CANDELA

AlexTriVantage™
Operator's Manual

AlexTriVantage™

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Candela Corporation

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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

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Preface

Welcome to the Candela Corporation's *AlexTriVantage 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.

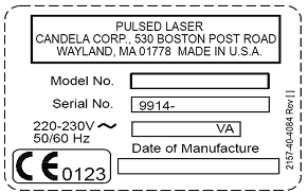
General Safety Statements and Guidelines

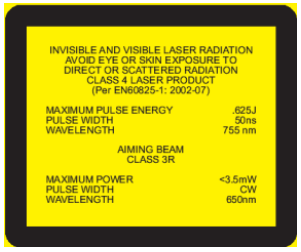
Routine Maintenance

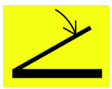
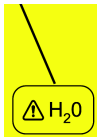
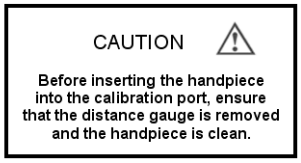
Only qualified personnel who are fully informed of the system's safety hazards should operate, maintain, and troubleshoot this equipment.

Definitions of Symbols (Labeling on the Equipment and Location)

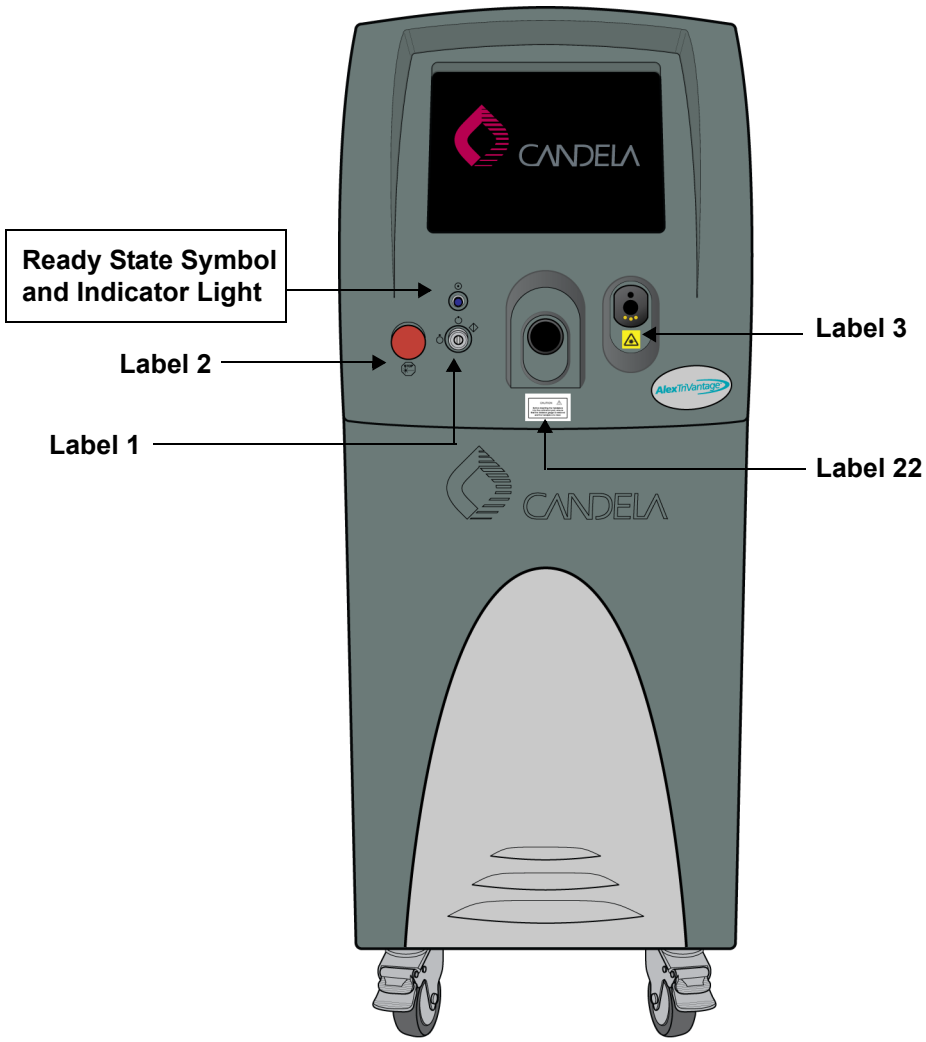
This section details the meaning, intent, and location of the labels (containing symbols) that appear on the AlexTriVantage Laser System.

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 and 19:** 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 5:** Identification Label indicates manufacturer's information, date of manufacture and power requirements of the device.

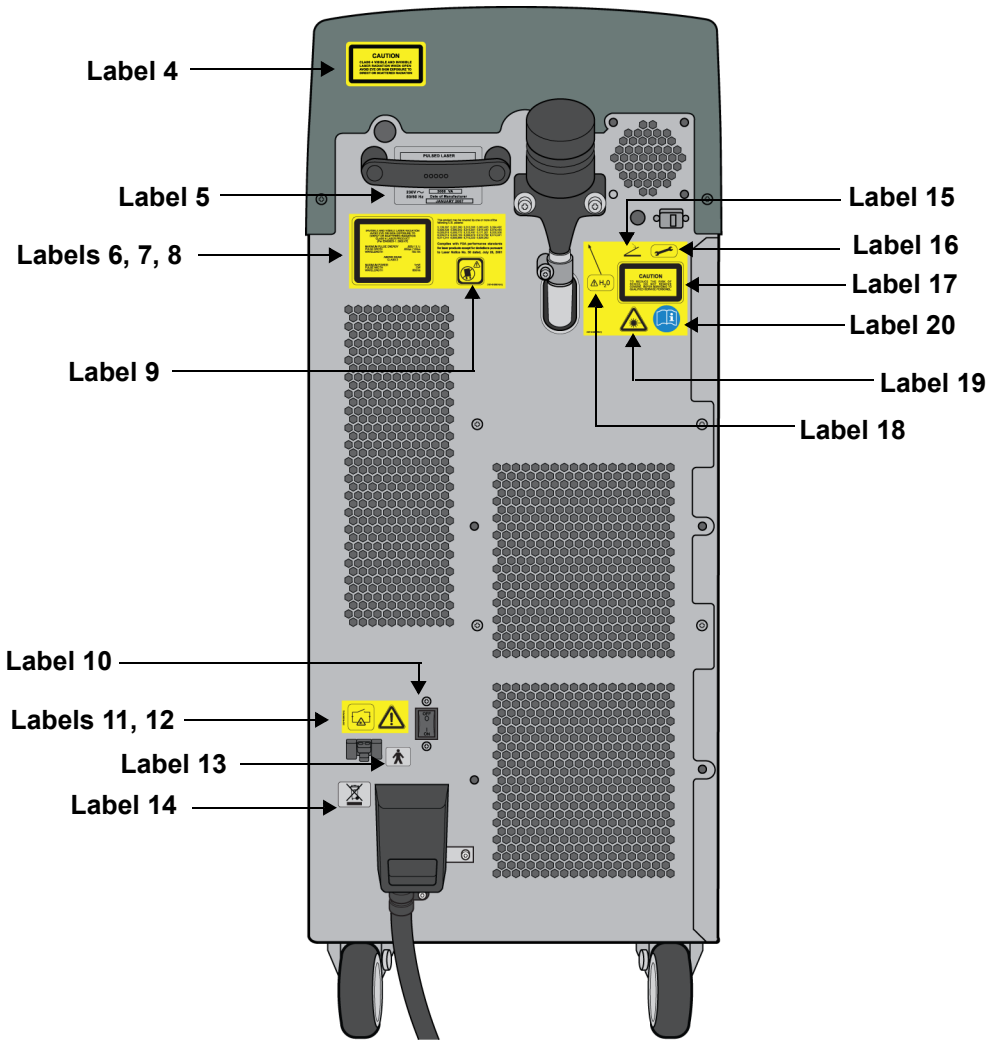
Label	Description
	**Label 6:** Indicates laser emission characteristics and classification per the IEC/EN standards.
This product may be covered by one or more of the following U.S. patents: 5,109,387 5,287,380 5,312,395 5,360,425 5,394,492 5,598,426 5,599,342 5,810,801 5,814,040 5,979,454 6,026,816 6,059,772 6,120,497 6,171,301 6,200,308 6,235,015 6,248,103 6,364,872 6,512,782 6,514,241 6,514,244 6,659,999 6,743,222 6,829,260	**Label 7:** Indicates U.S. patents that may be covered on this laser system.
Complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice No. 50 dated, July 26, 2001	**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 9:** 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.
O	**Label 10:** Main Power Switch - OFF position.
|	**Label 10:** Main Power Switch - ON position.
	**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 12:** 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 13:** IEC Type B Applied Part symbol. Provides delivery system information. The icon of a man indicates that the delivery system is equipped with a “Type B” applied part.
	**Label 14:** Waste Electrical and Electronic Equipment symbol. Indicates that the AlexTriVantage laser system and its components cannot be disposed of as regular trash. Contact Candela for disposal information.

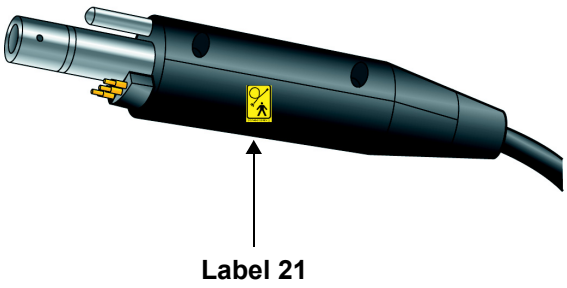
Label	Description
	**Label 15:** Footswitch Connection. Indicates the location of the Footswitch connection on the rear of the laser system.
	**Label 16:** USB Software Upgrade Port. Indicates the location of the USB port on the rear of the laser system. Contact Candela Clinical Sales or Service for the latest software upgrades.
	**Label 17:** CAUTION: Risk of electrical shock if laser covers are removed or serviced by unauthorized persons. There are lethal voltages inside the system enclosure.
	**Label 18**: Water reservoir. Indicates that the reservoir should be filled with deionized or distilled water. The reservoir should be filled approximately once a week.
	**Label 20**: Refer to the Operator's Manual for the safe use of this device.
	**Label 21:** 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 22:** CAUTION: Remove the distance gauge before inserting the Handpiece into the Calibration port.

Front Panel Labels



Rear Panel Labels





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: Pre-Treatment Visit**
  This section provides pre-treatment visit guidelines.

- **Appendix B: Treating the Patient**
  This section provides guidelines on treating the patient.

- **Appendix C: Post-Treatment Care**
  This section provides post treatment information.

- **Appendix D: 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:

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Overview

This chapter provides a a brief introduction to the Candela AlexTriVantage 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.

Laser Treatment of Skin Pigmentation Abnormalities

The Candela AlexTriVantage Laser system is a flashlamp excited, Q-switched Alexandrite laser designed for the treatment of tattoos, benign cutaneous pigmented lesions, Nevus of Ota and lesions like Nevus of Ota. Blue, green and black pigments respond best to treatment, whereas other pigments show more variable response and test spots are recommended.

With the 755 nm nominal wavelength, laser irradiation is selectively absorbed by the targeted pigment with minimal effect on the surrounding tissue. This is accomplished by careful selection of the wavelength that yields maximum absorption by the target and minimum absorption by surrounding skin structures. In addition, the laser pulse duration is controlled to be equal to or shorter than the thermal relaxation time of the target, to minimize heat transfer to surrounding tissues. This principle was first described by Anderson and Parrish.

Tattoo pigments vary in composition depending on the color of the tattoo and its origin (amateur, professional, or traumatic). Ideally, the wavelength selected for eradication of the tattoo should be highly absorbed by the tattoo pigment and only minimally absorbed by other chromophores in the skin. Absorption of radiation by most pigments in amateur and professional tattoos is strong in the near-infrared region of the spectrum. Melanin has a very broad absorption band throughout the ultra-violet, visible, and near-infrared regions of the spectrum, with absorption of light greatest in the ultraviolet, and least in the near-infrared. Other chromophores in the skin, such as hemoglobin and oxyhemoglobin, have little to no absorption of light within the selected wavelength.

The 755 nm nominal wavelength of the AlexTriVantage Laser has been carefully selected to utilize the difference in absorption for the treatment of dark tattoo pigments. Treatment of tattoos can therefore be performed with minimal adverse effects on normal skin structures.

The laser pulse duration should be shorter than the thermal relaxation time of the target absorbing the laser radiation to confine the thermal damage and spare surrounding skin structures. The relaxation time of a target is determined by its size. In the case of tattoos, the targets are the solid pigment particles of the tattoo inks or dyes. The thermal relaxation time of these micron size absorbers is approximately one microsecond (Margolis, et al), and, according to selective photothermolysis theory, pulse durations as long as several hundred nanoseconds should be effective. However, experiments show that a greater effect is obtained by fragmenting the absorber into smaller particles so that phagocytes can more effectively dispose of the fragmented particulates after laser exposure. This fragmentation is accomplished by using pulse durations shorter than the upper limit predicted by selective photothermolysis theory. The shorter pulses instantaneously raise the temperature of pigmented structures to a very high level and cause fragmentation and further decomposition, a desirable effect in the treatment of tattoos.

The wavelength and pulse duration considerations outlined above indicate that the AlexTriVantage Laser is appropriate for treatment of tattoos. The wavelength of the AlexTriVantage Laser is about 755 nm, in the near-infrared region. It produces pulses approximately 50 nanoseconds in duration. The pulse energies it produces allows delivery of energies up to 625 mJ. Because the wavelength and pulse duration of the Candela AlexTriVantage Laser are closely controlled, treatment of tattoos can be achieved with minimal energy densities, reducing the possibility of adverse effects on adjacent normal skin structures.

Indications for Use

The Candela AlexTriVantage, Q-Switched Alexandrite Laser, is indicated for the treatment of tattoos or benign cutaneous pigmented lesions. The decision to treat with laser therapy should be based upon appropriate diagnostic evaluation and consideration of all patient factors.

Contraindications and Precautions

- Do not treat recently tanned skin. Blisters and hyper / hypopigmentation may occur. Allow tan to fade prior to treatment.
- With infected "target" tattoo site or adjacent areas
- With a personal history of skin cancer, such as melanoma.
- Accutane: Wait 6 months after the completion of Accutane therapy
- History of photosensitivity to infra red light..
- Pregnancy: Refer to Candela Corporation policy # 0920-23-0814.
- Seizure disorders :Do not treat patients with a history of light-triggered seizures.
- Medications and Supplements : Daily anticoagulation therapy, iron supplements, herbal supplements such as ginko, ginseng or garlic and fish oil supplements may bruise more readily.
- Photosensitizing Medications: Medications that induce photosensitivity or medications within or above the 755nm wavelength range. Refer to Candela Corporation Drugs That May Cause Photosensitivity. Stop the medication if possible for 3-5 days prior to treatment.
- Topical Medications and skin care products: Stop 72 hours pre and post
- HSV 1 & 2: Do not treat if active lesion(s) are present within the intended treatment area. Patients with a known history of frequent HSV 1&2 lesions should begin prophylaxis prior to treatment as prescribed by their healthcare provider.
- Poorly controlled Medical Conditions: These patients should be carefully evaluated by their healthcare provider for medical clearance.
- Active skin infection: Avoid treatment of open wounds and skin that is actively infected.
- Cold sensitivity: Use caution when treating patients with Raynaud's phenomenon.
- Keloid scarring: Perform test spots prior to treating larger areas.
- Implanted medical devices: Pacemakers, cardioverters and other implantable devices or fillers: consult healthcare provider.

Note: Safety and efficacy of treating a tattoo located in the facial area with the AlexTriVantage Q-switched Alexandrite Laser has not yet been determined by FDA review. Therefore, the AlexTriVantage laser system is not to be used in treating a tattoo located in the facial area.

Patient Selection

Candela's AlexTriVantage, Q-Switched Alexandrite Laser, is intended for the treatment of tattoos or pigmented lesions.

Tattoos

Blue, green, and black pigments respond best to treatment, whereas other pigments show more variable response and test spots are recommended. Different color tattoo pigments may respond at different rates so that some colored areas may require more treatments than others. In general, darker colors should be expected to respond more than lighter colors. Also, the denser the concentration of tattoo pigment, the greater the number of treatments required. Patients with previously treated tattoos can be candidates for selective photothermolysis therapy with this laser system. Tattoos that have not been effectively removed by other treatments may respond well to AlexTriVantage laser therapy, providing prior treatment modalities caused no excessive scarring or skin damage.

Pigmented Lesions

Pigmented lesions to be treated with the Candela Q-Switched Alexandrite Laser include, but are not limited to the following:

- Solar or Senile Lentigines
- Freckles (Ephelides)
- Café au lait
- Nevus of Ota, Ito
- Beckers Nevus

Epidermal lesions will usually respond in 1 to 2 treatments whereas dermal lesions will require multiple treatments. Patients with skin types 3 to 4 may experience hypopigmentation or hyperpigmentation initially after treatment but this is usually transient.

Warnings, Cautions, and Precautions

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

Warnings and Cautions

General Hazards

- **WARNING!** The electrical and laser radiation hazards present during servicing of the AlexTriVantage Laser can be extremely dangerous if proper safety precautions are not taken. Consequently, the AlexTriVantage Laser is to be serviced only by those qualified technicians who have received appropriate training on the AlexTriVantage Laser from Candela, and who are familiar with the safety considerations discussed in this section.
- **WARNING!** The AlexTriVantage 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 AlexTriVantage Laser is no exception. The potential hazards associated with the AlexTriVantage 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 Guide. 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, or Distance Gauge.
- **WARNING!** Always recalibrate the laser after fixing, cleaning, or replacing the Delivery System, Handpiece, or Distance Gauge. Failure to initiate a calibration after cleaning/ replacing the Handpiece, Distance Gauge, or Delivery System may result in the delivery of excessive laser energy.
- **WARNING!** Ensure that the spot size on the Handpiece matches the Handpiece size displayed in the Handpiece 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 not present! This may be an indication of a broken fiber optic. If the aiming beam is not present, replace the Delivery System. If this does not correct the problem, call 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 fiber installed and without having the proper protective eyewear on.
- **Caution!** Before the laser system is turned on, a Handpiece must be installed on the end of the optical fiber.
- **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 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!** Light energy emitted by the AlexTriVantage Laser lies in the invisible, near-infrared region of the electromagnetic spectrum. Use only safety eyewear that is known to have an optical density of 7.0 or more at 755 nm, the wavelength emitted by this laser system. 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 AlexTriVantage 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 half angle beam divergence for each Handpiece is shown in **Table 1-1**.

Table 1-1: Vision Hazards for AlexTriVantage Laser NOHD Zone

Spot Diameter (mm)	Beam Divergence Full Angle (radians)	NOHD (meters)
2 mm	0.23	41
3 mm	0.16	51
4 mm	0.12	77

  - **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, available from Candela 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 AlexTriVantage 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 AlexTriVantage 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 AlexTriVantage 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 AlexTriVantage 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 1-10**).
- **WARNING!** Although the AlexTriVantage Laser System is well balanced, it weighs more than 290 pounds (almost 135 kg) and may cause injury if proper care is not used when moving it. The system should always be moved carefully and slowly.
- **Caution!** To prevent the laser from moving, both front wheels must be locked. The lock wheels, step down on the tabs on the front of the wheels. To unlock, pull up on the extending tabs.

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:

  1. 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.
  2. 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.
  3. 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.
  4. This momentary, and possibly unnoticeable, ignition sets off a more significant flash fire. The fire then follows a path from the peripheral area of the oxygen enriched atmosphere towards the most oxygen enriched zone. This is generally the oxygen source (mask, cannula, endotracheal tube).
  5. 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.
  6. 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 AlexTriVantage Laser System can be extremely dangerous. The system should be serviced only by those qualified technicians who have received appropriate training on the AlexTriVantage 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 AlexTriVantage 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 D-1**.

- **WARNING!** The AlexTriVantage 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.

Precautions

General Precautions

To reduce the risk of shock, do not remove covers. Refer servicing to 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 AlexTriVantage 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

- 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 laser light escaping from the laser room.
- Restrict entry to the laser room when the AlexTriVantage Laser is in operation. Allow access to the laser room only to those personnel both essential to the procedure and well trained in laser safety procedures.
- Make sure that all laser room personnel are familiar with the laser system controls and know how to shut down the laser system instantly.
- 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 AlexTriVantage 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 AlexTriVantage 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 password protected Screen Lock Button on the Touch Screen/Display Panel 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 AlexTriVantage 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 left side of the control panel) is pressed, the AlexTriVantage laser is shut down immediately.

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

Screen Lock Button

When the Screen Lock button on the Touch Screen/Display Panel is pressed, a dialog box request if you want to lock the screen. Locking the screen prevents unauthorized use of the laser system.

Lock the screen by selecting the checkmark (confirm) in the dialog box. The system will be put into Standby and all screen buttons, except for the Screen Lock button itself, will be locked.

A Candela logo screen with a padlock and key button displays indicating the display is locked.

▸▸ For more information, see **"Screen Lock Button" on page 2-31**.

Lasing Beep Sound Alert

An audible beep sounds and 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 blue lamp mounted on the front panel (above the Keylock Switch) illuminates when the laser is in the Ready state. 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 2-13**

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. As a safety precaution, there is a delay of two seconds from the time that the system enters the Ready state to the time that the laser emission is enabled.

When the laser system is not being used, it should be returned to the Standby state. The laser will automatically revert back to the Standby state after 2 minutes of inactivity in the Ready state.

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 **“Calibration Button” on page 2-23** and **“Standby/Ready Button and Status Area” on page 2-23**.

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

Remote Interlock

An external connector for a remote interlock switch is provided on the rear panel of the system. It is located on the lower left side of the rear panel. 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 Interlock” on page 2-11**.

Chapter 2: Understanding the Laser

Topics described in this chapter include:

Introduction	**page 2-3**
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Front Panel	**page 2-5**
Touch Screen/Display Panel	**page 2-5**
Controls and Connections	**page 2-6**
Locking Wheels	**page 2-9**
Rear Panel	**page 2-10**
Main Power Switch and Power Cord	**page 2-11**
Remote Interlock	**page 2-11**
Water Receptacle	**page 2-11**
Footswitch Connector	**page 2-11**
USB Port	**page 2-11**
Handle	**page 2-11**
Delivery System	**page 2-12**
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Handpieces	**page 2-14**
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Fiber Pole	**page 2-16**
Cabling	**page 2-17**
Connecting the Handpiece to the Delivery System Cable	**page 2-17**
Connecting the Delivery System Cable	**page 2-18**
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Applications Menu	**page 2-20**
System Status Messages	**page 2-22**
Calibration Button	**page 2-23**

Standby/Ready Button and Status Area	**page 2-23**
Fluence Controls and Indicators	**page 2-26**
Pulse Duration Control	**page 2-26**
Spot Size Identifier Bar	**page 2-27**
Pulse Rate Control	**page 2-27**
Pulse Count and Pulse Count Reset Button	**page 2-27**
Treatment Summary Button	**page 2-28**
Screen Lock Button	**page 2-31**
Dialog Boxes	**page 2-33**

Introduction

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

The Laser System

Figure 2-1 shows the AlexTriVantage Laser system.

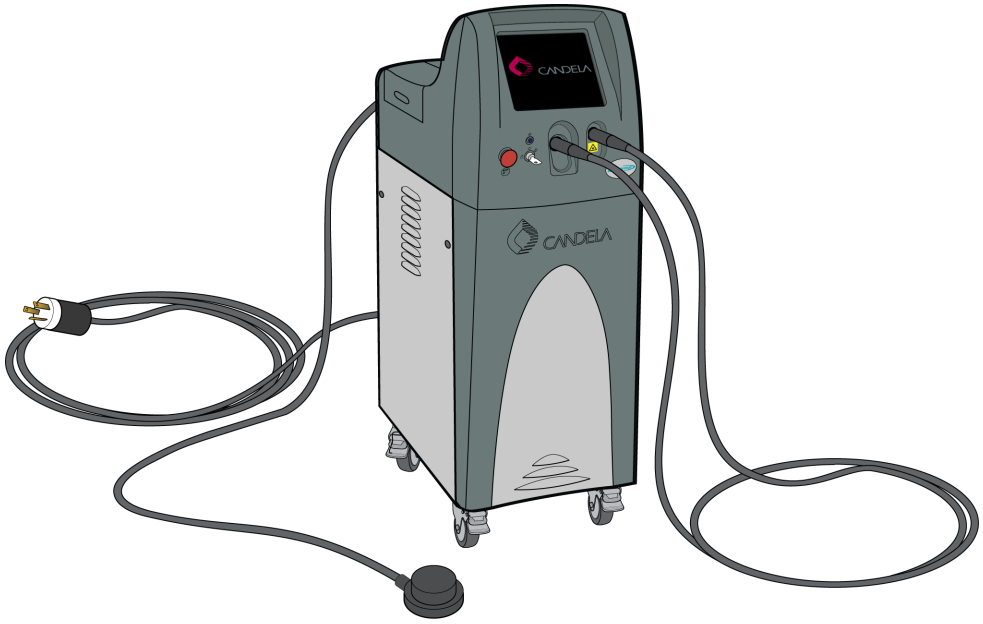


Figure 2-1: Candela AlexTriVantage Laser System

System Description

The AlexTriVantage Laser consists of an Alexandrite laser head, a Q-switching mechanism, a power supply and a deionized (or distilled) water circulator. The laser head contains the cavity mirrors, Pockels cell, solid state laser medium (the Alexandrite rod), and two high intensity xenon flashlamps which excite the laser medium. A calibration port with an internal meter is located on the control panel, which is used to verify the transmission of the optical fiber and Handpiece, and to calibrate the output of the Handpiece at selected fluence levels. The temperature of the laser head is regulated by the circulation of deionized (or distilled) water at a controlled temperature.

To provide energy to the flashlamps, a high voltage power supply charges a storage capacitor; a trigger pulse applied to the gate pins of four SCRs (high voltage switches) causes the capacitor to discharge through the flashlamp. The resulting flash excites the Alexandrite rod, causing the emission of a pulse of laser energy. A low voltage is supplied to the flashlamps to maintain ionization in the tubes. This "simmer" ionization is not sufficient to produce the optical gain required for laser output, but it improves the response time of flashlamps and extends their life.

A microprocessor based system controller is used to monitor and direct all system functions. Users of the laser 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 AlexTriVantage Laser system delivers laser energy at a wavelength of about 755 nm with a nominal pulsewidth of 50 nanoseconds. The output of this laser is delivered to the area of treatment by means of a lens coupled user replaceable optical fiber with a treatment Handpiece attached to its distal end. A trigger switch (footswitch) is used to control the delivery of pulses. The user may choose to deliver a single pulse each time the trigger switch is depressed, or pulses may be delivered repetitively as long as the switch is depressed, at repetition rates up to 5 pulses per second.

The AlexTriVantage Laser control panel enables the user to select the desired energy density (fluence) level and repetition rate. The control panel is also used to enable or disable the triggering of the laser, to initiate the calibration feature and to obtain feedback from the system, such as the number of pulses delivered or spot size selected.

Under CDRH regulations, the AlexTriVantage Laser is classified as a Class IV laser. Under the Medical Device Directive, the AlexTriVantage Laser is classified as a Class IIb, non invasive, active device. The electrical classification for the AlexTriVantage under EN 60601-1, with regards to protection from electric shock is Class 1 with a Type B applied part. Under EN60825-1, the AlexTriVantage Laser is classified as a Class 4 laser.

The laser system is equipped with interlocks that inhibit the lasing function if the remote interlock circuit is opened or parts of the delivery system removed.

Front Panel

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

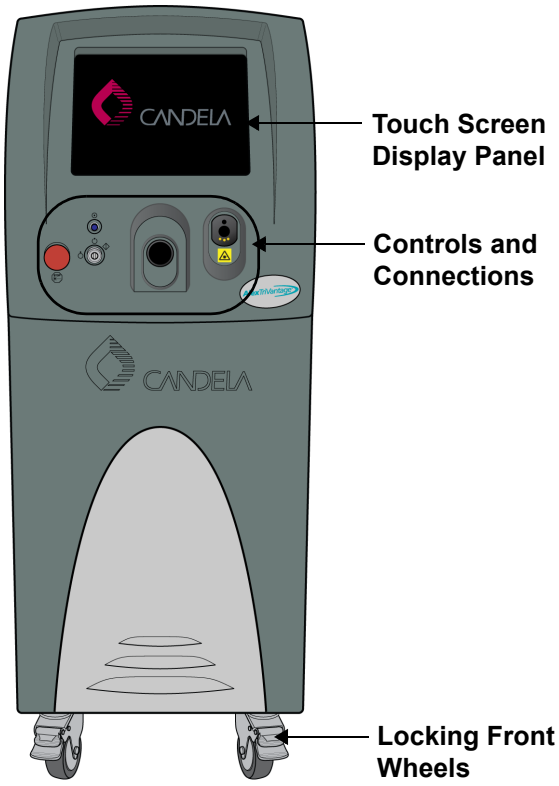


Figure 2-2: Front View of Laser System

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 for the operator. The operator uses this panel to set the operating mode and laser parameters. 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 2-19**

Controls and Connections

- **Figure 2-3** shows a detailed view of the controls and connections and a brief description of each one.

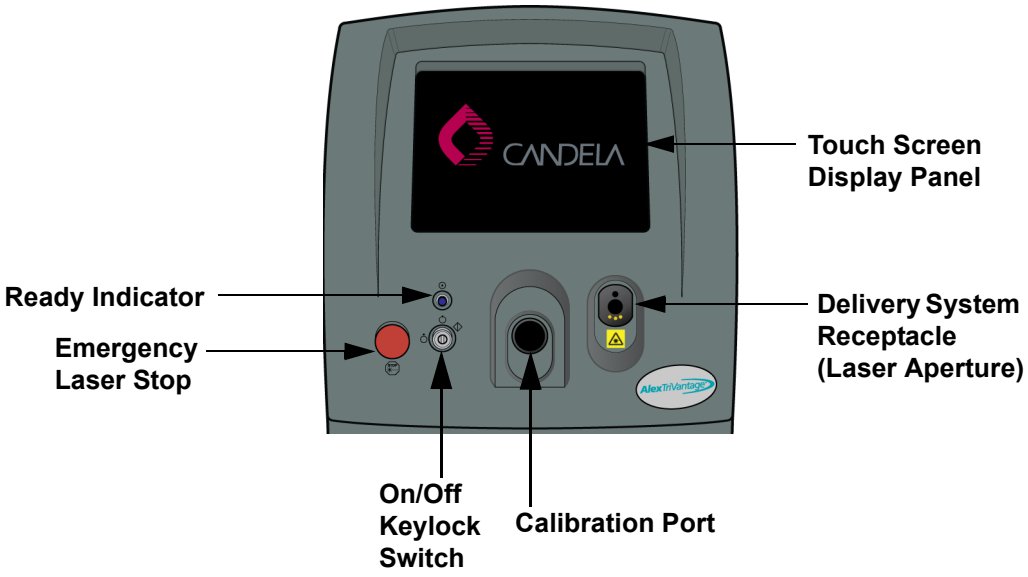


Figure 2-3: Controls and Connectors on the Front Panel

Ready Indicator

This indicator shows that the laser has been calibrated and is armed. It will remain in Standby (no energy will be released) until you press the Ready button and then press the footswitch.

Emergency Laser Stop

An emergency stop button. When this button is pressed, the AlexTriVantage Laser is shut down immediately. See **Figure 2-4** for a detailed view of the button:

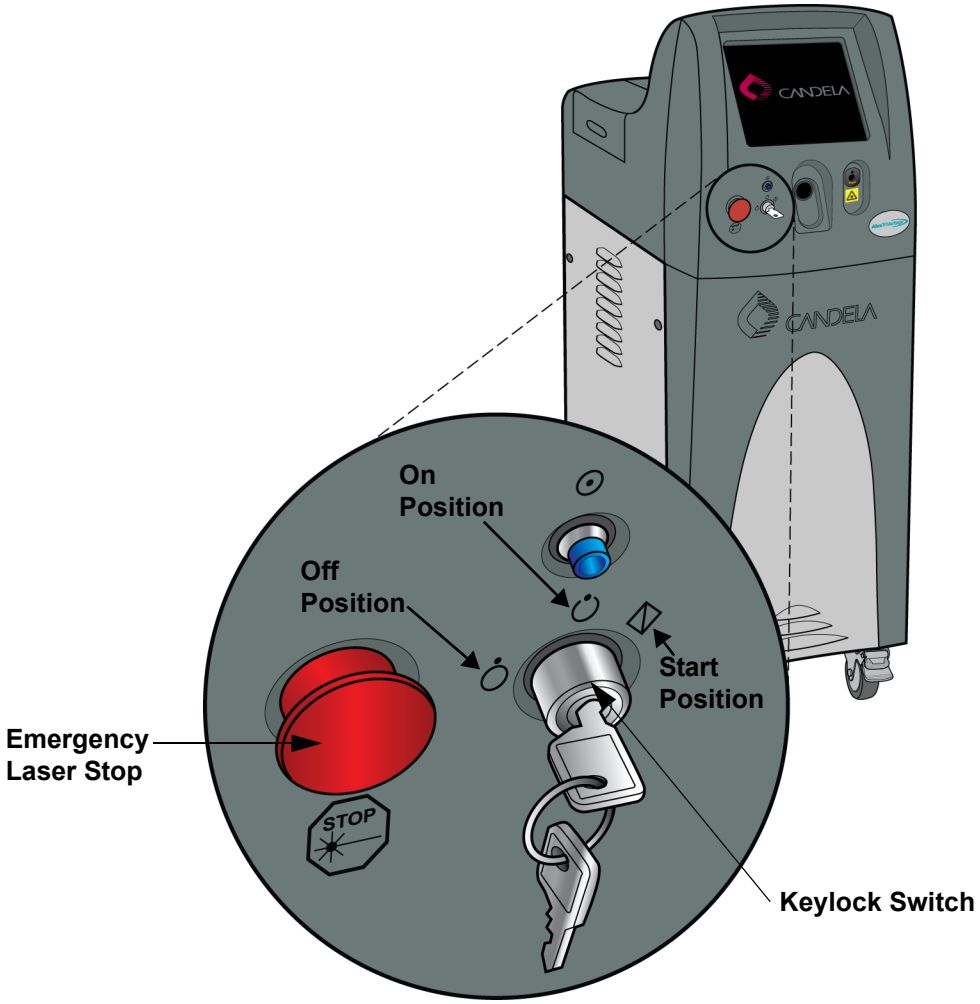


Figure 2-4: Keylock Switch Positions

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 	When the Keylock switch is in the Off position, all circuits are de-energized, except the Keylock switch circuit itself.
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.

▸▸ For more information on the Handpiece, see **"Delivery System" on page 2-12**.

Caution: Before inserting the Handpiece into the calibration port, ensure that the distance gauge is removed and the Handpiece is clean.

Delivery System Receptacle

This receptacle is used to connect the Delivery System Cable to the laser system. The Proximal end of the Delivery System cable is connected to this receptacle. This is a keyed receptacle so that the Delivery System cable cannot be installed incorrectly.

▸▸ For more information on the Delivery System cable, see **"Delivery System" on page 2-12**.

Locking Wheels

The AlexTriVantage 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 wheels provide a locking mechanism which prevent the wheels from swiveling or moving.

To lock the front wheels, use your foot to press down on the locking On level (see **Figure 2-5**).

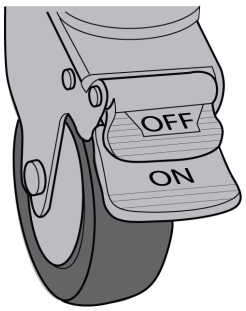


Figure 2-5: Front Wheel Locks

To release the wheel lock, either press on the Off level or put your foot under the On level and press up.

Rear Panel

Figure 2-6 shows the rear view of the AlexTriVantage Laser System.

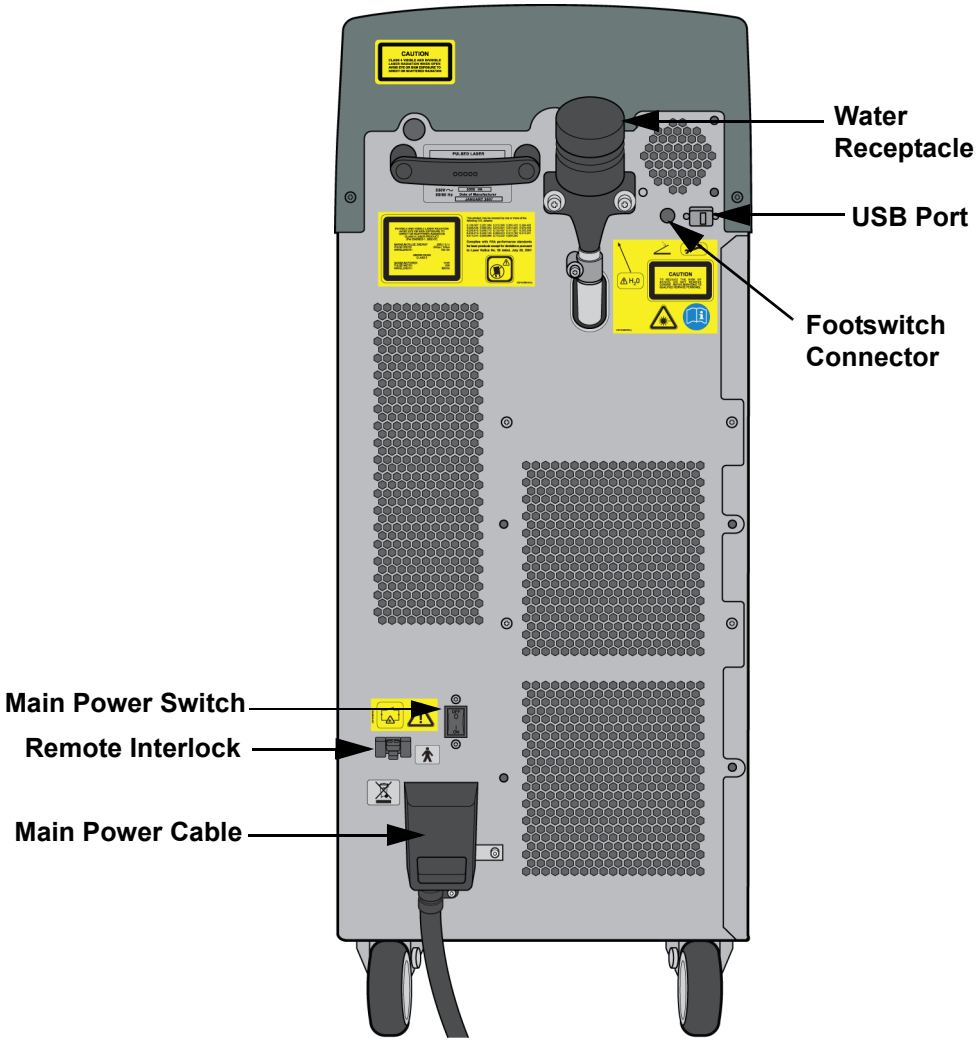


Figure 2-6: Rear View of Laser System

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

Main Power Switch and Power Cord

The main power switch (circuit breaker) and power cord for the laser system are located on the rear of the AlexTriVantage Laser system. The power switch must be in the ON position for the laser system to operate.

Typically, the power switch is left in the ON position, even when the laser is not in use. Energy is not delivered by the laser when the power is turned on. The Keylock Switch must be in the On position and the Ready button on the Touch Panel must be selected before laser energy is delivered.

The power cord is approximately 11 feet long with a locking NEMA L6-30P plug for power connection in the United States. The installation site required a mating NEMA L6-30R power receptacle located within 10 feet of the intended laser system location.

Remote Interlock

This connector allows for a remote interlock for safety. The cable plugged into the remote interlock is attached to a switch on the laser room door. If the door is opened when the laser is in the Ready State, the interlock causes the laser to revert to the Standby state

Water Receptacle

The laser head is cooled with deionized Water (DI) or distilled water, which is in turn cooled by ambient air passing through a heat exchanger.

The water receptacle holds about 3/4 of a gallon of DI water. Water should be refilled once a week through the vented cap.

▸▸ For more information on how to refill the water, see **“Maintaining the Water Cooling System” on page 4-5**.

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 **“Footswitch” on page 2-15**.

USB Port

The USB port is used for software updates to the AlexTriVantage Laser system.

Handle

There is a handle on the rear panel of the laser system to help you easily roll the system around on its wheels.

Caution: The handle is 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 Distance Gauge, and a Fiber Pole.

Figure 2-7 shows the Delivery System Cable. **Figure 2-8** shows the connectors on each end of the Delivery System Cable and the Handpieces and the Distance Gauge.

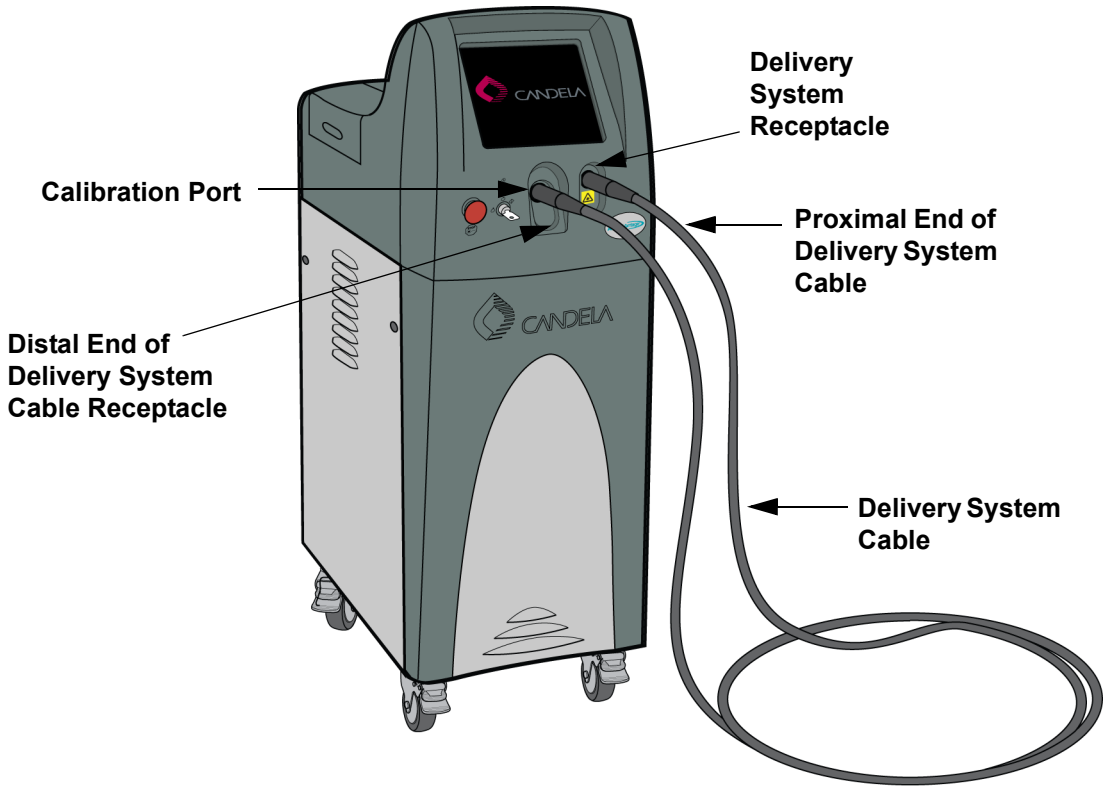


Figure 2-7: Delivery Cable System

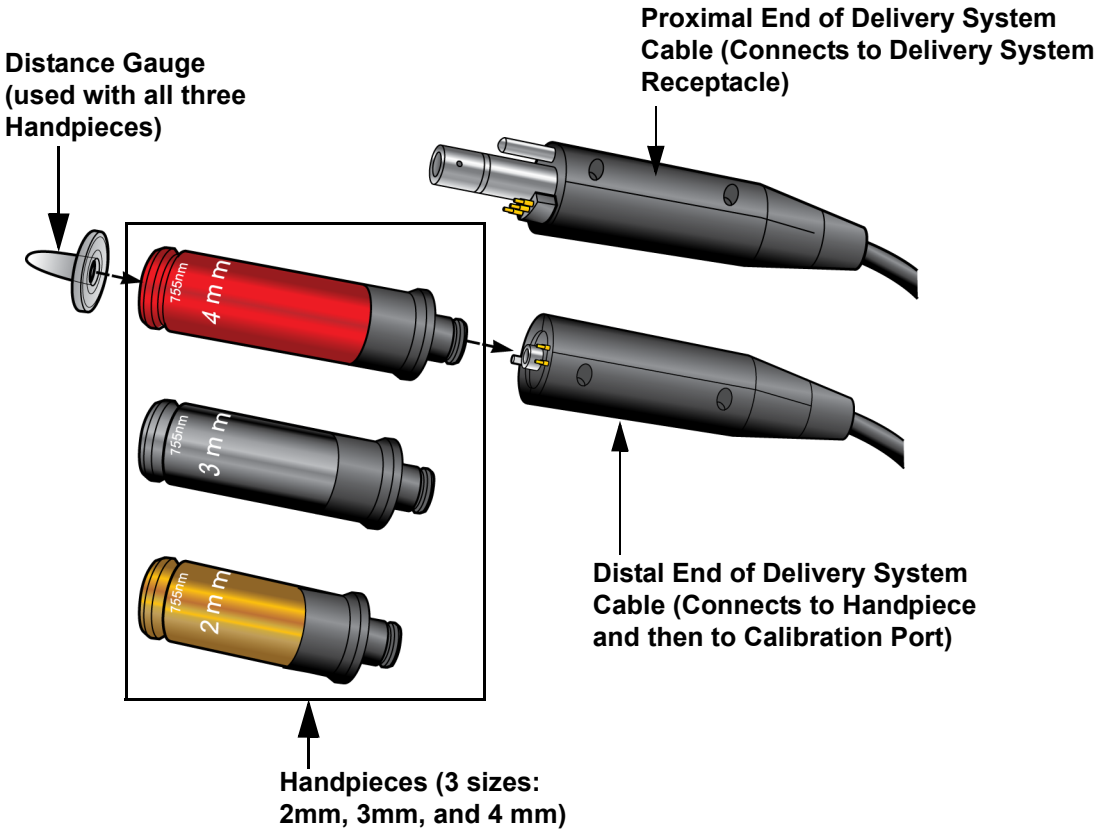


Figure 2-8: Delivery System Cable Connectors, Handpieces, and the Distance Gauge

Delivery System Cable

The output of the laser is delivered through this cable and an associated Handpiece and Distance Gauge.

The Delivery System cable is approximately 8 feet long. The Proximal end of the cable is connected to the Delivery System Receptacle on the front panel of the system. The Distal end of the cable is connected to one of the three Handpieces provided. The Distal end of the cable (with the Handpiece attached) is inserted into the Calibration Port to calibrate the laser before treating a patient. There is an Indicator on the Distal end of the Delivery System cable that indicates that the laser is armed and ready for use (see **Figure 2-9**).

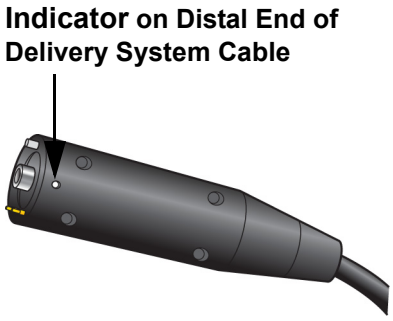


Figure 2-9: Location of Ready Indicator on the Delivery System Cable

Each end of the Delivery Cable system (and the associated connectors on the front panel) is keyed, so the cables cannot be connected incorrectly.

▸▸ For more information on connecting the cables, see **"Connecting the Delivery System Cable" on page 2-18**

Handpieces

The AlexTriVantage Laser System includes three color-coded Handpiece for different spot sizes (see **Figure 2-8**):

- 2mm - gold
- 3mm - black
- 4mm - red

A Handpiece is connected to the Distal end of the Delivery System Cable. The Handpieces are keyed so they can cannot be connected incorrect.

The Handpiece also has a Ready Indicator that is illuminated when the system is armed and ready to deliver energy to treat a patient.

Use the Treatment Guidelines to determine the Handpiece to be used for a specific treatment. The correct Handpiece is then connected to the Delivery System Cable. After the Handpiece is connected to the cable, it is inserted into the Calibration Port to calibration the laser before treatment. When the laser is successfully calibrated, the Handpiece is removed from the Calibration Port and the Distance Gauge is attached to it before the treatment begins. The Handpiece is inserted into the Calibration Port.

Distance Gauge

The Distance Gauge is the only part of the Handpiece that comes in contact with the patient (see **Figure 2-8**). It is used to ensure proper focusing and spot placement on the treatment area. It is used with all of the three Handpieces.

The Distance Gauge must be removed before the distal end of the Delivery System cable is inserted into the Calibration Port.

Footswitch

The energy is delivered through the laser when the Footswitch is depressed. The amount of energy delivered and the length and number of pulses delivered depends on the settings selected during setup. The Footswitch is connected to the Footswitch connector on the rear of the system. **Figure 2-10** shows the Footswitch.

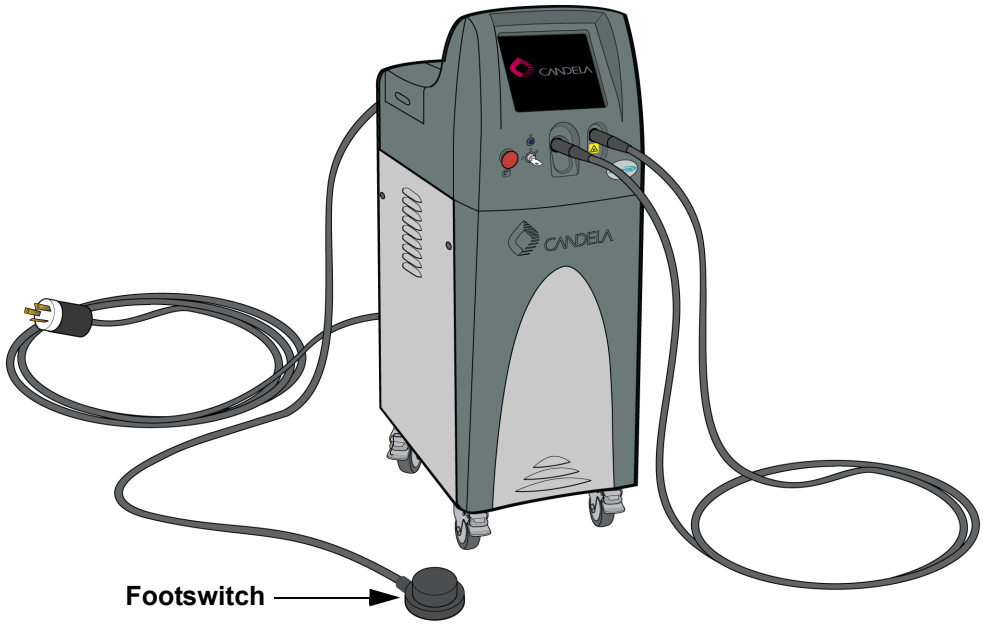


Figure 2-10: Footswitch

Fiber Pole

The optional Fiber Pole supports the Delivery System cable as shown in **Figure 2-11**. This device keeps the cable suspended and out of the way.

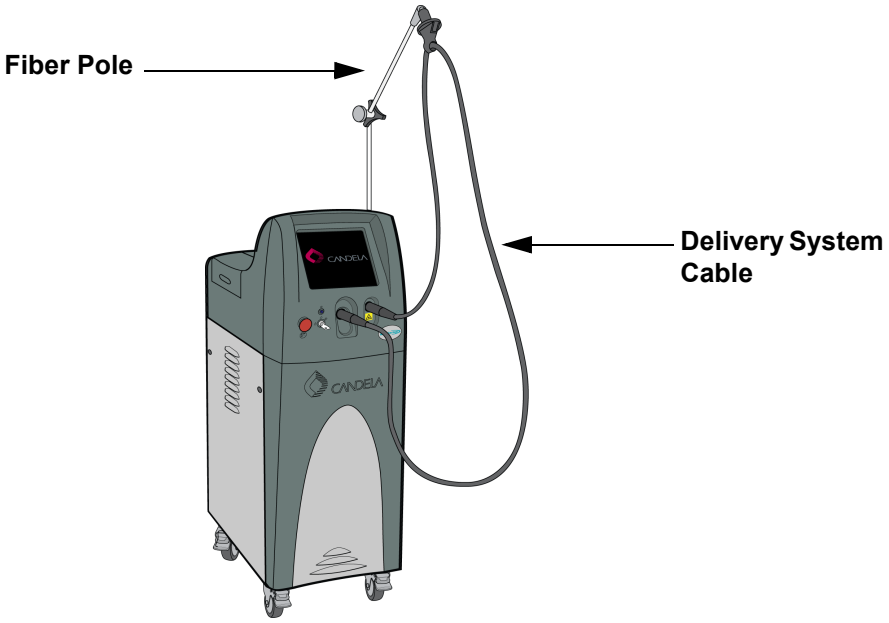


Figure 2-11: Fiber Pole

The adjustable Fiber Pole supports the Delivery System cable. This device will keep the cable suspended and reduce the weight of the Delivery System during use.

The Fiber Pole height is adjustable via the locking nut at its base at the top of the laser system. Once extended, the top part bends at 90 degrees and can be moved in a 360 degree motion. There is a bearing with a hook 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.

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.

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

Cabling

This section describes how to properly connect cables to the front and rear panels of the AlexTriVantage Laser System. **Figure 2-1** shows all cable connected to the system.

Connecting the Handpiece to the Delivery System Cable

Connect the Handpiece to the distal end of the Delivery System cable (see **Figure 2-12**). All three Handpieces connect in the same way.

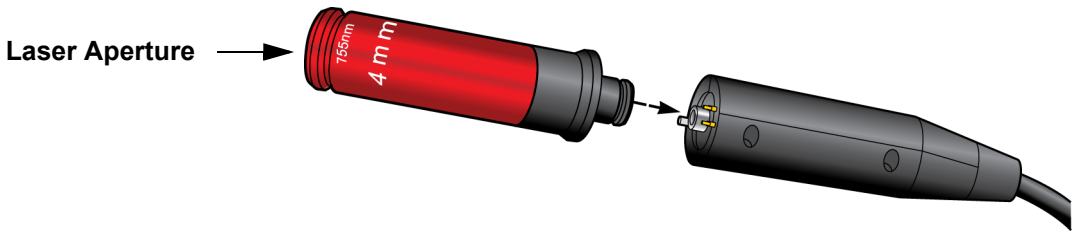


Figure 2-12: Connecting the Handpiece to the Delivery System Cable

The connectors are keyed and have orientation marks to help you align the connectors correctly.

The range for the Fluence parameter will be set up automatically based on the Handpiece that is installed.

Connecting the Delivery System Cable

Figure 2-13 shows how to connect the two ends of the Delivery System Cable to the front panel. Both connectors are keyed and have orientation marks, to ensure they are connected correctly.

One of the three Handpieces must be connected to the distal end Delivery System cable before it is inserted into the Calibration Port.

The Distance Gauge cannot be attached to the Distal end of the Delivery System cable when it is inserted in the Calibration Port.

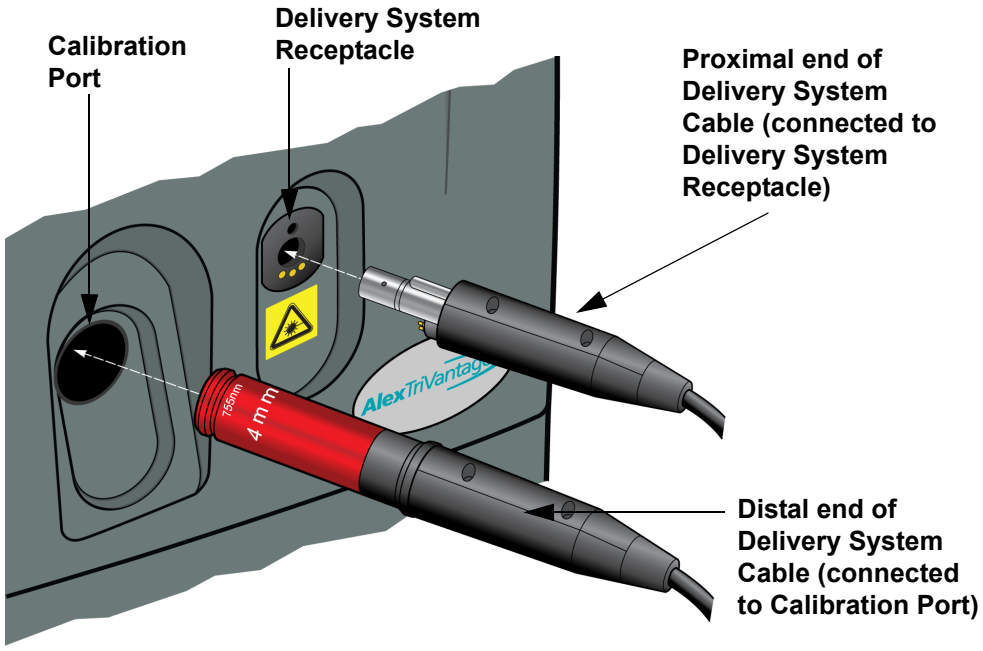


Figure 2-13: Cable Connections on the Front Panel

Touch Screen/Display Panel

This section provides an overview of the graphical user interface provided on the Touch Screen/Display Panel.

Figure 2-14 shows the main display screen:

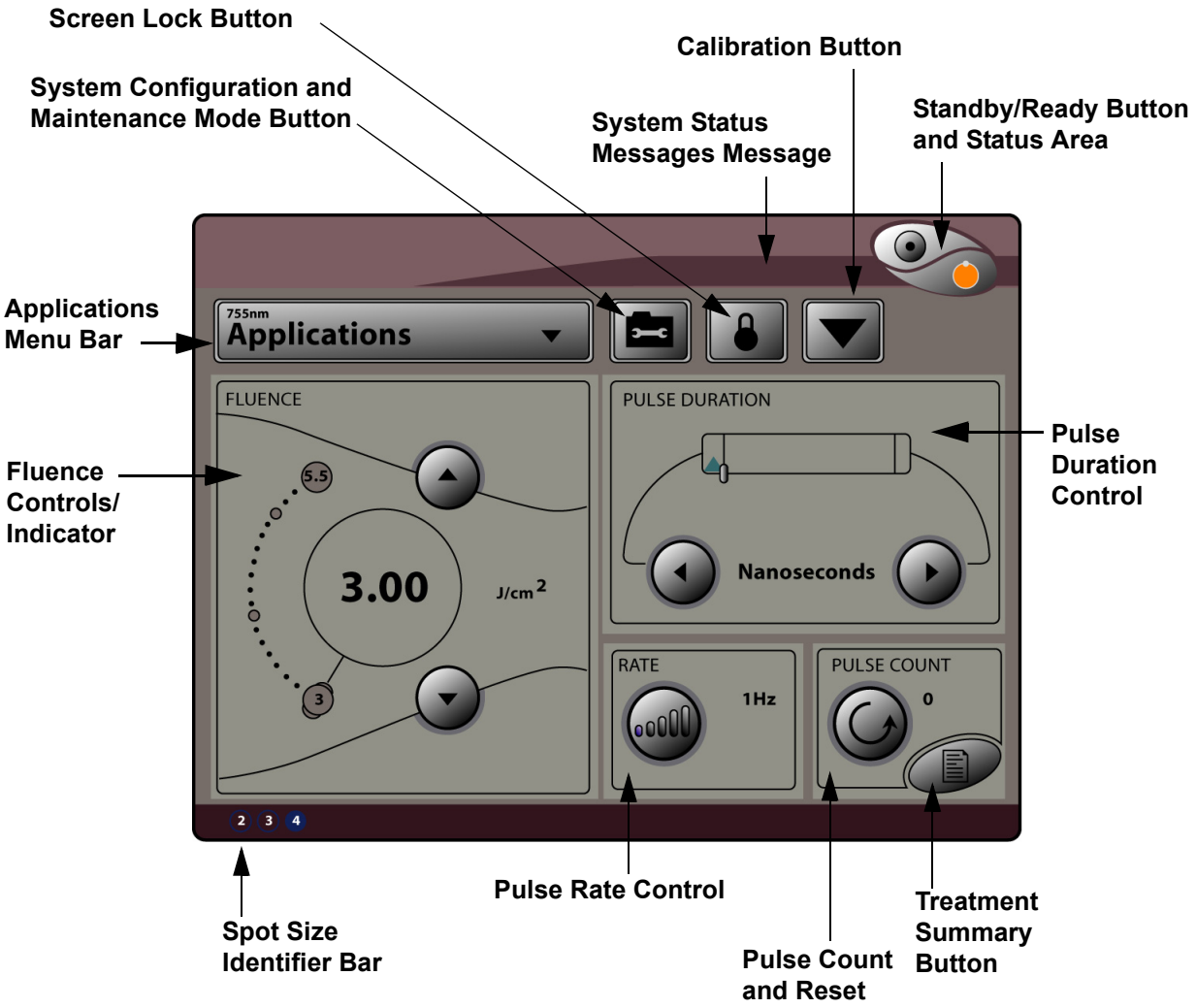


Figure 2-14: Touch Screen/Control Panel Main Screen

Applications Menu

Selecting the Applications menu displays a drop down menu with a list of Preset Treatment Parameters (see **Figure 2-15**). Each of these parameters are pre-programmed treatment applications based on the Candela Clinical Treatment Guidelines.

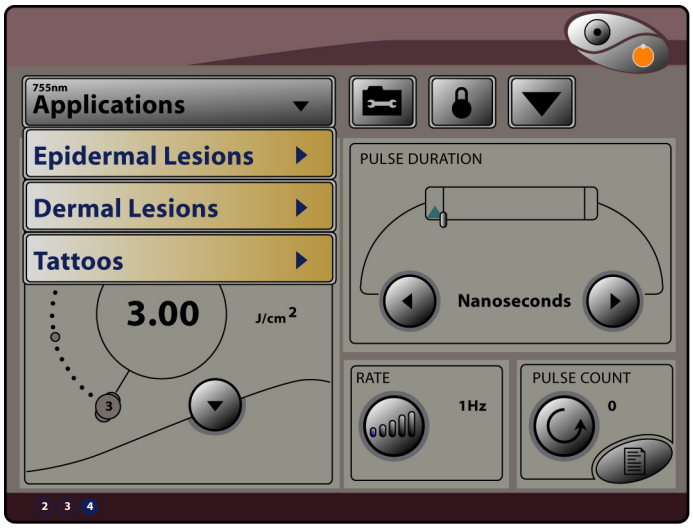


Figure 2-15: Applications Drop Down Menu

When you make a selection from this list, the selected application turns blue and a submenu with additional options will appear. The submenu also lists the spot sizes available for each treatment type.

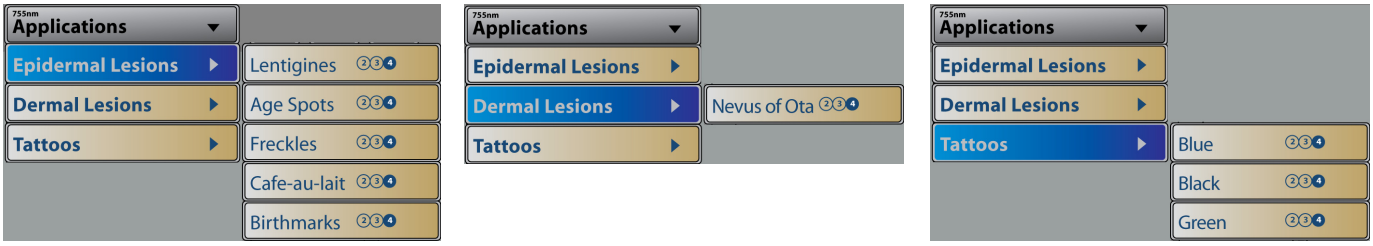


Figure 2-16: Applications Submenus

When you select the treatment option and install the selected Handpiece, the system will automatically set the operating parameters to the preset treatment parameters and will display the selected application on the Applications Menu Bar (see **Figure 2-17**).

If you select a treatment application before a Handpiece is installed, the “Install Handpiece” message displays on a dialog, indicating that you need to install a Handpiece.

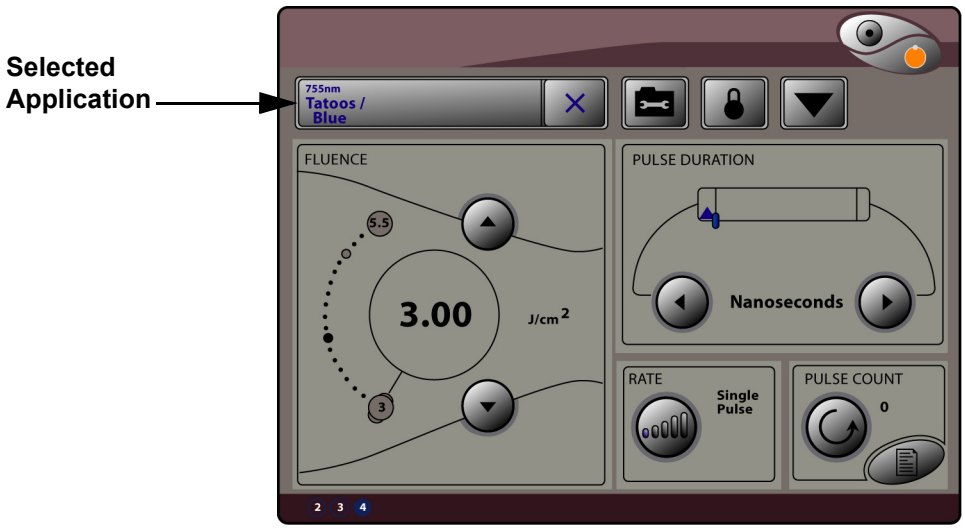


Figure 2-17: Example of a Selected Application

To exit the Applications menu or a submenu, select the Application Menu Bar, or press X next to the Application Menu Bar.

Refer to the Candela Clinical Treatment Guidelines (**“Candela Clinical Treatment Guidelines” on page 2-22**) 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, one the Touch Panel/Display Panel, 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 Guide.

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 AlexTriVantage laser. Each treatment application has its own set of starting operating parameters. If needed, each operating parameter can be adjusted by pressing the up and down buttons to adjust the value to the desired setting. If questions arise or additional information about a treatment application is needed, refer to the Candela Clinical Treatment Guidelines (Candela P/N # 8502-00-0843) for laser treatment guidelines or contact Clinical Support for additional information. Refer to **"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.

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 Messages

System messages, such as Needs Calibration, Ready, Standby, etc. are displayed in this area.

Calibration Button

The Calibration button is used to place the system into the Ready state and to begin the calibration process (see **Figure 2-18**).

Figure 2-18: Calibration Button

The Handpiece must be inserted into the Calibration Port before calibration can take place. If the Handpiece is not installed, a dialog appears prompting you to install it. If the Handpiece is in the Calibration Port, the system prompts you to press and hold the Footswitch. The action starts the calibration.

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

When you enter Ready state, the System Indicator displays the Ready status (green) and the Ready Indicators above the Keylock Switch and on the Delivery System Cable are illuminated.

You must perform a calibration when you start the system and anytime you change the Handpiece. 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.

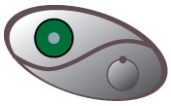
Standby/Ready Button and Status Area

This control is located in the upper, right corner of the screen. It allows you to toggle between the Ready and Standby state and it also shows the status of the system.

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 2-25**).

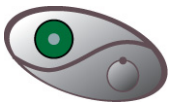
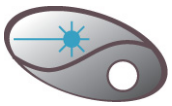
Table 2-2: Standby/Ready Button Functions

Button	Description
Ready 	**Caution:** Do not enter the Ready state without a fiber installed and having the proper protective eyewear on. 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. When the system enters the Ready state, the Ready button displays in green and the Ready Indicator on the front panel and the Delivery System Cable Indicator are illuminated. Select the Ready button to begin treatment after all of the following events have occurred: • The Handpiece has been calibrated, if needed. • The Handpiece has been removed from the Calibration Port. • The Distance Gauge has been installed. 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 	Select the Standby button (the lower right button) to place the system in Standby. The laser is disabled when the system is in Standby. When you select Standby, the Standby button displays in yellow. The system automatically reverts to Standby when the laser remains idle in the Ready state for more than 2 minutes. Select to Standby button when a treatment session is complete, before you remove the Distance Gauge and 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 2-23**).

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 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.
Ready 	When the Ready button is green, the system is in the Ready state. When Ready, the laser is armed and ready for use. Laser energy will not be emitted until you press the Footswitch while the system is in the Ready state. The Ready Indicator above the Keylock Switch and the Indicator on the Delivery System Cable are also illuminated when the system status is Ready.
Lasing 	The Standby/Ready button displays the Laser symbol when the laser is pulsing. This symbol appears when you press the Footswitch to begin laser treatment. The symbol displays while the Footswitch is depressed. When the Footswitch is released, the system reverts back to the Ready state and the Ready button is green.

Fluence Controls and Indicators

The Fluence parameter specifies the amount of energy (in Joules) delivered to the treatment spot size (in cm). The Fluence setting is adjustable in increments of 0.25J/cm^2 between the lower and upper Fluence values for each spot size and duration.

To change the Fluence setting, select the up and down arrows (see **Figure 2-19**). The Fluence defaults to the lower setting for the selected spot size.

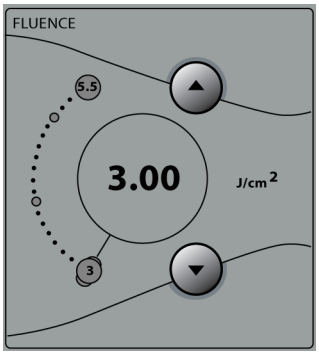


Figure 2-19: Fluence Control

Pulse Duration Control

The Pulse Duration parameter is the duration of the pulse delivered to the patient (see **Figure 2-20**). The buttons are inactive for future use.

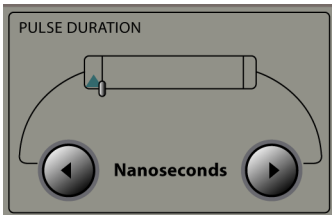


Figure 2-20: Pulse Duration Control

Spot Size Identifier Bar

A bar on the bottom left side of the main screen identifies the spot size selected, based on the Handpiece that has been connected to the Deliver System cable. The selected Spot Size is highlighted in blue on the Spot Size Identifier Bar (see **Figure 2-21**)

Figure 2-21: Spot Size Identifier Bar

Pulse Rate Control

The Pulse Rate controls the number of times the laser will pulse each time the Footswitch is depressed.

To set the Pulse Rate, select the Rate button (see **Figure 2-22**). You can select Single or a number between 1 and 5. The number of pulses selected is indicated with blue highlighting on the bars on the on the Pulse Rate button.

In Single Pulse mode, the laser will pulse once for each depression of the Footswitch. If you select a number between 1 and 5, the laser will pulse the selected number of times for each depression of the Footswitch. For example, if you press 3, the laser will pulse three times for each depression of the Footswitch, while if you press 4, the laser will pulse four time for each Footswitch depression.

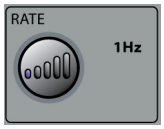


Figure 2-22: Pulse Rate Control

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 2-23**). In this example, no pulses have been delivered.

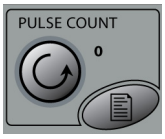


Figure 2-23: Pulse Count and Reset Button

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 for at least two seconds. The system responds by setting the Pulse Count value displayed back to zero.

Treatment Summary Button

The Treatment Summary table displays the number of laser pulses and the operating parameters used for the last six parameter changes.

Select the Treatment Summary button (see **Figure 2-24**) to display the Treatment Summary Table (see **Figure 2-25**).

Figure 2-24: Treatment Summary Button

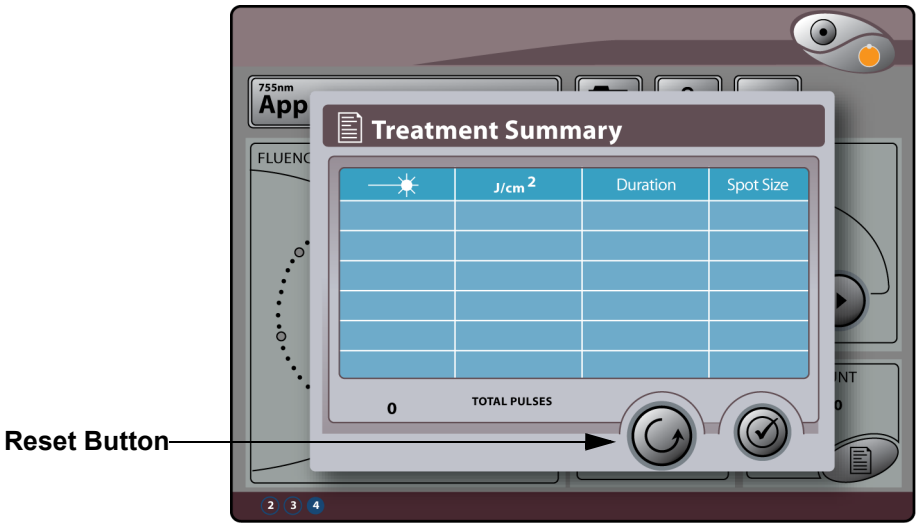


Figure 2-25: Treatment Summary Table

Press and hold the Reset button on the Treatment Summary Table to clear all treatment data from the table memory.

System Configuration and Maintenance Mode Button

The System Configuration and Maintenance Mode button is represented by a wrench (see **Figure 2-26**).

Figure 2-26: System Configuration and Maintenance Mode Button

The button has two functions:

- Set System Configuration - quickly tap the Wrench button
- Set Main ten ace Mode - hold the Wrench button for at least 5 seconds

Setting the System Configuration

If you quickly tap the wrench button, the system allows you to set the system configuration. **Figure 2-27** shows the System Configuration screen:

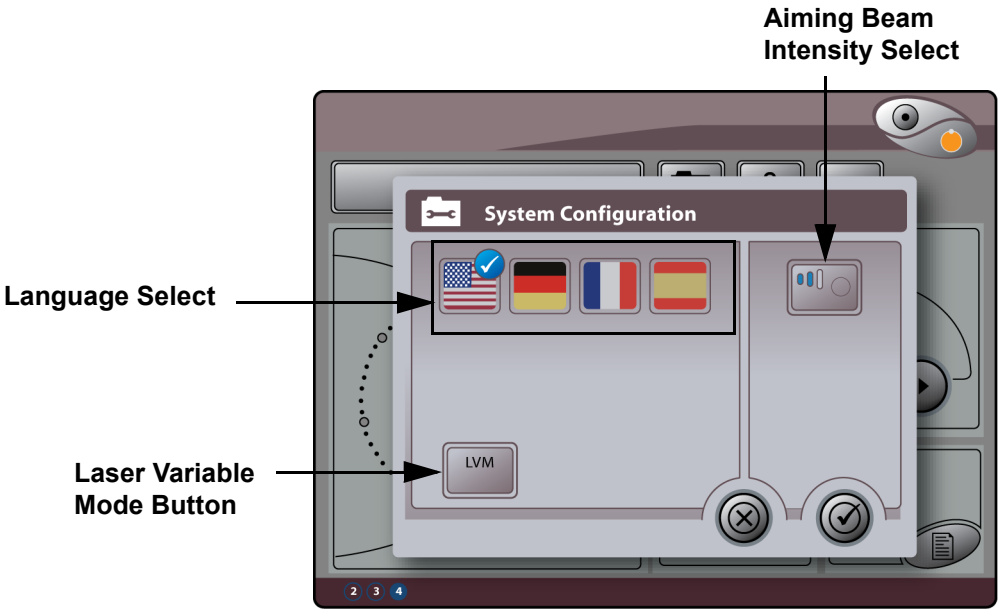


Figure 2-27: System Configuration Screen

These settings are described in **Table 2-4**:

Table 2-4: System Configuration Parameters

Configuration Parameter	Description
Language Select	Use the Language Select button to select the language shown on the display. The choices are: English, French, Spanish, and German The selected language is highlighted with a white check mark in a blue circle next to it (see **Figure 2-27**).
Aiming Beam Intensity Button	Use this button to select from three aiming beam intensity levels. The red aiming beam, which is visible only in the Ready state, serves as a treatment area target as well as an emissions warning indicator. The aiming beam cannot be turned off.
Laser Variable Mode Screen Button	This screen displays the Laser Variable Mode Screen (see **Figure 2-28**) which contains information about the laser including system parameters. This mode is used by Candela Field Service and users to monitor system performance.

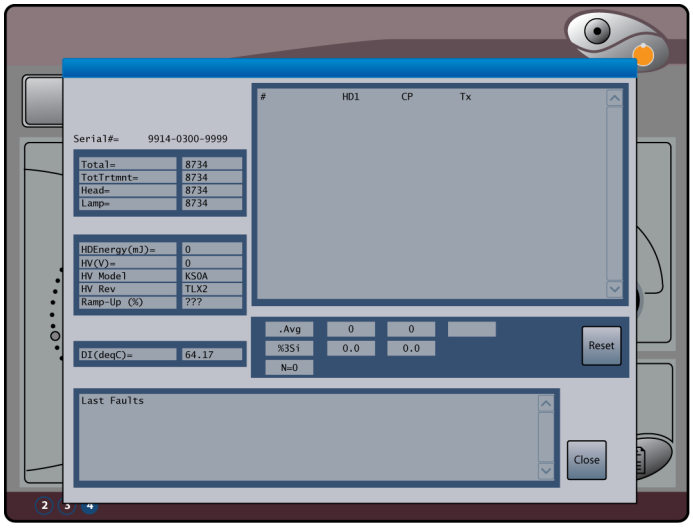


Figure 2-28: Laser Variable Mode Screen

Setting Maintenance Mode

If you hold the wrench button for at least 5 seconds, the system enters Maintenance mode.

Maintenance mode is only used by Candela Service Personnel.

Screen Lock Button

The AlexTriVantage Laser system has a password protected software lock to prevent unauthorized use of the laser. The laser remains in warm up mode when the software lock is engaged.

To lock the screen, select the Screen Lock button (see **Figure 2-29**).

Figure 2-29: Screen Lock Button

A dialog appears asking if you want to lock the screen now (see **Figure 2-30**).

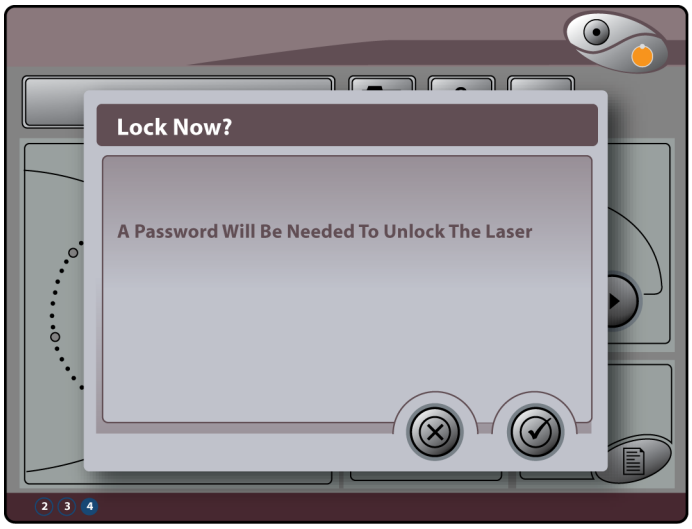


Figure 2-30: Lock Screen Now Screen

Select the checkmark to confirm the screen lock or select the X to cancel.

If you select the checkmark, the system is put into Standby and all screen buttons are locked except for the Screen Lock button.

A Candela logo screen with a padlock and a key button displays indicating the display is locked (see **Figure 2-31**).

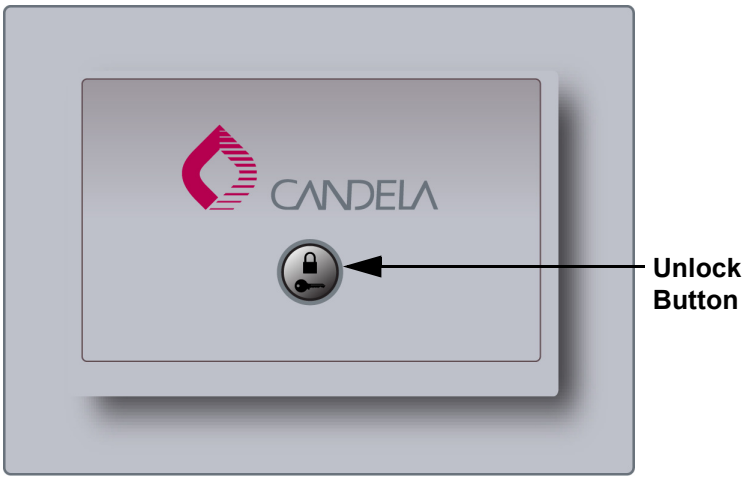


Figure 2-31: Candela Screen Lock Screen

To unlock the screen, press the Unlock button on the Lock screen. A keypad displays on which you can enter a 4-digit code (see **Figure 2-32**).

Figure 2-32: Keypad to Unlock Screen

The code will be the same for all lasers and the code is ***5277***. If the laser is locked and the system power is cycled off and on, the system will remain locked until the 4-digit code is entered.

Dialog Boxes

During operation of the laser, there are several situations in which a message appears on the Touch Screen/Display Panel to provide information. **Figure 2-33** shows an example of a dialog box:

Figure 2-33: An Example of a Dialog Box

Many dialog boxes provide a message and required that you either confirm the message or cancel the action.

To confirm a message in any dialog box, select the checkmark. To cancel the action, select the X (see **Figure 2-34**).

Select Checkmark to Confirm Message **Select X to Cancel Action**

Figure 2-34: Confirm and Cancel Buttons in Dialog Boxes

Chapter 3: Using the Laser

Topics described in this chapter include:

Introduction	**page 3-2**
Performing a Laser Treatment	**page 3-2**
Before You Begin	**page 3-2**
Treatment Procedure	**page 3-3**

Introduction

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

Caution: Before starting up the laser system for any reason, the operator must ensure that all personnel in the area are familiar with the safety concerns outlined in **"Warnings, Cautions, and Precautions" on page 1-5**, and that they are equipped with the correct safety eyewear.

Caution: Before the laser system is turned on, a Handpiece must be installed on the end of the optical fiber.

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. Proper eyewear must filter light at a wavelength of more than 755 nm with an O.D. of 7.0 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 Handpieces and the Distance Gauge, which will be used during this procedure, are clean.

Warning: Always put the laser system into Standby or turn it off before attempting to check, clean, and/or replace the Delivery System, Handpiece, or Distance Gauge.

Warning: Always recalibrate the laser after fixing, cleaning, or replacing the Delivery System, Handpiece, or Distance Gauge. Failure to initiate a calibration after cleaning/replacing the Handpiece, Distance Gauge, or Delivery System may result in the delivery of excessive laser energy.

Treatment Procedure

1. Turn the Keylock Switch from Off to the Start position. The key will automatically spring back to the On position.

   The system will enter a brief warm up state during which the water begins circulating and warms up.

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

A message appears in the System Status Message Area (top right side of the screen) indicating the system is warming up. The warm up process takes about 10 minutes. When the warm up is complete, the system enters the Standby state. The Standby/Ready button is yellow, indicating the system is in Standby (see **Figure 3-1**).

Figure 3-1: System is in Standby

2. Select the Handpiece to be used for the treatment and connect it to the Distal end of the Delivery System cable (see **Figure 3-2**). All three Handpieces connect in the same way.

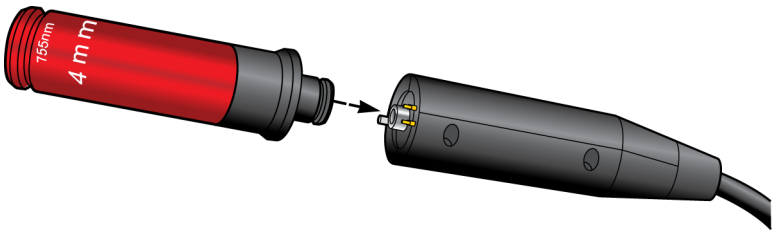


Figure 3-2: Connecting the Handpiece to the Delivery System Cable

The connectors are keyed and have orientation marks to help you align the connectors correctly.

The range for the Fluence parameter will be set up automatically based on the Handpiece that is installed.

3. Insert the Handpiece into the Calibration Port. The connectors are keyed and have orientation marks to help you align the connectors correctly (see **Figure 3-3**).

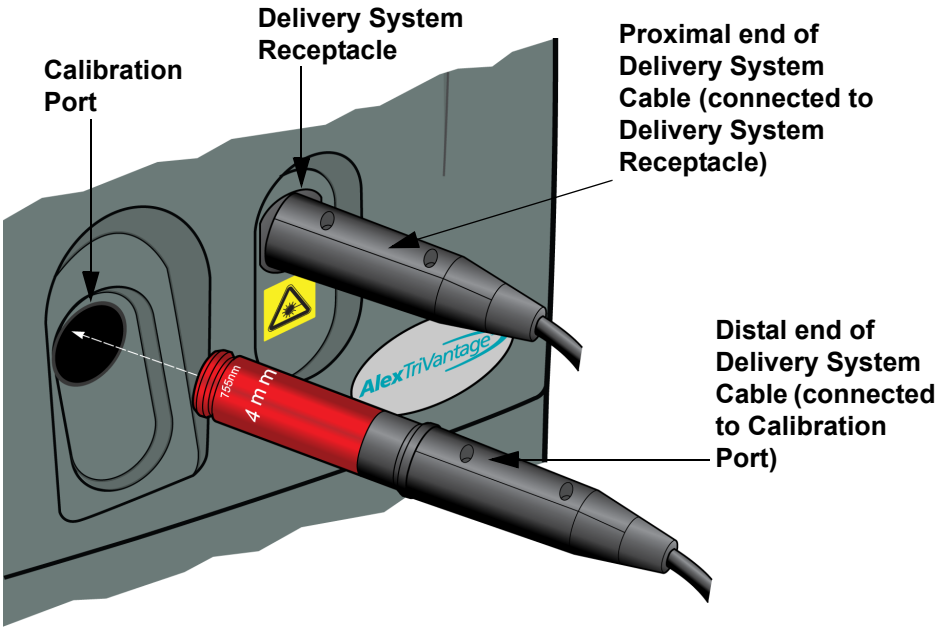


Figure 3-3: Insert the Handpiece into the Calibration Port

If the Handpiece is not installed, a message displays indicating the Handpiece is not in the Calibration Port.

4. A dialog prompts you to perform a Delivery System Test (see **Figure 3-4**). During this test the system analyzes the Handpiece that has been inserted into the Calibration Port.

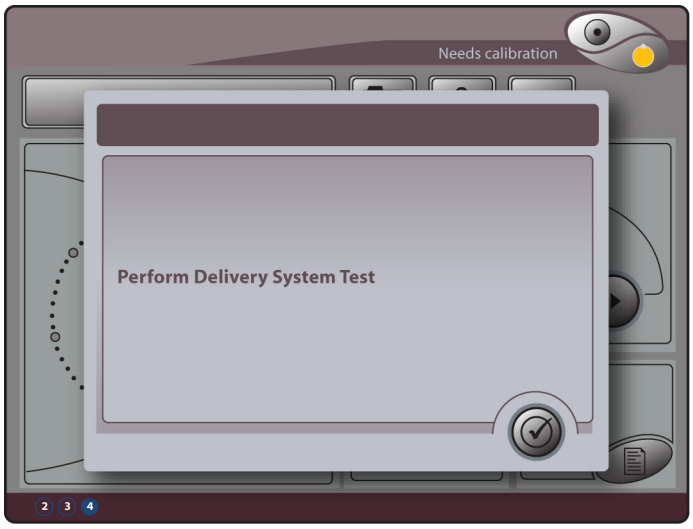


Figure 3-4: Delivery System Test Dialog

Select the checkmark to perform the test.

5. The system prompts you to use the latest version of the Treatment Guidelines for information on treating the patient (see **Figure 3-5**). See ***www.MyCandela.com*** for the latest version of the guidelines.

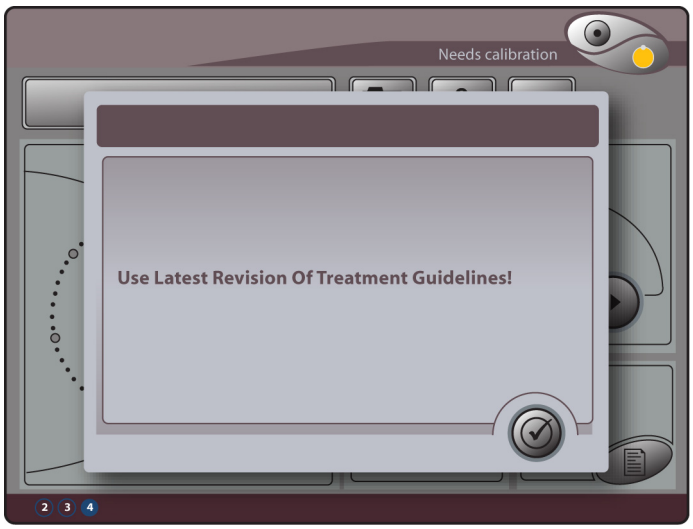


Figure 3-5: Treatment Guidelines Dialog

Select the checkmark when you have completed this task.

6. From the main screen on the Touch Screen/Display Panel (see **Figure 3-6**), select the settings for the patient being treated as described in **Table 3-1**.

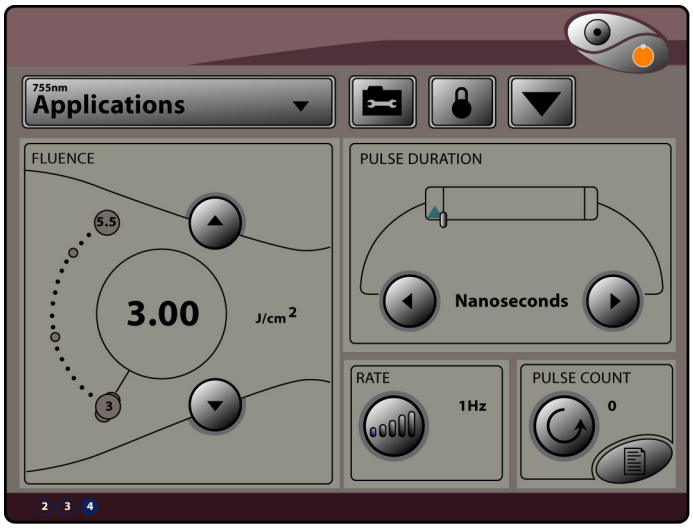


Figure 3-6: Main Screen on Touch Screen/Display Panel

Table 3-1: Treatment Settings

Setting	Description
Applications	Select the application from the drop down menu. The choices are: ● Epidural Lesions ● Lentigines ● Age Spots ● Freckles ● Cafe-au-lait ● Birthmarks ● Dermal Lesions ● Nevus of Ota ● Tattoos ● Blue ● Black ● Green
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 (Nanoseconds): 50 ns - 100 ns.
Pulse Rate	Select the pulse rate. The pulse rate is the number of pulses delivered with each depression of the Footswitch. The choices are: ● Single - one pulse delivered ● 1 - one pulse delivered ● 2 - two pulses delivered ● 3 - three pulses delivered ● 4 - four pulses delivered ● 5 - five pulses delivered
Pulse Count	The Pulse Counter is automatically reset to zero when the system is started. Reset the Pulse Counter to zero for this treatment session by selecting the Pulse Count Reset button.

Note: If you are experiencing difficulty setting the operating parameters, check the ensure the settings are allowed for the selected Handpiece.

7. Put on safety eyewear.

8. Select the Calibration button (see **Figure 3-7**).

Figure 3-7: Calibration Button

The system enters the Ready state. The Standby/Ready button turns green (see **Figure 3-8**).

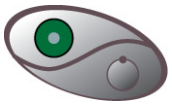


Figure 3-8: System is in the Ready State

The Confirm Calibration Parameters dialog appears asking you to confirm the parameters you have specified (see **Figure 3-9**).

Figure 3-9: Confirm Calibration Parameters Dialog

9. Verify that the parameters selected are correct for the patient and select the checkmark to confirm the settings. If the settings are not correct, select the X to cancel.

10. The system prompts you to press and hold the Footswitch (see **Figure 3-10**). This action starts the calibration.

Figure 3-10: Press and Hold Footswitch Dialog

11. Press and hold the footswitch to begin a system calibration.

When the calibration is complete, the Calibration Complete dialog displays.

12. Release the Footswitch.

A dialog prompts you to remove the Handpiece from the Calibration Port.

13. Remove the Handpiece from the Calibration Port.

- A message appears in the System Status Message Area indicating the calibration is complete.
- The system reverts to Standby (the Standby/Ready turns yellow) when you remove the Handpiece (see **Figure 3-11**)

Figure 3-11: Standby

Note: After a calibration is completed, the laser will remain in the Ready State.

14. Insert the Distance Gauge onto the Handpiece (see **Figure 3-12**).

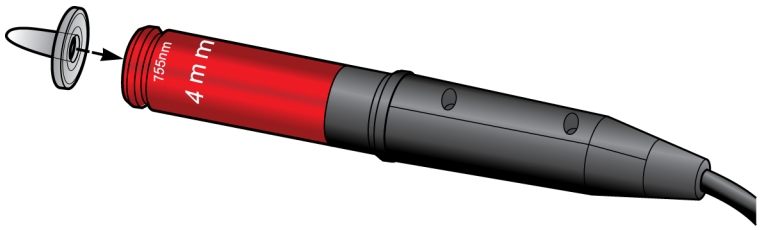


Figure 3-12: Connect Distance Gauge

15. Select the Ready button. The Standby/Ready button turns green (see **Figure 3-13**).

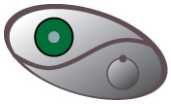


Figure 3-13: Ready Button

The laser is now armed and ready to use. The Ready Indicator on the front panel and the Indicator on the Delivery System Cable are illuminated (see **Figure 3-14**), but no energy is being delivered yet.

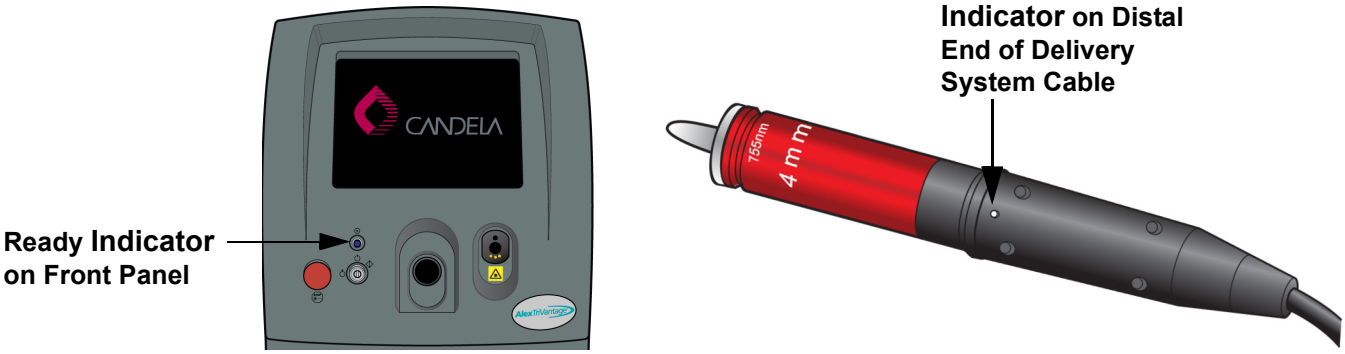


Figure 3-14: Ready Indicators on Front Panel and Delivery System Cable

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

16. Use the Footswitch to perform the laser treatment.

When the Footswitch is depressed, laser energy is released and the Ready/Status button displays the Lasing symbol (see **Figure 3-15**).

Figure 3-15: The Laser is Being Used for Treatment

When the 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.

17. When the treatment is complete, select the Standby button to place the system in Standby. The Standby/Ready button turns yellow (see **Figure 3-16**).

Figure 3-16: System is in Standby

18. When the system is in Standby, remove the Distance Gauge from the Handpiece.

19. Insert the Handpiece in the Calibration Port.

Notes:

- To return the Pulse Counter to zero, press the Pulse Count Reset button 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 or Pulse Duration parameters are changed.
  - Delivery System is changed.
  - The Handpiece was changed or became disconnected from the distal end of the Delivery System cable.
  - Specific faults occur
  - The laser system is in Standby for more than 30 minutes.

Chapter 4: Maintaining the Laser

Topics described in this chapter include:

General Information	**page 4-2**
Cleaning and Disinfecting	**page 4-3**
Cleaning the Exterior of the Laser System	**page 4-3**
Cleaning the Handpieces, Distance Gauge, and Lens	**page 4-3**
Cleaning the Touch Screen/Display Panel	**page 4-4**
Maintaining the Fiber Optic Delivery System	**page 4-5**
Maintaining the Water Cooling System	**page 4-5**
Calibration Procedure	**page 4-6**
System Calibration Requirements	**page 4-6**

General Information

In general, the laser system requires no special maintenance by the user. Routine care of the Handpieces, cleaning and disinfecting of the exterior of the system are covered in **“Cleaning and Disinfecting” on page 4-3**. During normal operation, the user is required to calibrate the energy output of the laser system, as discussed in **“Calibration Procedure” on page 4-6**. 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 5-3**.

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.

Cleaning and Disinfecting

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

Cleaning the Exterior of the Laser System

The exterior of the laser system may be cleaned 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 Handpieces, Distance Gauge, and Lens

Warning: Always put the laser system into Standby or Off before checking, cleaning, and/or replacing the Delivery System, the Handpiece or the Distance Gauge.

Warning: Always clean the Handpiece with disinfecting wipe prior to insertion into the Calibration port.

Warning: Always recalibrate the laser after fixing, cleaning or replacing the delivery system, Handpiece or distance gauge. Failure to initiate a calibration after cleaning/replacing these parts may result in delivery of excessive laser energy.

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.

To disinfect the Handpieces or Distance Gauges:

- Wipe them with a gauze pad moistened with isopropyl alcohol.

  Care should be taken to avoid contamination of the internal optical surfaces of the Handpieces.

  Autoclaving of Distance Gauges is acceptable.

If the lens inside the Handpiece becomes contaminated, it should be cleaned immediately, or else the laser beam will burn the contamination onto the lens surface.

To clean the lens:

1. Moisten a cotton applicator with alcohol or acetone. Isopropyl alcohol is recommended to minimize streaking.
2. Wipe the lens once. Make a single pass in one direction then lift the applicator off the lens.
3. Discard the used applicator. (If the lens is wiped more than once with the same applicator, the contamination will spread around the lens.)
4. Repeat using new applicators for each single pass until the contamination has been removed.

A Handpiece with minor deposits burned onto the lens can still be used for treatment. The calibration procedure will compensate for the resulting loss in Handpiece transmission to ensure that the proper energy is delivered.

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.

Maintaining the Fiber Optic Delivery System

Warning: Always put the laser system into Standby or Off before checking, cleaning, and/or replacing the Delivery System, the Handpiece or the Distance Gauge.

The AlexTriVantage 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.

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

Maintaining the Water Cooling System

The system is cooled with deionized (DI) or distilled water. The water level should be checked 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 cooling system holds about 3/4 of a gallon of DI water. The water tank is located on the rear of the laser system.

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 reservoir.
5. Replace the filler cap and tighten.
6. After the reservoir is completely refilled, restart the laser system and allow the system to warm up.

Calibration Procedure

Energy calibration is the automatically controlled procedure by which the laser calibrates the energy output to deliver pulses at the energy density selected on the control panel. During the calibration procedure, the Handpiece is inserted in the Calibration Port, the system is pulsed, and the energy output of the delivery system is read by an internal laser energy meter. The laser determines the high voltage level necessary to obtain each selectable Energy setting, and stores this information. Depending on the status of the system, the calibration can require as few as 2 pulses or as many as 20 pulses.

System Calibration Requirements

There are a number of system conditions that cause a calibration to be required. The system will not allow treatment unless a calibration has been completed.

A calibration is required by the system when:

1. The system is turned on.
2. The user changed the control panel Energy field.
3. The user changed the control panel Handpiece field.
4. A warning or fault has occurred requiring a calibration before treatment can continue.
5. The system has been in the Standby state for more than 30 minutes.

If a calibration is required, and the user attempts to treat by pressing the trigger switch, the system will not allow the treatment pulses, and indicates a calibration is required by displaying the following message:

INSERT HANDPIECE INTO CAL PORT

If this occurs, continue with the Calibration Procedure below.

Initiating a Calibration

Sometimes it may be necessary to initiate a calibration. If the user desires a calibration OR if the Handpiece was removed and replaced with another Handpiece having the same spot size, a calibration should be initiated.

A calibration is initiated by changing the Energy field one setting lower (or higher), and then putting the Energy field back to its original setting. Then, complete the Calibration Procedure as normal.

Calibration Procedure

1. Be sure that the desired Handpiece is attached to the optical fiber. Select the Handpiece on the control panel. (The control panel handpiece selection and the Handpiece must match for proper calibration.)

Warning: Ensure that the spot size on the Handpiece matches the Handpiece size displayed in the Handpiece field on the control panel. Failure to do so can result in the delivery of improper energy to the patient.

2. Select the desired Energy setting for treatment. This can be done at any time, but if the Energy setting is changed after calibration, another calibration procedure will be required.
3. Before the Handpiece is placed in the calibration port, the distance gauge must be removed, and the Handpiece cleaned and dried.
4. Depress and hold the trigger switch. The laser will automatically pulse the laser as required for calibration (2-20 pulses) and the following message will be displayed:

   CALIBRATING Xmm HANDPIECE

5. When the calibration procedure is complete, the following message will be displayed:

   CAL OK* - RELEASE TRIGGER SWITCH

6. Release the trigger switch.
7. Remove the Handpiece from the calibration port.
8. Reattach a cleaned or new distance gauge. See **"Cleaning and Disinfecting" on page 4-3** for the Handpiece, distance gauge and aiming guide cleaning procedure.

If a failure is detected during the calibration procedure a fault message will be displayed. If this occurs, **see page 5-3** for instruction.

Chapter 5: Troubleshooting the Laser

Topics described in this chapter include:

Introduction	**page 5-2**
Troubleshooting	**page 5-2**
Fault Messages	**page 5-3**

Introduction

This chapter provides troubleshooting and diagnostic information for the AlexTriVantage 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 troubleshooting information for the AlexTriVantage Laser system.

Table 5-1: Troubleshooting the AlexTriVantage Laser System

Situation/Symptom	Probable Cause or Fault Message	Solution
The system cannot be turned on properly.	The power is not connected properly.	Check the power cable and the facility circuit breaker.
	The laser system circuit breaker is in the "off" position.	Switch the circuit breaker to the "on" position.
	The keylock switch was not fully engaged.	Turn the keylock switch fully clockwise to the "S" position and release.
The system will not go into the Ready state.	WARNING--SECURE REMOTE INTERLOCk CONNECTOR.	Check the remote interlock connection. Press any control panel switch to clear the warning message.
	WARNING --RELEASE TRIGGER SWITCH.	The trigger switch must not be pressed when entering the Ready state. This is a safety precaution to prevent unexpected pulsing. Press any control panel switch to clear the warning message.
	PLEASE WAIT--SYSTEM DELAY REQUIRED.	The system has been cycled between Ready and Standby states too many times over a short period. Delay prevents HV dump resistor from overheating. When message is cleared, system can be put in Ready state. (1 minute wait or less.)
The rate is set at 5 Hz and the laser pulses at 4 Hz.	The system has degraded.	A preventative maintenance (PM) visit is required. Call Service.
Coolant over-temperature	WARNING--COOLANT OVER-TEMPERATURE.	Insure that the system's air circulation is not blocked. There should be a 15" clearance between the rear panel and a wall. Remove any items draped over system. Allow the system to cool for 10 minutes in the Standby state before continuing. If problem persists, turn off system and call Service.

Fault Messages

A fault message typically occurs due to a system malfunction. Sometimes clearing the fault and retrying the previous operation can be successfully accomplished without further faults occurring. If 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 (see page 5-3 for an example of a fault message).

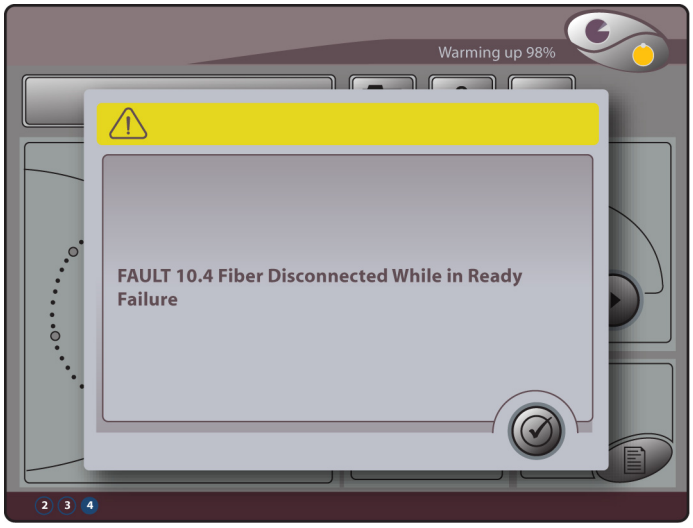


Figure 5-1: Example of Fault Message

Table 5-2 lists the possible 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 AlexTriVantage Laser System

Situation/Symptom	Fault #	Reason	Solution
Fault 3 - Shutter Fault	3.1	Shutter isn't in the correct state when checked. Does not respond to actuation to correct state.	• Go to Standby, and then try to calibrate the laser. • Restart the laser and recalibrate the laser. If fault message persists, call Candela Technical Support.
Fault 3 - Atten1 Fault	3.2	Attenuator 1 is not in correct state when checked. Does not respond to actuation to correct state. OR Attenuator 1 transmission is outside valid range of <74% or >86%.	Call Candela Technical Support.
Fault 3 - Atten2 Fault	3.3	Attenuator 2 is not in correct state when checked. Does not respond to actuation to correct state. OR Attenuator 2 transmission is outside valid range of TBD.	Call Candela Technical Support.
Fault 4 - HVPS Fault	4.2	High Voltage Power Supply Communications Time-out.	• Turn off laser for at least 5 seconds. • Restart and calibrate laser. If fault message persists, call Candela Technical Support.
Fault 5 - HV Tolerance Fault	5.1	HVred and HVsmp at Ready entry not within ± 5% at EOC.	• Turn off laser for at least 5 seconds. • Restart and calibrate laser. If fault message persists, call Candela Technical Support.
Fault 5 - HV Tolerance Fault	5.2	No EOC signal present within 2 secs after HV setting.	• Turn off laser for at least 5 seconds. • Restart and calibrate laser. If fault message persists, call Candela Technical Support.

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

Situation/Symptom	Fault #	Reason	Solution
Fault 6 - Calibration Fault	6.2	Laser failed to Calibration to desired Fluence.	Recalibrate laser after each step in the order listed below until a successful calibration is achieved: ● Clean or replace Handpiece. ● Change fluence by two settings up or down. If fault message persists, call Candela Technical Support.
Fault 7 - DI System Fault (Water)	7.1	DI temp < 64°C while in Ready or CAL.	● 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. If fault message persists, call Candela Technical Support.
Fault 7 - DI System Fault (Water)	7.2	DI temp > 66°C.	● 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 water level is correct. If fault message persists, call Candela Technical Support.

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

Situation/Symptom	Fault #	Reason	Solution
Fault 7 - DI System Fault (Water)	7.3	DI pressure switch does not change when power turned on. OR DI pump is not On or DI pressure switch not actuated.	Turn laser off. ● Check DI water level (the level should be no more than 1/2” to 1” from the top of reservoir. Refill reservoir if needed. ● Check for DI water leaks underneath the laser. If water leak is present, call Candela Technical Support. ● Restart and turn off laser 2-3 times to allow fluid system to pump water and flush out bubbles. If fault message persists, call Candela Technical Support.
Fault 7 - DI System Fault (Water)	7.4	Temperature Sensor Fault (sensor circuit open or shorted) OR DI temp < 9°C. OR DI temp > 90°C.	Call Candela Technical Support.
Fault 9 - Warm-Up Timeout	9.1	DI temperature not in normal range after 30 minute warm-up.	Call Candela Technical Support.
Fault 10 - Delivery System Fault	10.1	Unrecognized spot size while entering Ready.	Change the Handpiece and calibrate the laser. If fault message persists, call Candela Technical Support.

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

Situation/Symptom	Fault #	Reason	Solution
Fault 10 - Delivery System Fault	10.2	No Handpiece detected while in Ready.	● Remove the Delivery System Handpiece. ● Reinstall the Delivery System Handpiece and calibrate the laser. If fault message persists, call Candela Technical Support.
Fault 10 - Delivery System Fault	10.4	No Fiber detected while in Ready.	● Remove the Delivery System and reinstall. Calibrate the laser. ● Replace the Delivery System with a spare or new Delivery System. Calibrate the laser. If fault message persists, call Candela Technical Support.
Fault 12 - Energy out of Range Fault	12.1	Head energy (HD) of last treatment pulse was 14% lower than expected head energy (xHD).	Try to calibrate the laser system. Contact Candela Technical Support.
Fault 12 - Energy Out of Range Fault	12.2	Head energy (HD) of last treatment pulse was 14% higher than expected head energy (xHD).	Try to calibrate the laser system. Contact Candela Technical Support.
Fault 12 - Energy Out of Range Fault	12.3	Head energy (HD) of last treatment pulse > Max Treatment HE energy of 800+mJ.	Try to calibrate the laser system. Contact Candela Technical Support.
Fault 13 - Trigger Switch Fault	13	The redundant trigger switches were in two different states for > 1 second while in ready.	Contact Candela Technical Support.
Fault 14 - Simmer Fault	14	The simmer did not start or dropped to while in Ready.	Contact Candela Technical Support.

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

Situation/Symptom	Fault #	Reason	Solution
Fault 15 - Transmission Fault	15.1	Transmission (Tx) is >110%.	Recalibrate laser after each step in the order listed below until a successful calibration is achieved: ● Clean the Handpiece. ● Try another Handpiece (the same size if available). If this works, contact Customer Service to replace the bad part. ● Replace the Delivery System. If fault message persists, call Candela Technical Support.
Fault 18 - Circuit Cal Fault	18.1	HD, CP CktCal Test Energy incorrect or checksum corrupt.	Contact Candela Technical Support.
Fault 18 - Circuit Cal Fault	18.2	DI Factor checksum corrupt.	Contact Candela Technical Support.
Fault 21 - Code Update Fault	21	Not currently implemented.	
Fault 22 - Interprocessor Comm	22	Not currently implemented.	
Fault 23 - 1-Wire Fault	23	One Wire Communications Failure.	Contact Candela Technical Support.
Faults 25 - Pulse Duration Fault	25	Pockels Cell didn’t control pulse width correctly.	

Chapter 6: Specifications

Topics described in this chapter include:

System Specifications	**page 6-2**
Electrical Requirements	**page 6-4**
Environmental Requirements	**page 6-5**
Internal Cooling Water Requirements	**page 6-6**

System Specifications

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

Table 6-1: AlexTriVantage System Specifications

Specification	Description
Laser Type:	Flashlamp-excited, Q-switched alexandrite laser rod
Wavelength (nominal):	755 nm
Q-Switch:	Electro-optical switch (Pockels cell)
Method of Optical Output:	Lens coupled user replaceable optical fiber light guide with snap-on Handpiece
Beam Output Mode:	Multimode
Aiming Beam:	Class 3R aiming beam per EN60825-1 Laser Hazard Classification 650 nm $\pm$ 20%, <3.5mW
Maximum Radiant Power:	12.5×10^6 W
Maximum Radiant Energy:	625 mJ
Pulse Repetition Rate:	Single pulse; repetitive pulsing at 1, 2, 3, 4 & 5 Hz
Pulse Duration (Nanoseconds):	50 ns - 100 ns
Beam Spot Sizes:	2, 3, and 4 mm diameter
Cooling Method:	Air cooling
Stability of Output Energy:	±14%
Accuracy of Output Energy Including Cumulative Uncertainties:	< $\pm$ 20%
Electrical Requirements: USA Europe Asia Pacific (Maximum line voltage variation ± 10%) 50/60 Hz, single phase, 20 A minimum service recommended	 208 V~ 230 V~ 200 V~

Table 6-1: AlexTriVantage System Specifications

Specification	Description
Dimension	43” H x 16” W x 30” D
Weight	290 lbs
Voltage and Power	220-230 V~, 50/60 Hz, single phase, 4000 VA or 16 A at 230 V~ (26 A peak)

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 required a mating NEMA L6-30R power receptacle located within 10 feet of the intended laser system location.

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

The power receptacle must be within 10 feet (approximately 3 meters) of the intended laser system location, and must be earth-grounded. The safety ground wire of the power system (green or green with a yellow stripe) is an acceptable ground for the laser system, provided that it is terminated only to an earth ground stake or dedicated ground grid. Poor grounding can interfere with the operation of the laser system.

The power receptacle for the laser system must meet the following requirements:

Electrical Requirements:

- USA 208 V~
- Europe 230 V~
- Asia Pacific 200 V~
- Maximum line voltage variation ± 10%) 50/60 Hz, single phase,
  Rated Current 26 A peak at 230 V~
  16 A RMS at 230 V~

Electrical Service

- For CE Countries: 20 A minimum service supported by a 100 A mains**
- For non-CE Countries: 20 A service minimum

Note: **The Alex TriVantage is subject to a conditional connection to the public mains to reduce the effects of Flicker emissions. For details on Flicker and line impedance requirements, please refer to the EMC Guidance document (8501-00-1822) provided in your accessory kit.

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

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

Environmental Requirements

Before 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 AlexTriVantage Laser System.

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 50° and 80°F (10° and 27°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 AlexTriVantage Laser System. Before moving the laser, disconnect the Footswitch tubing from the connector located on the rear panel of the laser and the Delivery System from the front of the laser (place the Delivery System into its original box for transportation if necessary). A handle located on the rear panel allows easy movement of the system, but take special care when maneuvering over thresholds, elevator doors, ramps and other uneven or sloping floor surfaces. A severe physical shock could cause the alignment of the laser head or the optical fiber to be disturbed resulting in personal injury or physical damage.

Warning: Do not use the Fiber Pole 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 AlexTriVantage Laser System is not designed for mobile use.

Transport and Storage

For transport and storage of the AlexTriVantage 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: 1.8 liters, provided by the customer (readily available at hospitals, where it is used for sterile water).

Using water that is not 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:

Laser Parts and Accessory Kit	**page 7-2**

Laser Parts and Accessory Kit

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

Table 7-1: Laser Parts and Accessory Kit

Description	Quantity	Part Number
Fiber Delivery System	1	7122-00-3908
2mm Handpiece	1	7122-00-3909
3mm Handpiece	1	7122-00-1100
4mm Handpiece	1	7122-00-1101
Distance gauge kit (Qty 6)	1	7122-00-1099
Footswitch	1	5103-00-0030
Eyewear, Alex, OD>7, 755nm	2	8095-00-0260
Patient Goggles	1	8095-00-0470
Operators Manual	1	8501-00-1800
Candela key ring	1	1301-00-3409
Laser Radiation Wall Sign	1	2157-40-5000
Alex2 Radiation Label	1	2157-40-0001
Treatment Guidelines Alexlazr	1	8502-00-0843

Chapter 8: Service Internal Calibration Procedure

Topics described in this chapter include:

Calibration Schedule	**page 8-2**
Introduction	**page 8-2**
Parts List	**page 8-2**
Internal Calibration	**page 8-4**
Starting the Circuit Calibration Procedure	**page 8-4**
Laser Energy Circuit CAL	**page 8-4**
Final Verification of User Calibration Energy	**page 8-5**

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 AlexTriVantage can be extremely dangerous if proper safety precautions are not taken. The AlexTriVantage 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 for the user to calibrate the energy output of the laser system. During that procedure, the handpiece is inserted in the calibration port, the laser is pulsed, and the energy output of the handpiece is read by internal laser energy detectors. The system determines the power and energy levels necessary to provide the correct delivered energy for the currently selected fluence setting.

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

Parts List

1. Energy meter (OPHIR with 10A-P head).
2. Delivery System with known good transmission (85%).
3. 3mm Handpiece with clean optics.

Warning: Make sure all personnel in the area are wearing safety eyewear appropriate for the AlexTriVantage 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 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. Prior to starting the Circuit CAL, verify that the Laser Head and Optical Rail are properly aligned.
2. Install the delivery system with a 3 mm Handpiece.

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

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

Laser Energy Circuit CAL

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

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

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

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

Note: 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 (expect ~ .500). Pulse Laser and Enter Ophir Data**. This means to aim the handpiece (HP) to pulse the laser into the external Ophir meter head and then enter the Ophir energy (in this case the expected OPHIR reading should be within .500 Joules) using the keypad that will pop-up after the first laser pulse.
     - **Pulse HP in Calport**.
       This means to insert the handpiece in the Calport 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 Calport as the calibration progresses. When pulsing into the Ophir, a keypad will pop up so that the technician can enter the Ophir reading (If the Ophir doesn't read any energy, then enter a "0".) All entries into the pop up keypad must be entered in Joules (J). The keypad has a fixed decimal point and accepts entries as follows:
     - **Example 1:** If the meter is reading 0.769J, the technician will enter 769 into the keypad. This will appear as 0.769 on the keypad.
     - **Example 2:** If the meter is reading 2.20J, the technician will enter 4350 (must add the "0" at the end to make it J). This will appear as 2.200 on the keypad.
   - If the laser software is prompting for the technician to pulse into the Calport and the laser is mistakenly pulsed into the Ophir, a "PreGain Error" may occur. If this error or any other error happens, restart the procedure
4. The software will prompt the technician with "Circuit Cal Successful" when it is complete.
5. Press the CAL Factors tab. If the PreGain for HD1 or HD2 show 150 or 100 respectively with a b factor of 0, then the calibration was not completed successfully and needs to be restarted. If the PreGain for CP shows 12 or 7 with a b factor of 0, then the calibration was not completed successfully and needs to be restarted.
6. Press the CAL Test tab. Press the Ckt Cal Test button. Ensure that all Pass/Fail indicators for HD1, HD2 and CP (in the Sts Column) show "PPPP". If these do not show "P", then the Circuit CAL needs to be restarted.

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 Calibrations Table using the specified spot size, fluence, and pulse width (See Table 9.1 on the next page). After each Calibration, pulse 3 times into the Ophir meter. Record each Ophir energy reading.
3. Note that on entry to Ready State (Ready Button pressed or started CAL), if a fault 18.1 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 Tables

3mm, 5.0 J/cm^2 Expected Energy = .308 J Pulse #	**Ophir Energy (J)**
1	
2	
3	
Average (J)	
Percent Difference (%)	

3mm, 10 J/cm^2 Expected Energy = .616 J Pulse #	**Ophir Energy (J)**
1	
2	
3	
Average (J)	
Percent Difference (%)	

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

Appendix A: Pre-Treatment Visit

General

At the first visit the physician obtains a detailed patient history and examines the tattoo for suitability of Q-Switched Alexandrite Laser therapy. The physician typically determines why the patient is seeking treatment and what expectations the patient has formed regarding the outcome of treatment. He/she then discusses treatment options with the patient, including AlexTriVantage Laser and other treatment modalities. This discussion gives the patient the opportunity to explore the technique further and help decide whether to proceed with AlexTriVantage laser therapy.

Counseling

During this first visit, the physician should inform the patient of the following:

1. Q-Switched Alexandrite Laser therapy may consist of multiple treatments given over many months, with 4 to 8 weeks between treatment. Clinical evidence to date suggests that epidermal lesions can usually be retreated within 4 to 6 weeks. Dermal lesion treatments performed after 8 or more weeks have shown the most effective clearance.
2. There may be discomfort/pain resulting from the treatment.
3. Transient edema may occur immediately following laser therapy.
4. Occasionally, pinpoint (punctate) bleeding at laser impact sites.
5. A white-gray discoloration of the treatment area may appear immediately following treatment and last for a few minutes to a few days. This may be replaced with an erythema or purpura which may persist for several days. A scab may form at the treatment area and drop off in 7-10 days. (It may be helpful to use an anti-bacterial ointment on the treated area and to cover it with a dressing for a few days after AlexTriVantage laser therapy. This will protect the skin from being abraded and the site infected, a potential source of scar formation.)
6. The treated area may not clear with the first treatment. The same area may be treated more than once for the best results.
7. Possible risk of adverse reactions, e.g., scarring, infection, and hypo- or hyperpigmentation.

Photographs

Before and after treatment photographs should be used to document progress of treatment. Because many patients are not able to objectively assess their own progress, photographs provide documented evidence on the course of treatment. At each session, before and after treatment photographs should be taken under standardized conditions. Care should be taken so that photographs are similar in magnification, light exposure or flash conditions and color balance. Inclusion of a standard color bar in the photograph serves as a helpful reference.

Appendix B: Treating the Patient

Training Requirements

The Candela AlexTriVantage Laser is intended for use only by trained and qualified physicians. This portion of the manual describes clinical techniques developed by experts in the field, and is presented as a reference.

DO NOT rely solely on this information, or this manual, in lieu of formal training in the use of the Q-Switched Alexandrite Laser (AlexTriVantage Laser).

Generally, no anesthesia is required for this procedure. If circumstances require its use, local anesthesia may be administered.

Determining the Therapeutic Energy Level

The following summarizes the clinical techniques used and established by experts in the field.

1. Applying a Test Dosage
   Optimum therapeutic energy density is dependent upon the tattoo or pigmented lesion and individual variations that occur from patient to patient. For example, optimum dosage for the treatment of a tattoo can depend on the origin of the tattoo (amateur, professional, or traumatic), the depth of pigment and the patient's skin type. To determine the correct therapeutic energy density, first test one or more sites on the lesion area with low energy density(ies) (5.5 to 6.5 J/cm2).

Energy settings above 12 J/cm2 are considered investigational and are not recommended.

Caution: Because of variations in age, the skin color of the patient, and the type or site of the tattoo or pigmented lesion, the physician should evaluate patient response using test sites. The patient should be treated with the lowest energy density that produces clearance of the test site.

Avoid retreating the same area when increasing the energy density to determine the therapeutic threshold.

The appearance of a raised, white spot is the usual marker of a laser pulse delivered using an energy density (fluence) at or above the therapeutic threshold. If a raised, white spot fails to appear at an irradiated site, the energy density is most likely subtherapeutic. The energy density may be increased at additional test sites, using increments of 0.5 J/cm2, until a raised, white spot is noted.

Further, the occurrence of punctate (pinpoint) bleeding at irradiated sites can be a marker of excessive energy density (always use universal precautions). If laser pulses cause frequent punctate bleeding to appear at irradiated sites, decrease the energy density, using increments of 0.5 J/cm2, until it no longer occurs.

2. Return Visit - Confirming the Therapeutic Energy Level

Evaluate the patient response in approximately upon return visit.
If no clearance of the tattoo or pigmented lesion is observed, test an additional site with a higher energy density, using an increment of 0.5 J/cm2 higher than the level previously applied. If an adverse effect (e.g., hypo- or hyperpigmentation) is seen, treatment should be adjusted or discontinued.

Note: Enter any changes in the treatment energy level in the patient's medical record.

Treatment should be at the lowest energy density that produces clearance at the test site(s). Inappropriate selection of an initial therapeutic energy density may result in choosing a level that is higher than needed and could possible result in hypo- or hyperpigmentation or scarring.

Treatment

Tattoos

The laser exposure dosage applied to treat tattoos may be in the range of 3.5 to 10.0 J/cm2. Clinical evidence to date suggests the majority of tattoos are effectively treated in the range of 6.0 - 8.0 J/cm2. Clinical effects of fluences higher than 12.0 J/cm2 are not yet known. Therefore, it is not recommended to use fluences over 12.0 J/cm2.

If more than one treatment is needed due to incomplete clearance, the physician should use the lowest energy density producing clearance or lightening of the tattoo at the time of each subsequent treatment. Different pigmented areas within tattoos may have different optimal therapeutic energy levels, therefore the fluence level should be adjusted appropriately to the area being treated. When treating large tattoos, a series of treatment sessions may be used rather than treating the entire tattoo in one session. However, most patients prefer treatment of the entire tattoo at each session and tolerate the treatment well.

Pigmented Lesions

The laser exposure dosage applied to treat pigmented lesions may be in the range of 5.0 to 6.0 J/cm2. The laser exposure dosage will vary depending upon whether the melanin in the lesion is epidermal or dermal in depth.

Clinical evidence to date suggests that the majority of epidermal lesions (lentigines and freckles) respond to fluences between 5.0 and 6.6 J/cm2.

Dermal lesions may require higher fluences for complete clearance. It is recommended that these lesions be tested at fluences between 5.0 and 6.6 J/cm2 and the response evaluated before using higher energies. Clinical effects of fluences higher than 12.0 J/cm2 are not yet known. Therefore, it is not recommended to use fluences over 12.0 J/cm2.

The size of the treatment area for the second and/or subsequent visits is directly related to patient tolerance, success with the test site, and the rate of clearing.

Determining the End of Treatment

Laser therapy may be conducted over multiple treatment sessions. Determining the end of treatment is left to the physician's judgment. The factors involved in this decision relate to the clearance (or lightening) of the tattoo or pigmented lesion and the restoration of normal skin color and texture. Often the decision to end treatment is arrived at jointly between the physician and the patient (or parents or guardians, as applicable). Treatment should cease when the tattoo or pigmented lesion is completely cleared or no further progress is being obtained. Poor patient compliance with post-treatment protocol, which could jeopardize the results of treatment, should also be considered a reason for ending treatment.

Adverse Effects

Warning: Treating the tattoo or pigmented lesion with excessive energy levels may result in adverse effects such as scarring (hypertrophic and/or atrophic) and/or hypo- or hyperpigmentation. Care must be taken when choosing the energy density for treatment. Each laser pulse should only be delivered within the tattoo or pigmented lesion area.

Treating the tattoo or pigmented lesion with excessive energy levels can result in adverse effects such as hypertrophic or atrophic scarring and/or hypo- or hyperpigmentation. Patients with darker skin types (>IV), or who are deeply tanned, may be more susceptible to hypopigmentation at effective treatment dosages.

Appendix C: Post-Treatment Care

General

The treated area should be cared for delicately until healing is complete. Care should be taken to prevent trauma to the treated area for the first 4 to 7 days following treatment.

An antibacterial ointment may be applied to the treated area immediately following treatment and a gauze bandage placed over it. The use of ointment and a bandage for the first 4 to 7 days may be beneficial. For epidermal lesions where the tissue is not disrupted, a mild moisturizer may be applied following 1 to 2 days of antibiotic ointment treatment.

The use of sunblock (#15 or greater) on a regular basis may also prove helpful.

Makeup

The use of makeup during the first 7-10 days after treatment is not recommended. The removal of makeup can disrupt the skin increasing the chance for infection.

Other Recommendations

Following treatment, excessive perspiration to the treated area may cause tissue disruption. Physical exercise (aerobics, lawn mowing, sports activities) should be discontinued for 1 to 2 days to reduce the risk of infection.

The patient should **not** participate in any rough physical activities (playing football or ice hockey, etc.) for 10 days after treatment.

If the patient is likely to expose the treatment area to dirt, it is recommended that the treated area be covered by a dressing.

Appendix D: 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 (8501-00-1822) 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 AlexTriVantage Laser.

AlexTriVantage Laser is EMC compliant with the following accessories:

- Optical delivery system
- Pneumatic footswitch

Warning: AlexTriVantage Laser should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the AlexTriVantage Laser should be observed to verify normal operation in the configuration in which it will be used.

The AlexTriVantage Laser complies with IEC 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 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 AlexTriVantage Laser have been reduced as far as practical without compromising functionality.

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

Table D-1 lists the system specifications of the AlexTriVantage Laser System.

Table D-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 3R 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 AlexTriVantage complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated July 26, 2001

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