



POLYLASE MX & POLYLASE AL

BEAUTY THROUGH LIGHT

Laser Operator's Manual



POLYLASE MX and POLYLASE AL LASER SYSTEMS

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.

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General Description

The POLYLASE MX Pulsed Dual Output Alexandrite and Nd:YAG Laser is designed to deliver precise long pulse fluences of laser energy at 755 nm and 1064 nm wavelength to a predetermined target site to induce 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 or handpiece trigger button is depressed, light is administered to the treatment area by placing the distal end of the handpiece in contact with tissue.

The POLYLASE MX Pulsed Dual Output Laser has a dual stage microprocessor-based operation controller 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 storage of various laser parameters' settings, which provides the operator with fast and repeatable laser setup.



Figure 1-1. POLYLASE MX Dual Output Laser

Operator Training

The POLYLASE MX Pulsed Dual Output Laser:

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 only 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 topics 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 POLYLASE MX Pulsed Dual Output 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 POLYLASE MX Pulsed Dual Output Alexandrite and Nd:YAG Laser indications for use are based upon the selective absorption of natural chromophores, particularly melanin. The Alexandrite laser wavelength of 755 nm and Nd:YAG laser wavelength of 1064 nm is well absorbed by this chromophore.

Indications for use:

The POLYLASE MX Pulsed Dual Output Laser is intended to affect stable long-term or permanent hair reduction in patients with skin types I-III with use of 755 nm wavelength and skin types IV and V with use of 1064 nm wavelength through selective targeting of melanin in hair follicles.

POLYLASE MX is also intended for photocoagulation and hemostasis of dermatological vascular lesions with 1064 nm output wavelength and for incision/excision of soft body tissues in dermatology with 1064 nm output wavelength.

POLYLASE MX is also intended for non-ablative wrinkle reduction and skin collagen rejuvenation with 1064 nm output wavelength.

Patient Exclusion Criteria

There are no known absolute contraindications to laser treatment with the POLYLASE MX Pulsed Dual Output Alexandrite and Nd:YAG 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 and/or Nd:YAG laser treatment.

Relative patient exclusion criteria to Alexandrite and/or Nd:YAG 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 POLYLASE MX Pulsed Dual Output Laser is designed for treatment of intact skin only.
- Do not treat around the outer canthus of the eye.
- Closing the eye is not sufficient protection from Alexandrite and Nd:YAG 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 POLYLASE MX Pulsed Dual Output Laser 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, in 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 levels result in greater effectiveness and higher inflammatory response.
- Begin treatment with a conservative exposure dose. If more tissue reaction is desired, increase the energy level in 1-3 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.
- Clearly identify the laser room and post appropriate warning signs at all entrances.
- It is recommended that all windows be opaque or covered, and all reflective surfaces should be covered or removed.
- When the Polylase MX laser system is in operation, restrict access to the laser room to personnel who are essential to the procedure and well-trained in laser safety precautions.
- Ensure that all laser room personnel are familiar with the laser system controls and know how to immediately shut down the system in case of an emergency.

Complications/Adverse Effects

In clinical studies involving the long pulse Alexandrite and Nd:YAG laser treatments, the following minor complications were observed in some patients:

- Hypopigmentation or hyperpigmentation may occur (**Note:** These complications have been rated as both transient and minor and appear to resolve spontaneously within several weeks or months after laser treatment.)
- Pain during treatment sometimes occurs, but local anesthesia is generally not required for these procedures.
- Erythema and edema may occur immediately following treatment but resolve 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 POLYLASE MX Pulsed Dual Output Laser and improve the care of patients who choose this method of hair removal. For more information regarding training on the use of the POLYLASE MX Pulsed Dual Output Laser, please refer to page 10 of this Operator's Manual.

- Possible side effects or complications that may arise from use of the POLYLASE MX Pulsed Dual Output 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 POLYLASE Alexandrite or Nd:YAG 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 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 healed completely. If vesiculation or Nikolsky 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 POLYLASE MX 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 cotton swabs.
- 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. Overlapping using the aiming beam as a guide is sufficient.
- 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 POLYLASE MX 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 POLYLASE MX Laser users take frequent breaks or limit the length of each scheduled treatment session in order to minimize eye strain of fatigue that could otherwise adversely affect the clinical response.

Symbols Used in this Manual



Danger

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.



Danger

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.



Caution

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.

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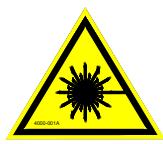
Overview

All persons operating the POLYLASE MX Pulsed Dual Output Laser and all who are in the vicinity of the laser must be aware of the potential hazards of the POLYLASE MX Pulsed Dual Output Laser output. Be certain all personnel carefully review the safety precautions pertaining to the POLYLASE MX Pulsed Dual Output 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 POLYLASE MX Pulsed Dual Output Laser can be very dangerous if proper safety precautions are not taken. Therefore, the POLYLASE MX Pulsed Dual Output 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 POLYLASE MX Pulsed Dual Output 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 POLYLASE MX Pulsed Dual Output 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, 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 POLYLASE MX Pulsed Dual Output Alexandrite and Nd:YAG Laser is capable of causing loss of vision. The laser operates at 755 nm and 1064 nm, which fall within the near-infrared (IR) light spectrum. The cornea and lens of the eye are partially transparent to near-IR light, therefore any energy transmitted by the POLYLASE MX Pulsed Dual Output Alexandrite and Nd:YAG Laser that enters the eye will be focused directly onto 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 POLYLASE MX Pulsed Dual Output Alexandrite and Nd:YAG 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 POLYLASE MX 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.

DANGER



- 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 and Nd:YAG laser light.

Safety Considerations

- Identify the laser room clearly by 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 and Nd:YAG laser wavelength, with an Optical Density of 7 or greater at 755 nm and 1064 nm including 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 POLYLASE MX Pulsed Dual Output Laser has many safety features in its design, certain precautions must be observed:

No one should attempt to operate the POLYLASE MX Pulsed Dual Output Laser with any panel removed. This may expose personnel to dangerous high voltages and potentially dangerous optical radiation. Qualified DDC Technologies Service Representatives should perform any service requiring access to the interior of the device (except the flashlamps change procedure described in this manual). To contact a Service Representative, dial (516) 770-0441.



The electrical safety hazard of any laser cannot be ignored or taken lightly. The POLYLASE MX 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 exists 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 and it is also the reason why these applications require precautions against the risk of igniting combustible materials in and around the treatment area. When the POLYLASE MX Pulsed Dual Output 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 (CDRH) 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 POLYLASE MX Laser is a long pulse dual output Alexandrite and Nd:YAG laser operating at 755 nm and 1064 nm in the near-infrared (IR) light spectrum. The laser light

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is emitted from the distal 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 where 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 POLYLASE MX Pulsed Dual Output Alexandrite and Nd:YAG Laser produces a maximum possible output of 70 J/cm^2 of fluence, also known as energy dosage (or density), or radiant exposure. The MPE for long pulse Alexandrite and Nd:YAG Laser is given in ANSI Z136.1 as $2.3 \times 10^{-5} \text{ J/cm}^2$. 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 (SOPs). The recommendations regarding these standards must be followed. The use of safety eyewear specific for the Alexandrite laser wavelength of 755 nm and the Nd:YAG laser wavelength of 1064 nm with an adequate optical density rating of $\geq \text{OD } 7$ 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 room. Please refer to the latest editions of these documents.

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Overview

The POLYLASE MX 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 POLYLASE MX Laser incorporates several features that provide high reliability, versatility, compact size, and superior performance. The system controller is microprocessor 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

The information is displayed on a color LCD display, mounted on the front panel of the laser chassis.



Figure 3-1. POLYLASE MX Laser Control Panel

Wavelength

The POLYLASE MX Dual Output Alexandrite and Nd:YAG Laser emits laser radiation at 755 nm and 1064 nm wavelength. The beam is coupled to and delivered to the treatment area via an optical fiber with an attached handpiece device.

POLYLASE MX System Specifications

Item	Description	
Laser Type	Long Pulse Alexandrite Laser	Long Pulse Nd:YAG Laser
Laser Wavelength, nm	755 nm	1064 nm
Max. Energy Per Pulse, J	75 J	70 J
Laser Pulse Width	0.5-100 ms (user selectable)	0.5-100 ms (user selectable)
Max. Average Power	120 W	120 W
Pulse Repetition Rate	Single Shot – 5 Hz	Single Shot – 10 Hz
Beam Delivery	Optical fiber, 10 feet (3 m) length	Optical fiber, 10 feet (3 m) length
Optical Fiber Core Diameter	1000 μm	1000 μm
Handpiece Spot Size	10 mm, 12 mm or 16 mm dia. (Optional: 14, 16 and 20 mm)	10 mm, 12 mm or 16 mm dia. (Or 2mm, 3mm, 4mm in "Vein" mode)
Max. Energy Fluence @ 16 mm spot size	37.5 J/cm ²	35 J/cm ²
Skin Cooling	Compressed chilled air jet Optional chilled mist (AQUA COOL)	
Dimensions (HxWxL)	33.5" x 18.5" x 43.5" (850x470x1105 mm)	
Weight	70 kg (155 lbs.)	
Power Requirements	215...240V single phase ~50/60Hz, 20A	
Noise Level	<70 dB	

Components

The POLYLASE MX Laser consists of the following components: Optical Laser Head, Power Supply Unit, System Control Electronics Module, Internal Cooling System, Beam Delivery System with Handpiece.

Optical Laser Head

The optical laser head consists of an optical rail with two flashlamp pump chambers that house the Alexandrite and Nd:YAG crystals, xenon flashlamps, laser resonator mirrors, energy meter sensors, and other optical components.

Power Supply Unit

The power supply unit consists of a high voltage power supply with capacitor charger, pulse-forming network (PFN) electrical circuit, and power distribution system with power factor corrector (PFC).

System Control Electronics

The system control electronics consists of the User Interface Controller (mini-PC) with high resolution 10" touch screen control panel, System Input-Output PCB (microprocessor-controlled I/O Board), system controls, interlocks, and sensors.

Cooling System

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

Optical Delivery System

The optical beam delivery system delivers laser energy from the device chassis to the treatment area. The optical fiber cable, enclosed in a 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 (**Spot 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.

Component	Description
Handpiece Handle	The user holds the laser handpiece by the body-handle during treatment. The handpiece is also equipped with a trigger button (pulse finger trigger), which can be used instead of the footswitch. The use of the finger trigger or the footswitch can be selected by the  button (see Fig. 3-9).
Protective Window (Output Aperture)	The handpiece output window serves as the laser aperture. It protects the internal handpiece imaging lenses from contamination during laser treatment. The collimating lens inside the handpiece changes the laser beam divergence out of the fiber, and in combination with imaging zoom lens provides fixed laser beam spot size at a certain distance from the handpiece.
Fiber Cable Umbilical Jacket	Contains optical fiber, electrical cables and cooling air tubing. The reinforced umbilical jacket protects optical fiber from mechanical damage. It also prevents the fiber from being bent beyond a safe radius during treatment. Warning! The umbilical jacket provides limited protection for the optical fiber. Do not apply excessive force to bend the cable beyond its smallest natural radius or by pulling on the fiber by the handpiece. This can lead to permanent fiber cable damage, which is not covered by the Limited Warranty.
Distance Gauge	Provides fixed distance to get correct beam spot size on the treatment area. The second gauge also serves as a guide and output nozzle for the skin cooling air jet.

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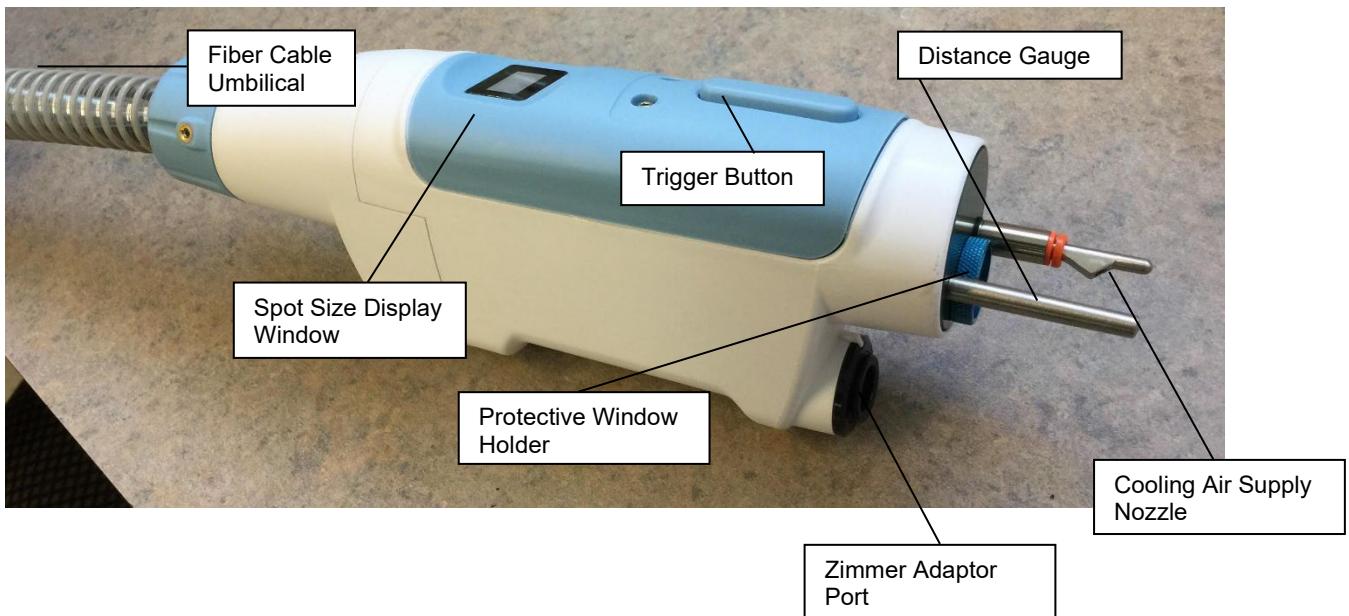


Figure 3-2. Laser Handpiece Components

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.

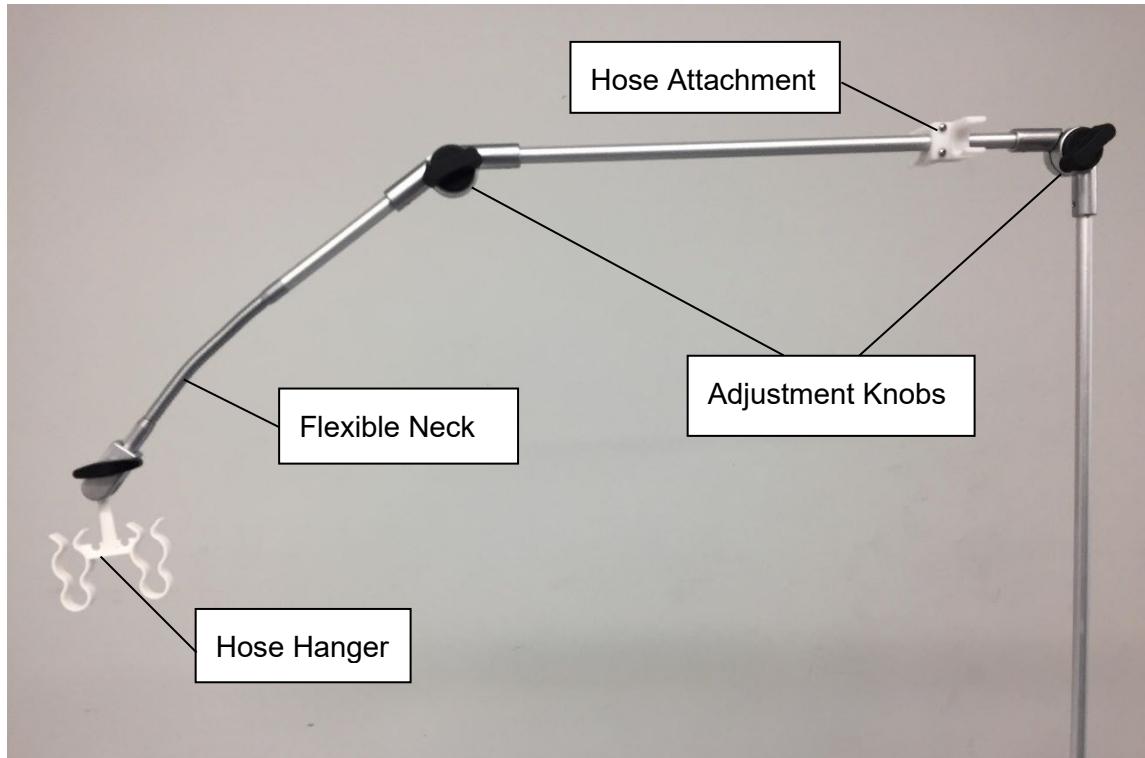


Figure 3-3. Fiber Support Arm Components

Air Filter

The Polylase MX is equipped with two air filters that prevent dust and foreign matter from building up inside the laser frame. These are located in the front of the laser housing, behind the air vents on the bottom of the front panel, as shown in Figure 3-4. The direction of the air flow is indicated by the yellow arrows.

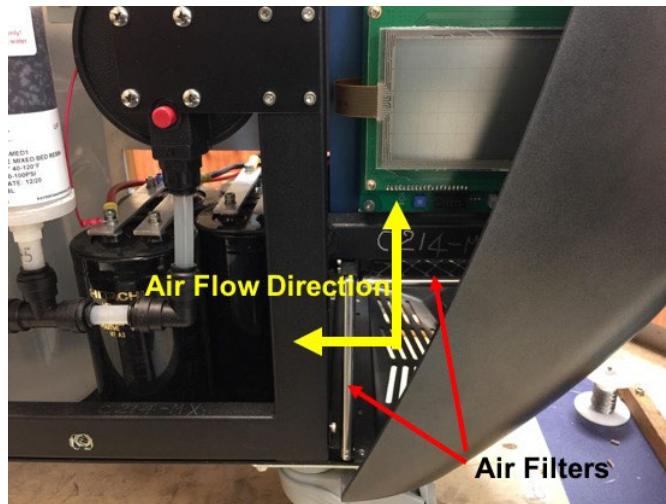


Figure 3-4. Air Filter Location

There are two filters of different sizes: the vertical sitting filter is 5.6" x 12.9" and the horizontal filter is 7.6" x 10". There is a mesh screen on one side of the filter, and the direction of air flow is marked as shown in Figure 3-5.



Figure 3-5. Air Filter Flow Direction

Air Filter Cleaning / Replacement

To access the air filters, remove the machine side panel. Then the vertical filter can slide out of the bracket. Clean the horizontal filter in place with a vacuum and small brush. To install cleaned or new filters, slide them into the brackets, making sure the mesh screens on the filter face the inside of the machine.

To clean the filters, remove them from the machine and thoroughly wash with warm water and allow to dry. Filters should be replaced when the foam begins to wear.

Controls and Indicators

The POLYLASE MX 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.

Component	Description
Main Power Switch	This switch disconnects the system from the power source when put in OFF position (see Fig. 3-8).
Display	Touch-screen color LCD display prompts the user to enter and initiate important operating parameters.
Emergency Off Button	A large red circular push-button switch that disables the laser power supply. (NOTE: The EMERGENCY OFF button will remain depressed until it is rotated clockwise and pulled up).
Key (power) Switch	A key switch that activates the DC power supply and laser controller. The key may be removed only when in OFF position.



Figure 3-6. Front controls

Chapter 3 System Description
POLYLASE MX/AL Laser System Operator's Manual



Figure 3-7. Front and side of the POLYLASE MX Laser



Figure 3-8. Rear of the POLYLASE MX Laser

Component	Description
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 the motorized zoom lens and provide fixed laser beam diameter on the skin, helping to maintain desired energy density (fluence) during treatment.
Rear Panel	The power cord and footswitch cable are attached at this panel, as well as Alexandrite and Nd:YAG beam delivery systems (see Fig. 3-8).
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 operate laser controls, select treatment parameters, and displays various messages to the user.

Main Control Panel

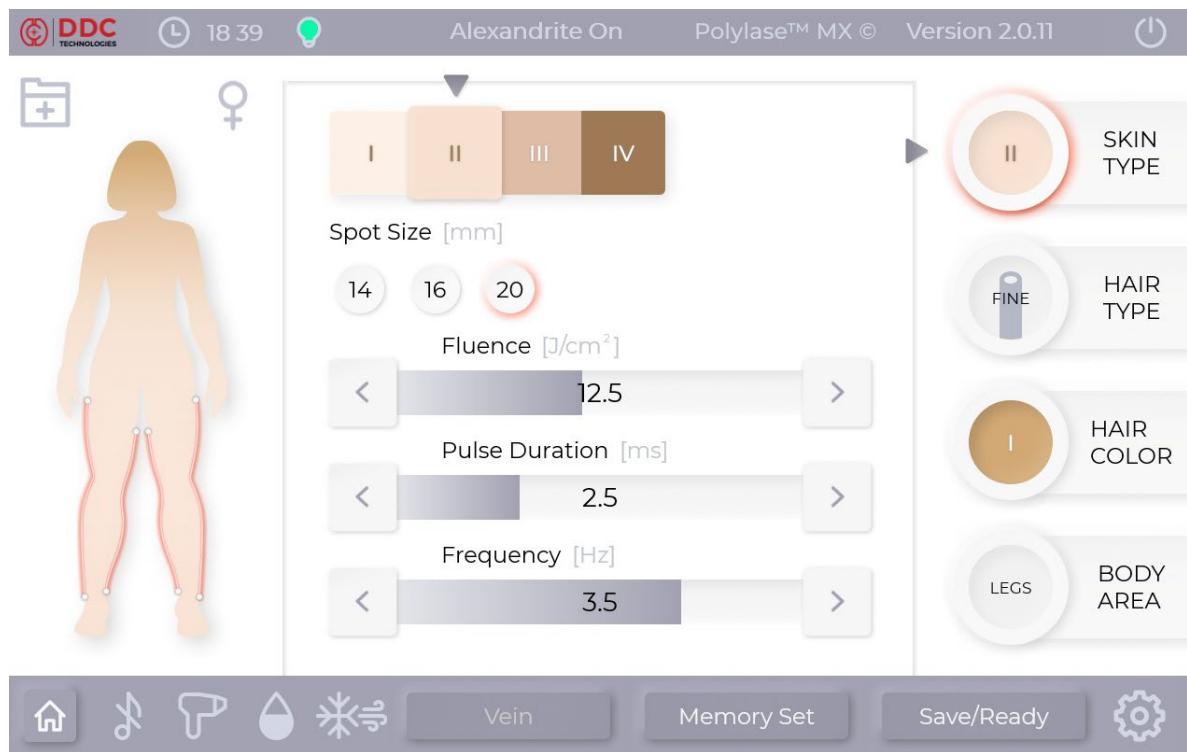
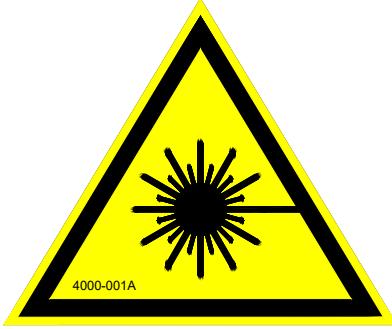
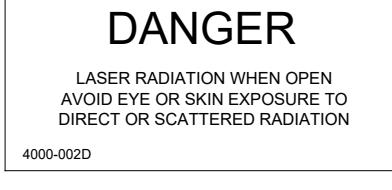


Figure 3-9. Control Panel – Parameter Setting (Edit) Screen

Control	Description
Parameter Setting Buttons 	Serves to display current device settings: Spot Size (mm); Pulse Duration (pulse width, ms); Frequency (Hz)-pulse repetition frequency. Parameter (except for the Spot Size) can be edited by either using increase/decrease arrow buttons (incremental change) or by sliding the gray bar left or right. The current value of each laser setting is displayed in the center of the corresponding horizontal window. The Spot Size can be selected by pressing the corresponding round Spot Size button.
Fluence Button 	Serves 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) current Pulse Duration, and Spot Size settings. Fluence is a measure of energy density and is shown as Joules/cm ² . Fluence can be changed the same way as other parameters (see above).
Memory Selection Buttons	Serves to recall pre-set Operating Parameters stored for each combination of Skin Type, Hair Type, Hair Color and Body Area. The recalled pre-set treatment parameters can be still adjusted with Parameter Setting Buttons, as described above.
Save/Ready Button 	Serves to switch between EDIT and READY system modes while saving new parameter settings for the current treatment session.
Vein Button 	Serves to switch between HAIR and VEIN treatment modes.
Home Button 	Serves to bring the user to the start screen.
Memory Set Button 	Used to enter pre-set Operating Parameters Edit Screen, where user can override factory memory settings for preferred treatment parameters and customize it based on his/her desire and experience.
Service Button 	Used to switch between EDIT and SERVICE screens.
Sound ON/OFF Button 	Used to turn the pulse beep sound ON or OFF.
Footswitch/Finger Trigger Selection Button 	Used to switch between footswitch or finger trigger use.
Shutdown Button 	Used to initiate system shutdown or software restart procedure.
AQUA COOL Button 	Used to enter the AQUA COOL settings menu and displays current status.
Chilled Air Jet Button 	Used to turn the chilled air jet ON or OFF and displays current status.
Patient Database Button 	Used to enter the Patient Database.

Required Labels

Government regulations require that certain labels appear on the POLYLASE MX Laser and be reproduced in this manual.

Label/Symbol	Description/Location
	<p>Located on front lower panel of the laser system (4000-001D)</p> <p>DANGER: Visible and/or invisible laser radiation avoid eye or skin exposure to direct or scattered radiation</p>
	<p>Located on the laser rear panel and output end of the handpiece (4000-001A)</p> <p>The laser system emits laser energy.</p>
	<p>Located on front and rear panels of the laser system (4000-003D)</p> <p>The laser system emits laser energy.</p>
	<p>Located on the laser head cover (4000-002D)</p> <p>DANGER: Laser radiation when open. Avoid eye or skin exposure to direct or scattered radiation.</p>

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Label/Symbol	Description/Location
 <p>DDC TECHNOLOGIES INC.</p> <p>DDC Technologies, Inc. 311 Woods Avenue, Oceanside, NY 11572 USA Tel: (516) 594-1533 www.ddctech.com</p> <p>Alexandrite + Nd:YAG Laser System Model: PolyLase LP Voltage Range: ~215-240V, 50/60 Hz Max. Power Input: 4 kW Class I, IPX1</p> <p>READ INSTRUCTIONS BEFORE OPERATION</p> <p>This equipment conforms to provisions of US 21 CFR 1040.10 and 1040.11</p> <p>SN PL- 0717</p>	<p>Located on rear panel of the laser system. (4000-001S)</p> <p>VA rating, model number, serial number, and date and place of manufacture. Read instructions before use. Equipment conforms to provisions of CDRH 21 CFR 1040.10 & 1040.11</p>



Figure 3-10. Labels, front of the POLYLASE MX Laser



Figure 3-11. Labels, rear of the POLYLASE MX Laser

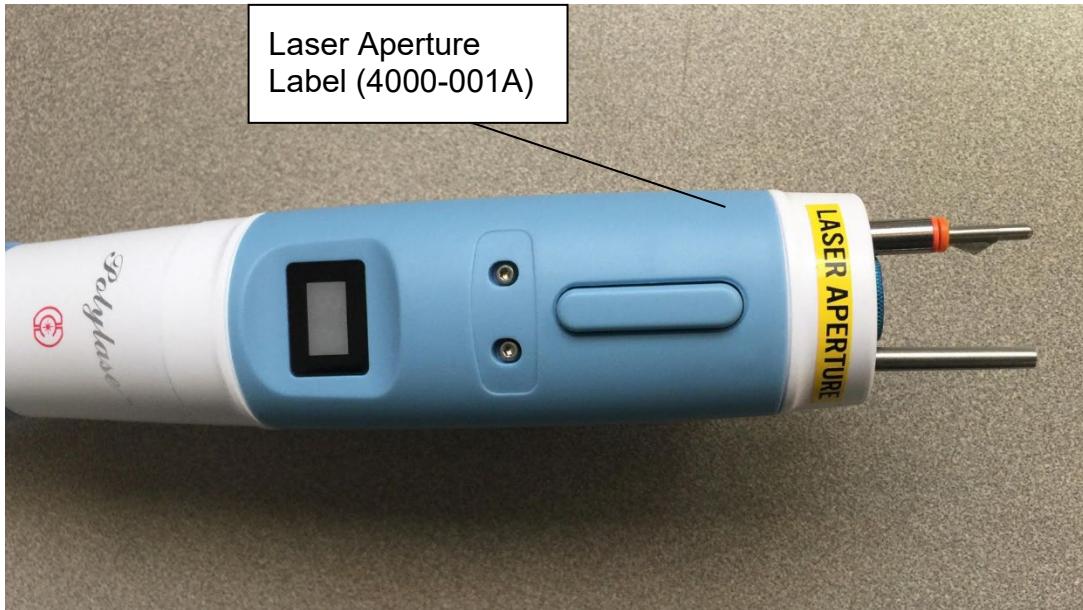


Figure 3-12. Handpiece Label



Figure 3-13. Laser Head Cover Label

Peripheral Devices

Peripheral devices contained with the POLYLASE MX Laser are as follows:

- (1) Footswitch
- (2) Pairs of Laser Safety Eyewear
- (1) Vein Objective
- (1) Key
- (1) Operator's Manual
- Laser Safety Door Sign (optional)
- AQUA COOL Filling Funnel (optional)

System Accessories

Laser Safety Eyewear

Order P/N GCYN-35

These glasses are designed to protect the person operating the POLYLASE™ MX Dual Alexandrite/Nd:YAG Laser, as well as the patient and others who may be in the room. It is designed to provide OD>7.0 at 755 nm and 1064 nm. Their shape is designed to protect the wearer at various angles. Two pairs are included with each system.

Laser Key

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 4000-002M

Replacement or additional copies of this Manual are available. The Manual is also available for free download at DDC Technologies web site: www.ddctech.com. Everyone who works with the POLYLASE MX 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 POLYLASE MX 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 upon request.

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Chapter 4: Installation

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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. cannot guarantee the operating parameters of any system installed on a site that does not meet the specifications described in this section.

Note: Generally, laser installation is performed at customer's facilities by qualified laser engineer(s) or technician(s). However, certain experienced customers and authorized specially trained distributors can successfully perform device installation on their own. Please, refer to **POLYLASE MX: 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 technician. (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 POLYLASE MX Laser System and position it in the location you have pre-selected.
- Couple the laser to the existing 215-250V AC receptacle and check the ground connection.
- Fill the cooling system with fresh 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 215-250VAC, single phase, 20 A electrical service. It is recommended that the electrical supply to the equipment be independently fused and switched by a 20 A circuit breaker, mounted at a convenient height in the operating area. This will enable the POLYLASE MX Laser to be electronically isolated for maintenance purposes.

Due to 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 key switch and Main switch are in 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 conditions may take place.

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.

If the coolant water is colder than 15 °C the laser controller will not allow starting the laser and will respond with the Error Message: "System is too cold" with actual coolant water temperature being displayed on the screen. The water in this case must be naturally warmed up to above 15 °C without the pump running the cold water through the system, before the laser controller will allow the system to start.

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 particles can cause permanent damage to optical surfaces and excessive dust can clog the cooling system heat exchanger and air intake filters. Never place the laser in an environment proximal to areas undergoing construction or remodeling.

Space Requirements

Sufficient floor space is 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 POLYLASE MX Laser is easily moved 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 laser is moved, care must be taken to ensure that the optical fiber cables and laser handpieces 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.

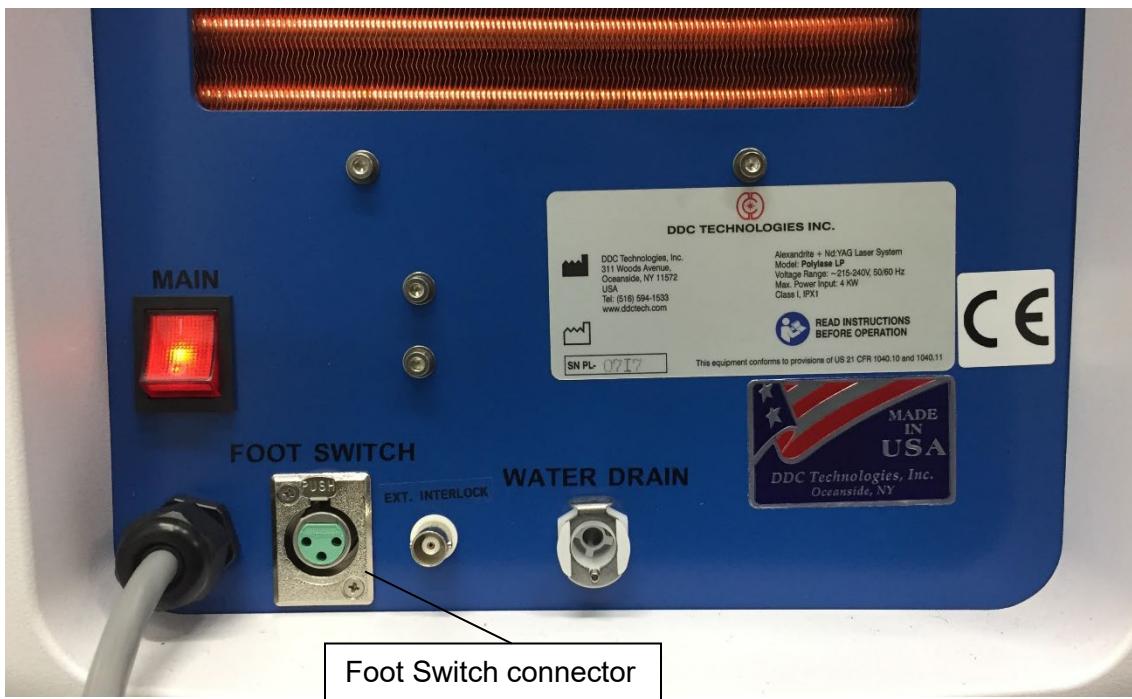


Figure 4-1. Footswitch connection.

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.

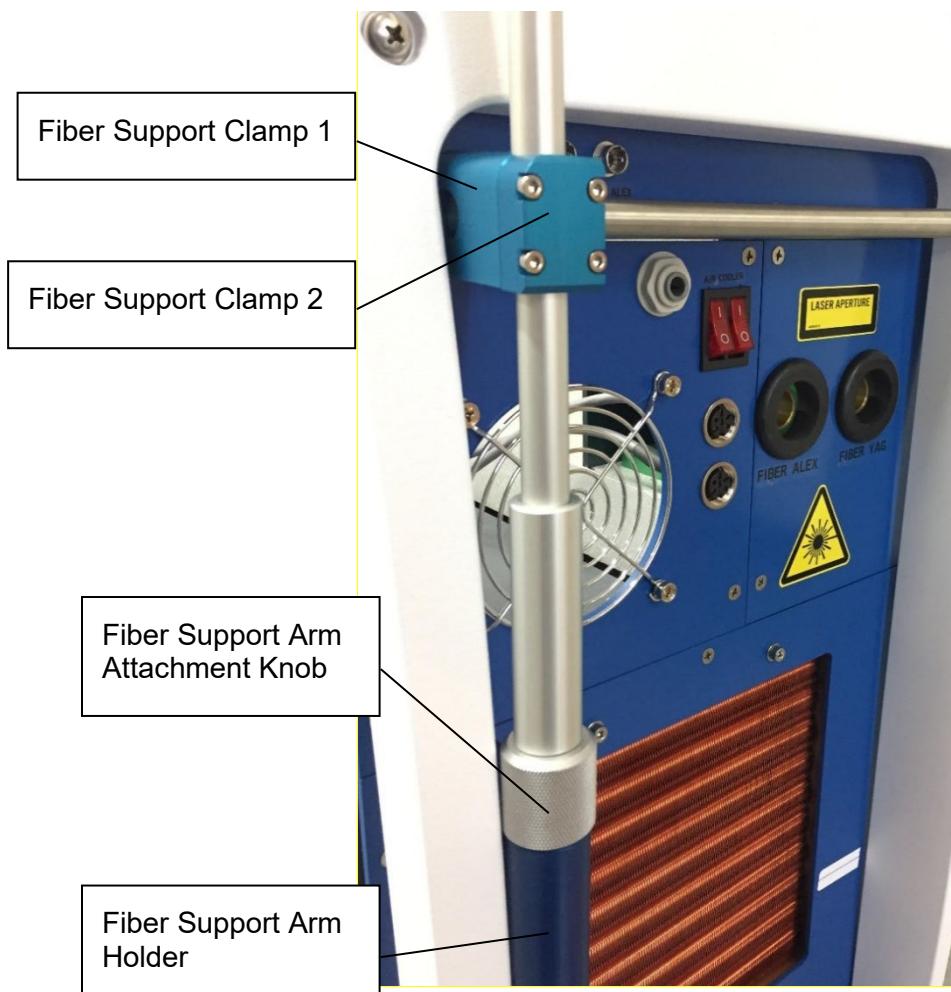


Figure 4-2. Fiber Support Arm Installation

Beam Delivery System Attachment

After the fiber support arm is installed, the beam delivery systems 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. 4-5). Before attachment of the fiber to the fiber port remove the protective black vinyl cover from the end of the fiber. Connect all electrical cables to appropriate sockets. Connect air cooling system tubing (if equipped) to the cooling air supply connector.

1. Locate the Quick Connect fiber adapter with protective blast shield window, installed on the input end of the fiber cable.

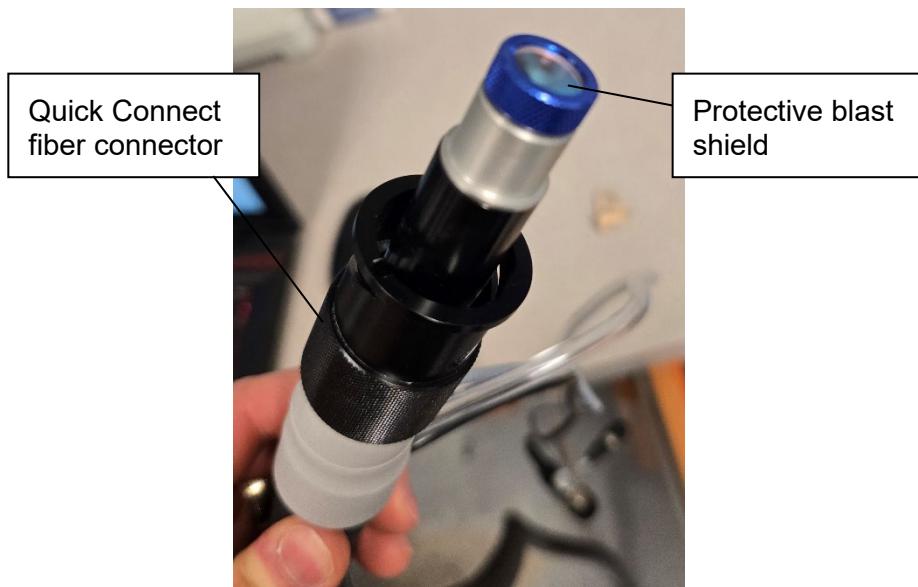


Figure 4-3. Quick Connect fiber connector and Blast Shield Window

2. Inspect the window and make sure it is clean before installation. Clean the window with acetone or methanol, if necessary.
3. Insert the Quick Connect fiber connector, with the attached fiber, into the corresponding fiber port (labeled Nd:YAG and/or ALEX). Ensure that the pins on the Quick Connect receptacle align with the slot on the Quick Connect connector. Once aligned push the Quick Connect connector forward and twist clockwise until a click is felt and the pin is locked in the circular detent. (Figure 4-4.)

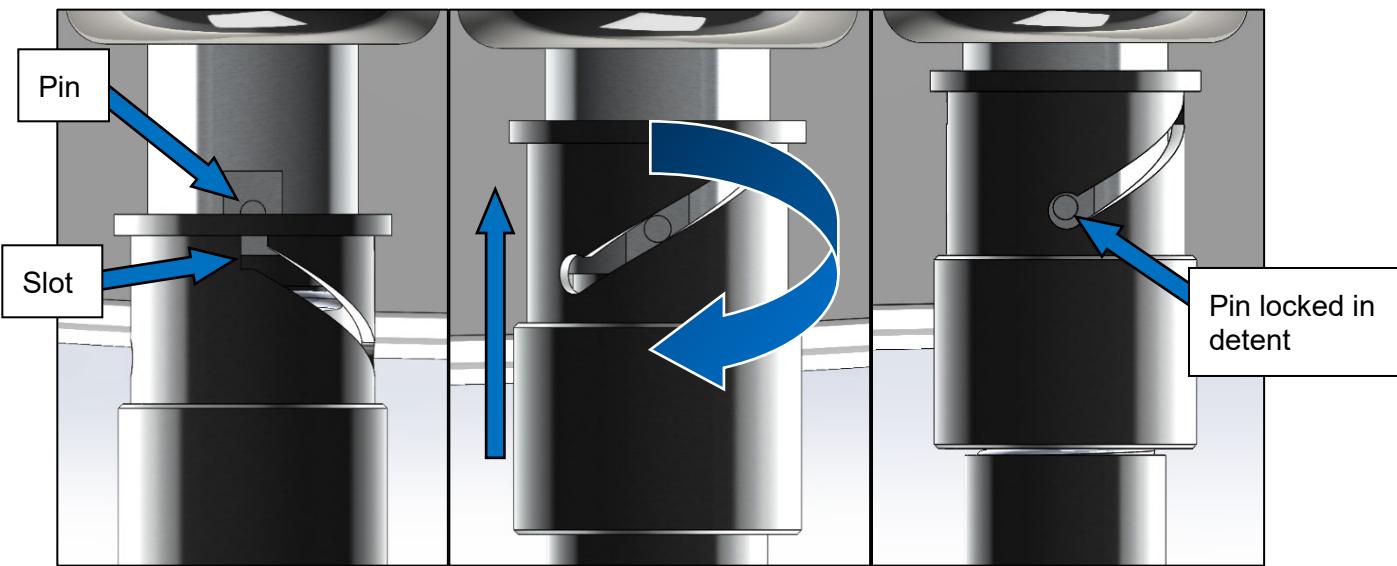


Figure 4-4. Quick Connect fiber connector attachment diagram

CAUTION



- 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 to visually see the pin on the receptacle has locked into the detent on the Quick-Connect connector. Failing to make a proper connection can result in damage to the input end of the optical fiber. Figures 4-4 and 4-5 show the fiber securely attached to the arm and the fiber port at the rear panel of the laser.

NOTE: For more information about this procedure, refer to SOP 01 Rev 1-24 Beam Delivery System Installation in the Service Manual.



Figure 4-5. Fibers Installed on Fiber Support Arm

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CAUTION



- 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 includes 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 POLYLASE MX 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.

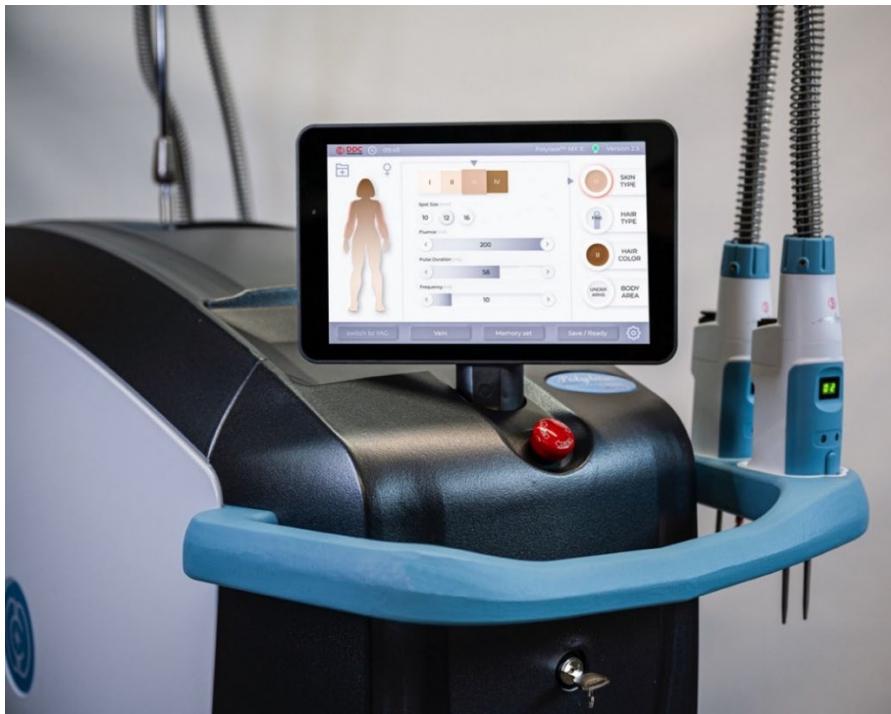


Figure 5-1. Main control panel

Before Beginning

Before you turn on the laser, ensure that the location of the POLYLASE MX 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.

CAUTION



- **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 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 / Nd:YAG Laser system (>OD 7 at 755 nm and 1064 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.

DANGER



- **Everyone in the treatment area must wear protective eyewear at this point and for the entire duration that the system is turned on**

Operating Instructions

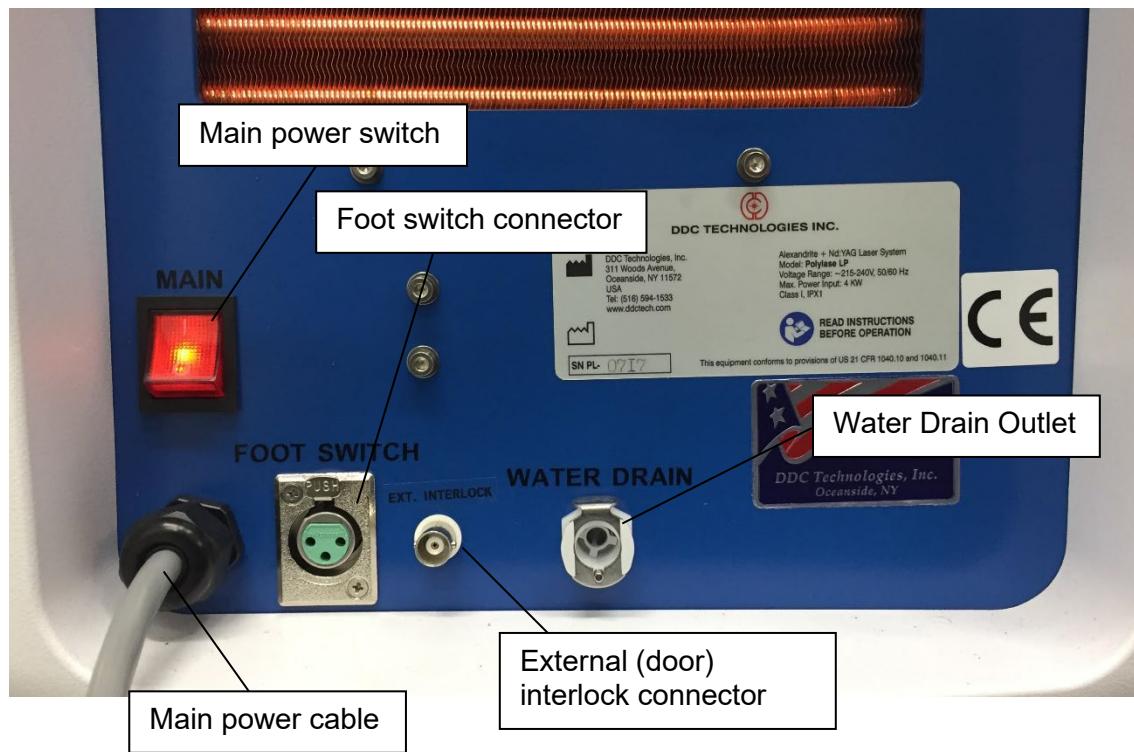


Figure 5-2 (a). Rear panel controls and connectors (bottom)

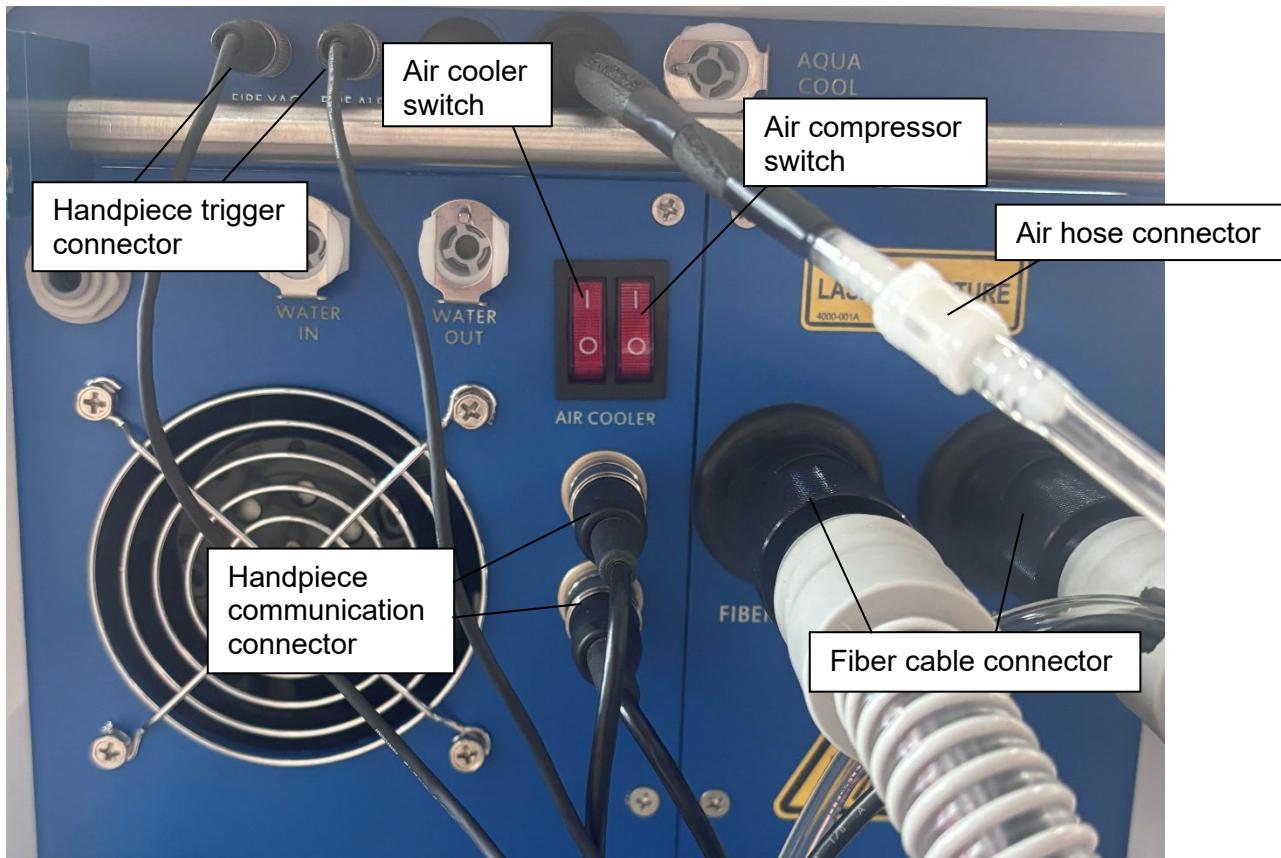


Figure 5-2 (b). Rear panel controls and connectors (top)

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 (a). Front control panel (key on)

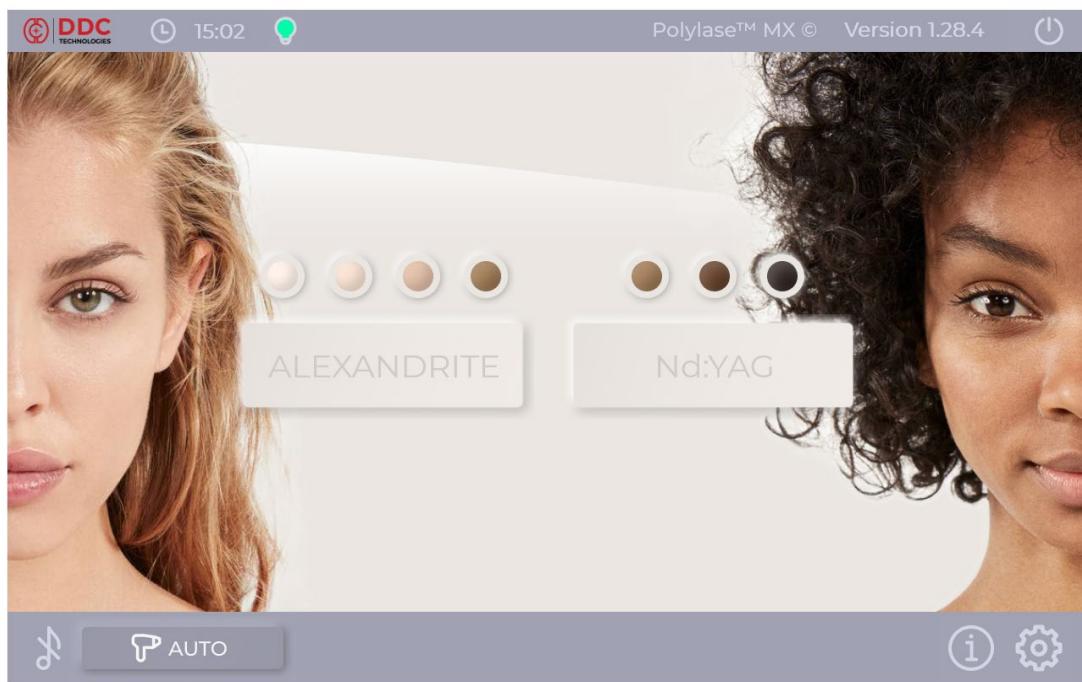


Figure 5-3 (b). Laser Output Selection Screen

To activate the POLYLASE MX Laser:

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

After the system is turned on and the software self-test procedure is complete, the Laser Output Selection screen will be displayed.

Press corresponding button on the touch screen to select the Alexandrite or Nd:YAG laser output (see Fig. 5-3 (b)).

At this moment the cooling system pump will start, and laser lamp(s) will ignite. After the system has completed a startup and warmup cycle, laser will stay in **Edit** mode (see Fig. 5-4). In this mode laser operating parameters can be modified by the operator and the laser energy cannot be emitted.

After the system is turned on, Parameter Settings used during previous session are used as default operating parameters, until different parameters are selected by the user.

NOTE: If the coolant water temperature is measured $< 40^{\circ}\text{C}$ after Alexandrite laser start button was pressed, the automated laser warm up procedure will start. Since the power of the flash lamps is used to warm up the coolant water in the POLYLASE MX Laser, the sound of the flash lamp discharge pulses can be heard during the warmup procedure. This is normal.

The following message is displayed on the screen during the warmup procedure: see Fig. 5-3 (c). The warmup procedure automatically stops when the coolant water temperature reaches 40°C .

There is no laser warm up procedure if Nd:YAG laser is selected.

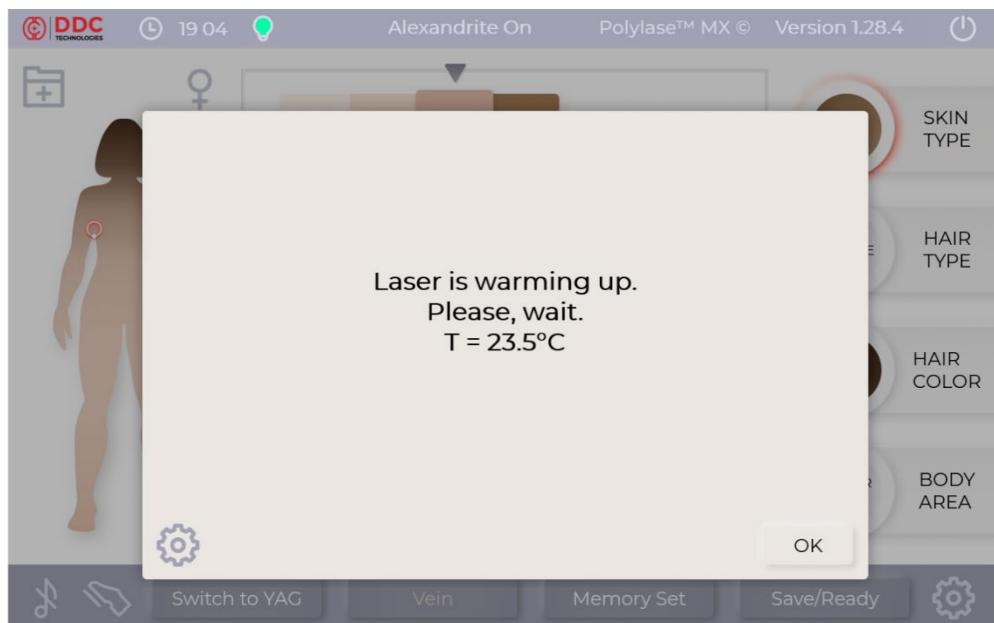


Figure 5-3 (c). Laser Warmup Message

Edit Mode (Setting Parameters)

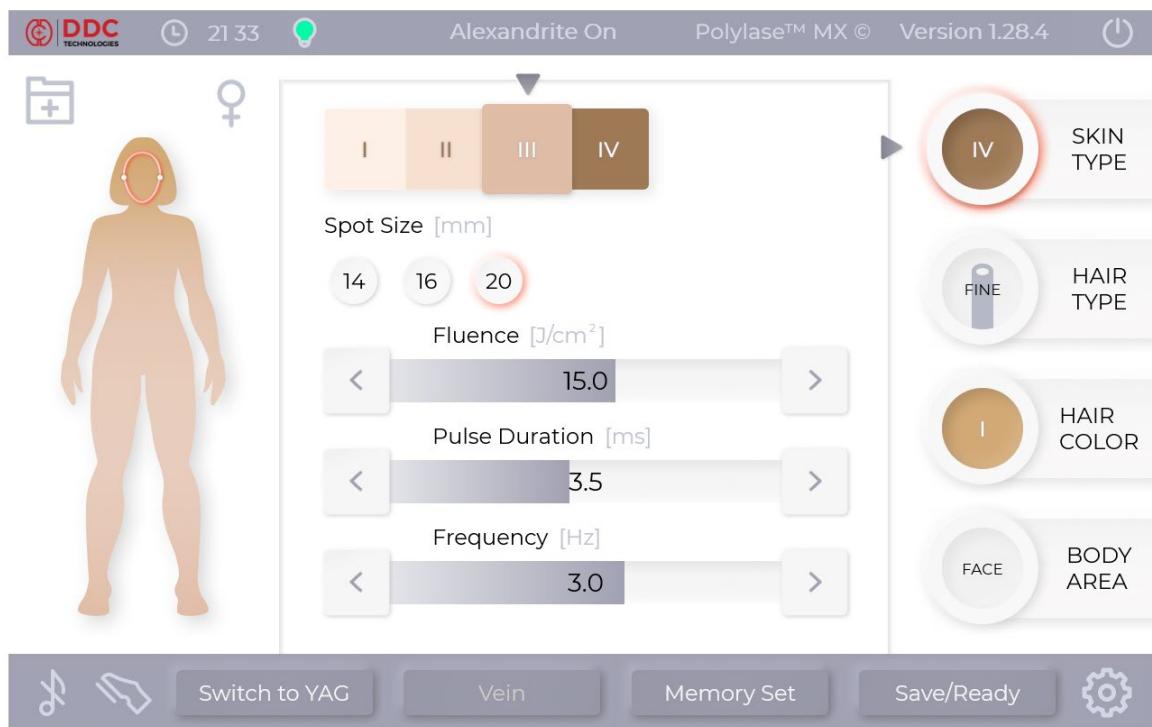


Figure 5-4. Edit Mode Screen

All parameters that can be modified by the operator are entered while in **Edit** mode. To switch between **Ready** and **Edit** mode, the **Save/Ready** button on the touch-screen panel must be depressed. Pressing **Save/Ready** button will save all parameter changes that have been made in **Edit** mode.

Parameter Setting Buttons serve to change and display current device settings: Fluence (J/cm^2); Spot Size (mm); Pulse Duration (pulse width, ms); Frequency (Hz)-pulse repetition frequency. Parameters (except for the Spot Size) can be edited by either using increase/decrease arrow buttons (incremental change) or by sliding the gray bar left or right. The current value of each laser setting is displayed in the center of the corresponding horizontal window. The Spot Size can be selected by pressing correspondent round Spot Size button.

Fluence Setting arrow buttons and slide serve to set Fluence on the target. After user presets the 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 $Joules/cm^2$.

The operator can access the Parameter Settings by selecting the appropriate buttons based on the patient's evaluated skin and hair characteristics. Pre-set Operating Parameters are available for each combination of Skin Type, Hair Type, Hair Color, and Body Area. The system allows selection from 4 different skin types in standard modes and 6 types in Nd:YAG mode. It also provides options for 2 hair types, categorized as Coarse and Fine, and 3 different hair color tones. Additionally, various body areas can be selected

based on the treatment site. These options enable quick and precise adjustments to optimize treatment outcomes. (♀ button can be used to switch between 5 women's and 6 men's body areas). The currently selected setting is highlighted with a red circle and/or pointed with a triangle.

Memory Set Button switches to Pre-set Operating Parameters Edit Screen, where the user can override factory memory settings for preferred treatment parameters and customize it based on their desire and experience.

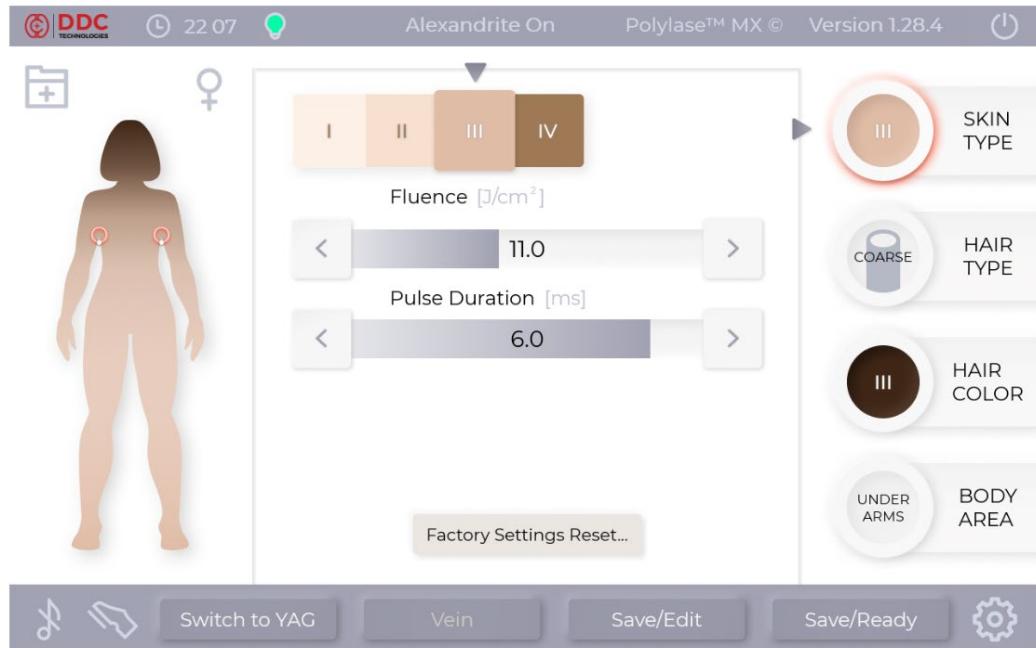


Figure 5-5. Memory Set Screen

After pre-set parameter adjustments are finished, press **Save/Edit** button to return to **Edit** screen.

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 (14 mm, 16 mm and 20 mm for Alexandrite and 10, 12 and 16 mm for Nd:YAG) are available in the POLYLASE MX handpieces. The currently selected spot size is displayed on the highlighted **Spot Size Button** on the laser control 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/Ready** 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 corresponds to the actual laser beam spot size.

The system will keep the pre-selected **Fluence** value constant, no matter what spot size has been chosen by the user. However, if the pre-set **Fluence** level cannot 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 **Pulse Duration** will be automatically adjusted to the higher value by the system software if selected Fluence is too high and cannot be achieved with currently selected **Pulse Duration**.

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

When the **Save/Ready** button is pressed after parameters selection and editing is finished, a new set of operating parameters is saved for the current treatment session and the system switches to **Ready** mode.

Long Pulse Mode

All pulses with Durations above 10 ms (Nd:YAG) and 7 ms (Alexandrite) 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 10 or 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 select and then adjust the **Fluence** setting for the patient with Skin Type 3 and coarse dark hair for underarm hair removal, do the following:

1. Press the **SKIN TYPE** button and then select the Skin Type III option from the horizontal row (see Fig. 5-4)
2. Press the **HAIR TYPE** button and select Coarse from two options that will appear on the screen.
3. Press the **HAIR COLOR** button and select III (the dark one) from three options in the horizontal row.
4. Press the **BODY AREA** button and select Underarms from the options in the horizontal row or use the body figure on the left and pick the underarm area using the touch screen.
5. If there is a desire to adjust the recommended settings recalled from the system memory, use **>** button if you want to increase the Fluence and **<** button if the Fluence must be decreased or use a slide bar to quickly change its value.
6. When the desired Fluence value is displayed, adjust the other parameters (if necessary) and then press **Save/Ready** button to switch the laser to **Ready** mode.

Ready Mode

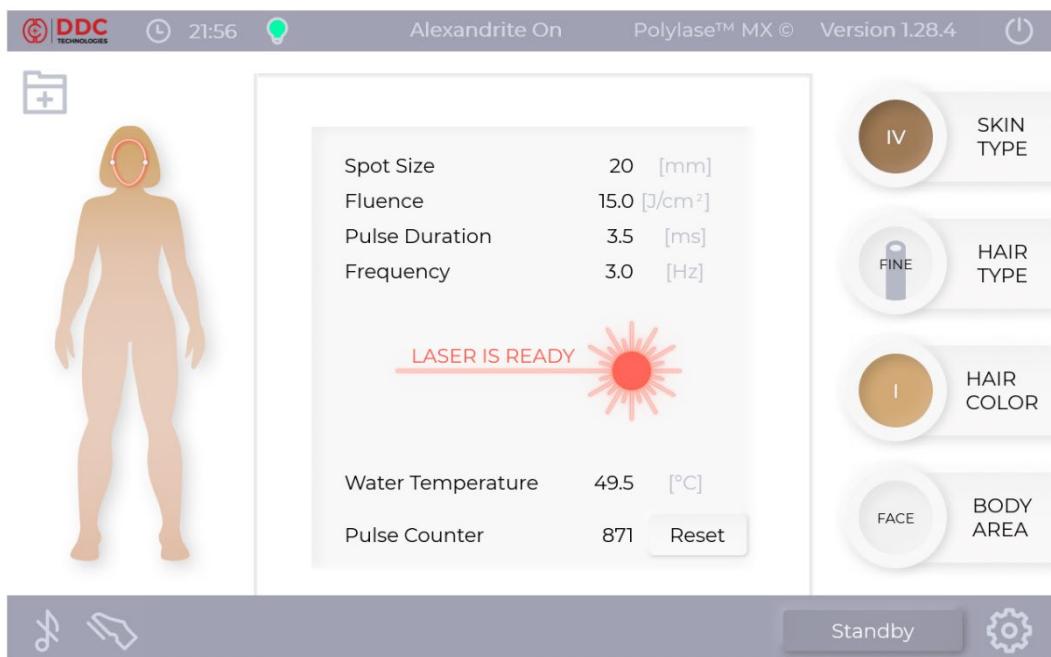


Figure 5-6. Ready Mode Screen

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/Ready button to switch the laser from *Edit* to *Ready* mode. The screen will change to *Ready* mode. The red sign on the LCD display will read: "LASER IS 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 a footswitch or a trigger button on the handpiece. The use of the footswitch or the handpiece trigger button can be selected by the  button (see Fig. 5-4, 5-6). Unless the footswitch or the handpiece trigger button is depressed, it is not possible to fire the laser in this mode. When you are ready to begin laser treatment, press the footswitch. At this moment laser energy will be delivered to the treatment area.

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

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

The Frequency display in the Treatment Parameters display area will show laser Pulse Repetition Frequency (PRF) in Hz. In the Single Shot mode only one laser pulse will be delivered when the footswitch is depressed. To fire the laser again, the footswitch must be released and then pressed once more. In this mode, the frequency display in the Parameter Settings area will read "0".

The laser PRF will be automatically reduced by the system software to the maximum possible value, if selected combination of **Fluence**, **Beam Size** and **Frequency** results in the average power that cannot be supported by the laser power supply. This is normal.

Pulse Counter displays number of laser pulses fired since last counter reset. To reset the pulse counter, press and hold the **Reset** button for ~2 sec.

Aqua Cool (Optional)

The Polylase MX/AL is equipped with a highly advanced, patent-pending skin cooling system that intelligently combines water and chilled air to create an ultra-cold mist. Upon contact with the skin, this mist evaporates rapidly, cooling only the epidermis. The evaporation occurs before, during, and after the laser pulse is delivered, ensuring a virtually pain-free treatment while maintaining the exceptional efficacy for which the Polylase MX/AL is known.

Aqua Cool Controls

To enter the Aqua Cool menu, press the water droplet  button. In addition, this button displays the status of the Aqua Cool system.

Icon	Status
	Low water setting
	Medium water setting
	High water setting
	OFF

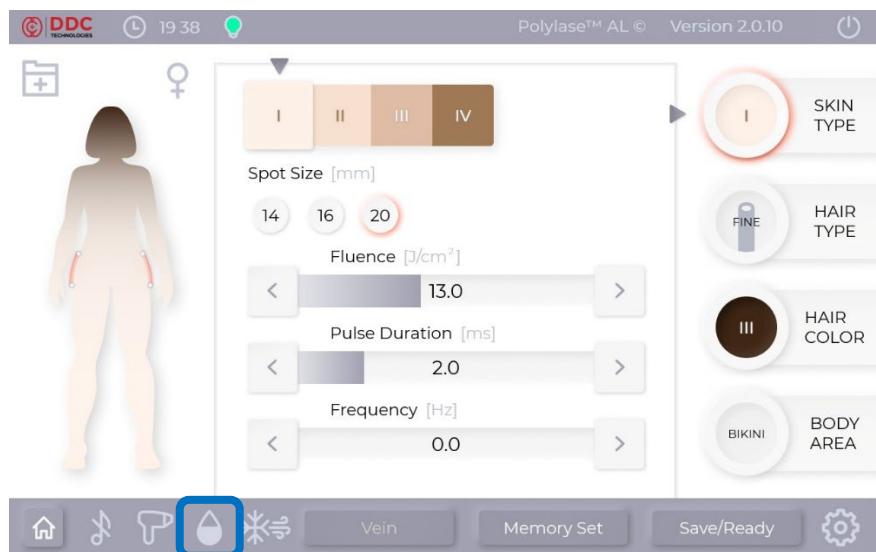


Figure 5-7. Aqua Cool Button

Aqua Cool Menu Controls

Control	Description
Low (ON  (OFF 	Low Water ON/OFF Status: If set to OFF, pressing the button enables this setting.
Medium (ON  (OFF 	Medium Water ON/OFF Status: If set to OFF, pressing the button enables this setting.
High (ON  (OFF 	High Water ON/OFF Status: If set to OFF, pressing the button enables this setting.
Auto	When 'Auto Mode' is enabled, the previous state of Aqua Cool will be remembered when the laser is in Ready Mode .
Manual	When 'Manual Mode' is enabled, the previous state of Aqua Cool will NOT be retained when the laser enters Ready Mode . Aqua Cool must be turned on manually each time.
ON	Activates Aqua Cool
OFF	Deactivates Aqua Cool
Settings	Opens the Aqua Cool fine-tuning settings for the Low, Medium, and High presets.
OK	Exits Aqua Cool with the selected settings the user selected.



Figure 5-8. Aqua Cool Menu

NOTE: If Air Jet is turned off, Aqua Cool will be deactivated. You may use Air Jet without Aqua Cool, but Aqua Cool cannot operate without Air Jet. If both were on and Air Jet is turned off, the icons for both will display the off status. When Air Jet is turned back on, Aqua Cool must be manually reactivated.

Aqua Cool Refill

NOTE: Before refilling the Aqua Cool tank, ensure that no mist is coming out of the nozzle. This indicates that the tank is fully empty.

1. Fill a measuring cup with 1.5 cups (350 ml) of distilled water. Locate the "AQUA COOL" valve on the rear panel of the laser system (see Figure 3-8).
2. Insert the provided filling funnel into valve. The funnel is properly inserted when a "click" is heard.

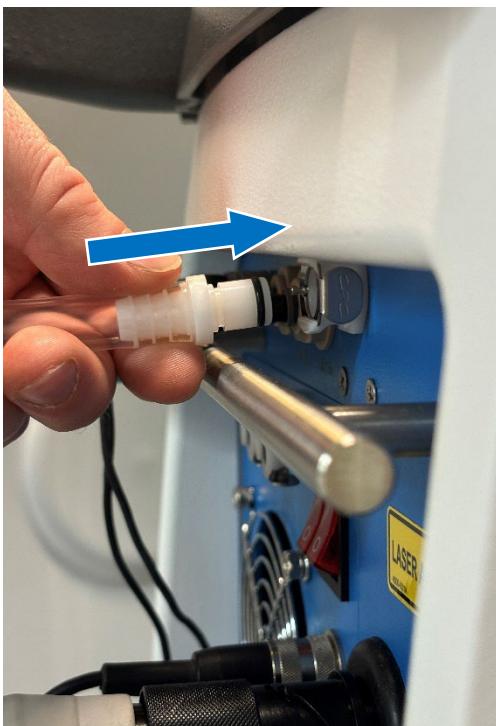


Figure 5-9. Inserting Filling funnel

3. Slowly pour 1.5 cups (350 ml) into the funnel.
4. Press the button on the side of the valve to release the filling funnel and pull to remove.



Figure 5-10. Removing filling funnel

5. Turn the laser on and enter Ready Mode. Set Aqua Cool to the highest flow setting and wait approximately 2 minutes for the system to prime. A mist should begin ejecting from the nozzle. Adjust the settings to achieve the desired mist amount.

Switch Laser Function

In order to quickly switch between Alexandrite and Nd:YAG laser modes, press and hold **Home** button on the **Edit** screen for ~3 sec. The laser controller display will switch to the Start Screen (see Fig. 5-3 (b)), where Nd:YAG or Alexandrite laser can be selected for the next treatment session.

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 the next patient treatment. See the handpiece cleaning procedure below.

If the system is not used again within 30 minutes, it is recommended to turn off the system by pressing the **Shutdown**  button in the upper right corner of the screen (see Fig. 5-9).

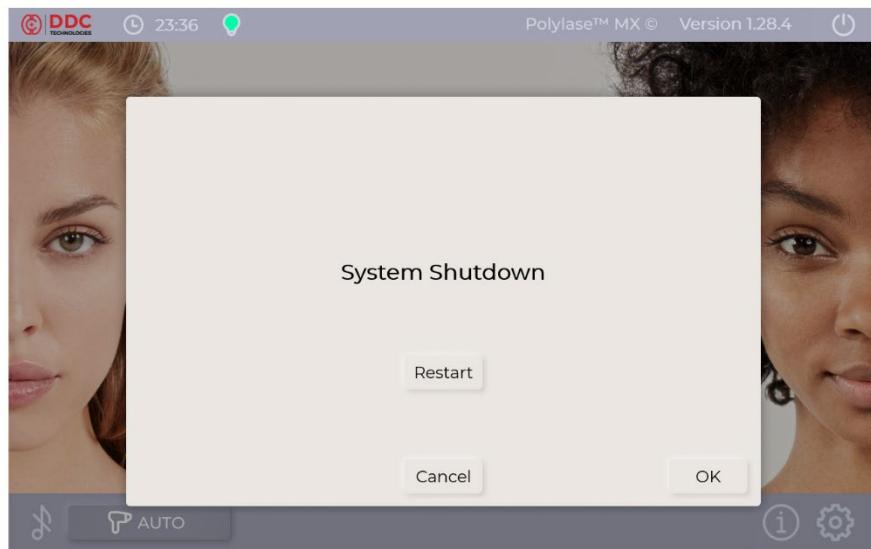


Figure 5-11. Shutdown Screen

Press “OK” to initiate system shutdown procedure and follow instructions on the screen. Press “Restart” to quickly restart the laser software and return to Laser Output Selection Screen.

Handpiece Cleaning

The handpiece is a non-critical product per APIC Guidelines and requires cleaning of the output 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 cotton swab soaked with acetone or methanol may be used to clean the laser handpiece protective window between patients. Always finish the cleaning process with a fresh wipe or cotton swab 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 the protective window from the holder.



Figure 5-12. Handpiece protective window is located inside the snap-in holder between distance gauges.

NOTE: After extended use the optical surface of the protective window can be damaged, despite regular cleaning. This is normal. If extensive damage can be seen on the window surface, replace it with a new one. Please, contact DDC Technologies Customer Service department and ask for **Part # W-755/1064-0501** to order.

Replacing the Protective Window

1. Using 2 fingers, pull out the snap-in holder at the handpiece output aperture.

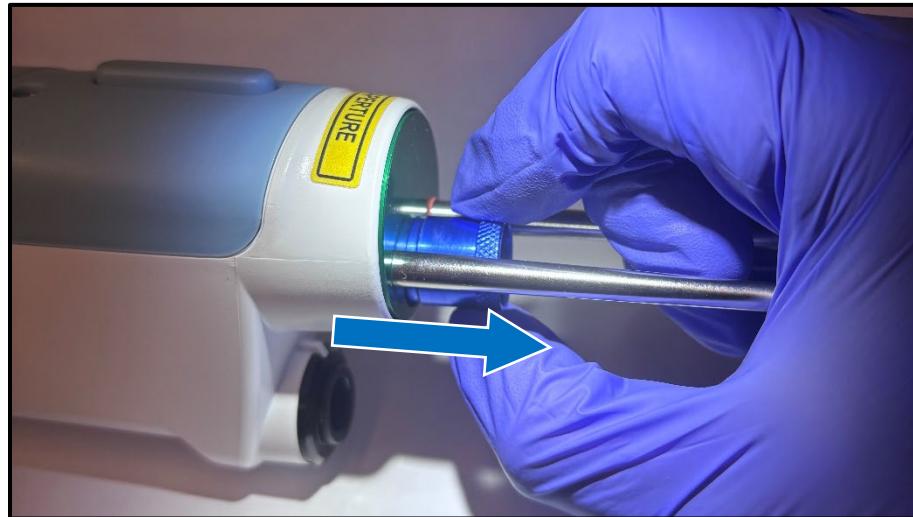


Figure 5-13. Removing snap-in holder

2. Unscrew the cap by turning counterclockwise. This will expose the protective window and give you full access to clean it with a wipe. Clean both sides of the protective window making sure there is no debris left.

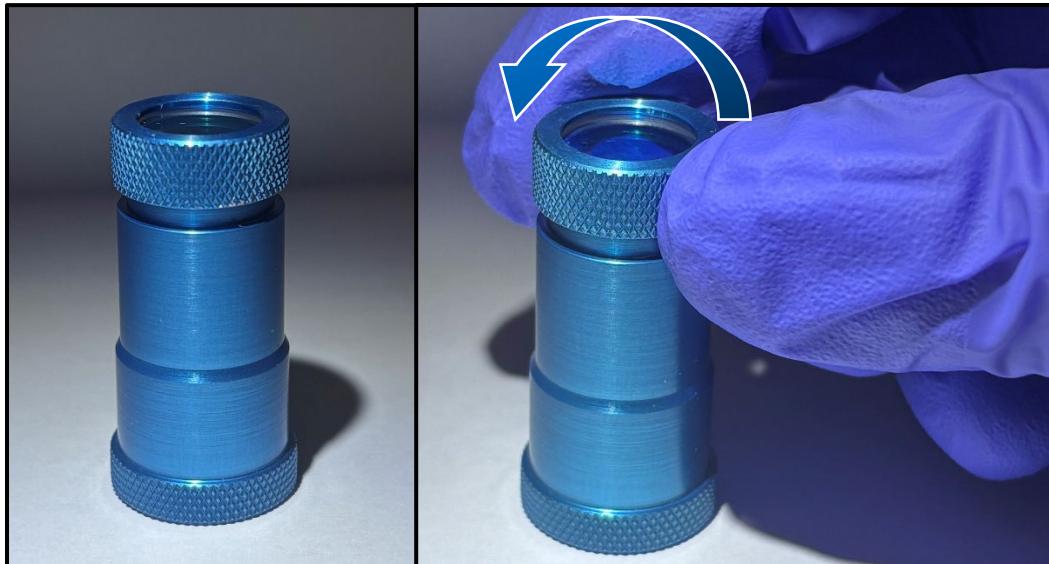


Figure 5-14. Unscrew protective window cap

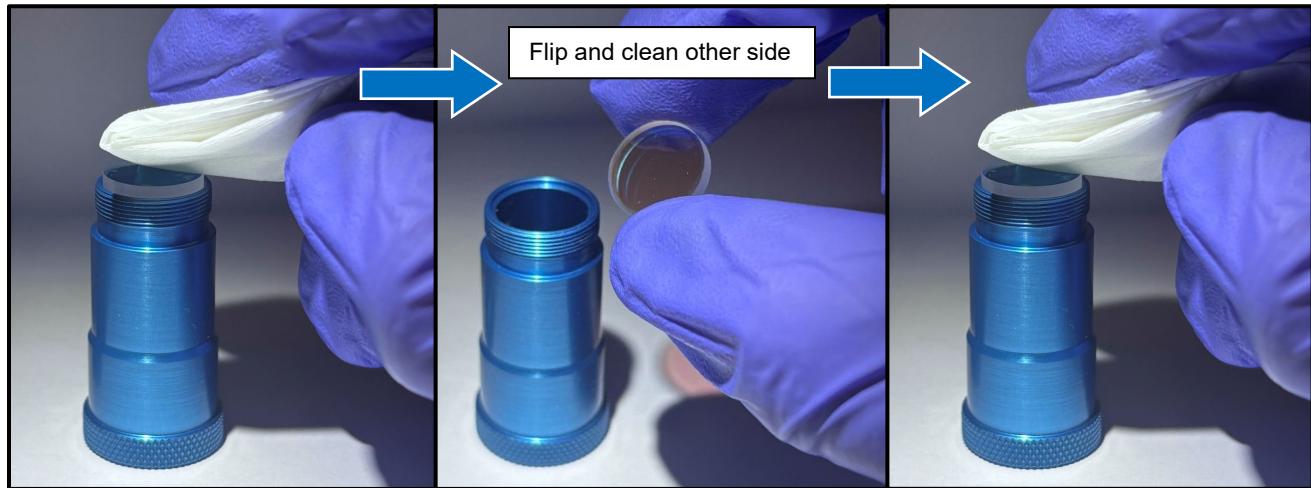


Figure 5-15. Cleaning both sides of protective window

3. When both sides are clean screw the cap back on by rotating clockwise and reinsert the snap-in holder at the handpiece output aperture (between two distance gauges).

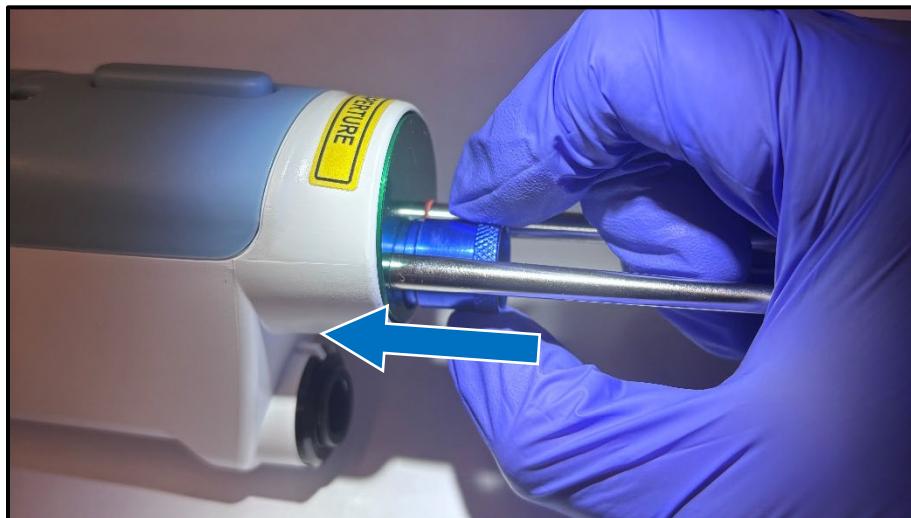


Figure 5-16. Reinserting snap-in holder

NOTE: Never touch the surface of the protective window; always hold it by its edges. Even when wearing dust-free or plastic gloves, avoid contact with the window surface, as some gloves may leave a residue.

Cleaning the Laser Console

Periodically clean the external surfaces of the laser console using a clean cloth dampened with a spray cleaner. **Do not use acetone** to clean any part of the laser console. After cleaning, dry with a clean, dry cloth.

CAUTION



- **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.

DANGER



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

Other System Features

Handpiece Vein Mode

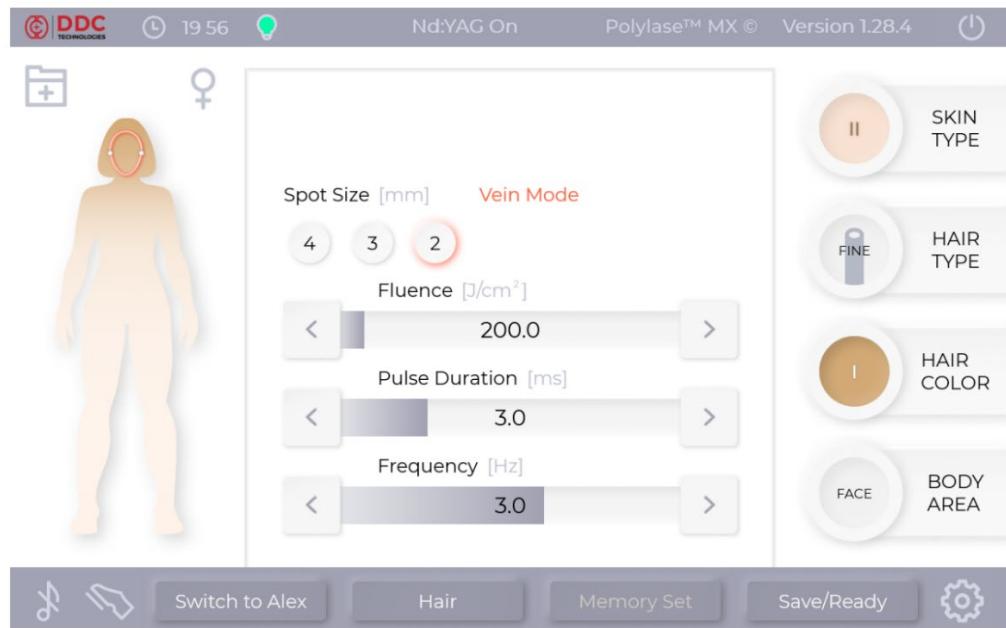


Figure 5-17. Vein Mode Screen.

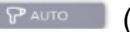
The POLYLASE MX software allows both Nd:YAG and Alexandrite handpieces to operate in **Vein Mode**, i.e., with the optional insert objective. The optional VEIN OBJECTIVE allows the handpiece to operate with 3 small spot sizes (2, 3 and 4mm), which allow to generate high fluences during spider and varicose vein treatment (specifically, with Nd:YAG laser). This objective must be installed in the handpiece output aperture instead of the Protective Window Holder prior to entering **Vein Mode**. When this optional objective is installed, the user must switch the laser into **Vein Mode**. The handpiece mode selection button (**Vein** or **Hair**) is located on the footer toolbar on the **Edit** screen (see Fig. 5-4 and 5-17). The laser is always in **Hair** mode by default after system start-up, therefore this button is normally displayed as **Vein**. To switch to **Vein Mode**, press and hold **Vein** button for at least 3 sec. The button will change its name to **Hair** and the laser software will switch to **Vein Mode** (see Fig. 5-17). The spot size selection options will change to 2, 3 and 4 mm and all displayed Fluence values will be re-calculated to reflect the small spot size selected. To switch the laser back to **Hair** mode, press and hold the **Hair** button for at least 3 sec.

WARNING



- POLYLASE MX does not have automatic recognition of the optional VEIN OBJECTIVE. Please, remember to switch the laser into Vein Mode every time you use the OBJECTIVE. Failure to do so will lead to incorrect Fluences displayed and may result in patients' skin burns and/or other injuries.

Handpiece Manual Mode

In some situations, the POLYLASE MX laser handpiece detection system can be turned off. This is useful when handpiece-related errors happen in the system and the operator needs to complete the treatment session. 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 cannot 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 the 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.

Patient Database

The POLYLASE MX laser features an integrated patient database designed to assist users in managing patient records efficiently. This database securely stores patient information, including personal details, treatment history, and specific treatment parameters for each session. By maintaining detailed records, the system enhances workflow efficiency and ensures consistency in treatment protocols.

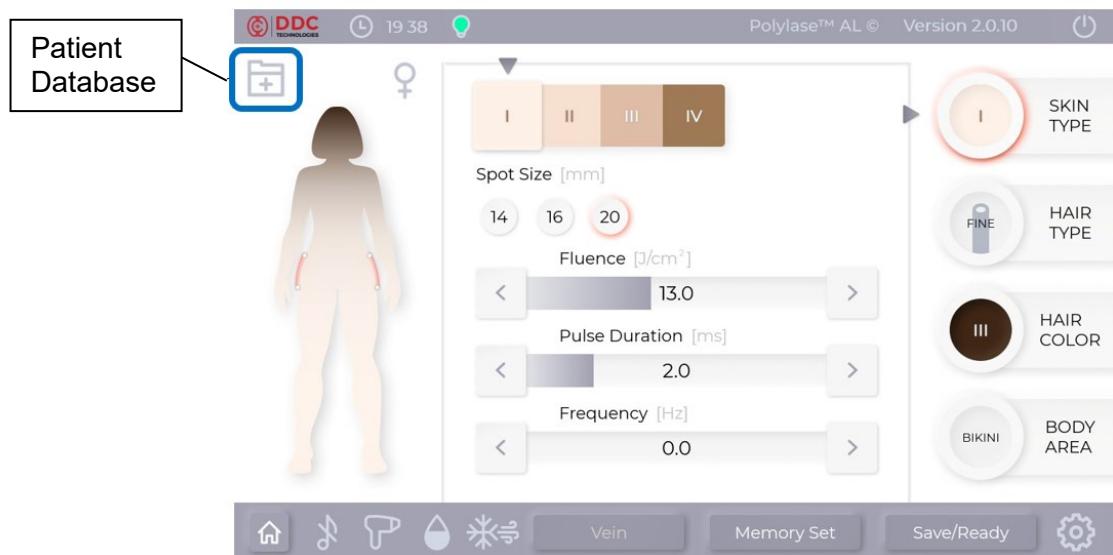


Figure 5-18. Patient Database Button

Accessing the Patient Database

To access the patient database, press the **folder icon** located in the **top left corner** of the screen. When prompted, enter the default password "**15524**". Users can change this password by selecting the "**Change Password**" button in the database settings. It is recommended to update the default password to enhance security and protect patient information.

Navigating the Patient Database

Upon entering the patient database, you will be greeted by the **Patient List**, which displays all previously entered patients. The following options are available:

Control	Description
Create	Opens the Create Patient screen, allowing you to add a new patient record.
Clear	Prompts you to confirm the deletion of all existing patient records.
Exit	Closes the patient database session and returns to the main screen.
Search Bar	Allows you to quickly locate a patient by entering their name.
Sort Feature	Enables you to organize the patient list based on different criteria for easier navigation.

New Patient

To enter a new patient, press the **Create** button. This will open the **Create Patient** screen, where you can input the patient's personal details and contact information.

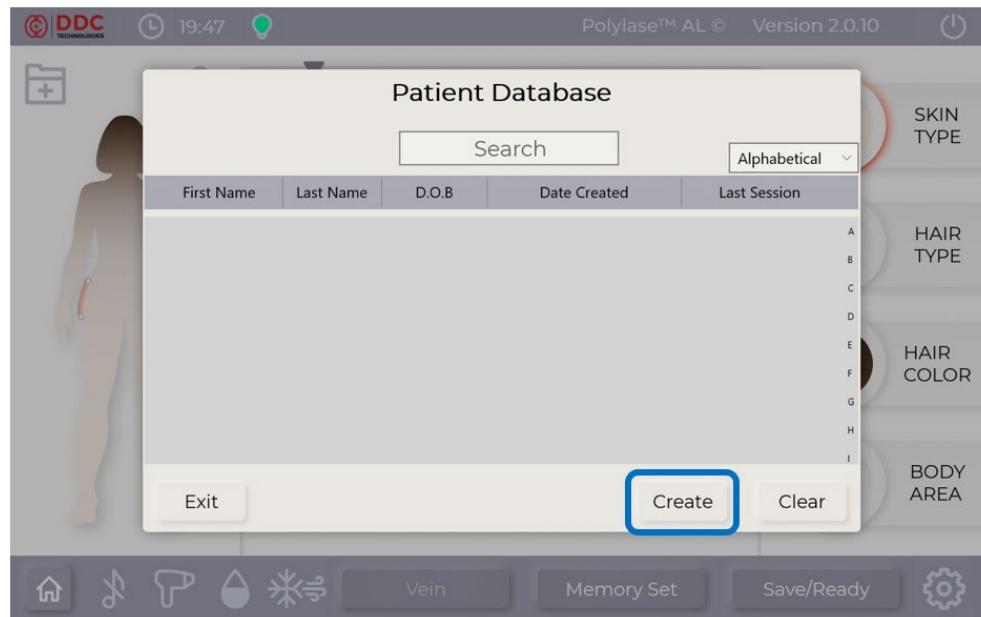


Figure 5-19. Create Patient Button

Once all the required information is entered, press the **Save/Exit** button to return to the **Patient List**. From there, you can tap on the desired patient and press **Select** to proceed.

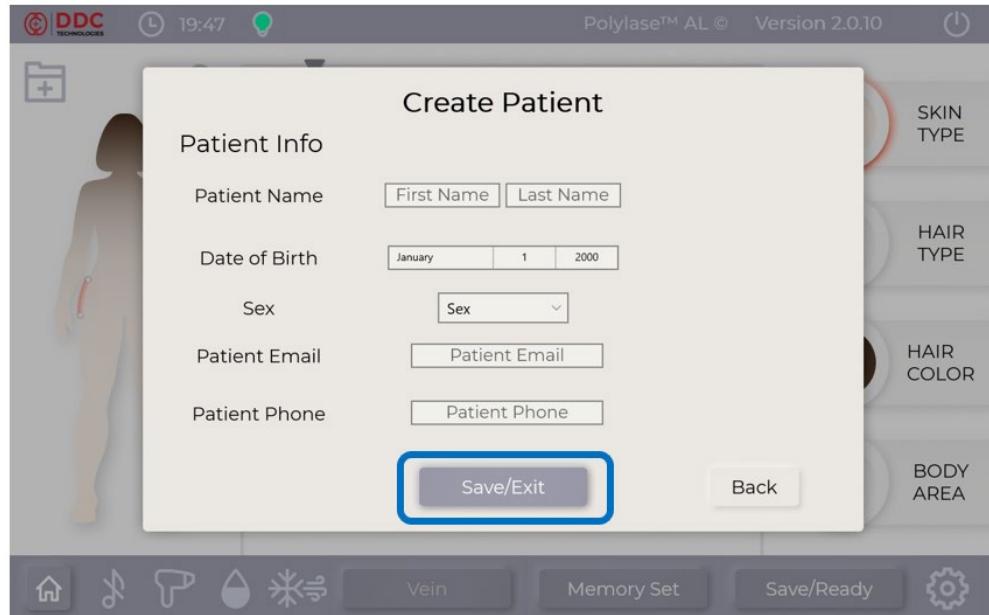


Figure 5-20. Patient Info Save/Exit Button

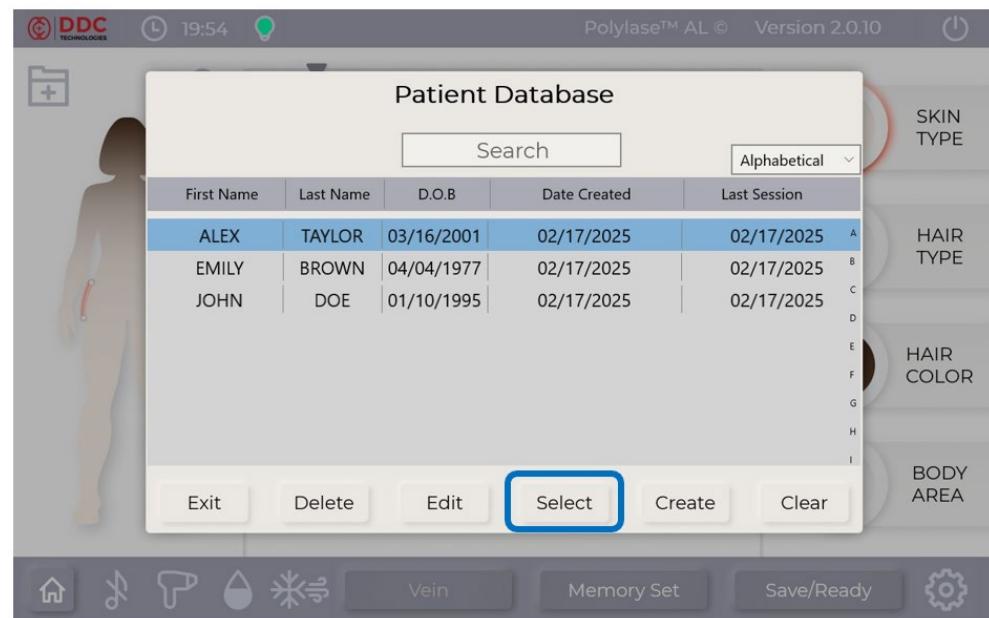


Figure 5-21. Patient Select Button

Starting a New Session

After selecting a patient, you will see that a newly created patient does not have any sessions saved. To begin the first session, press the **Create** button.

You will know the session is **active** when the patient's name appears above the body figure. It is important to select all treatment parameters, including:

- **Skin Type**
- **Hair Type**
- **Hair Color**
- **Body Area**
- **Spot Size**
- **Fluence**
- **Pulse Duration**
- **Fluency**

Entering all parameters ensures accurate record-keeping and helps maintain comprehensive treatment logs in the database for future reference.

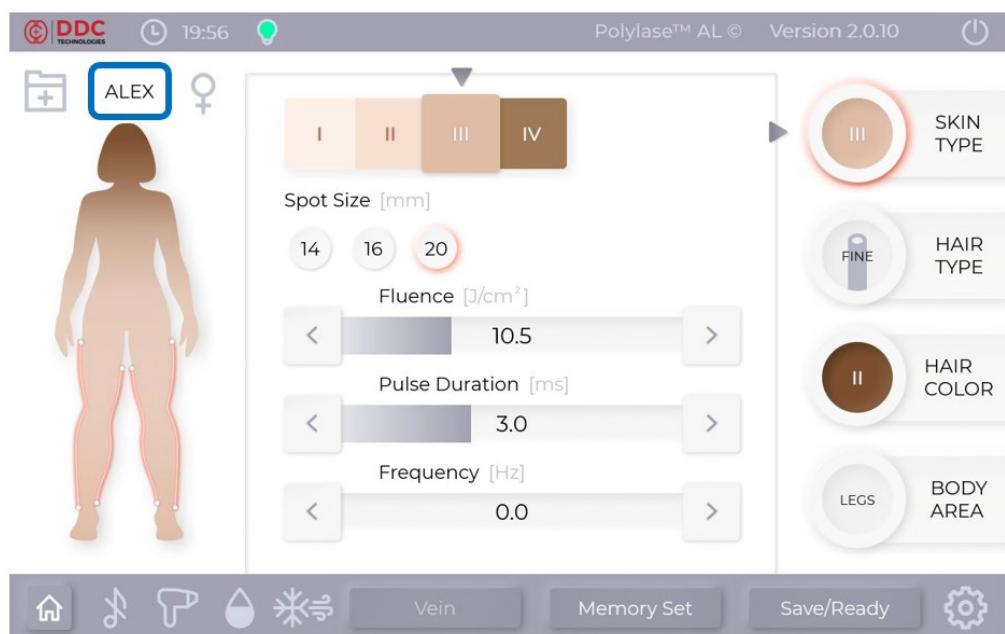


Figure 5-22. Active Patient Session

Completing and Saving a Session

After selecting all parameters, you may continue with the session. Once the session is complete, it will be automatically saved to the patient database. To view the session, enter the **Patient Database**, where you will find the most recent session listed at the top of the page. Here, you will see:

- The **date and time** the session occurred
- All **parameters** used during the session
- The **pulse count**

To quickly reuse the same parameters from a previous session, tap the desired session. When the session is highlighted, press **Select**. This will automatically populate the **Edit** screen with the same parameters. You may then proceed with the current session using those pre-filled settings.

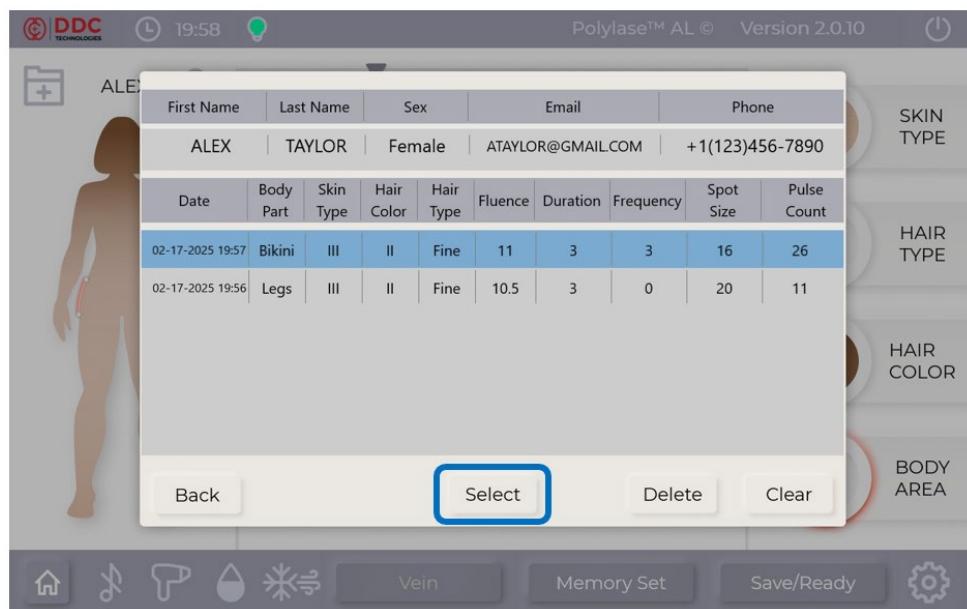


Figure 15-23. Populate session with previously used parameters

System Sounds

The POLYLASE MX is equipped with the system sounds function. This includes Pulse Sound and Error Sound options. The laser is factory-configured with Pulse Sound option turned OFF by default, but it could be turned ON from the laser **Settings and Constants** screen in the **Service Mode**. Error Sound is turned ON by default.

To turn system sounds on or off, select (Service) button from the **Edit** mode, then turn the desired sound option (either both or only one) ON or OFF by the corresponding slider button in the **Settings and Constants** screen of the **Service Mode**.

The **Sound ON/OFF** **Button** can also be used to turn the pulse beep sound ON or OFF directly from the **Edit** screen.

Error Messages and Troubleshooting

The POLYLASE MX 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 (door) interlock is open	Check the external interlock circuit.
Lamp change is due. Please, replace the flashlamps.	The # of pulses for the currently installed flash lamps exceeded recommended number	Perform Flashlamp Service (see p. 20 below)
Laser Autocalibration is due: Low Fluence Reading. Please, perform the Autocalibration Procedure.	Laser output fluence is measured below set value during operation	Confirm the warning with OK button and continue to work normally. Perform Laser Output Autocalibration Procedure at convenient time (see p. 20 below)
Laser Autocalibration is due: Lamp Counter Over Limit. Please, perform the Autocalibration Procedure.	The # of pulses on the flash lamps exceeded recommended amount since last autocalibration	Confirm the warning with OK button and continue to work normally. Perform Laser Output Autocalibration Procedure at convenient time.
Laser Autocalibration is due: Lamp Counter Reset. Please, perform the Autocalibration Procedure.	Laser Output Autocalibration Procedure was not performed since last lamp counter reset	Perform Laser Output Autocalibration Procedure as soon as possible.
Laser not calibrated	Laser autocalibration procedure was not performed when it was required	Perform Laser Output Autocalibration Procedure (see p. 20 below)
System Is Too Cold XX °C	Water Temperature in the laser cooling system is less than 15 °C	Laser Controller will not allow the system start until the 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.
System Overheat, XX.X°C > 50°C. Please, Wait.	Water temperature in the cooling system is too high	Release the footswitch and wait ~1 to 3 min until the error message disappears. 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 completing system TURN OFF procedure and then turning it back on.

NOTE: Turning the system OFF using red Emergency Button is also considered by the controller as a SYSTEM FAULT. To resume operation, the Emergency Button must be released by slightly rotating it clockwise 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
Charger Not Ready. Please, call for service.	The Capacitor charger cannot 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.
Charger Overheat Error. Please, call for service!	The capacitor charger IGBT 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.
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.
Lamp not ignited. Please, restart the laser	The simmer circuit is not on. Flash lamp cannot be ignited.	Restart the laser. If the problem persists, turn the system OFF and call Customer Service for flash lamp replacement.
Low water flow. Please, call for service!	There is insufficient water flow in the cooling system.	Check the water level in the cooling tank. Add distilled water, if necessary. Restart the laser. If the problem persists, turn the system OFF and 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.
Over Fluence Error. Please, restart the laser.	The measured Output Fluence was more than 20% higher than pre-set by the operator.	Restart the laser. If the problem persists, call Customer Service for assistance.

Error Message	Possible Cause	Recommended Operator Action
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.
PFC Fault. Please, call for service!	PFC circuit output voltage is incorrect.	Critical system fault. Please, call Customer Service for assistance.
Shutter Error!	Improper operation of the laser resonator shutter.	Restart the laser. If the problem persists, turn the system OFF and 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 the 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
Error: I/O Board Communication Error! Please, call for service!	There is no response from the I/O Board 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.
Handpiece Error: Handpiece not connected	There was no response from the handpiece to User Interface Controller within the required timeout period. May also indicate handpiece zoom lens movement malfunction.	Check the handpiece communication cable connection to the laser. 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.
Handpiece Error: Please check the Handpiece	There was no response from the handpiece to User Interface Controller within the required timeout period during laser operation.	Check the handpiece communication cable connection to the laser. Restart the laser. 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. If the problem persists, call Customer Service for assistance.

Flashlamp Service

The POLYLASE MX Laser will eventually need to have a certain internal component known as a "flashlamp" replaced. The system will start giving a warning message "**Lamp change is due. Please, replace the flashlamps**" at the startup when flashlamp replacement is due. The replacement of the flashlamp is covered under the standard warranty and extended service contracts, however it does necessitate a visit of a field service technician. The advanced laser head design of the POLYLASE MX Laser allows fast and easy 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 02 Rev 1-24 Nd:YAG Flashlamp Replacement Procedure and SOP 47 Rev 2-24 Alexandrite Flashlamp 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 must be replaced at least every 6 months. It is recommended to replace coolant water every 2 months during summertime or in the regions with a warm climate. Always drain coolant water when the laser is put into storage or if you do not plan to use the laser for more than 1 month.

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 the 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 the laser left side panel. Locate white water tank in the middle of the compartment. Pull the strap that holds the water tank lid to the side. Remove the lid and refill the 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 the side panel.
4. Alternatively, the water tank can be re-filled through the drain valve without removing the side panel. Use supplied refill hose with attached funnel to do it. When refilling 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 POLYLASE MX 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. If necessary,

the autocalibration procedure must be performed in accordance with SOP 03 Rev 2-24 Polylase Autocalibration Procedure. Complete Calibration Procedure (SOP 03) should be performed by a qualified trained technician after any service or repair work.

Autocalibration Procedure

NOTE: Laser autocalibration should be performed when the following message appears: "Laser Autocalibration is due: Lamp Counter Over Limit. Please perform the Autocalibration Procedure."

WARNING



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

1. Put on the appropriate laser safety eyewear.
2. Press the Service Button in the lower right corner of the screen

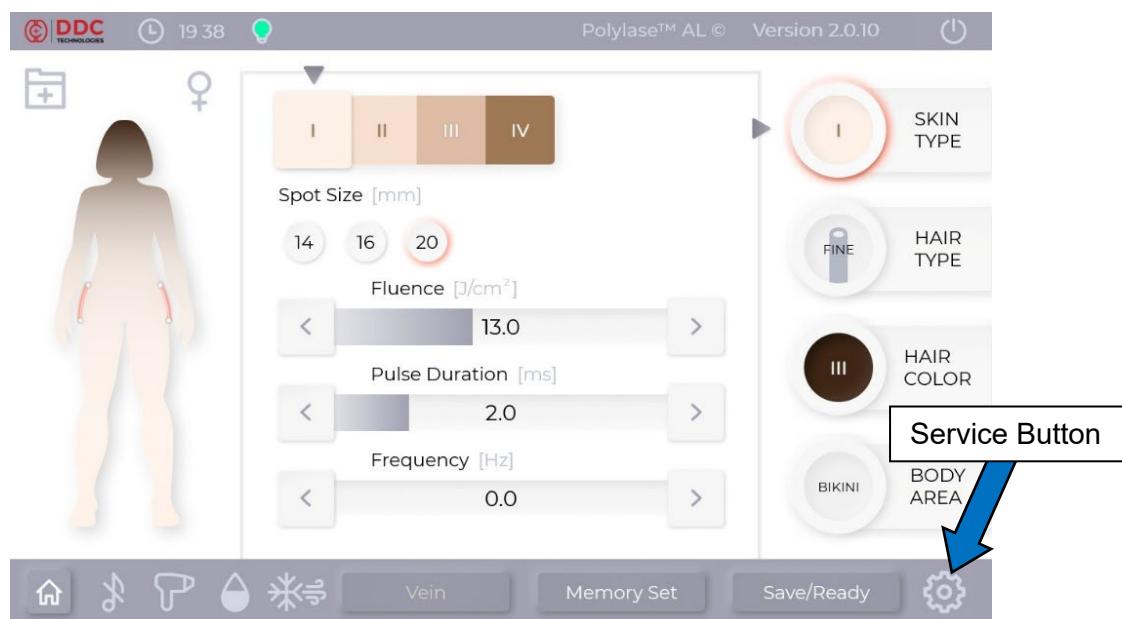


Figure 5-24. Service Button

3. Enter the default user password (15524) and press 'Enter' to access the Service Menu.
4. Press "Laser Calibration".

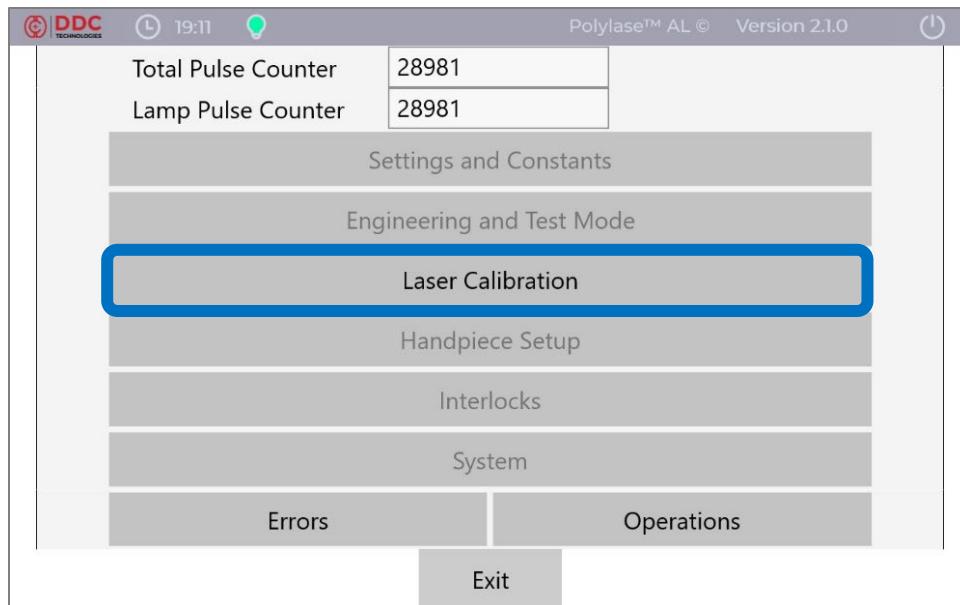


Figure 5-25. Laser Calibration Button

5. Press "LASER Output Autocalibration".

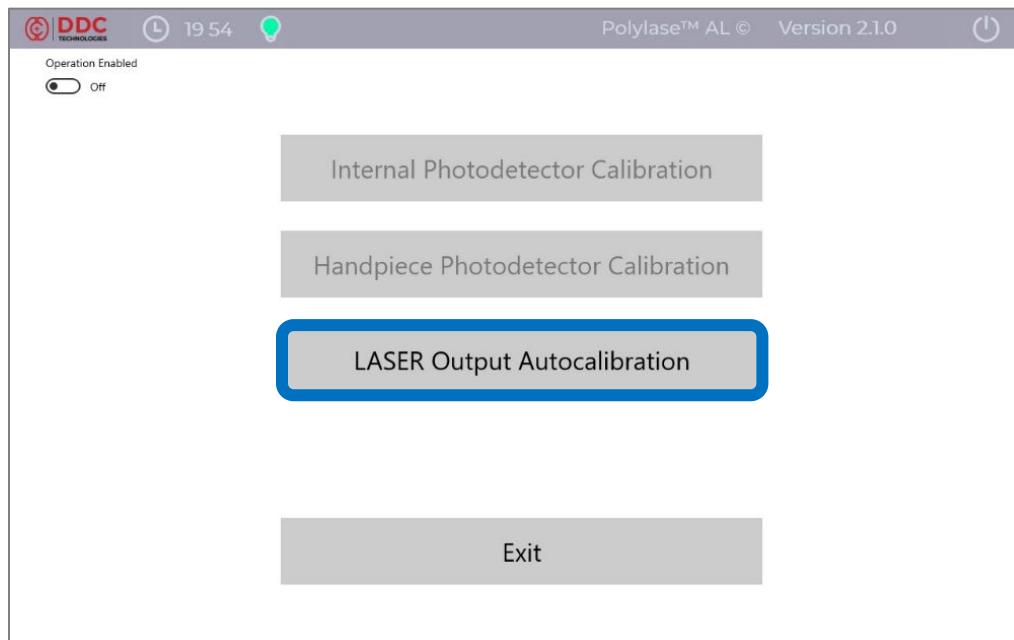


Figure 5-26. LASER Output Autocalibration Button

6. Ensure the output of the handpiece, corresponding to the laser being calibrated, is securely seated in the handpiece holder and facing the floor. If the floor material is flammable, install appropriate floor protection (e.g., a white sheet of printing paper or similar).

WARNING



- Powerful laser radiation remains present at the handpiece output during the laser autocalibration procedure. Ensure the handpiece is always pointed toward the appropriate target that can safely diffuse or absorb laser radiation.
- Always wear laser safety goggles throughout the entire laser autocalibration procedure!

7. From the Autocalibration screen (Figure 5-24), select “Start Calibration” and then press “OK” on the dialogue box warning about laser radiation danger (see also step 6 and make sure you comply with requirements), and then the Laser Output Autocalibration Procedure will begin.
 - a. The laser will now fire a long series of pulses in order to create an internal calibration table. This process will take ~10 minutes.

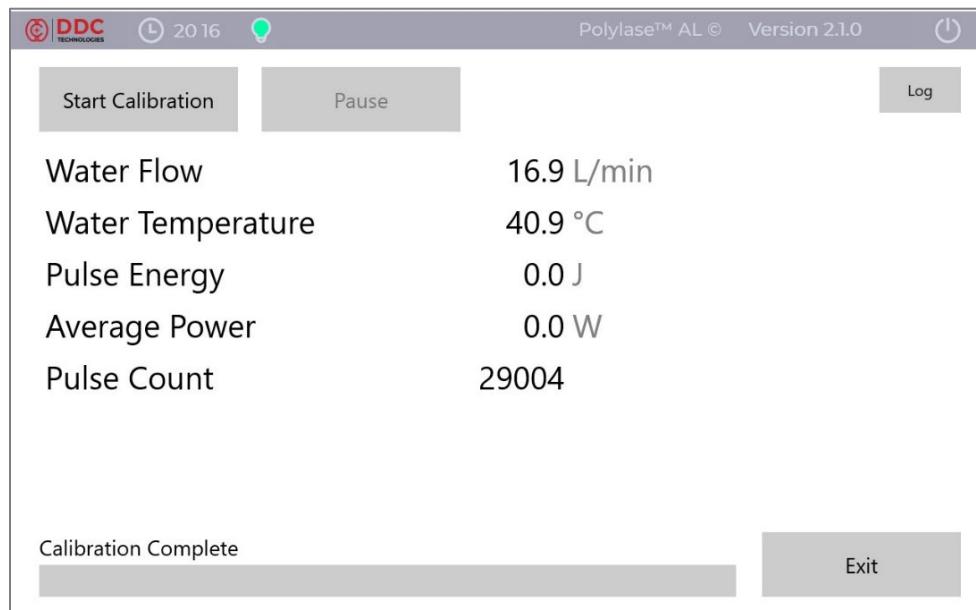


Figure 5-27. Autocalibration Screen

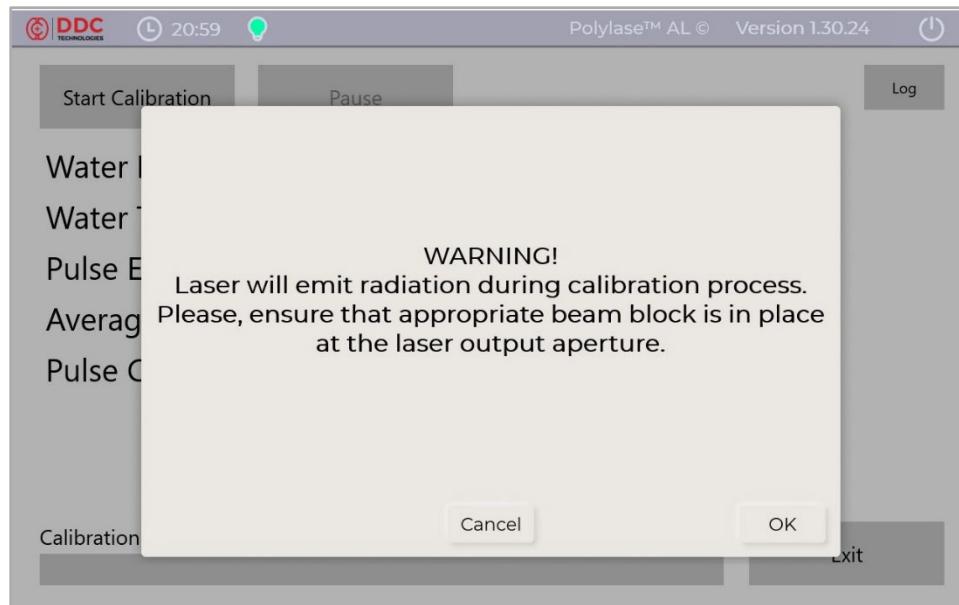


Figure 5-28. Laser radiation warning dialogue box

- Once autocalibration is complete, the laser will display a 'Calibration Complete' message at the bottom of the screen. The final voltage displayed should be 500V, with a final pulse duration of 7 ms for the Alexandrite laser and 10 ms for the Nd:YAG laser. Make a note of the last calibration pulse energy (i.e., the maximum available laser output energy, displayed in the center of the screen) for your records. Press 'Exit' in the bottom-right corner to exit the Autocalibration screen.
- Laser Autocalibration procedure is now complete.

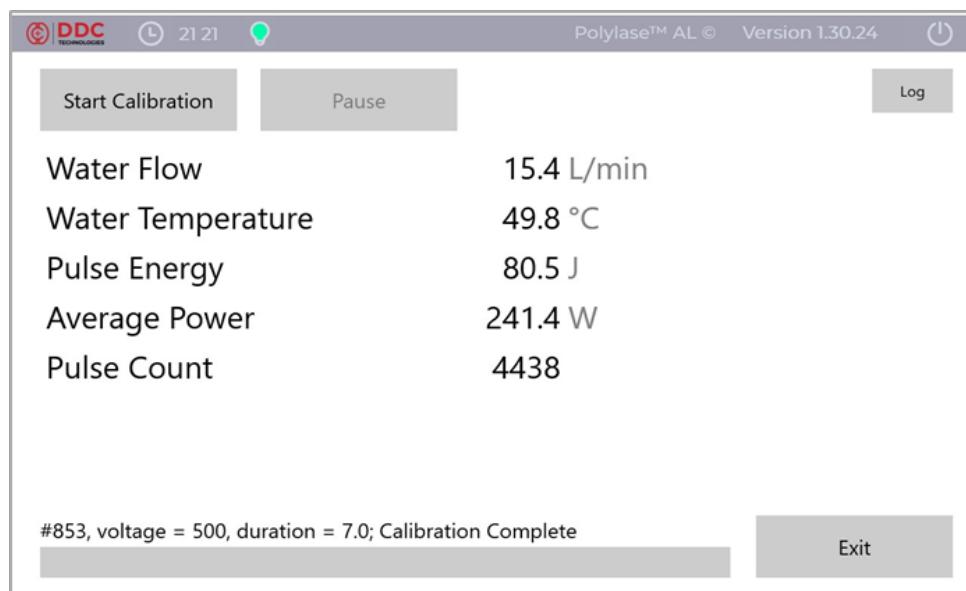


Figure 5-29. Laser Autocalibration complete