

AL-40 PULSED ALEXANDRITE LASER

Operator's Manual

Caution: In the United States, federal law restricts this device to sale to or on the order of a physician or any practitioner licensed by state law to use or order the use of this device.

Document Number 4000-001M

See Revision History page for revision of this manual.

Manufactured by



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General Description

The AL-40 Pulsed Alexandrite Laser is designed to deliver precise fluences of long pulses of laser energy at 755 nm wavelength to a predetermined target site to effect the elimination of unwanted hair.

The laser system (see Figure 1-1) is housed in a single protective cabinet. Delivery of laser energy to the treatment site is through a fiber optic cable fitted with a handpiece, designed to provide pre-determined laser beam spot sizes on the patient's skin during treatment. Once a foot switch is depressed, light is administered to the treatment area by placing the distal end of the handpiece in contact with tissue.

The AL-40 Long-pulsed Alexandrite Laser is microprocessor-based to ensure optimal flexibility and "user-friendly" control of the laser system. A touch-screen control panel with color LCD display controls all laser system user functions. This display provides visual feedback of system settings and operating parameters. Memory function allows to store up to 5 five laser parameters' settings, which provides the operator with fast and repeatable laser setup.



Figure 1-1. AL-40 Alexandrite Laser

Operator Training

Caution: In the United States, federal law restricts this device to sale by or on the order of a physician or any practitioner by state law to use or order the use of this device.

It is to be used by those trained in the safe handling and operation of this system. It is recommended that, in addition to laser safety training of all operation room or clinic personnel, the user/institution adopt a training and safety program as outlined in the latest revision of the ANSI Standard Z-136.3, the American National Standard for the Safe Use of Lasers in Health Care Facilities.

It is further suggested that practitioners desiring privileges for laser use should obtain approval from the appropriate credential issuing body within their respective institutions.

Practitioners should consider the following training avenues:

1. An accredited training course within the practitioner's specialty;
2. "Hands-on" training under the preceptorship of a qualified user;
3. Attendance at specialty-specific courses presented during academy or college meetings.

All practitioners handling lasers, including physicians, nurses and other allied professionals, should also complete a training program which may include subjects such as basic laser physics, laser safety, tissue interaction, laser operating procedures, laser set-up procedures, potential hazards, and hands-on experience.

In-service training in the use of the AL-40 Alexandrite Laser will be provided near the time of the initial system installation. Clinical techniques described here are presented only as a reference based on clinical experience with the device and other laser devices reported in the published literature.

Indications for Use

The AL-40 Alexandrite Laser indication for use is based upon the selective absorption of natural chromophores, particularly melanin. The Alexandrite laser wavelength of 755 nanometers is well absorbed by this chromophore.

Indication for use:

The AL-40 Alexandrite Laser is designed to effect hair removal of patients with skin types I-IV through selective targeting of melanin in hair follicles.

Patient Exclusion Criteria

There are no known absolute contraindications to laser treatment with the AL-40 Alexandrite Laser System. Patients who have had prior problems with laser therapy, however, should be carefully screened prior to treatment.

Persons known to form skin keloids may be more prone to scarring after any skin trauma, including Alexandrite laser treatment.

Relative patient exclusion criteria to Alexandrite laser therapy include:

- History of keloid scarring;
- Active infections;
- Herpes simplex within the treatment area;
- Recent sun tanning;
- Use of chemical or mechanical epilation 6 weeks prior to laser treatment;
- Hypersensitivity to hydroquinone, if applicable.

Warnings

Patients should be cautioned if any of these situations apply.

- The AL-40 Pulsed Alexandrite Laser is designed for treatment to intact skin only;
- Do not treat around the outer cantus of the eye;
- Closing the eye is not sufficient protection from Alexandrite laser light, therefore appropriate eye protection measures should be taken when treating near the eye;
- Should bleeding result at any time during the use of the AL-40 Pulsed Alexandrite Laser contact cooling handpiece, discontinue use immediately and quarantine the handpiece. Contact your DDC Technologies Customer Service Representative for further instructions.

Be sure to observe all precautions described in Chapter 2: Safety, of this manual.

Precautions

Clinical studies have shown that both treatment effectiveness and inflammatory response to injury of the skin is exposure dose (FLUENCE) related; higher fluence level result in greater effectiveness and also higher inflammatory response.

Begin treatment with a conservative exposure dose. If more tissue reaction is desired, increase the energy level in 2-5 J/cm² increments until the desired tissue effect is observed.

Treatment exposure dose should be based on test sites applicable to both the treatment site and skin type of the patient to be treated.

Complications/Adverse Effects

In clinical studies involving the long pulse Alexandrite laser treatments, the following minor complication were observed in some patients:




- Hypopigmentation or hyperpigmentations may occur (Note: These complications have been rated as both transient and minor and appear to resolve spontaneously within several weeks or month after laser treatment).
- Pain during treatment sometimes can be felt, but local anesthesia is generally not required for these procedures.
- Erythema and edema may occur immediately following treatment, but usually resolves after several hours or days.
- Blisters may occur during or sometimes after treatment, but since they are intra-epidermal in nature they usually heal without scarring.

Operator Guidelines

The following operator guidelines are provided as an outline of the general concepts for properly using the AL-40 Pulsed Alexandrite Laser, and improve the care of patients who choose this method of hair removal. For more information regarding training on the use of the AL-40 Pulsed Alexandrite Laser, please refer to page 1-2 of this Operator's Manual.

- Possible side effects or complications that may arise from use of the AL-40 Pulsed Alexandrite Laser may include, but are not limited to: hypopigmentation, hyperpigmentation, depigmentation, vesiculation (blister formation), prolonged erythema and edema, scarring and poor clinical response. These side effects are rare and can be minimized by following established preoperative and postoperative instructions and using proper surgical technique.
- Any hair that lies on the skin surface during treatment will absorb laser energy and cause unnecessary discomfort or present other complications to the epidermis. Therefore, all treatment areas should be shaved and cleared of all hair prior to exposure to AL-40 Alexandrite Laser pulses.
- Performing tests at different energy fluences and properly evaluating the tissue's response prior to initiating treatment will help determine the proper energy fluence for each site and reduce the risk of complications and unwanted side effects.
- Vesicles (blisters) may sometimes occur at areas where the energy fluence used was excessive. If a vesicle should form, it is important to recognize that it is generally intra-epidermal and will usually heal without scarring. Vesicles should be treated conservatively with gentle cleansing and application of a topical antibiotic ointment until they have completely healed. If vesiculation or nikolsky's sign is encountered, the energy fluence should be reduced until these reactions are no longer produced. If vesiculation occurs at even the lowest fluence, then that person should be excluded from treatment.
- Residue from hair shafts that have been destroyed by exposure to AL-40 Alexandrite Laser energy may accumulate on the surface of the handpiece protective window during treatment. This debris may interfere with the effectiveness of the treatment if it is not wiped off frequently using lint-free lens cloths or Q-tips.
- It is recommended that the pulses be overlapped slightly to ensure that effective energy is delivered to disable all hair follicles in the treatment site. The risk of injury to the skin from overlapping pulses is very low.
- Since hair follicles typically grow at angles within the skin, it is possible to affect follicles that are not directly in the beam's apparent path at the skin surface. For this reason, it is not advisable to use the AL-40 Alexandrite Laser for shaping or sculpting precise hair-bearing areas such as eyebrows.
- Treatment of large areas may be somewhat time consuming and tedious. For that reason, it is strongly recommended that AL-40 Alexandrite Laser users take frequent breaks or limit the length of each scheduled treatment session in order to minimize eye strain or fatigue that could otherwise adversely affect the clinical response.

Symbols Used in this Manual

	<p>Danger</p> <p>Indicates an imminent situation in which the possibility of exposure to hazardous laser radiation may occur that could result in serious injury to the operator, patient, or staff.</p>
	<p>Danger</p> <p>Indicates an imminent situation in which the possibility of exposure to electrical shock or a fire hazard could result in serious injury to the operator, patient, or staff.</p>
	<p>Caution</p> <p>Indicates a potentially hazardous situation that, if not avoided, could result in damage to the equipment and serious injury to the operator, patient, or staff.</p>

Chapter 2: Safety

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Overview

All persons operating the AL-40 Pulsed Alexandrite Laser and all who are in the vicinity of the laser must be aware of the potential hazards of the AL-40 Pulsed Alexandrite Laser output. Be certain all personnel carefully review the safety precautions pertaining to the AL-40 Pulsed Alexandrite Laser. Only authorized individuals with appropriate laser training and knowledge should operate, assist in the operation of, or provide maintenance/service to the laser system.

Warning



The electrical and laser radiation hazards present during servicing of the AL-40 Pulsed Alexandrite Laser can be very dangerous if proper safety precautions are not taken. Therefore, the AL-40 Pulsed Alexandrite Laser may only be serviced by qualified technicians who have received appropriate training on the laser from DDC Technologies, Inc., and who are familiar with the safety considerations discussed in this section.



The AL-40 Pulsed Alexandrite Laser 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 and serviced. The potential hazards associated with the AL-40 Pulsed Alexandrite Laser may include: ocular 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 laser.

Caution



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

To avoid these hazards, the following precautions must be observed when installing, operating, moving or servicing the system.

Optical

The laser beam emitted by the AL-40 Pulsed Alexandrite Laser is capable of causing loss of vision. The laser operates at 755 nm, which falls within the near-infrared (IR) light spectrum. The cornea and lens of the eye are transparent to near-IR light; therefore, any energy transmitted by the AL-40 Pulsed Alexandrite Laser that enters the eye will be focused directly on the retina. Direct absorption of laser energy by the retina can result in temporary clouded vision, retinal lesions, long term scotoma (isolated voids in field of vision), and long term photophobia (sensitivity to light).

To avoid these vision hazards, everyone in the area where the AL-40 Pulsed Alexandrite Laser is operating or being serviced must wear appropriate eye protection as described below. All windows in the room where the laser is being used must be covered with opaque material, and measures should be taken to prevent unauthorized access to the room. Laser warning signs must be posted at all entrances wherever the AL-40 Pulsed Alexandrite Laser is in use. An ANSI approved laser safety sign is provided with each laser system, and additional signs may be purchased directly from Customer Support.



All personnel in the treatment room during operation or service, including the person being treated, shall wear the appropriate eye protection before starting the system and then during use. Eye protection should not be removed until the system is turned off. Note: merely closing your eyes offers insufficient protection from Alexandrite laser light.

Safety Considerations

- Identify the laser room clearly, posting appropriate warning signs in prominent locations.
- Block all windows, portholes, etc. to prevent laser light from escaping the laser room.
- Restrict entry to the laser room when the laser is in use. Allow access to the laser room only to those personnel both essential to the procedure and well-trained in laser safety.
- 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 laser system controls during the procedure.
- Never operate the laser in the presence of flammable liquids (such as alcohol) or flammable anesthetics (such as ether). Moisten combustible solids (such as gauze and swabs) with water or saline for safety.

Safety Considerations continued

- Ensure that the laser system and ancillary equipment are working properly before beginning a procedure.
- Never direct the laser beam at anything other than the intended treatment site, especially not at reflective objects such as metal surgical instruments.
- Be certain the laser footswitch is clean and working properly. Place the footswitch where it will not be mistaken for another piece of equipment.
- Appropriate eye protection must be provided for the patient.
- Never look directly into the distal end of the handpiece.
- All personnel in the operating room must wear laser safety eyewear approved for the Alexandrite laser wavelength with an Optical Density (OD) of 7 or greater at 755 nm; this includes both practitioners and those being treated. Patients may also wear opaque stainless steel eye shields.
- Post warning signs on all doors and cover all windows with nonflammable window covering in the operating area.
- Always ensure that the handpiece is in proper contact with the area to be treated prior to the delivery of each laser pulse.

Electrical

Although the AL-40 Pulsed Alexandrite Laser has many safety features in its design, certain precautions must be observed:

No one should attempt to operate the AL-40 Pulsed Alexandrite Laser with any panel removed. This may expose personnel to dangerous high voltages and potentially dangerous optical radiation. Any service requiring access to the interior of the instrument (except the flash lamps change procedure described in this manual) should be performed by a qualified DDC Technologies Service Representative only. To contact a Service Representative, dial (516) 770-0441.



The electrical safety hazard of any laser cannot be ignored or taken lightly. The AL-40 Alexandrite laser system uses AC line voltage to produce high DC voltages inside the cabinet which have the potential to cause fatal electrical shock. **It is possible for the high voltage components to retain a charge even after the laser has been turned off.** Therefore, no part of the exterior housing (with exclusion for the top cover panel during flash lamp change procedure) should be removed except by trained and authorized laser technicians.

A safety self-surveillance system monitors appropriate electrical, temperature, contact and other variables and notifies the user of abnormalities by generating an error or warning message.

Fire

The potential for fire hazards exist because of the nature of laser treatment. The absorption of emitted laser energy, no matter how brief, may raise the temperature of any material. This phenomenon is the basis of many useful medical and surgical applications; it is also the reason that these applications often require precautions against the risk of igniting combustible materials in and around the treatment area. When the AL-40 Pulsed Alexandrite Laser is used, the following precautions should be taken:

- Do not use any flammable substances, such as alcohol or acetone, in the preparation of the skin for treatment. Use soap and water if necessary.
- Anesthetics administered either by inhalation or topically must be approved as nonflammable.
- Exercise particular care in the use of oxygen. The presence of oxygen can accelerate the combustion of any flammable material.
- Avoid using combustible materials, such as gauze and drapes, in the treatment area. When they are required, these materials may be made fire-retardant by keeping them moist with water or saline. Clothing should be kept well away from the area of treatment.
- Simple and effective means of extinguishing a small fire should be kept on hand during each procedure. A CO₂ fire extinguisher is recommended.

Laser Safety Information

The FDA's Center For Devices and Radiological Health and laser safety professionals recognize the American National Standards Institute (ANSI) series of Safe Use of Laser standards as an excellent means of establishing and maintaining an adequate laser safety program. Moreover, Federal and State Occupational Safety and Health Administration (OSHA) inspectors and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) use these standards as guidelines for inspections and audits.

ANSI Standard Z136.3 for Safe Use of Lasers in Health Care Facilities contains specific guidance for medical users of lasers. ANSI Standard Z136.1 is the primary source for more detailed information on laser safety. Both standards should be used in conjunction with this system.

The AL-40 Alexandrite Laser is a long pulse Alexandrite laser operating at 755 nanometers (nm) in the near-infrared (IR) light spectrum. The laser light is emitted from the end of an optical fiber with a cooled handpiece. When the laser is directed to the tissue being treated there is little chance of health care worker exposure. However, as with any device, precautions must be taken to ensure there are no unintended injuries.

The ANSI Z136.1 standard uses the concept of Nominal Hazard zone (NHZ). The NHZ is an indication of the distances a laser may be capable of exceeding the Maximum Permissible Exposure (MPE) and therefore cause eye injury. Persons within the NHZ may, under ideal conditions for laser reflections, be exposed to levels of laser radiation above the MPE.

The AL-40 Pulsed Alexandrite Laser produces a maximum possible output of 80 J/cm² or fluence, also known as energy dosage, or called radiant exposure. The MPE for long pulse Alexandrite laser is given in ANSI Z136.1 as 2.3×10^{-5} J/cm². Using the equations in Appendix B of ANSI Z136.1, the NHZ for this laser has a radius of approximately 11 meters, or 36 feet. This means that there is a potential for exposure above the ANSI MPE within 36 feet of the laser during operation, maintenance or service. Since this distance is larger than most installations in which the laser is to be used, it would be safe to assume that the entire operating room or theater is within the NHZ.

The ANSI standards contain guidance on protective procedures and administration of a laser safety program as well as sample Standard operating Procedures. Please, follow the recommendations of these standards. In particular, the use of safety eyewear, specific for the Alexandrite laser wavelength of 755 nm with an adequate optical density rating (\geq OD 6) must be used for all personnel with the potential for laser exposure. Consult with your laser safety eyewear supplier for recommendations, or contact DDC Technologies Customer Service.

The laser system should also be placed in relation to doors or entry ways in such a manner as to contain stray laser emissions. ANSI Z136.1 and Z136.3 contain diagrams and suggestions on how to properly set-up a laser laboratory. Please refer to the latest editions of these documents.

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Overview

The AL-40 Alexandrite Laser provides the hair removal market with a solid-state laser for use in hair removal applications requiring the precise delivery of laser treatment energy to a predetermined target site.

The design for the AL-40 Alexandrite Laser incorporates a number of features that provide high reliability, versatility, compact size and superior performance. The system is micro-processor based to ensure maximum safety, flexibility in function and ease of use. The touch-screen control panel (see Figure 3-1) displays:

- Sequential use instructions
- Key operating data
- System status information

This information is shown on a color LCD display, which is mounted on the front panel of the laser chassis.

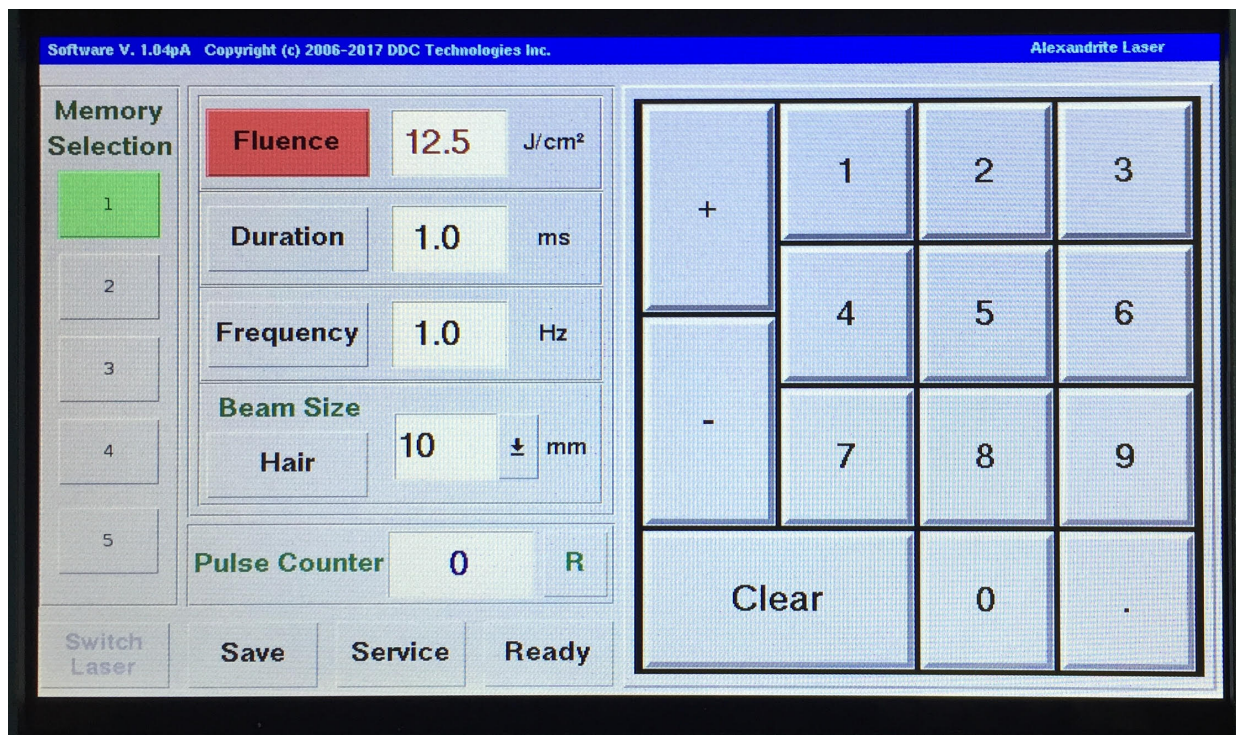


Figure 3-1. AL-40 Laser Control Panel

Wavelength

The AL-40 Alexandrite Laser emits laser radiation at a narrow wavelength band around 755 nanometers (nm). The beam is aligned and delivered to the treatment area via an optical fiber with attached handpiece device.

AL-40 System Specifications

Item	Description
Laser Type	Solid-state, Long Pulse Alexandrite Laser
Laser Wavelength	755 nm
Max. Energy Per Pulse, J	60 J
Laser Pulse Width	0.5-100 ms (user selectable)
Max. Average Power	100 W
Pulse Repetition Rate	Single Shot – 5 Hz
Beam Delivery	Optical fiber, 10 feet (3 m) length
Optical Fiber core diameter	1000 μm
Handpiece Spot Size	10 mm, 12 mm or 16 mm dia. (Optional 20 mm dia. available)
Max. Energy Fluence @ 16 mm spot size	30 J/cm ²
Handpiece Cooling	Direct constant flow air cooling (compressed chilled air jet)
Dimensions (HxWxL)	31”x 13”x 27” (790x330x690 mm)
Weight	65 kg (143 lbs.)
Power Requirements	215...240V single phase ~50/60Hz, 20A
Noise Level	<70 dB

Components

The AL-40 Alexandrite Laser consists of the following components: Optical Laser Head, Power Supply Unit, System Control Electronics Module, Internal Cooling System, Delivery System with Handpiece.

Optical Laser Head

The optical laser head consists of an optical bench with a flashlamp pump chamber that houses the Alexandrite crystal and two xenon flashlamps; laser resonator mirrors; an energy meter sensor, red aiming beam and other optical components.

Power Supply Unit

The power supply unit consists of a high voltage power supply with IGBT-based Pulse-Forming Network (PFN) electrical circuit, and power distribution system.

System Control Electronics

The system control electronics consists of the touch screen control panel with interface controller (mini-PC), main system controller (microprocessor PC board with touch-screen control pad), system controls, interlocks and sensors.

Cooling System

This system uses self-contained water-to-air cooling unit for laser pump chamber and electronics cooling.

Optical Delivery System

The optical delivery system delivers laser energy from the device chassis to the treatment area. The optical fiber cable, enclosed in reinforced protective jacket, is attached to the fiber port at the rear panel of the laser.

Laser Handpiece

The laser handpiece is equipped with the distance gauge, which provides fixed laser beam spot size on the treatment area. The spot size and the fluence level can be changed from the laser control panel. The motorized zoom lens position is electronically recognized by the system and is reflected as the Laser Beam Spot Size (**Beam Size**) on the LCD display. The system processor will calculate the energy fluence delivered to the patient skin in accordance with selected laser beam spot size.

<i>Component</i>	<i>Description</i>
Handpiece Handle	The user holds the laser handpiece by the body-handle during treatment.
Protective Window (Output Aperture)	The handpiece output window serves as the final laser aperture. It protects the spot size forming optics (imaging lenses) inside the handpiece from contamination during treatment. The imaging lenses change the laser beam divergence out of the fiber, and form fixed laser beam spot size at the certain distance from the handpiece.
Fiber Jacket	Contains optical fiber. The reinforced corrugated jacket protects optical fiber from mechanical damage. It also prevents the fiber from being bent to the too small radius during treatment. <u>Warning!</u> Fiber jacket can protect the optical fiber to the certain extent only. Do not apply force to try to bend the cable to the smaller radius than the jacket easily allows or by pulling on the fiber by the handpiece. This can lead to the permanent fiber cable damage, which is not covered by Limited Warranty.
Distance Gauge	Provides fixed laser beam spot size on the treatment area. Second gauge also serves as a guide and output nozzle for the cooling air jet.

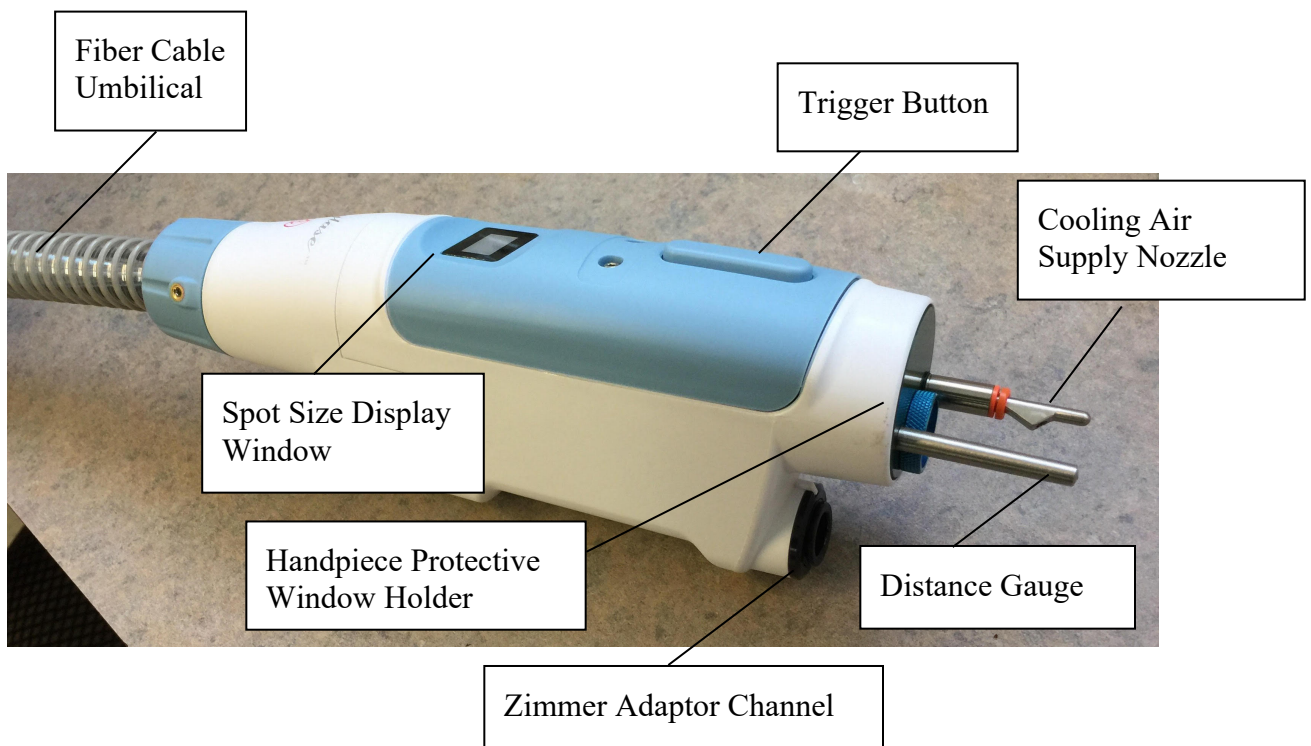


Figure 3-2. Laser Handpiece Components

Fiber Support Arm

The fiber support arm is intended to support the beam delivery system so that the conduit is kept clear of the operation area, as well as providing support for the conduit while in use. It is recommended to use the handpiece while the fiber conduit is attached to the fiber support arm. The arm is capable of swinging to a convenient location, or locking in place by tightening the fiber support clamp on the rear of the machine (see “Fiber Support Arm and Fiber Attachment” section of Chapter 4 for more details). By keeping the handpiece attached to the arm, it will also prevent accidental dropping of the hand piece.

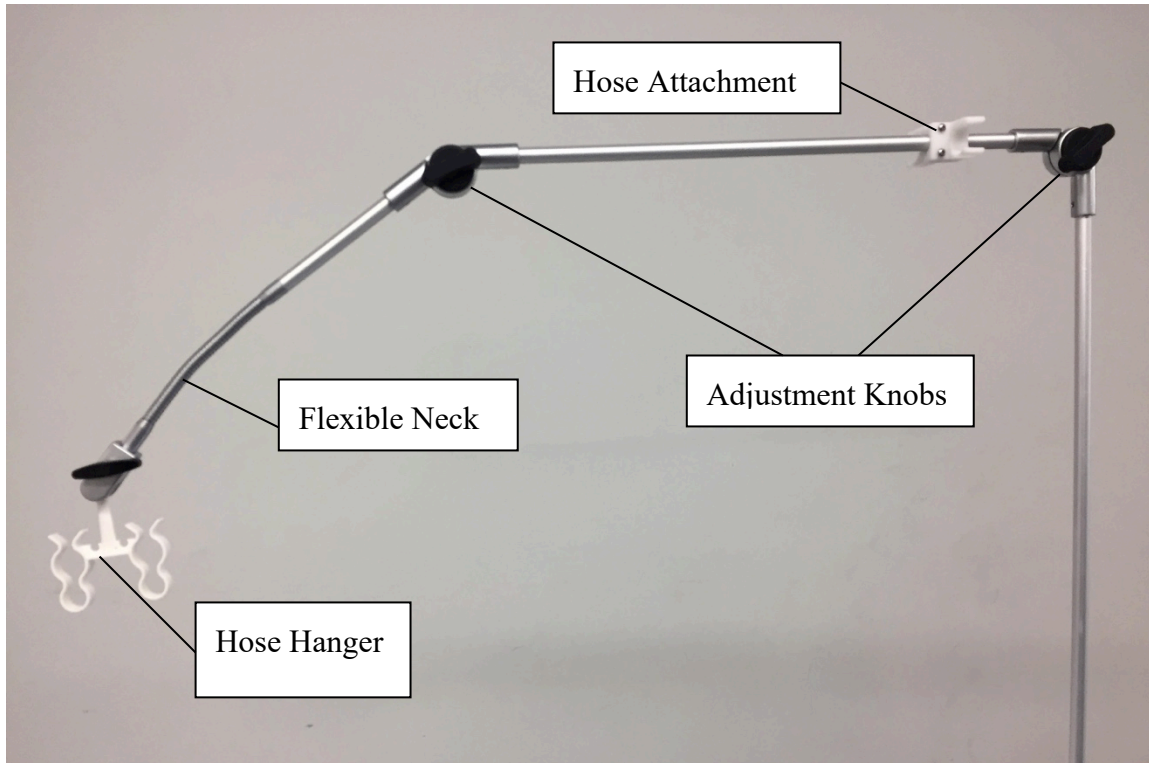


Figure 3-3. Fiber Support Arm Components

Controls and Indicators

The AL-40 Alexandrite Laser is equipped with features designed specifically to provide safe and reliable operation to laser users. All laser personnel should become familiar with the location (see Figures) and operation of the safety features discussed below and on the following pages.

<i>Component</i>	<i>Description</i>
Main Power Switch	This switch disconnects the system from the power source when put in OFF position.
Display	Touch-screen Color LCD display prompts the user to enter and initiate important operating parameters.
Emergency Stop Button	A large red circular push-button switch that disables the laser power supply. (Note: The EMERGENCY STOP button will remain depressed until it is rotated clockwise and pulled up.)
Key (power) Switch	A key switch that activates the computer and laser system. The key may be removed only when in the OFF position.

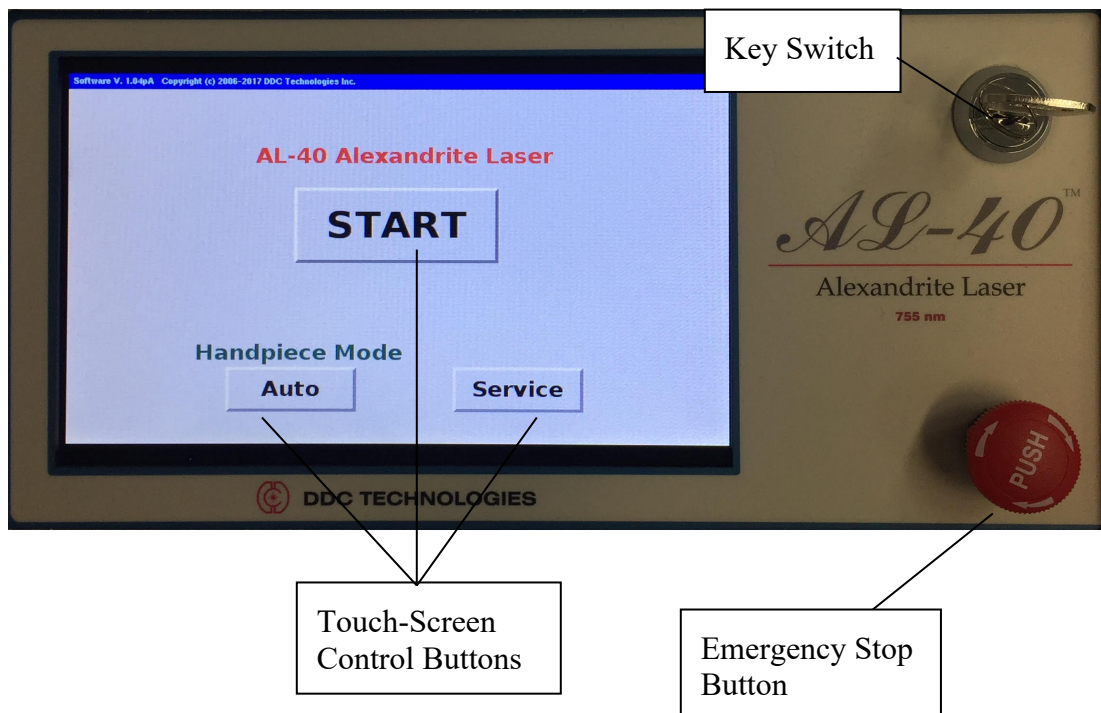


Figure 3-4. Front controls



Figure 3-5. Front and side of the AL-40 Laser

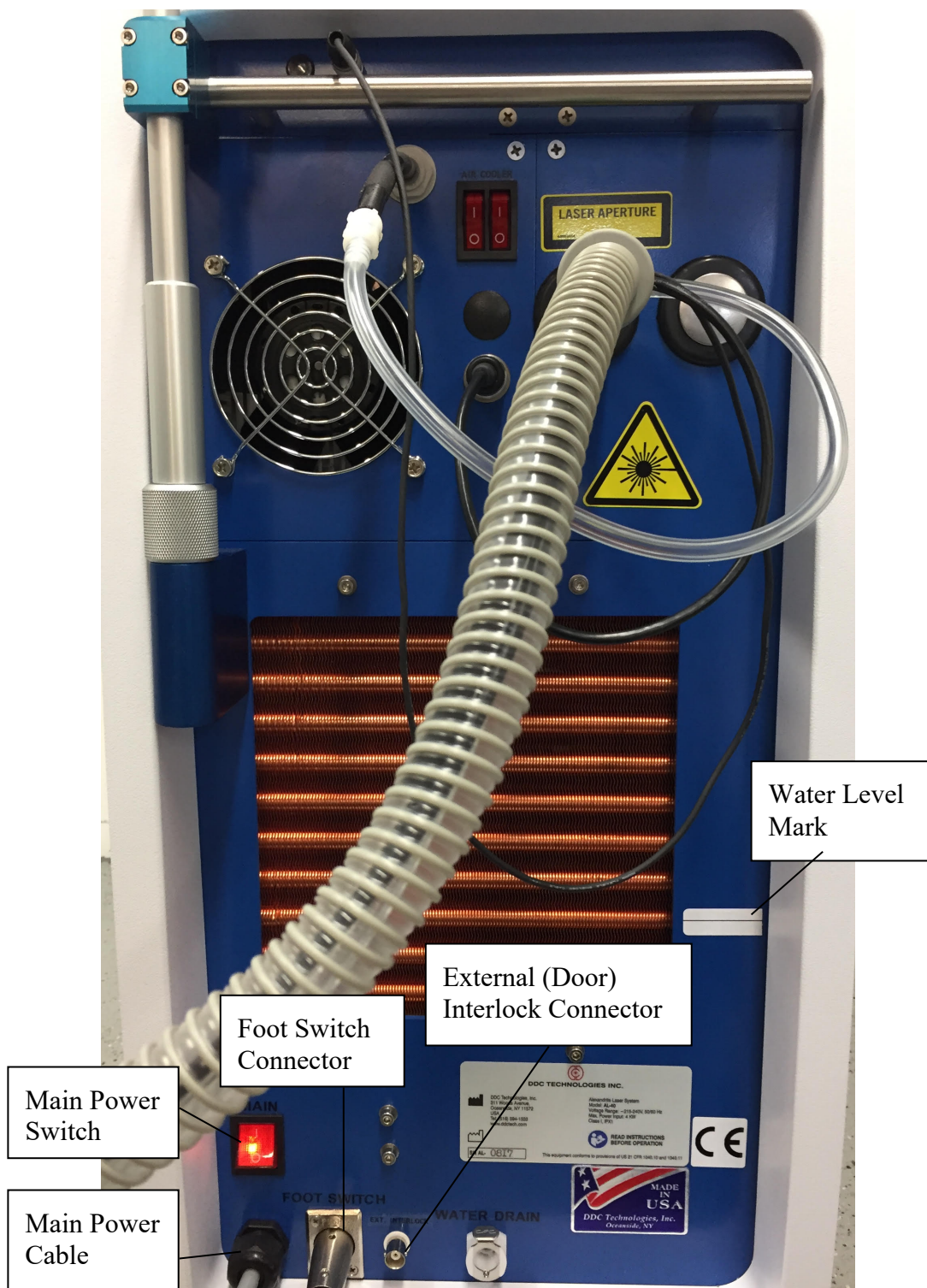


Figure 3-6 Rear of the AL-40 Laser

<i>Component</i>	<i>Description</i>
Optical Fiber Cable	Laser light pulses are delivered via a fiber optic cable.
Laser Handpiece	The handpiece provides accurate laser beam delivery to the treatment area. Different spot sizes can be generated by motorized zoom lens and provide fixed laser beam diameter on the skin, helping to maintain desired energy density during treatment.
Rear Panel	The power cord and footswitch cable are attached at this panel.
Footswitch	Depressing the footswitch activates the laser, permitting it to fire when the laser is in READY mode.
Control Panel	The control panel with touch-screen LCD display shows the system status at all times, allows the user to select treatment parameters and displays messages to the user.

Main Control Panel

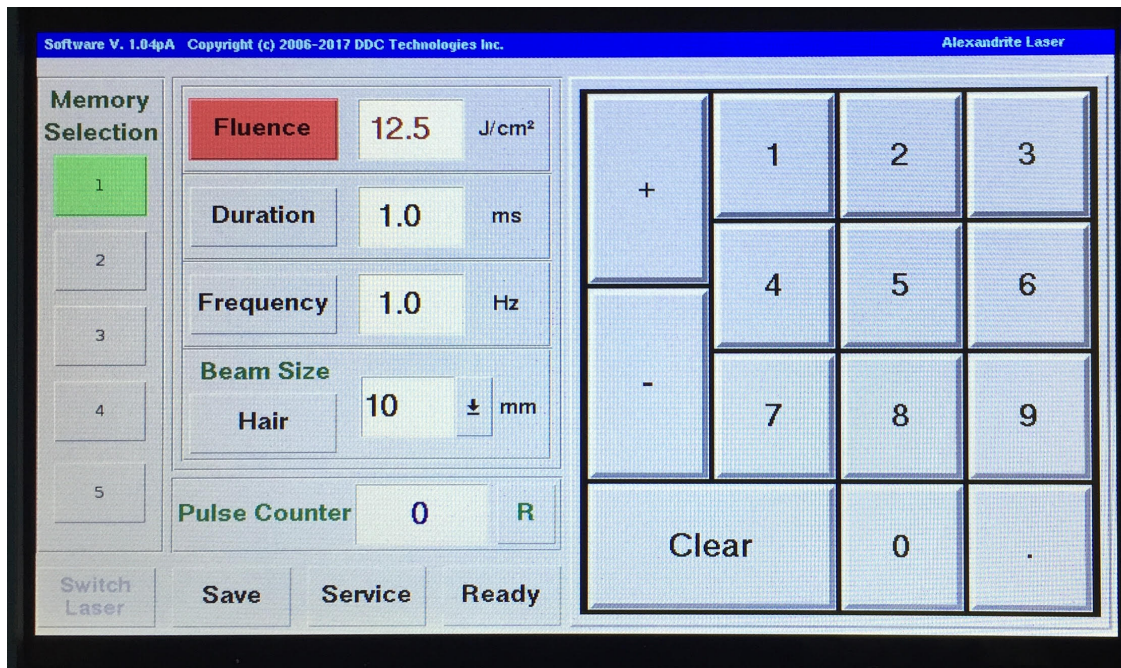


Figure 3-7. Control Panel – Parameter Setting (Edit) Screen

<i>Control</i>	<i>Description</i>
Parameter Setting Buttons / Display	Used to display current device settings: Beam Size (mm); Duration (pulse width, ms); Frequency (Hz)-pulse repetition frequency. By pressing the corresponding button the Parameter can be selected for editing.
Fluence	Used to set Fluence on the target. After user presets desired fluence level, the system parameters are adjusted based on the laser calibration table (stored in system memory) and current Pulse Duration and Beam Size settings. Fluence is a measure of energy density and is shown as Joules/cm ²
Message / Prompt Area	Used to display current system status, as well as Help and Error messages. The Parameter Edit Keypad is also displayed in this area when one of the Parameter buttons is depressed.
Memory Selection Buttons	Used to recall pre-set Operating Parameters stored in each of 5 Memory Buttons.
Save Button	Used to switch between EDIT and READY system modes while saving new parameter settings.
Ready Button	Used to switch between EDIT and READY system modes without saving any changes in parameter settings.
Keypad Buttons	Used to edit system operating parameters.
Pulse Counter (P/C)	Pulse Counter displays number of laser pulses fired since last counter reset. In order to reset, press “R” button.
Service Button	Used to switch between EDIT screen and SERVICE screen.

Required Labels

Government regulations require that certain labels appear on the EPY-50 Laser and be reproduced in this manual.



Located on front lower panel of laser system
(4000-001D)



Located on output end of handpiece
(4000-001A)



Located on front and rear panels of laser system
(4000-003D)



Located on rear of laser system (4000-001S)

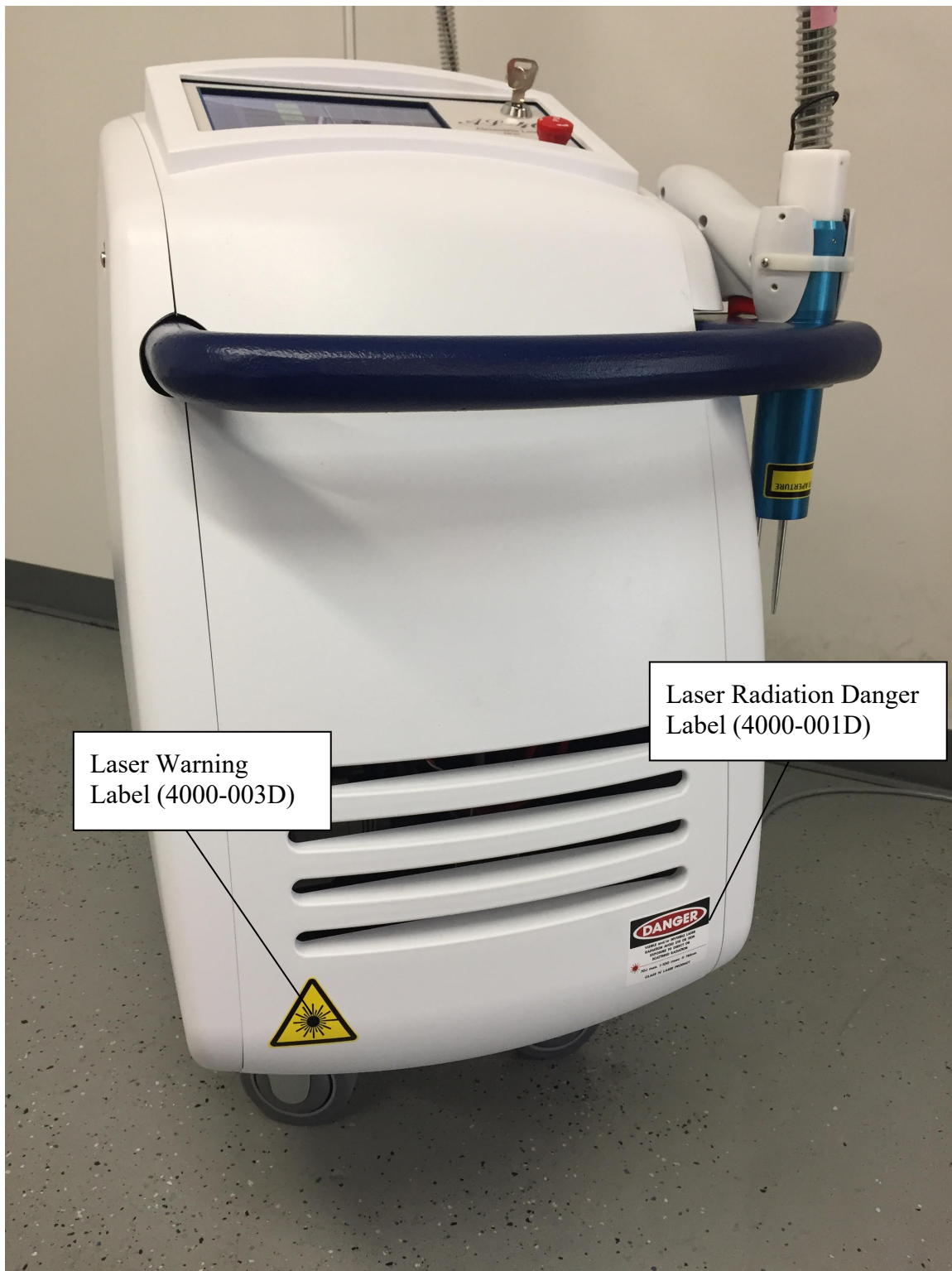


Figure 3-8. Labels, front of the AL-40 Laser

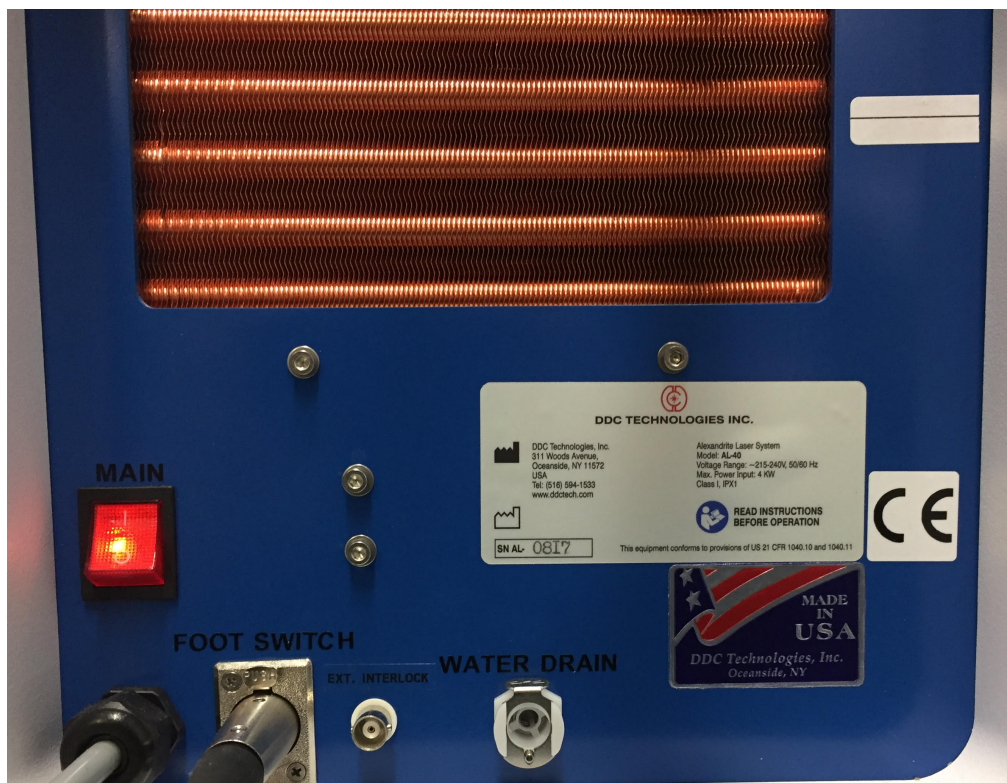
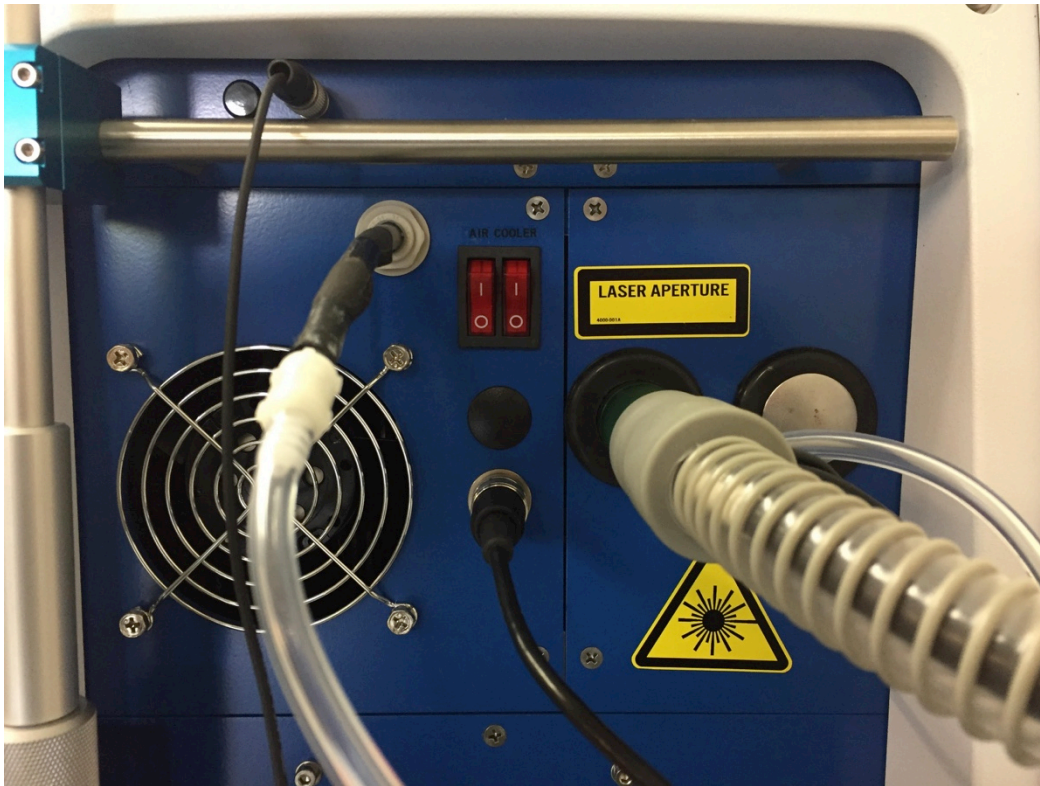


Figure 3-9. Labels, rear of the AL-40 Laser



Figure 3-10. Handpiece Label

Peripheral Devices

Peripheral devices contained with the AL-40 Alexandrite Laser are as follows:

- Footswitch
- 2 Pairs of Safety Glasses
- 1 Key
- Operator's Manual
- Laser Safety Door Sign

System Accessories

Laser Safety Eyewear

Order P/N GCYN-35

These glasses are designed to protect the person operating the AL-40 Alexandrite Laser, as well as the patient and others who may be in the room. They are designed to provide OD > 7 at 755 nm. Their shape is designed to protect the wearer at various angles. Two pairs are included with each system.

Keys

Order P/N CKL12BFW01

The laser is powered up by turning the supplied key in the switch located on the upper-front console. One key is included with each system.

Operator's Manual

Order P/N 4000-001M

Replacement or additional copies of this manual are available. Everyone who works with the AL-40 Alexandrite Laser should read and familiarize themselves with the contents of this manual. One is included with each system.

Laser Safety Door Sign

Order P/N 4000-010D

This sign should be posted outside of the room where the AL-40 Alexandrite Laser is located. It serves as an informative warning to those who wish to enter the room that there are potential hazards related to the device and what level of precaution they should consider before entering. One sign is supplied with each system.

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Customer's Responsibilities

Before installation of the laser system, the intended site must be prepared as described in this section. The selected site must have sufficient space to accommodate the laser system, must possess the proper electrical power configuration and receptacles, and must meet the environmental specifications outlined in this section. DDC Technologies, Inc. can not guarantee the operating parameters of any system installed in a site that does not meet specifications described in this section.

Note: Generally laser installation is performed at customer's facilities by qualified laser engineer or technician. However, certain experienced customers and authorized specially trained distributors can successfully perform device installation on their own. Please, refer to **AL-40: Brief Installation Guide** attached to this Manual for step-by-step installation instructions.

Manufacturer's Responsibilities

Installation of the laser system is performed by a qualified laser engineer. (NOTE: Initial installation and test can be a lengthy process; the room where the laser will be housed should be blocked off for about one day to allow adequate time for this procedure.) Upon arrival, the DDC Technologies Service Technician will complete the following:

- Uncrate the AL-40 Laser System, and position it in the location you have pre-selected.
- Couple the laser to the existing 215-240V AC receptacle, and connect to an earth ground using #16 wire or larger.
- Fill the cooling system with distilled water and test the laser for proper alignment, calibration, and functional operation of all components.
- Coordinate the performance of on-site safety checks by biomedical engineering personnel.

Following installation, a qualified service representative will instruct designated personnel on the basic operation and care of the laser system, which supplements the information in this manual. This instruction is not a substitute for the in-depth clinical training required for a practitioner to become proficient in the use of this laser.

Facilities Requirements

Electrical Requirements

The room where the laser will be installed should be equipped with a 215-240V AC, single phase, 20 amp electrical service. It is also recommended that the electrical supply to the equipment be independently fused and switched by a 20 amp circuit breaker, mounted at a convenient height in the operating area. This will enable the Alexandrite Laser to be electronically isolated for maintenance purposes.

Due to many electrical codes and preferences of most facilities, it is the responsibility of the user to provide the male plug for attachment to the line cord for use in your receptacle. Before plugging the system, make sure that the rear panel Main Switch and the Key Switch are in the OFF position and the main electrical cable is tightly connected to the wall receptacle.

Ambient Temperature

Proper ambient temperature must not exceed 25 °C and must not fall below 15 °C. It is likely that the laser will continue to function normally if the temperature is not within these limits. However, high temperature warning message and system shut-off due to overheating condition may take place if the ambient room temperature is too high, as well as "System Is Too Cold" error message may come up if the coolant water temperature in the system is below 15 °C.

The laser will generate approximately 3500 watts of heat into the room when operating at full power. Therefore, the air conditioner you select for the laser room must be able to accommodate this additional heat.

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 airborne dust particles to a minimum. Dust particle can cause permanent damage to optical surfaces. Never place the laser in an environmental proximal to areas undergoing construction or remodeling.

Space Requirements

Sufficient floor space is also required for the laser system. The suggested minimum room size is 10 x 10 feet (3 x 3 meters). Allow 24 inches (61 cm) of clearance on all sides of the machine so that the air vents will not be obstructed.

The Alexandrite Laser is moved easily from room to room. Make sure that adequate space and appropriate electrical hookups are available in each room where its use is anticipated. If the system is moved, care must be taken to ensure that the optical fiber cable and laser handpiece are not damaged.

Footswitch Connection

Check to see that the footswitch cable is firmly connected to the footswitch receptacle input on the back of the laser unit.



Figure 4-1. Footswitch connection.

Beam Delivery System Connection

Fiber Support Arm Installation

Before attaching the beam delivery system, it is important to install the fiber support arm (fiber support pole) to the back of the machine. This arm provides support for the fiber conduit and handpiece both while in use and in standby.

The black adjustment knobs on the arm (see Figure 3-3) can be loosened in order to position the arm segments in the desired positions. Then, firmly lock the knobs in place to keep the arm rigid. For installation, position the arm as shown in Figure 4-2. Screw the attachment knob all the way into the fiber support holder. The pole should rest in the groove of the clamp already installed on the rear of the machine. Once the pole is installed, attach the second piece, Fiber Support Clamp 2 (see Fig. 4-2) with 4 M3 screws. Tightening the M3 screws all the way will lock the pole in place while loosening the screws will allow the pole to freely swing back and forth.

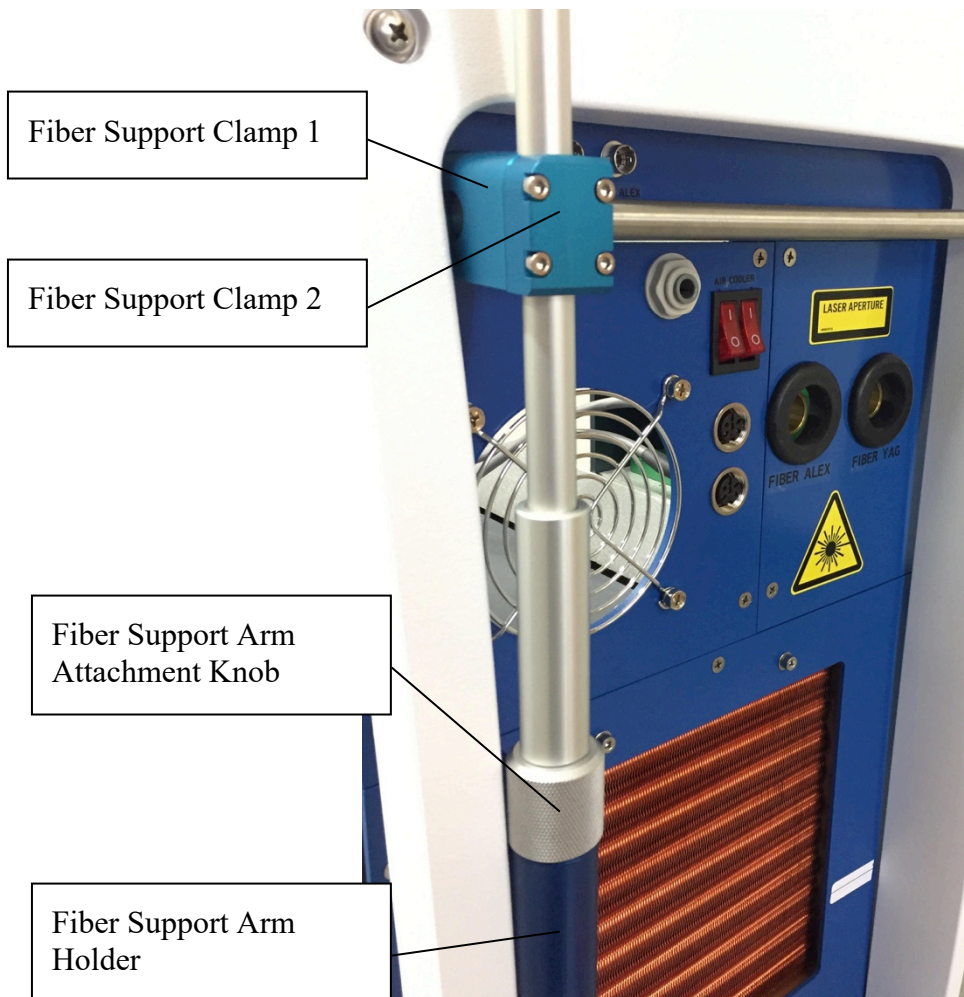


Figure 4-2. Fiber Support Arm Installation

Beam Delivery System Attachment

After the fiber support arm is installed, the beam delivery system can be securely installed. Remove the fiber from the box and place the handpiece into the handpiece holder (white grommet) on the laser front handle. Feed the fiber conduit into the hose hanger, then push it into the hose attachment (see Fig. 4-4). Before attachment of the fiber to the fiber port pull the green fiber cable attachment out of the grey rubber cuff of the conduit. Finally, remove the black vinyl cover from the end of the fiber. Insert the fiber end (Blast Shield Holder / FC Connector) into the fiber port receptacle on the laser rear panel. Screw the fiber cable attachment into the laser port all the way to the end. Gently push the rubber cuff back onto fiber cable attachment (see Fig. 4-3). Connect all electrical cables to appropriate sockets. Connect air cooling system tubing (if equipped) to the cooling air supply connector.

⚠ Never touch the glass surface of the fiber Blast Shield Window at the fiber end during this procedure! Only use metal parts for holding the assembly. Make sure the Blast Shield Window is clean from fingerprints and dust before inserting fiber end to the fiber port.

⚠ It is important not to over tighten the fiber cable attachment. Screw the part until it reaches the bottom of the threads but do not apply excessive force. Figure 4-3 and 4-4 show the fiber securely attached to the arm and the fiber port at the rear panel of the laser.

For more information about this procedure, refer to SOP1: "Beam Delivery System Installation" in the Service Manual.

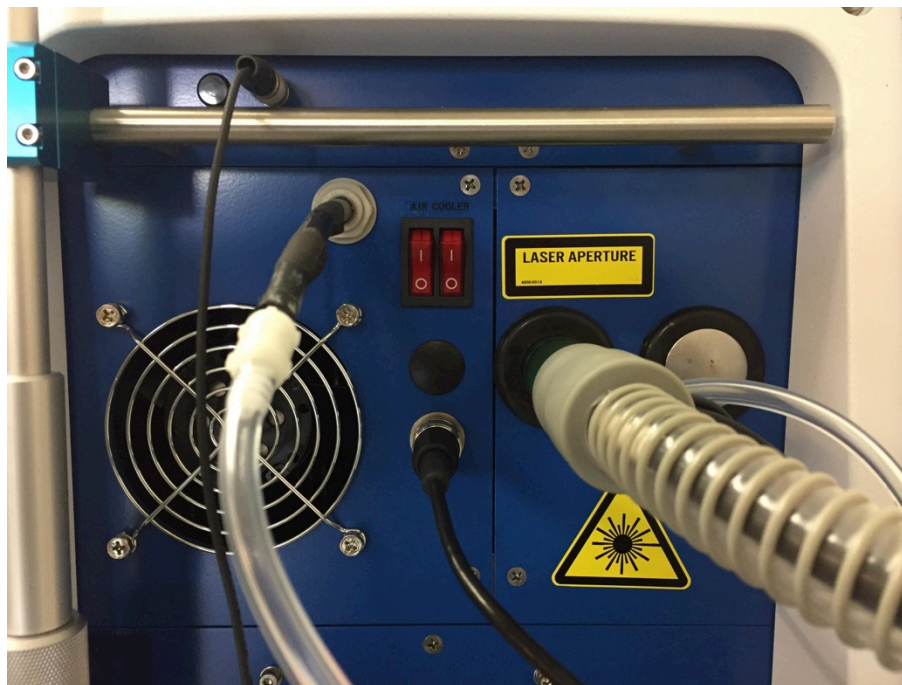


Figure 4-3. Fiber Cable Attached to the Fiber Port.



Figure 4-4. Fiber Installed on Fiber Support Arm

Chapter 5: System Operation

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In the United States, federal law restricts this device to sale by or on the order of a physician or any practitioner licensed by state law to use or order the use of this device. No such restrictions apply to international sales. Those who use the system should be properly trained and authorized by the practitioner or institution.

Although the determination of appropriate training criteria is the responsibility of the practitioner or institution, it is recommended that minimal training include education on laser physics, laser safety, laser interaction with tissue, guidelines for use in specific applications, and hands-on training with appropriate models.

Control System

The AL-40 Alexandrite Laser is a microprocessor-controlled system designed to be “user-friendly” while providing highly reliable laser output. The touch screen color LCD display shows important operating data, instructions for use and messages to the user.



Figure 5-1. Main Control Panel

Before Beginning

Before you turn on the laser, ensure that the location of the AL-40 Alexandrite Laser does not interfere with other objects (including the door) in the room. There should be at least two feet (61 cm) of free air space around all sides of the system.

Treat the optical fiber/handpiece assembly with care: if the handpiece hits the console, floor or other treatment room equipment, damage can result. Such damage is not covered in the standard warranty or service contract.

Do not have the main power cable stretched so tightly that it puts unnecessary strain on the cable and its terminations. Be sure that the main cable is out of pedestrian traffic around the system.

Ensure that protective eyewear appropriate for the Alexandrite Laser system ($>OD\ 7$ at 755 nm) is readily available to be put on **before the system is energized**.

Additional goggles or glasses are available. Please contact Customer Service for more information.



EVERYONE in the treatment area should have on protective eyewear at this point, and as long as the system is turned on.

Operating Instructions

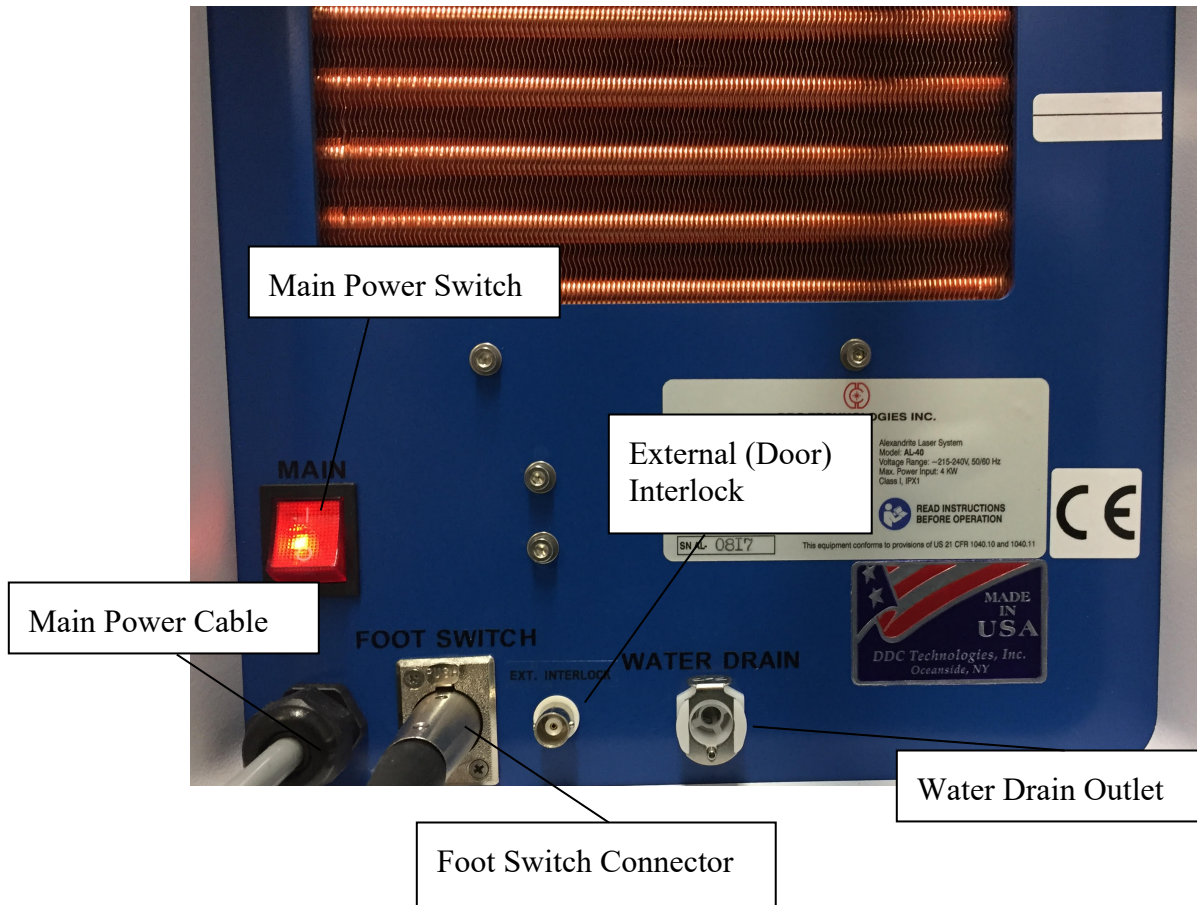


Figure 5-2 (a). Rear panel controls and connectors (bottom)

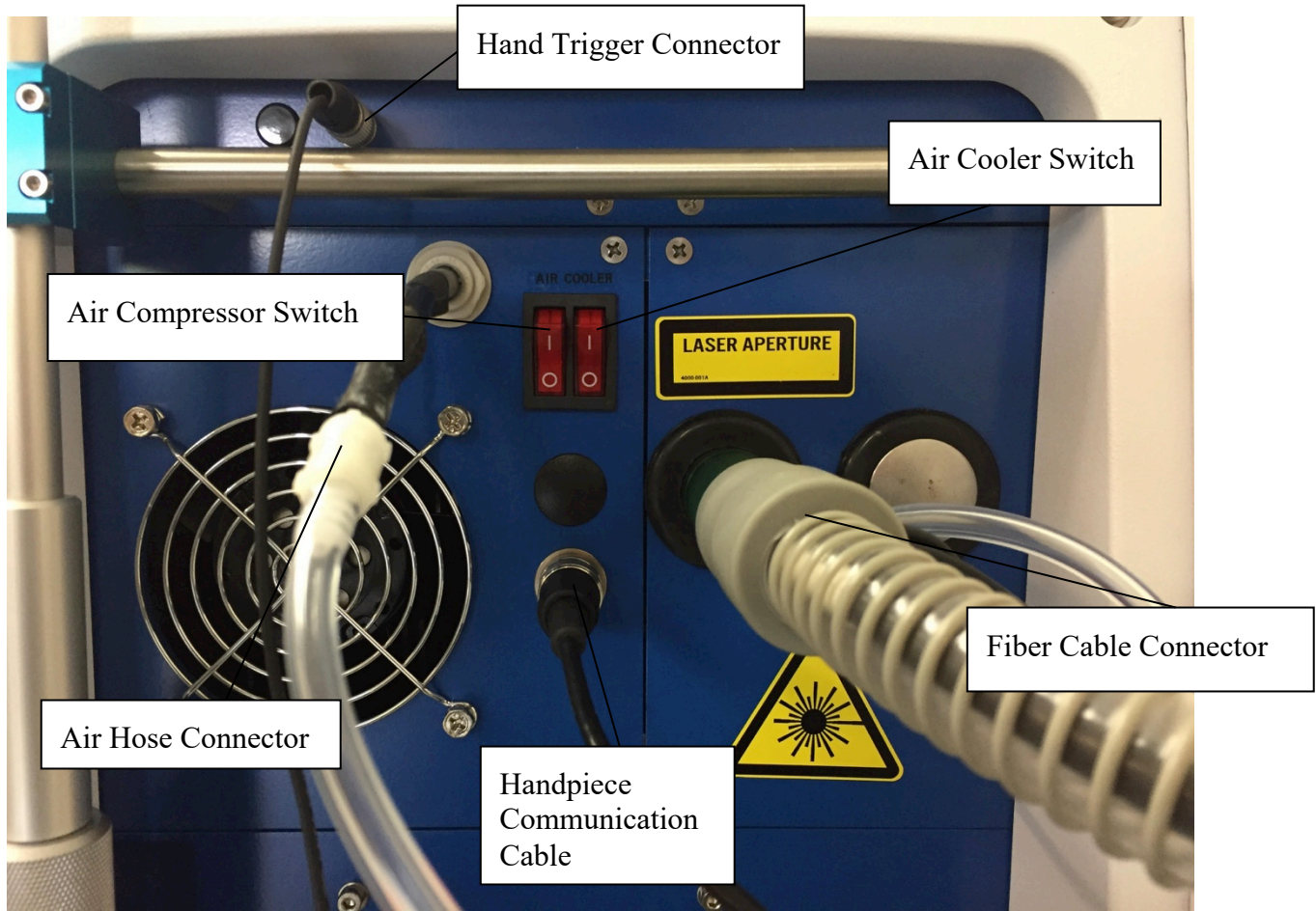


Figure 5-2 (b). Rear panel controls and connectors (top)

Start-Up

Ensure that the main power line is plugged into the wall receptacle.

Turn on the Main Power Switch located at rear of the unit by switching it to the ON position. (See Figure 5-2 (a)).

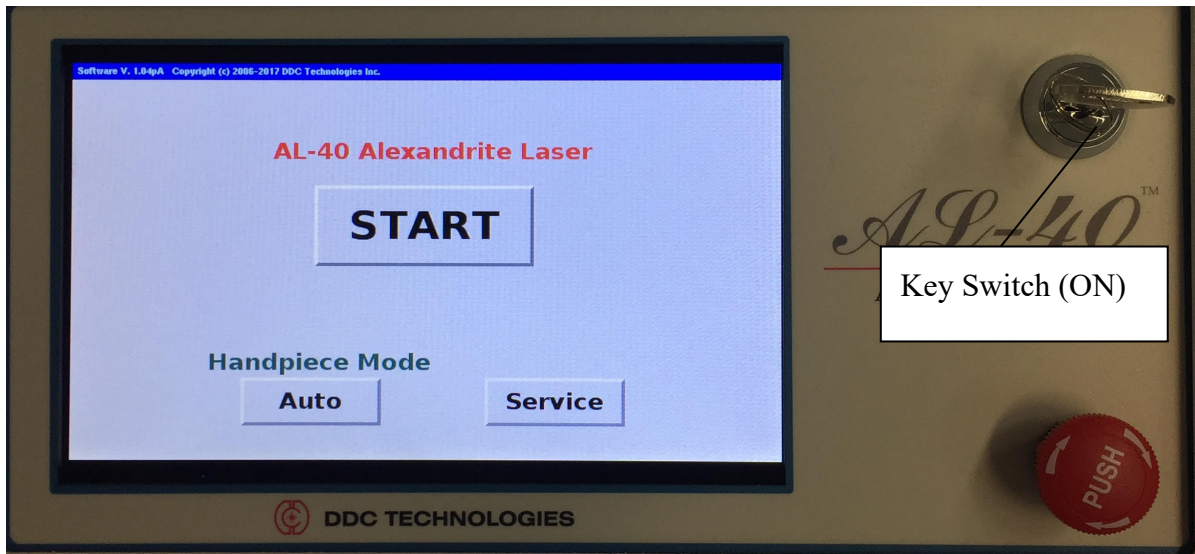


Figure 5-3. Front control panel (key on)

To activate the AL-40 Alexandrite Laser:

Insert the laser key and rotate clockwise. (See Figure 5-3).

After the system is turned on and software self-test procedure is complete, the Laser Output Initiation screen will be displayed. Wait for the message “Waiting for handpiece” to disappear. Press the Start button on the touch screen (see Fig. 5-3).

At this moment the cooling system pump will start and laser lamp will ignite. After the system has completed the start up cycle, laser will stay in *Edit* mode. In this mode laser operating parameters can be modified by the operator and the laser energy can not be emitted.

After the system is turned on, Parameter Settings stored in Memory #1 are used as default operating parameters, until different parameters are selected by the user.

Edit Mode (Setting Parameters)

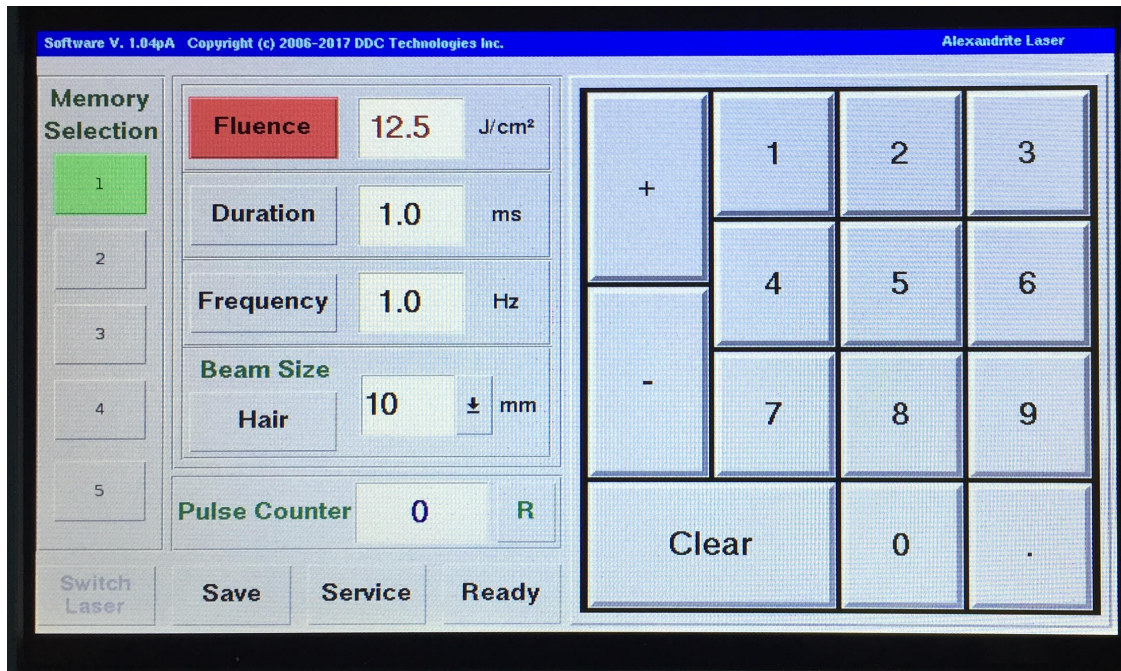


Figure 5-4. Edit Mode Screen

All parameters that can be modified by the operator are entered while in the **Edit** mode. To switch between **Ready** and **Edit** mode **Ready** or **Save** button on the touch-screen panel must be depressed. Pressing **Save** button will save all parameter changes that have been made, while pressing **Ready** button will cancel those changes. The operator can also select Parameter Settings by simply pressing corresponding Memory Button. Total 5 different Parameter Settings are available and can be stored in Memory Buttons #1 to #5. The currently selected setting is highlighted, others are displayed in dim mode. When **Save** button is pressed, new set of operating parameters is stored in highlighted Memory cell and laser switches to **Ready** mode with these parameters selected.

To modify parameters, stored in each of 5 memory settings, the **Keypad Buttons** must be used.

With **Parameter** buttons (**Fluence**, **Duration**, **Frequency** and **Beam Size**) operator can select parameter that he wishes to change. The selected parameter will be displayed on highlighted (green) background. The selected parameter value can be changed by pressing +/- buttons. Each time the +/- button is pressed, the next higher/lower parameter value will be selected. Operator can also enter desired parameter value directly, with keypad number buttons. The new settings will be stored in memory (in the memory cell #, which is currently highlighted) when **Save** button is pressed.

The laser beam spot size can only be changed from the touch-screen control panel. This function works only in **Edit** mode. Three spot sizes (10 mm, 12 mm and 16 mm or larger optional set of 14, 16 and 20 mm) are available in the AL-40 Alexandrite handpiece. The

currently selected spot size is displayed in the BEAM SIZE window on the LCD display. It is also displayed on the handpiece LED spot size indicator.

Note: handpiece LED spot size indicator always displays actual handpiece state, i.e. it will display previously used spot size until **Save** button is pressed and the zoom lens moves to new position.

The treatment area (laser beam spot size on the skin) will be also illuminated by the red aiming beam in **Ready** mode. The spot size of the aiming beam is changing proportionally to the actual laser beam spot size.

The system will keep pre-selected **Fluence** value constant, no matter what spot size have been chosen by the user. However, if the pre-set **Fluence** level can not be supported with selected spot size, the system will automatically reduce the Fluence to the maximum possible level and reflect the change on the LCD display. The laser pulse **Duration** will be automatically adjusted to the higher value by the system software if selected **Fluence** is too high and can not be achieved with currently selected **Duration**.

Note: Pulse **Duration** settings range is always limited by selected Fluence, i.e. some pulse widths may not be available at certain combinations of Fluence and Beam Size settings. This is normal.

LONG PULSE MODE

All pulses with Durations above 7 ms are “stretched”, i.e. consist of a train of shorter pulses spaced in time. The sum of the pulse widths in each train is equal to 7 ms respectively. This mode of operation is called Long Pulse Mode and is designed to provide a certain degree of pain relief for patients with too sensitive skin. It is not recommended to use this mode for treatment of areas with very fine (thin) hair.

Example: To change the **Fluence** in Parameter Settings #2, do the following:

1. Press Memory Button #2
2. Press **Fluence** button to select Fluence option (will be displayed in highlighted mode)
3. Use + button, if you want to increase the fluence and – button, if the fluence must be decreased or directly enter desired fluence with a keypad.
4. When desired fluence value is displayed, press **Save** button to switch the laser to **Ready** mode.

Ready Mode

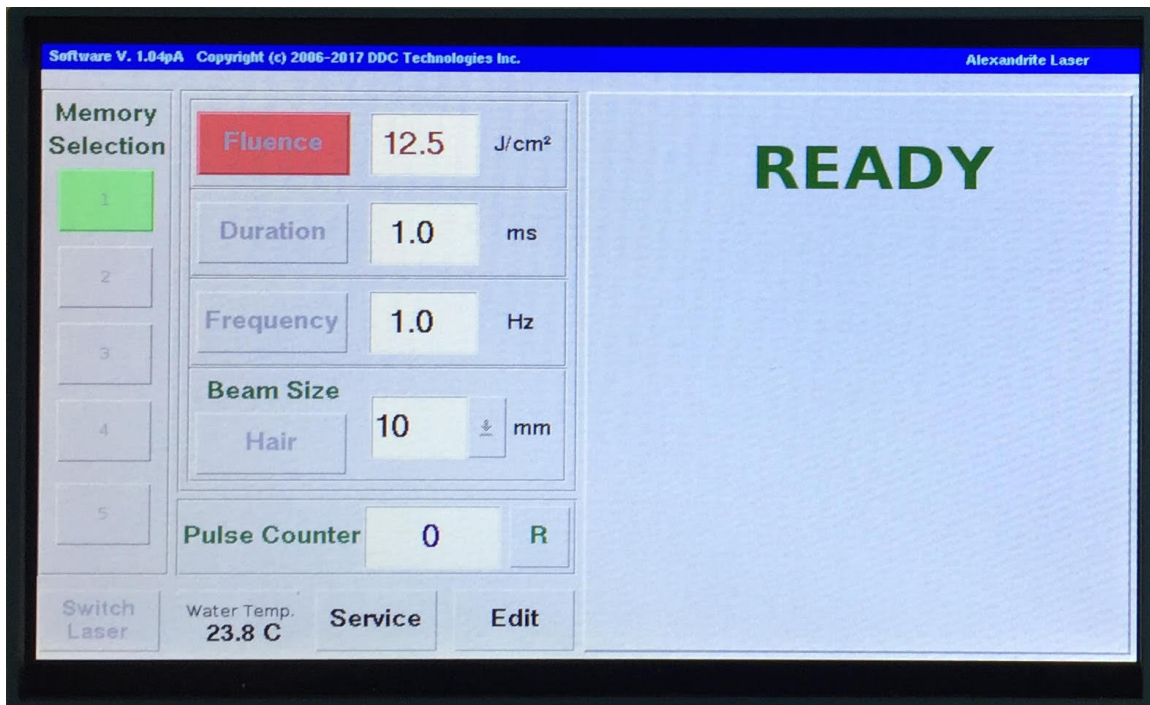


Figure 5-5. Ready Mode Screen

When in Ready mode, please ensure that everyone in the treatment room is wearing proper eye protection. For more information regarding eye safety, please see Chapter 2, Laser Safety Information.

Press **Save** or **Ready** button to switch the laser from *Edit* to *Ready* mode. The screen will change to Ready mode. The Message area on the LCD display will read: “Ready”. In *Ready* mode the laser is armed and ready to fire. The intra-cavity shutter is open and the laser power can be released by depressing the footswitch. Unless the footswitch or the finger trigger on the handpiece handle is depressed, it is not possible to fire the laser in this mode.

It is not possible to change parameters while in *Ready* mode.

To enter *Edit* mode from *Ready* mode, press **Edit** button.

When you are ready to begin laser treatment, press the footswitch. At this moment laser energy will be delivered to the treatment area.

The frequency display in the Parameter Settings area will show laser Pulse Repetition Frequency (PRF) in Hz. In the Single Shot mode the only one laser pulse will be delivered when the footswitch is depressed. In order to fire laser again, the footswitch must be released and then depressed one more time. In this mode the frequency display in the Parameter Settings area will read “Single”.

Session Complete

When the session is complete:

If another patient is scheduled within 30 minutes, place the system into the ***Edit*** mode and clean the handpiece. The handpiece **MUST** be cleaned prior to next patient treatment. See handpiece cleaning procedure below.

Note: The laser controller will automatically switch the laser from ***Ready*** to ***Edit*** (Standby) mode if no action was taken by the operator within last 5 minutes.

If the system is not used again within 30 minutes, it is recommended to turn off the system by:

Turning the key switch counterclockwise.

Handpiece Cleaning

The handpiece is a non-critical product per APIC Guidelines and requires cleaning of the Handpiece Protective Window by an alcohol swab in-between patients. This window is located inside the snap-in holder at the handpiece output aperture (between two distance gauges) and should be cleaned during extended use to reduce dirt accumulation. Products such as standard alcohol prep pads or Q-tips soaked with acetone, ethanol or methanol may be used to clean the laser Handpiece Protective Window between patients. Always finish the cleaning process with a fresh wipe or Q-tip to ensure that all areas are cleared of all debris. For better cleaning or for protective window replacement pull the holder out of the handpiece. Unscrew the holding nut and remove protective window from the holder.

Note: After extended use the optical surface of protective window can be damaged, despite of regular cleaning. This is normal. If extensive damages can be seen on the window surface, replace it with the new one. Please, contact DDC Technologies Customer Service department and ask for **Part #W-755-0501** (Alexandrite) to order.



Figure 5-6. Handpiece Protective Window is located inside the snap-in holder between distance gauges.

Cleaning the Laser Console

Clean the external surfaces of the laser console periodically with a clean cloth wetted with a spray cleaner (do not use acetone to clean any Laser Console parts!). Dry with a clean, dry cloth.



DO NOT spray or pour any type of cleaning agent directly onto the system, as it could lead to injury, such as electrical shock, or result in damage to the equipment.



To avoid electrical hazards, do not allow fluid of any kind to leak into the laser console.

Other System Features

HANDPIECE MANUAL MODE

In some situations the AL-40 Alexandrite laser handpiece detection system can be turned off. This is useful when handpiece-related errors happen in the system and operator needs to complete the treatment session. In order to start the laser in handpiece Manual Mode, on the laser controller Start Screen press and hold “Handpiece Mode” button for 3 sec. The button status will change from “**Auto**” to “**Manual**” and now the laser can be started with all handpiece-related errors ignored by the system.

WARNING! When laser is started in Manual Mode, handpiece spot size can not be changed as usual or automatically recognized by the laser controller! It is only possible to work with one currently installed handpiece spot size. If decision was made to start the laser in Manual Mode, the operator is responsible for the correct selection of the handpiece spot size (on the laser controller screen) that will match the actual handpiece output beam spot size. Failure to do so may result in severe skin burns due to incorrect Fluence settings or other injuries to the patient!

Do not use the laser in handpiece Manual Mode without need and arrange for laser handpiece service as soon as possible, to eliminate handpiece malfunction that results in handpiece errors.

SYSTEM SOUNDS

The AL-40 Alexandrite Laser is equipped with the system sounds function. This includes Pulse Sound and Error Sound options. The laser starts with both sound options turned OFF by default but it could be turned ON from the laser **Service** screen.

In order to turn system sounds on, select “Service” button from the **Edit** mode, then turn the desired sound option (either both or only one) ON by the corresponding buttons on the **Service** screen.

ERROR MESSAGES AND TROUBLESHOOTING

The AL-40 Alexandrite Laser has a number of internal interlock circuits and sensors that control the status of the laser. If the system detects an interlock error or inappropriate value of the monitoring parameter, the Error Message will appear in the Message area on the LCD display. The possible errors are divided into three categories:

SYSTEM/INTERLOCK ERRORS, SYSTEM FAULTS and LASER CONTROLLER ERRORS

System/Interlock Errors

When the error of this category takes place, the following error messages are possible:

Error Message	Possible Cause	Recommended Operator Action
External interlock open	The external interlock is open	Check the external interlock circuit
System overheat, please wait: T=XX.X	Water temperature in the cooling system is too high	Release the footswitch and wait ~1 to 3 min until the error message disappear. If it takes longer time to cool down the system, make sure that ambient room temperature is below 25°C. Remove the side panels and check if the system heat exchanger under main fan is clean from dust. Clean with vacuum cleaner, if necessary.

System Faults

When the error of this category takes place, the system controller automatically turns off the high voltage power supply, clears the LCD screen and displays corresponding error message. This procedure takes place after each SYSTEM FAULT and does not depend on the current system settings or operation mode. The laser operation can be resumed only after complete system TURN OFF procedure and then turning it back on.

Note: Turning the system OFF using red Emergency Button is also considered by controller as SYSTEM FAULT. To resume operation, the Emergency Button must be released by pulling it up and the system must be turned back ON using the Key Switch.

If any system fault occurs, the following error messages are possible:

Error Message	Possible Cause	Recommended Operator Action
Error: Lamp not ignited. Please, restart the laser.	The simmer circuit is not on. Flash lamp can not be ignited.	Restart the laser. If the problem persists, turn the system OFF and call Customer Service for flash lamp replacement.

Shutter Error: Please, restart the laser.	Improper operation of the laser resonator shutter.	Restart the laser. If the problem persists, turn the system OFF and call Customer Service for assistance.
Error: No water flow. Please, call for service!	There is insufficient water flow in the cooling system.	Check water level in the cooling tank. Add distilled water, if necessary and look for any signs of leak in the system. Restart the laser. If the problem persists, turn the system OFF and call Customer Service for assistance.
Emergency Button depressed. Please release the button and restart the laser.	Laser was turned off using the Emergency Button.	Release (rotate CW and pull up) the Emergency Button and restart the laser.
Charger Fault: Please, call for service!	Capacitor charger can not charge to required voltage or charging is too slow.	Restart the laser. If the problem persists, turn the system OFF and call Customer Service for assistance.
OverFluence Error. Please, restart the laser.	The measured Output Fluence was more than 25% higher than pre-set by the operator.	Restart the laser. If the problem persists, call Customer Service for assistance.
Overcharge Error: Please, call for service!	The measured charge on the capacitor bank was more than 10% higher than ordered by controller.	Critical system fault. Please, call Customer Service for assistance.
Charger Overheat Error: Please, call for service!	Capacitor charger temperature is too high.	Make sure that ambient room temperature is below 25°C. Do not turn the laser off. Please, allow time for the system to cool down and restart the laser. If the problem persists, call Customer Service for assistance.
Main Switch Error: Please, call for service!	One of the communication relays was not operating properly.	Please, restart the laser. If the problem persists, call Customer Service for assistance.
System overheat, T=xx.x. Please, call for service.	Water temperature in the cooling system was above critical level.	Please, allow time for the system to cool down and restart the laser. Make sure that cooling system fan has turned on. If not, please, call Customer Service for assistance.

Laser Controller Errors

When the error of this category takes place, the following error messages are possible:

Error Message	Possible Cause	Recommended Operator Action
Laser Controller Communication Error	There is no response from laser Main Controller through COM port within required timeout period.	The software will automatically reset the error when communication between controllers is re-established. If the problem persists, call Customer Service for assistance.
Laser Master Controller Error	There was unrecognized response from laser Main Controller through COM port.	Restart the laser. If the problem persists, call Customer Service for assistance.
Handpiece Error	There was no response from the handpiece to User Interface Controller within required timeout period. May also indicate handpiece zoom lens movement malfunction or spot size settings discrepancy between handpiece and Main Controller settings.	The software will automatically reset the error when communication between controller and handpiece is re-established. If the problem persists, call Customer Service for assistance.
Wrong Spot Size Error	There was handpiece zoom lens movement malfunction or spot size settings discrepancy between handpiece and Main Controller settings.	Restart the laser. Check if the handpiece zoom lens actually moves to the desired spot size. Check if correct handpiece is used with the unit (i.e. if its spot size set is matching the one stored in the laser Main Controller). If the problem persists, call Customer Service for assistance.
System Is Too Cold	Water Temperature in the laser cooling system is less than 15 °C	Laser Controller will not allow system start until water temperature is within normal range. Warm up the room and wait until water temperature will increase above 15 °C, then start the laser as usual.

Flashlamp Service

The AL-40 Alexandrite Laser will eventually need to have a certain internal component known as a “flashlamp” replaced. The flashlamp replacement procedure is covered under the standard warranty and extended service contracts (excluding cost of the new lamp), however it does necessitate a visit of a field service technician. The advanced laser head design of the AL-40 Alexandrite Laser allows easy and fast flashlamp replacement. The whole procedure takes approximately 15 minutes and can be performed by the user after the corresponding training course.

For more information regarding the flashlamp replacement refer to SOP 2: "Flash Lamp Replacement Procedure" in the Service Manual. For corresponding technical training availability call DDC Technologies Customer Service at +1 (516) 770-0441.

Coolant Water Replacement

The coolant water in the laser cooling system has to be replaced at least every 6 months. It is recommended to replace coolant water every month during summer time or in the regions with warm climate. Always drain coolant water when laser is put into storage or if you do not plan to use the laser for more than 30 days.

Use steam distilled or air condensed (obtained from dehumidifier) fresh distilled water **only**. Use of any other coolant can damage the system and will void manufacturer's warranty.

To replace coolant water:

1. Drain the old water using Water Drain Valve at the laser rear panel (see Fig. 5-2 (a)). Use the Water Drain Plug supplied with the laser to release the shut-off drain valve.
2. Remove laser left side panel. Locate white water tank in the middle of the compartment. Pull the strap that holds water tank lid to the side. Remove the lid and refill water tank from top with fresh distilled water. Fill the tank to ~ 4/5 volume. Start the laser and let it run for ~ 1 min, then turn it off and add water if necessary.
3. Replace the water tank lid and strap and reinstall side panel.
4. Alternatively, the water tank can be re-filled through the drain valve without removing side panel. Use supplied refill hose with attached funnel to do it. When refill through the drain valve make sure to stop when water level in the refill hose reached the level mark on the laser rear panel.

Calibration Procedure

The FDA and other regulatory agencies require that manufacturers of US FDA CDRH Class III and IV and European EN 60825 Class III and IV medical lasers supply their customers with power calibration procedures. Calibration of the EPY-50 laser output should be checked routinely. DDC Technologies recommends that under normal usage, calibration is checked semi-annually (every 6 months) to ensure that the laser output from the handpiece corresponds to the output selected by the user. Calibration procedure should also be performed after any service or repair work.

Warning: The attached calibration procedure (SOP 03 Rev 1-17) is only to be performed by service engineers or customers who have passed a DDC Technologies Service Certification Training Course. Adjustments and changes to the calibration by any non-authorized service personnel will void the warranty of the device. Service procedures will be distributed to trained and authorized engineers, but the sole possession of these SOPs does not authorize repair or service by uncertified personnel.

Chapter Summary

The AL-40 Alexandrite Laser user interface and operational features have been designed to be user friendly. Users of this system must read and understand the features detailed in this manual. As a guide, refer to the following overview:

- All personnel in the treatment room shall wear the appropriate protective eyewear before starting or energizing the system.
- Know the location and purpose of the key operating controls.
- Wipe off any dirt that builds up on the handpiece protective window before starting the treatment.
- Shut off the system if it is not scheduled to use within next 30 minutes.
- Clean the handpiece frequently, per page 5-16, at least following every daily usage.