ingress Protection	Ordinary enclosed
Not “AP” or “APG” equipment	

Regulatory Classifications

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

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

Candela Family of Pulsed Lasers complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated July 26, 2000

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

Index

W