

PioneerElite™

OPERATOR'S MANUAL



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SECTION 1 – INTRODUCTION

Dentists continually strive to create the perfect smiles, yet are often limited by the technology they use in their practice. Respected leaders from the dental profession and dental equipment manufacturers have sought to identify the most practical and least invasive technologies to deliver restorative and preventive care. Thanks to continuing efforts by these industry leaders, we have seen the introduction of many new devices that have advanced the dental professional's ability to perform at the highest standards.

The Pioneer™ Elite diode laser by Pioneer Lasers, LLC provides the latest in solid state diode laser technology available for soft tissue modification and preventative care. Unlike solid state lasers that utilize a man-made rod of elements such as yttrium, aluminum, and garnet, doped with a rare earth compound like Erbium, the diode has components that have become known for their durability, dependability and longevity. We are, of course, referring to semi-conductor crystal technology like that found in televisions, DVD players, telephones and many more household products that we have learned to rely on each day. The major components of the Pioneer Elite are semiconductor "chips" made from Aluminum, Gallium and Arsenide, together commonly referred to as AlGaAs. They are activated or "pumped" by passing an electrical current through the diode to produce an elliptical shaped display of monochromatic light that can be focused into a very small point and placed into the delivery fiber.

The wavelength produced by the diode is approximately 810 nanometers (nm) and produces invisible non-ionizing thermal radiation that does not create changes in cellular DNA. The diode is air cooled and highly efficient when used correctly. For safety, the laser system features several ways to stop energy flow to the diode if the operator wishes to deactivate the laser beam. The safety system includes a choice of an emergency shutoff switch, a power switch, a power cord or an electrical plug. Any of these items can be used to shut down the laser. The design and technology used in the Pioneer Elite allows the dentist or hygienist* to transport the laser between different operatories. It has a lightweight and durable chassis that is designed to use 110 – 120 V electricity found in most dental offices.

Training is recommended and opportunities for such are available through such outlets as Pioneer Lasers, LLC. Please visit our web site for instructional videos, training dates and locations at www.pioneerlasers.com. In addition, the Academy of Laser Dentistry, dental schools and many dental continuums offer suitable courses. You may also ask your authorized dealer representative for the names of dental professionals in your area who have a laser and who could help you in a mentoring capacity. Laser safety is paramount in importance and each office should quickly develop and implement a laser safety program and appoint a "laser safety officer" to be responsible for the laser. Their duties include management of the laser and all accessories as well as training office personnel in all aspects of laser safety. There are many applications for using this laser system and you will be amazed at the results and wonder how you ever practiced dentistry without the Pioneer Elite.

* In States / Provinces where the Dental Practice Act does not prevent hygienists to utilize a laser.



Laser safety is of paramount importance and each office should quickly develop and implement a laser safety program and identify a "Laser Safety Officer" to be responsible for the laser. The LSO's duties include management of the laser and all accessories as well as training office personnel in all aspects of laser safety.

ALWAYS test fire the laser away from tissue before using it on a patient. The doctor, staff, patient and anyone present in the operatory should be wearing the appropriate safety eyewear whenever the laser is being operated. Strict adherence to protocols for safe laser use is essential.

SECTION 2 – SPECIFICATIONS

2.1 Laser Specifications

| | |
|--|--|
| Weight | 2.5 lbs |
| Dimensions in inches (H x W x L) | In Cradle: 9.5" x 4" x 6" Out of Cradle: 7" x 4" x 3" |
| Laser Classification: (Per IEC 60825) Laser Diode | Class 4 Laser Device |
| Wavelength: Laser Aiming Beam | 810 nm ± 10nm 650 nm ± 10 nm |
| Beam Divergence | 9 degrees ± 1 degree |
| Power Range | 0.1 to 3.0 Watts |
| Hertz Rate in Pulsed Mode - fixed | 10.0 Hz |
| Pulse Duration - fixed | 0.05 seconds |
| Duty Cycle Pulsed Mode Continuous Wave | 50% 100% |
| Aiming Beam (3 mW) | Yes |
| Audible Notification | Yes |
| Visual Notification | Yes |
| Power Requirements | 110 – 120 VAC @ 60 Hertz 220 – 240 VAC @ 50 Hertz |
| Amperage | 1.5 Amps @ 110 – 115 V AC 0.75 Amps @ 210 -230 V AC |
| Battery Pack | Rechargeable lithium polymer 45 minutes continuous lasing time 8 hours stand-by time (laser on but not firing) |
| Cordless Foot Pedal: Frequency Battery | 2.4 GHz 9 volt Lithium |

2.2 Delivery System Specifications

| | |
|---|---------------------|
| Handpiece assembly with autoclavable sleeve | |
| Disposable, unit-dose silica-fiber tips | 400 micron diameter |
| Standard Tip - 6mm length | |
| Perio Tip - 9mm length | |
| Laser Aperture - Customized ST adaptor | |
| Therapy Handpiece | |
| Whitening Handpiece | |

2.3 Warranty

| | |
|------------------------------|------------------------|
| Laser | 2 year parts and labor |
| Rechargeable lithium battery | 1 year |
| Fiber cable assembly | 6 months |

2.4 Kit Contents

- 1 Pioneer Elite 3 Watt Diode Laser
- 1 Therapy Handpiece
- 1 Whitening Handpiece
- 1 Whitening Cone
- 1 Sample Pack of 10) Standard Tips
- 1 Sample Pack of 10) Perio Tips
- 1 Fiber cable assembly with removable handpiece sleeve (attached to laser)
- 1 Additional fiber cable handpiece sleeve
- 1 Charging Cradle
- 1 Wireless Footswitch
- 3 Protective Glasses
- 1 Lithium Polymer Battery (attached to laser)
- 1 Power Supply

Please check all items sent with your laser to insure that all components are accounted for.

SECTION 3 – LASER ASSEMBLY INSTRUCTIONS

3.1 Removing the Laser from the Packaging

3.1.1 – Instructions on Unpacking & Dealer Assistance

Your local authorized Pioneer dealer can provide a representative to assist you when you are ready to remove the laser from its shipping container. Do not attempt to unpack the laser and install the various components without reading this section first. If you are unsure about any aspect of the assembly, call your authorized dealer representative for assistance.

3.1.2 – Shipping Container Information

We recommend that you retain your original container in which you received your laser should you need to return the laser for service or repair. The shipping container you received with your laser has been specially designed to safely transport the laser.

3.2 Assembling the Laser

3.2.1 Foot Pedal Battery Installation Procedure

NOTE: The foot pedal does not come with the battery installed. Follow these procedures to install or replace the battery.

1. Make sure the laser is completely turned off before placing the battery in the foot pedal



Figure 3.1.1a

2. Place the pedal face down on a hard, clean surface (Figure 3.1.1a)

7. Place the battery in the well with the connector to the same side as the wire leads emerge from the housing (Figure 3.1.1e)



Figure 3.1.1e

8. Replace the battery cover.

3. Use a philips-head screwdriver to remove the two screws securing the battery cover. Turn the driver counterclockwise until the screws come out completely (Figure 3.1.1b)

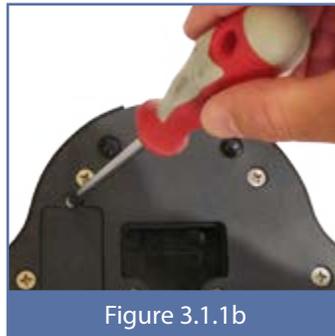


Figure 3.1.1b

9. Replace the screws. Turn the screwdriver clockwise to tighten the screws. The screws are sufficiently secure once they no longer turn with gentle finger-applied force. Do not over-tighten. (Figure 3.1.1f)

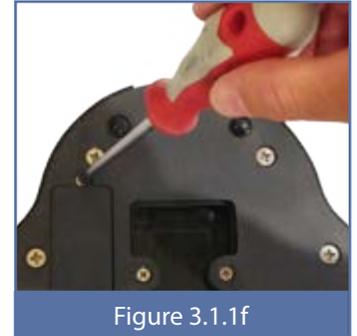


Figure 3.1.1f

4. Push down on one end of the battery cover while simultaneously lifting up on the other end to remove the battery cover (Figure 3.1.1c)



Figure 3.1.1c

NOTE: It is recommended to use a 9 volt Lithium battery to power the cordless foot pedal. This type of battery has been tested to last for over 100 hours of foot pedal operation. When the battery voltage begins to drop, the foot pedal will begin to beep, signaling that you have approximately 2 hours of operating time left before the battery life is completed.

NOTE: A 9 volt alkaline battery may be used; however the life expectancy of an alkaline battery is less than 35 hours of operating time.

5. Detach the existing battery from the connector. Do not pull on the wires to detach the connector. Lift up on the black connector itself.



Figure 3.1.1d

6. Remove the battery from its packaging and attach the battery to the terminal (Figure 3.1.1d)

3.2.2 Power Cord Installation

Remove the power cord from the Pioneer Elite package and plug the power cord into the appropriate receptacle on the back of the laser cradle. See Fig 3.2.1 Plug the power cord into a 120 Volt AC outlet rated at 60Hz. Use only the power supply that comes with the device. Use of other power supplies may damage the device or cause electrical shock. Touching the power contacts may result in a shock.



Figure 3.2.1

3.2.3 Direct Power Supply Attachment

If immediate power is needed and the battery is not charged, unplug the power cord from the cradle and plug it directly into the laser, Fig. 3.2.2.

- DO NOT leave the AC cord attached to the laser or cradle when the power supply is unplugged from the wall as this might inadvertently drain the battery.
- The battery will be charged if the cable is plugged directly into the laser.
- To prevent power surges due to electrical storms or spikes in line voltage, you should use a power strip with a circuit breaker or unplug the laser when you are not present.
- The laser can be switched on or off for the battery to be charged.
- ONLY USE THE POWER SUPPLY PROVIDED WITH THE UNIT. IN THE U.S., ONLY PLUG UNIT INTO 120V OUTLET.



Figure 3.2.2

3.2.4 Connection of Fiber Cable Assembly to the Laser

1. The handpiece assembly is already installed when you receive your new Pioneer Elite Diode Laser. Please leave the handpiece assembly connected to the laser unit unless you have to switch handpiece assemblies or if you have to ship the laser for technical reasons.

Disconnecting the handpiece for even short periods can lead to contamination of the precision polished end of the fiber connector. This may result in reduced power output of your laser over time.



Figure 3.2.2

2. If you have to disconnect the cable, keep the fiber tip connector of the handpiece and the connector on the bottom of your Pioneer Elite clean. Use the protective metal dust cap to protect the end of the handpiece assembly at any time and be sure not to touch the precision polished end of the connector. Fig 3.2.2. Install the protective metal cap to protect the connector on the bottom of your laser from dust and other contaminants. The protective metal cap serves also as protection from accidental firing of the laser. Fig 3.2.3. The handpiece contains a locking nut design to ensure longer service life of the optical connection. Never use force to detach the handpiece if needed, a special tool has to be used to be able to release the set screw of the handpiece connector. This special tool is provided with each handpiece replacement. Please contact the Pioneer Equipment Service Center if you have questions. Fig 3.2.4.



Figure 3.2.3

Contaminants on the fiber ends may lead to the malfunction of your handpiece. Please take special care in exchanging handpiece assemblies.

3. Installation of a handpiece assembly to the laser should be done in a clean environment. Attach the handpiece fiber assembly by screwing the knurled connector of the cable into the bottom of the laser unit. Lock the nut with the special tool provided with the handpiece replacement. Fig 3.2.4. Avoid scratching the end of the fiber connector when inserting the cable. Fig 3.2.4.



Figure 3.2.4



CAUTION: Do not detach the fiber cable unless to replace it.

The custom engineered connector at the bottom of your Pioneer Elite does not allow operation if there is no handpiece assembly attached. This is a feature for your protection. A Safety Alert window will pop up on your screen if you switch on the laser without the handpiece installed or if the connector is loose. Make sure to moderately hand tighten the connection of your handpiece assembly after installation and tighten the locking nut. Fig 3.2.5a and Fig 3.2.5b.

3.2.5 Attaching Single-Unit Fiber Tip

Remove a unit dose fiber tip from its package, remove the plastic protective cap, and snap it into the handpiece. Figs 3.2.6a - c. Avoid placing your finger on either end of the handpiece tips as the tips are gamma irradiated and have to be clean for optimal performance and safety. Use gloves while handling the tips as natural oils deposited on the fiber or fiber connection can burn and diminish the effective transmission of radiant energy once the laser is installed.

Slide the disposable barrier sleeve over the handpiece assembly. If needed, puncture the barrier sleeve with the tip so the tip fiber protrudes out of the barrier sleeve.

3.2.6 Placing the Laser in the Cradle

Place the laser unit in the cradle by tipping the laser unit slightly forward and inserting it into the cradle. Fig 3.2.7. Do not force the unit into the cradle and be sure to place the fiber cord through the cradle opening.

The Pioneer Elite diode laser is supplied with a rechargeable lithium polymer battery which provides up to 45 minutes continuous lasing or 8 hours stand-by time, (i.e. laser on, not being charged by cradle or AC power cord.)

THE LASER BATTERY MUST BE FULLY CHARGED BEFORE INITIAL USE.

THE LASER CAN BE SWITCHED ON OR OFF FOR THE BATTERY TO BE CHARGED.

Allow the battery to charge overnight before first use.

Recharging a completely discharged battery takes approximately 5 hours.



Figure 3.2.5a



Figure 3.2.5b



Figure 3.2.6a



Figure 3.2.6b



Figure 3.2.6c



Figure 3.2.7

3.2.7 Remote Interlock

The Pioneer Elite Laser is equipped with a Remote Interlock Jack. The Remote Interlock Jack is provided so that a clinician may install the laser in a dedicated laser treatment room such that the laser will be interlocked with the entrance door of the room. In such an interlocked installation, the laser would shut off anytime the door is opened, hypothetically, to protect the person's eyes who is entering the room. It is recognized that such installation is not facilitated nor required in many operatories or clinics. To that end, the Remote Interlock is available to any practitioner that requires or requests it. The Remote Interlock Jack is located and clearly labeled on the side panel of the laser. Fig. 3.2.8.

The miniphono jack is wired in the normally closed position; meaning that no further action is required to operate the laser without the interlock loop. If the interlock loop is desired you may purchase the loop from a local electronics store. You need only inform the local electronics store that you require a mini (1/8") miniphono jack wired into a normally closed momentary switch and select the switch design that best suits your needs. To install the loop, install the switch on the door and simply plug the miniphono jack into the Remote Interlock Jack on the side panel of the laser.

3.2.8 Laser Stop Switch

Before you activate the laser, make sure the red Laser Stop button is in the depressed position. The laser will activate only with the button in the depressed position. If the laser needs to be stopped quickly, pushing and releasing the red Laser Stop button will immediately shut the laser off.

The Safety Alert Window will appear on the screen if the button is released.



Figure 3.2.8

3.2.9 Turning on the Laser

Turn the laser on using the main power switch on the side of the laser. Fig. 3.2.9

3.2.10 Digital Keycode

The Elite has a keyless entry system for security purposes. After turning the power to the "On" position, the Elite Screen will appear. Touch the "Enter" key. The Login screen will appear, touch the screen and input the digital key code **1 2 3 4** and touch the "Enter" key. Fig 3.2.10.



Figure 3.2.9

3.2.11 Installation Test

1. After login, from the Main Menu, touch the "Quick Set Up" Button
2. The Pioneer Elite is pre-set to "Continuous Wave" (CW)
3. Power setting is pre-set to 1.0W
4. Hold the fiber approximately 2-4 mm away from a piece of articulating paper.
5. Touch "Ready" button – laser is in "Ready" mode. A green checkmark will be displayed, Fig. 3.2.11. You will be able to see the aiming beam on the articulating paper.
6. Depress the foot pedal to activate the laser.
7. The articulating paper will begin to develop smoke in 1-2 seconds.



Figure 3.2.10

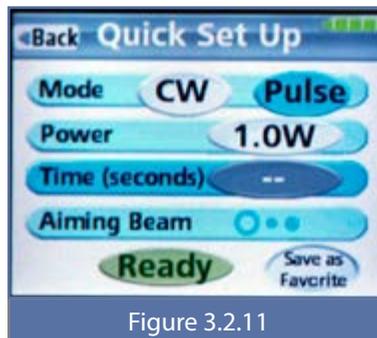


Figure 3.2.11

3.2.12 Check the Laser Stop

1. To check the “Laser Stop” system, simply press and release the red “Laser Stop” button while the laser is activated. The shut down system will take the laser out of active mode. Fig. 3.2.12a.
2. To activate the laser, depress the “Laser Stop” button and the laser will resume laser emission. Fig 2.2.12b.

NOTE: The red Laser Stop button should be depressed for the laser to activate. Fig 3.2.12b.

Remember: Always test fire the laser outside the mouth before using it on a patient. The doctor or hygienist, the patient and any staff member present in the operatory should be wearing the appropriate safety eyewear whenever the laser is being operated. Strict adherence to protocols for safe laser use is essential.



Figure 3.2.12a

3.2.13 Touch Screen Menu

The Main Menu screen gives you the choice to use a “Quick Set Up” (Fig 3.2.13a) - with settings you designate for each procedure—or you may select a pre-set program sorted in alphabetical order under the “Procedures”, or under the “Specialty” categories. The settings are portrayed with four adjustable settings: Mode, Power, Time and Aiming Beam. The settings can be changed as desired for any of the program modes and saved as “Favorites” if needed.

Battery Symbols

There are two battery symbols in the top right corner of the touch screen. Green color indicates a fully charged battery. The first battery symbol on top indicates the status of the internal Pioneer Elite battery. The lower battery symbol indicates the status of the replaceable 9V lithium foot pedal battery.

Mode

Mode refers to “continuous wave” or “pulsed power, Fig. 3.2.13b. Use the MODE key to toggle back and forth between Continuous and Pulse as desired. The chosen mode is displayed in gray color.

Power

Depressing the Power setting allows the operator to adjust the power settings from 0 to 3 watts in 0.1W increments, Fig. 3.2.13c. This control is for the working beam only. Hold the desired key to rapidly change the value. Touching the right arrow increases the power, touching the left reduces the power. Depress “Done” to return to the Main Menu.



Figure 3.2.12b

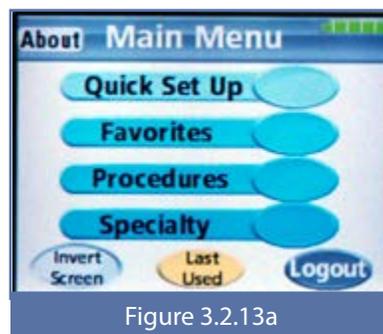


Figure 3.2.13a



Figure 3.2.13b

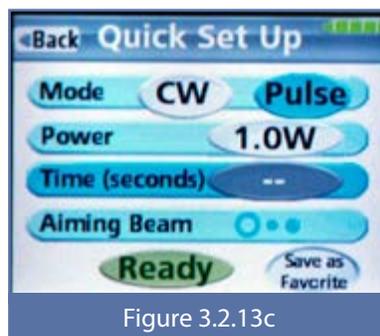


Figure 3.2.13c

Time

You have the ability to use the "Time" settings pre-set by procedure or modify the timer by using the arrow keys, Fig. 3.2.14. The laser will automatically shut off when the timer returns to 0. Touching the right arrow increases the time, touching the left reduces the time. Depressing "Done" returns to the main menu.

Releasing the foot pedal in the middle of a timed procedure will bring up a "Procedure Interrupted!" window. The timer will continue with the remaining time if you press "Continue" or go back to zero and start over if you press "Reset".

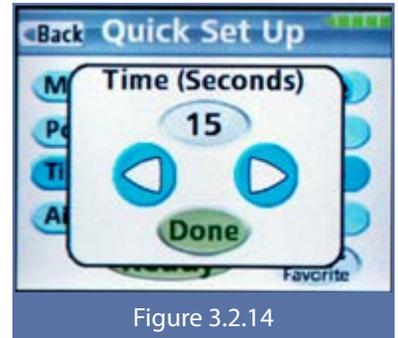


Figure 3.2.14

Aiming Beam

The Pioneer Elite diode laser is actually two lasers in one. The infrared 810 nm wavelength laser which performs the actual treatment of the soft tissue is called the "working beam". The 650 nm "laser pointer" illuminates the focal point of the "working beam" allowing the operator to aim prior to and during laser activation. In addition, the aiming beam control allows for five levels of illumination ranging from off to maximum intensity. The open circle indicates no aiming beam and the solid blue circle indicates the brightest aiming beam.

To adjust aiming beam intensity, the bar is depressed which activates the above screen, Fig 3.2.15. The arrows are depressed upward or downward as desired. Each increment adjusts the aiming beam intensity by about 20%. When complete, depress the "Done" key to return to the setting screen. Check if the new settings meet your desired aiming beam intensity.



Figure 3.2.15

Ready Indicator

This illuminates when the READY key is pressed. It will blink for 3 seconds, then remain steady. Once steady, the aiming beam will be activated and the laser is ready to be fired. Fig. 3.2.16.

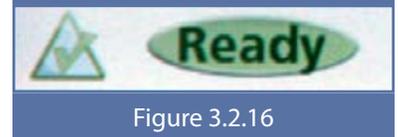


Figure 3.2.16

Laser On

This illuminates when the foot pedal is depressed, indicating that the working beam (810nm) energy is being emitted. Fig. 3.2.17.



Figure 3.2.17

Favorites

Any combination of settings can be easily saved for convenience with a user defined name. Press the button "Save as Favorite" in the lower right corner of the touch screen when you are in Quick Set Up Mode or in on one of the Specialty Procedure Screens.

Confirm "yes" on the next pop-up window (Fig 3.2.18a) and enter a descriptive name by pressing the respective buttons until you have the next letter in the box in the upper right corner of your screen. Either confirm this letter by touching it in the upper right corner or press another button or wait more than 2 seconds before pressing the same button. As a result this letter will be transferred to the name field in the middle of the dark grey portion of the upper screen (Fig 3.2.18b). It is possible to delete one character at a time by pressing "Clear". Note: Only lower case letters possible.

Press "Save" after the name is complete and confirm with "OK" to save your entry in a special non-transient memory for future use.

Favorites can be easily deleted by choosing a particular favorite setting from the "Favorites" menu and by pressing "Delete Favorite" and confirming with "Yes" in a second step.

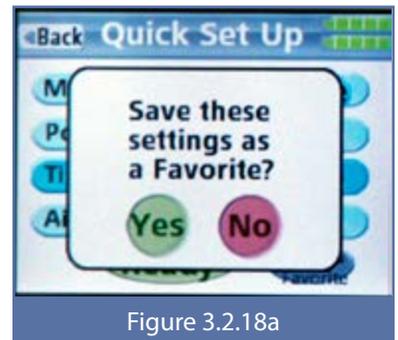


Figure 3.2.18a

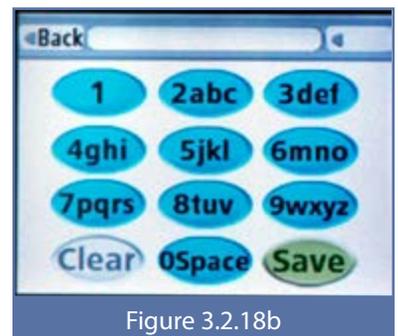


Figure 3.2.18b

3.2.14 Preset Programs

The Pioneer Elite comes with procedure specific settings installed. The Procedures are accessed from the Main Menu by depressing “Procedures” (Fig. 3.2.19). Procedures may also be accessed through the “Specialty” category. By accessing in this way, the procedures are sorted according to speciality, Fig. 3.2.20.

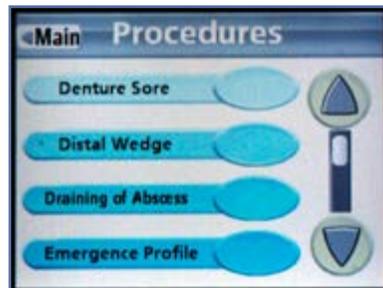


Figure 3.2.19



Figure 3.2.20

After selecting a procedure, the settings may be manually adjusted to suit your needs during a clinical procedure. The settings represent a good starting point and can be adjusted at any time.

| Preset Name | Tip Preparation | Technique | Laser Mode | Power Setting | Timer |
|---------------------|-----------------|-------------|------------|---------------|------------|
| Abscess | Un-initiated | Contact | Continuous | 1.0W | Set to 0 |
| Aphthous Ulcer | Un-initiated | Non-contact | Pulse | 1.4W | 30 seconds |
| Biopsy | Initiated | Contact | Continuous | 1.0W | Set to 0 |
| Contouring | Initiated | Contact | Continuous | 1.2W | Set to 0 |
| Denture Sore | Un-initiated | Non-contact | Pulse | 2.0W | 30 seconds |
| Distal Wedge | Initiated | Contact | Continuous | 1.5W | Set to 0 |
| Draining an Abscess | Initiated | Contact | Continuous | 0.9W | Set to 0 |
| Emergence Profile | Initiated | Contact | Continuous | 0.8W | Set to 0 |
| Expose Teeth | Initiated | Contact | Continuous | 1.0W | Set to 0 |
| Fibroma | Initiated | Contact | Continuous | 1.0W | Set to 0 |
| Flap | Initiated | Contact | Continuous | 1.0W | Set to 0 |
| Frenectomy | Initiated | Contact | Continuous | 1.0W | Set to 0 |
| Gingivectomy | Initiated | Contact | Continuous | 1.0W | Set to 0 |
| Gingivitis | Un-Initiated | Contact | Continuous | 0.4W | 20 seconds |
| Gingivoplasty | Initiated | Contact | Continuous | 1.2W | Set to 0 |
| Hemostasis | Initiated | Contact | Continuous | 0.8W | Set to 0 |
| Herpetic Lesion | Un-initiated | Non-contact | Pulse | 1.6W | 30 seconds |
| Hypertrophic Tissue | Initiated | Contact | Continuous | 1.5W | Set to 0 |
| Implant Exposure | Initiated | Contact | Continuous | 1.0W | Set to 0 |
| Lesion Removal | Initiated | Contact | Continuous | 1.0W | Set to 0 |
| Mucocele | Initiated | Contact | Continuous | 0.9W | Set to 0 |
| Operculectomy | Initiated | Contact | Continuous | 1.5W | Set to 0 |
| Ovate Pontic | Initiated | Contact | Continuous | 1.0W | Set to 0 |

| | | | | | |
|--------------------------------------|------------------|-------------|------------|------|-------------|
| Periimplantitis | Un-initiated | Contact | Pulse | 1.5W | Set to 0 |
| Perio - Chronic | Un-initiated | Contact | Continuous | 0.5W | 30 seconds |
| Perio - Severe | Un-initiated | Contact | Continuous | 0.7W | 45 seconds |
| Socket Treatment | Un-initiated | Non-contact | Continuous | 0.8W | Set to 0 |
| Sulcular Debridement | Initiated | Contact | Pulse | 1.4W | 30 seconds |
| Temporary Pain Relief - Circulation | Therapy Sleeve | Contact | Pulse | 2.5W | 300 seconds |
| Temporary Pain Relief - Muscle/Joint | Therapy Sleeve | Contact | Continuous | 1.5W | 300 seconds |
| Temporary Pain Relief - Tissue | Therapy Sleeve | Contact | Continuous | 1.5W | 300 seconds |
| Tissue Tag | Initiated | Contact | Continuous | 1.0W | Set to 0 |
| Tissue Welding | Un-initiated | Contact | Continuous | 0.6W | Set to 0 |
| Tongue Tie | Initiated | Contact | Continuous | 1.0W | Set to 0 |
| Tooth Whitening | Whitening Sleeve | Non-contact | Continuous | 3.0W | 540 seconds |
| Troughing | Initiated | Contact | Continuous | 0.8W | Set to 0 |
| Vestibuloplasty | Initiated | Contact | Continuous | 1.0W | Set to 0 |

3.3 Facility and Environmental Considerations

3.3.1 Power Requirements

120 V AC ±10 % at 50 - 60 Hz
 3 Amps
 9 volt Lithium battery for the foot pedal

3.3.2 Heating and Ventilation

The laser should be operated in areas with the optimum temperature range of 20° - 30°C (68° - 86° F).

3.3.3 Transport and Storage

Avoid storing or transporting the laser in temperatures below 0°C (32° F).

3.3.4 Lighting

Overhead lighting and/or dental unit light should provide enough illumination to allow good operator vision when activating the laser intra-orally.

3.3.5 Combustible Chemicals and Gases

All gases that are combustible or support combustion and are used in the operatory area where the laser is in use must be turned off during the procedure. Cleaning supplies or other flammable chemical compounds should be stored in an area away from the surgical site in order to avoid possible combustion (e.g. alcohol gauze, liquid topical anesthetics).

3.3.6 Plume Evacuation

Plume evacuation is a priority when vaporizing tissues. The Clinician or operator, and their chair-side assistants should keep themselves and the patient safe by using a high volume vacuum system and filtration masks that are suitable for virus and bacterial control. Please use a high filtration mask with 0.1 micron or less to protect from airborne viruses or bacterial particles.

3.3.7 Access and Signage

Access to the treatment area should be restricted while the laser is in use. A Laser In Use Safety Sign should be adjacent to the entrance to the treatment area, Fig. 7.2.1.

3.3.8 Wireless Technology

The Pioneer Elite diode laser wireless technology is electronically coded. Each foot pedal and Pioneer Elite diode laser share a UNIQUE SERIAL NUMBER INTERLOCK protocol for reliable operation:

- An Pioneer Elite foot pedal communicates with only one Pioneer Elite diode laser; there is 2-way electronic code which must be verified for every transmission and acknowledgement. The pedal and laser unit are interlocked to only each-other's electronic codes.
- If data from another Pioneer Elite pedal is ever received, embedded verification measures ensure that it will be ignored.

- If data were ever received from another wireless device with a compatible modulation scheme (2.4GHz frequency), it would immediately be ignored in the same way. In summary, the wireless receivers in the Pioneer Elite diode laser have less than 2% of the output power of typical Bluetooth or Wi-Fi devices, and therefore have no significant potential as an interference source. Pioneer Elite wireless receiver modulation is incompatible with Wi-Fi or Bluetooth devices, and therefore cannot mistakenly receive data from such devices. Through a unique internal communication structure, and strict verification of all incoming data, nothing activates a Pioneer Elite diode laser except the wireless pedal which it is paired with via electronic code.

SECTION 4 – SAFETY CONSIDERATIONS

4.1 General

The safe use of the Pioneer Elite is the responsibility of the entire dental team, the laser safety officer appointed, and the dental office team. Protocols for the safe use of lasers have been developed by a combination of medical and dental professionals working in concert with educators at the university level, scientists and laser manufacturers. Dental professionals have had to develop protocols and guidelines for using the laser on oral soft tissues. Sound judgment and the concern for patient safety should be the basis of all laser care.

Usually, states or provinces do not have a specific licensure requirement for use of a laser by a dentist. Certain states and provinces, like Texas and Alberta, however, require the dental office to be certified and inspected prior to using a laser. The user is advised to check with the local Dental Association or State website to be aware of any specific requirements in your location. Some states require a hygienist to attend licensure training that includes both a lecture and hands-on training. Prior to using the laser, the hygiene applicants are required to pass a proficiency test for certification. These courses are usually taught by members of the Academy of Laser Dentistry who possess instructor credentials. Worker safety is the responsibility of the employer. ANSI standard Z136.1 (US) and CAN/CSA standard Z386-08 concerning Laser Safety in Health Care Facilities are sources for analyzing safety with respect to medical lasers. Pioneer recommends implementation of a Laser Safety Program for the safety of your patients and office staff in connection with the use of the Pioneer Elite diode laser.

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4.2 Laser Safety Program

We recommend implementation of a Laser Safety Program appropriate for your dental office. The plan may include the following:

- Delegation of authority and responsibility for supervision and control of the laser to a designated Laser Safety Officer;
- Minimum training requirements for users of the laser;
- Security to restrict unauthorized use of the laser;
- Standard operating procedures to regulate the work environment in order to protect the patient and office staff from laser hazards.

The safe use of a laser is the responsibility of the Laser Safety Officer (LSO) who can be a full or part-time employee, or the laser operator. It is their responsibility to train the staff, maintain records concerning training and the laser's performance, perform safety checks and prepare the laser for use on a daily basis. The LSO must keep records of any incidents that relate to the failure of the laser or any adverse effects related to laser therapy and report such incidents as prescribed by law. The LSO assures that a medical follow-up has been sought or has occurred following any adverse incident during treatment. The LSO is responsible for training of all office personnel who are involved with the laser preparation and use. Daily checks of the facility and equipment are also the LSO's responsibility. The LSO should test fire the laser each day prior to beginning each treatment procedure. For more information on the contents of a Laser Safety Plan, you can review ANSI Standard Z136.3 for Safe Use of Lasers in Health Care Facilities (US) or CAN/CSA-Z386-08 Laser Safety in Health Care Facilities(Canada).

4.3 Continuing Education

The Laser Safety Officer should ensure that the operator and staff attend laser courses taught by qualified laser educators. Ongoing reviews of laser safety procedures should be a part of normal office routine.

4.4 In-Office Safety

4.4.1 Lighting

Always use the Pioneer Elite in a well lighted and ventilated area.

4.4.2 Combustible Chemicals or Gases

Make certain that chemicals or gases capable of supporting or causing combustion are not present when using the laser (e.g. alcohol gauze, liquid topical anesthetics).

4.4.3 Safety Eyewear

While using the Pioneer Elite laser, doctors, hygienists, auxiliary staff, patients, and anyone attending them in the operatory must wear the appropriate safety eyewear that has been designed for use with the 810 nm wavelength. Never point the laser tip directly at the face, eyes or skin of anyone while emitting energy. The aiming beam is also capable of causing eye damage.

4.4.4 Test-firing the Laser

Always test-fire the Pioneer Elite prior to using it intra-orally using a power of 1 Watt continuous wave or less. Place the laser in the ready mode, then, activate the laser for 1-2 seconds while aiming the fiber onto a 2X2 gauze sponge wetted with water. Do not use alcohol or any other combustible material to wet the 2X2 sponge as it may ignite. Please be aware the the 810 nm working beam is invisible to the human eye! You can only see the red 650 nm aiming beam if it is turned on.

4.4.5 Danger Signage

Each operatory where the Pioneer Elite is used should have a "Laser in Use" sign placed at the operatory entrance when a procedure is in progress. This signage will help to eliminate eye damage caused by inadvertent exposure to laser energy. Additional signs can be ordered through the Pioneer Customer Service.

4.4.6 Sharps Disposal and Sponge Removal

Used fiber tips should also be disposed of in a Sharps container. All sponges used for cleanup of lasers and fibers should be disposed of in a bag for contaminated soft products.

4.4.7 Plume Evacuation

Use high volume evacuation suction during procedures to remove laser smoke or 'plume' debris. Use masks suitable for viral filtration. Caution - laser plume may contain viable tissue particulates. Please use a high filtration mask with 0.1 micron or less to protect from airborne viruses or bacterial particles.

4.4.8 Laser Security

To prevent the unintentional use of the laser while not in use, the unit should be switched off. An electronic password is required to be entered before the unit may be used again. This code should be maintained by the Laser Safety Officer.

4.4.9 Emergency Shutdown

Any of these mechanisms can be used to shut down the emission of laser energy in a real or perceived emergency:

1. Depress and release the emergency shutdown button
2. Foot Pedal – remove your foot to stop lasing
3. Switch the Power/Fan to the off position (O)

4.4.10 Hard Tissue Procedures

The Pioneer Elite is not an appropriate laser for hard tissue procedures. The Elite is attracted to melanin, hemoglobin and, to some extent, water and oxygenated hemoglobin. Avoid prolonged exposure of the energy when working in and around the cervical areas of the tooth. Due to the thin layer of enamel in this area, the laser's energy may be absorbed by the hemoglobin in the pulp and pulpal hyperemia may occur. Extended exposure to laser energy could lead to pain and possible pulpal necrosis.

SECTION 5 – OPERATING THE LASER

5.1 Intended Uses

The Pioneer Elite diode laser is indicated for dentistry and oral soft tissue procedures of:

- 1) The removal of lesions, excision, incision, vaporization, ablation, hemostasis, and photocoagulation on soft tissue including abscess treatment, contouring, curettage, sulcular debridement, pulpotomy, frenectomy, gingivectomy, troughing, and removal of inflamed edematous tissue.
- 2) Temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain, muscle spasm, temporary increase in local blood circulation, and temporary relaxation of muscles by means of topical elevated tissue temperature from infrared spectral emissions;
- 3) Light activation of bleaching materials for teeth whitening and laser-assisted whitening/bleaching of teeth.

The pre-set programs in the Pioneer Elite laser provide suggestions for laser settings for certain procedures.

5.2 Standby and Ready Status

Standby mode is indicated by the laser having power and the digital key code entered to access programming options. However, laser energy will not be emitted even if the foot pedal is depressed. Ready mode is achieved by touching the Ready button found on the program screens. A green check mark on the screen will evidence Ready Mode, Fig. 3.2.16. Once Ready is touched, the laser may be activated by depressing the foot pedal.

5.3 Continuous or Pulse Mode

The Pioneer Elite will deliver energy in either a continuous wave (CW) mode or in a pulsed mode which are called temporal emission modes (time related modes). Selecting the appropriate mode is a factor of controlling target tissue temperatures and the efficiency of energy delivered. The pulse duration (0.05 seconds) and the number of pulses per second (10) have been fixed by the manufacturer using a 50% duty cycle. This setting can not be adjusted. The chosen mode is displayed in a gray color.



5.3.1 Continuous Wave Mode

Setting the laser to the CW mode, allows you to deliver the specified amount of power in one second. Setting the laser to 2 Watts CW will allow you to deliver 2 Watts per second as long as you have the foot pedal depressed. The CW mode is generally the fastest way to ablate tissues but heat can build up and cause collateral damage to the target and adjacent tissues. Cool the tissues being lased by using periodic blast of air from a triplex syringe and high speed suction. You may use water to cool areas where there is prolonged exposure to the laser's beam.



Avoid using the air syringe when you have an opening in soft tissue adjacent to or within the surgery site. An air embolism may occur as a result of air captured within the tissue during the cooling process.

5.3.2 Pulse Mode

Pulsing the laser energy will allow some cooling of the tissue in between emissions of energy. The "duty cycle" is the percentage of the time in each second that the laser is emitting energy. The pulses per second, the duty cycle and the energy intensity per pulse will determine your average power. In the pulsed mode, the Pioneer Elite is programmed to deliver 10 pulses per second with each pulse lasting for 0.05 seconds. The duty cycle is set for 50% so you will have 1 energy pulse with 1 period of rest with no energy between each pulse. The result will be an average power per second that will be 50% of what you have set the laser for. Therefore, when using pulsed energy, you will have to adjust your power upward in order to achieve the same rate of work as the same power set in CW, i.e. 2 Watts of Pulsed energy will be the same average power output as 1 Watt CW.

5.4 Tissue Responses to Laser Energy

Maximum results will be achieved by regulating the power and the speed that the operator moves the fiber tip. Tissue charring is an undesirable after effect of too much power or the tip moving too slowly. Always use the least amount of power necessary to complete your procedure. The ideal tissue response will show little or no discoloration after lasing and there will be less residual damage and faster healing. Avoid penetrating or damaging the periosteum, and do not use the laser on alveolar bone. Because the laser energy is attracted to melanin and hemoglobin, power must be reduced when treating patients with darker soft tissue. Always begin lasing with the lowest power you can use to remove or modify the target tissues. Avoid damage to the gingival sulcus by moving the fiber tip quickly and using low power settings. Check so that no shard is present on the tip. A shard may act as a miniature scalpel and damage the small blood vessels, thus preventing hemostasis and coagulation.

5.5 System Procedures

5.5.1 Treatment Area Requirements

The laser should be placed in an area with good ventilation and lighting. The electrical service required is a 120 Volt AC outlet 50 - 60 Hz. The area where the laser is placed should be free of standing water. Combustible gases or those that support combustion should be turned off and all flammable materials or chemicals stored in the area should be removed.

5.5.2 Foot Pedal

It is recommended to use a 9 volt Lithium battery to power the cordless foot pedal. This type of battery has been tested to last for over 100 hours of foot pedal operation. When the battery voltage begins to drop, the foot pedal will begin to beep, signaling that you have approximately 2 hours of operating time left before the battery life is completed.

NOTE: A 9 volt Alkaline battery may be used, however the life expectancy of an Alkaline battery is less than 35 hours of operating time.

5.5.3 Surgical Sleeve and Single-use Fiber Tip

The surgical handpiece sleeve as provided to the operator is not sterile. Make sure the sleeve is sterilized prior to use. Make sure the tip is "snapped" onto the handpiece. Please read section 6.4.4 for test instructions.

5.5.4 Fiber Preparation/Initiation

To prepare the fiber for cutting, if your procedure calls for it, set the power to 1 watt, activate the laser, and touch the tip to black or blue articulating paper. This initiates the tip for cutting.

5.5.5 Laser Stop Button

Check the Laser Stop Button to see that it is depressed, if not, gently depress the button.

5.5.6 Digital Key

Activate the digital key by entering **1 2 3 4** on the touch pad. The Main Menu screen will appear.

5.5.7 Laser Settings in the Quick Setup Screen

Review your power and mode requirements and then depress the mode button to select either Continuous (CW) or pulsed mode.

5.5.8 Select Your Power

Press the arrows until you have reached the desired Wattage. Beginning with a low of 0.1 Watts, the power increases in increments of 100 mW up to a maximum of 3.0 Watts (CW). By holding the arrow keys to increase or decrease the power, you can have an un-interrupted increase until you reach your desired power.

5.5.9 Selecting Presets

At the Main Menu Screen you will have choices to select a program by scrolling the "Procedures" list in alphabetical order, or by choosing "Specialty" which lists programs grouped by specialty categories such as Cosmetic or Periodontics. You can also create your own Favorites programs by following the screen instructions under "Save as Favorite".

5.5.10 Aiming Beam

The aiming beam laser pointer can be turned on and off by pressing the aiming beam button on the laser control panel. Press the arrow buttons to progressively increase or decrease the aiming beam intensity from 0 (off) to full intensity. Each circle represents approximately 20% of the aiming beam output.

NOTE: Adjusting the intensity of the aiming beam has no effect on the output power of the primary working laser.

5.5.11 Tips

The tips are provided pre-cleaved and polished for immediate use. For infection control reasons, tips shall be used for one patient only and are supplied to the user in a sterile condition. It is not possible to autoclave tips.

5.5.12 Procedure

1. Depress the Ready button and the aiming beam should light after 3 seconds. Review your power and mode requirements and then depress the mode button to select either CW or Pulsed mode.
2. Test fire the laser outside the mouth by activating the laser into a 2 X 2 gauze sponge that has been wetted with water to prevent combustion. Do not use flammable liquids to wet the sponge.
3. Initiate tip as described in section 6.2.2, if needed.
4. Depress the foot pedal and make short quick strokes at the lowest power that you can to remove the target tissues while lightly contacting it.
5. Remove your foot from the foot pedal and use a clean 2 X 2 gauze sponge wetted with water to remove debris from the fiber tip. Do not use flammable liquids to wet the sponge.
6. Remove your foot from the foot pedal and touch the Ready button to place the Laser in Standby Mode until you are ready to start another procedure.
7. Remove the unit dose fiber tip and dispose in a suitable biowaste Sharps disposal.
8. Remove the handpiece sleeve only and follow the autoclave instructions in section 6.4.2.
9. If you are not going to be starting another procedure, return back to the Main Menu and press Logout. It is now safe to turn the power button to the OFF position.
10. Insert a new unit dose fiber tip or the protective metal cap and snap it into the hand piece to prevent the fiber lens from becoming contaminated. Please read section 6.5 for proper care of the handpiece. If you insert a new unit dose fiber tip into the handpiece, simply drape the tip package over the tip as an indication that this is a new, unused tip.
11. Record the Powers and total lasing times used for each procedure in the patient's chart.

Example:

Patient Name: Mary Jones

Procedure: Gingivectomy # 6 and # 7

#6 Lasing time 90 seconds @ 2.0 Watts CW air cooled, 810 nm wavelength

#7 Lasing time 60 seconds @ 1.5 Watts CW air / water spray, 810 nm wavelength

5.5.13 Therapeutic Procedures

The therapy sleeve as provided to the operator is not sterile. When using the Pioneer Elite for Therapeutic procedures, make sure the handpiece sleeve is sterilized and assembled according to Section 6.6 prior to use, and the appropriate laser settings are established as indicated in the Procedures table in Section 3.2.14. If exterior surfaces of the skin are to be treated, use a gauze pad moistened with isopropyl alcohol to wipe the skin clean of excess oils, lotions, or other substances on the skin as these will collect on the handpiece window and absorb the laser energy. This will cause the handpiece to become warm, and may heat the top layers of the skin without achieving the desired tissue penetration. Advise the patient accordingly about this cleaning step.

Position the handpiece over the target area and lightly contact the end of the handpiece onto the tissue. Press and hold the foot pedal down. Use consistent, circular motions to move the handpiece over the target area. Avoid holding the handpiece over the same area for more than a few seconds. Small treatment areas may not require the full 300 seconds of exposure time.

5.5.14 Tooth Whitening

The whitening sleeve and cone as provided to the operator are not sterile. When using the Pioneer Elite for the Tooth Whitening procedure, make sure the handpiece sleeve and cone are sterilized and assembled according to Section 6.7 prior to use, and the appropriate laser settings are established as indicated in the Procedures table in Section 3.2.14. Apply the whitening gel as indicated in the instructions for the whitening gel that you are using. Once the gel is applied, position the whitening handpiece over the patient's arch. DO NOT touch the handpiece directly to the gel or to the teeth. Press and hold the foot pedal. Slowly move the handpiece from side to side along the arch and back and forth between upper and lower arches to expose the whitening gel to the laser energy. NOTE: If only one

arch is being treated, then the exposure time will be 270 seconds. Once the exposure is completed, the laser energy can be stopped and the whitening gel allowed to remain in contact according to the gel instructions.

5.5.15 Self Diagnostic and Monitoring

When the Pioneer Elite Laser's microprocessor detects an issue with performance it will immediately notify you by way of an audible beep. There are two different ways in which the Pioneer Elite will alert you to any issues:

1. Continuous audible beep when foot pedal is engaged. If you are operating the Pioneer Elite with the foot pedal engaged and the Pioneer Elite emits a constant audible beep and stops the beep when you release the foot pedal, the microprocessor has determined that the laser power output has fallen outside the set level. In this event the Pioneer Elite Laser should be turned off and allowed to sit for 5 minutes then turned on again. If the Pioneer Elite then performs without beeping, the microprocessor has been able to make operational adjustments to the laser and the unit will perform its functions. If, however, upon restart the unit continues to beep when the foot pedal is engaged, the microprocessor was unable to adjust the unit enough and the unit will need to be sent in for adjustment.
2. Continuous audible beep when the unit is turned on. If you are operating the Pioneer Elite and it emits a constant audible beep whether or not the foot pedal is engaged, the microprocessor has determined that the laser has either low power or a general fault has occurred. In this event the Pioneer Elite Laser should be turned off, allowed to sit for 5 minutes and turned on again. If the Pioneer Elite then performs without beeping the microprocessor has been able to make operational adjustments to the laser and the unit will perform its functions. If, however, upon restart the unit continues to beep, the microprocessor was unable to adjust the unit enough and the unit will need to be sent in for adjustment.

SECTION 6 – PREPARATION, CLEANING, AND CARE

All portions of the device should be cleaned of visible contaminants prior to disinfection and sterilization processing. Cleaning should be done with a soft cloth or gauze moistened with a mild soap solution or alcohol solution to remove visible contaminants. Avoid use of abrasive cleaning compounds that contain suspended insoluble particles. Disposable tips are provided in a sterile condition. Handpiece sleeves should be cleaned and sterilized prior to use. Once cleaned, proceed to the disinfection and/or sterilization processes indicated in the relevant sections below.

6.1 Single-use Fiber Tips

The fiber optic element of a laser is responsible for carrying the light from the diode array to the tissue being treated. The dental laser fibers are usually made of quartz, sapphire, silica or a combination of those elements. Quartz/silica is the most popular product used in diode lasers. Be advised about the potential hazards when inserting, steeply bending or improperly securing the fiber optics to the handpiece. Radiation exposure may occur in these instances which could be harmful to yourself, your staff and your patient. Special care should be taken not to break or snap the fiber when removing tips from packaging. As the Aiming Beam passes down the same delivery system as the Working Beam, it provides a good method of checking for integrity of the delivery system. If the aiming beam spot is not present at the distal end of the delivery system, its intensity is reduced, or it looks diffused, this is a possible indication of a damaged or not properly working delivery system.

The unit dose fiber tips contain a pre-cleaved and pre-stripped piece of fiber. They are individually wrapped and have been sterilized by gamma irradiation. As delivered to you, the tip is sterile and no further treatment of the tip is required prior to use. They are designed for single application and should be discarded after each use. Remove the plastic cover and push the tip into the handpiece until it locks into place. Do not touch the polished fiber connector after removing the plastic cover and keep the fiber connection clean.

6.2 Fiber Preparation

The unit dose tips are pre-stripped and pre-cleaved for immediate use.

6.2.1 Quartz/Silica Fiber

The fiber is fairly flexible but can be broken if bent into a small circle or bent at an angle of 90 degrees. The cladding will burn as protein from the gingival accumulates on the fiber and will deteriorate the tip. It can fracture once the blackened area has reached 3-4 mm. Stop lasing and wipe off the tip regularly as you work to avoid accumulation of protein debris. Use water on a 2 x 2 gauze sponge to clean the tip. Do not use flammable materials like alcohol products when cleaning a hot tip.

6.2.2 Initiating the Fiber

Some procedures require that the fiber tip be initiated. The tip of the fiber can be prepared to retain heat by introducing it to a dark material. The easiest way to prepare the tip is to lightly move the end of the fiber across a piece of articulating paper at about 1 Watt CW. The tip will retain pigment which will make the tip glow. Do not exceed contact time of 1 second.

6.3 Laser Cleaning and Maintenance

6.3.1 Laser Body Disinfection

Prior to use, the exterior of the laser should be cleaned using a liquid disinfectant such as BIREX™, CaviCide®, or a 0.5% sodium hypochlorite solution. Do not spray the disinfectant directly on the chassis as liquids could damage the LCD display. Apply with a gauze sponge or wipe. Allow the surface to remain moist for 5 minutes (10 minutes for BIREX). Multiple applications may be needed to achieve the indicated contact time. Allow to air dry. Do not use abrasive materials to clean the system. Place an adhesive barrier material over the LCD screen prior to treating the next patient.

6.3.2 LCD Display

Over the lifespan of the device, the display may become opaque from repeated scratches, abrasions and/or organic debris. This could impair the proper display of information. Should your display show evidence of wear or scratches, the unit should be returned for service. In the event the LCD display becomes cracked or damaged, the liquid crystal chemical could leak. Use of the device should be immediately discontinued and the unit returned for servicing in this case.

6.3.3 Fiber Cable and Handpiece Stem

The exterior surface of the fiber cable and handpiece stem should be cleaned using a liquid disinfectant such as BIREX™, CaviCide®, or a 0.5% sodium hypochlorite solution. Do not spray the disinfectant directly on the cable or stem. Apply with a gauze sponge or wipe. DO NOT IMMERSIVE the handpiece stem as cleaning solution residuals could contaminate the optics in the stem and prevent laser transmission. Allow the surface to remain moist for 5 minutes (10 minutes for BIREX). Multiple applications may be needed to achieve the indicated contact time. Allow to air dry. Do not use abrasive materials to clean the system.

6.3.4 Calibration

The Pioneer Elite Laser uses solid-state circuitry to continuously monitor the power output, and adjusts the power supplied to the laser module to keep the output consistent with the user defined setting. If output levels are more than ± 20% of the set value, the unit is designed to shut down power to the laser, and an audible alarm will sound. If this happens, the unit should be turned off and allowed to sit for 5 minutes and turned on again. If the laser then performs without beeping, the microprocessor has been able to make operational adjustments and the unit will perform its functions. If, upon restart, the unit continues to beep, the unit will need to be sent to the Pioneer Service Department for adjustment.

We suggest that your practice establish an internal calibration program for your laser. Recalibration is recommended a minimum of once per year based on average usage. Recalibration may be performed by the manufacturer by returning the unit. In the alternative, you may purchase a calibrated hand held power meter approved for use with 810nm devices to check power output. The laser should be set at 1, 2 and 3 Watts with output checked at each level. The output display should be within 20% of the meter reading. If not, replace the unit dose fiber tip and re-check. If the output display is still outside the 20% tolerance, return the unit to the manufacturer for recalibration. There are no methods available for the user to adjust the calibration of the unit and the unit chassis must not be removed by the user for any reason.

6.3.5 Battery Use

The Pioneer Elite diode laser is supplied with a rechargeable lithium polymer battery which optimally provides up to 45 minutes continuing lasing time or 8 hours standby time i.e. laser on, not being charged by cradle or AC power cord. If you find the battery runs the laser for 30 minutes or less after being charged for several hours, the battery may need replacing. A replacement battery can be ordered. To remove the battery, press on the center button while sliding the battery downward, then lift away from the unit. Install the new battery by placing it onto the back of the laser, the sliding upward until the lock clicks in place. The new battery must be charged overnight prior to using the laser.

6.4 Handpiece Sleeve Sterilization

6.4.1 Handpiece Components

For sterilization, the handpiece has two (2) components:

1. Handpiece stem and fiber assembly (Fig 6.4.1a).
See Section 6.3.3 for cleaning instructions.
2. Handpiece sleeve (Fig. 6.4.1b)

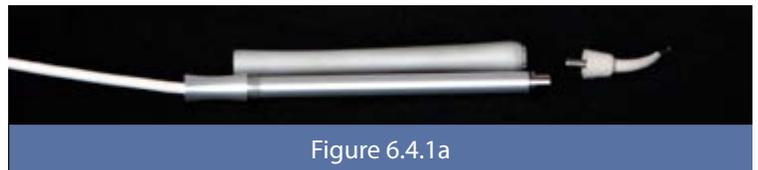


Figure 6.4.1a

6.4.2 Recommended Autoclave Procedure

1. **Autoclave the handpiece sleeve only.** First remove the unit-dose tip after the procedure and discard. Unscrew the metal handpiece sleeve counterclockwise and separate from the handpiece. Set the autoclave parameters for 250°F, at least 18 psi, and run for 30 minutes. Allow the handpiece sleeve to remain in the autoclave for at least an additional 30 minutes to complete the cycle. Fig 6.4.2a and b.
2. **Do not place the laser unit or the fiber cable in the autoclave!**
The recommended procedure is to wipe the fiber cable with a liquid disinfectant according to the materials and procedures described in Section 6.3. After the procedure, please wear gloves for disassembly and cleaning. Do not disconnect the fiber cable from the laser unit for cleaning procedures as this may contaminate the optical connections.

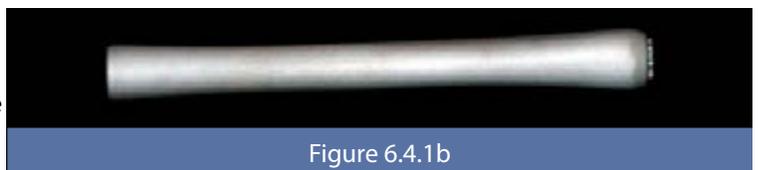


Figure 6.4.1b

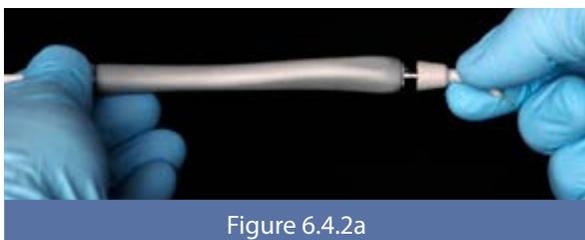


Figure 6.4.2a



Figure 6.4.2b

6.4.3 Prepare Fiber

If the packaging is visibly damaged or holes are visible, do not use the fiber tip. The unit dose fiber tips are pre-stripped and pre-cleaved and once inserted on the handpiece are ready for use. The aiming beam should create a near perfect circle when directed onto a white surface from a distance of 1/4 - 3/8 inch. Ensure that the tip packaging is opened and the tip handled in a surgically sterile environment.

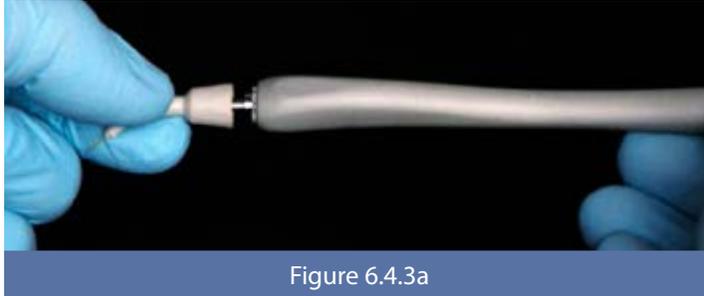


Figure 6.4.3a



Figure 6.4.3b

6.4.4 Attaching the Tip

Seat the disposable fiber tip securely on the handpiece body and snap the tip into place.

The fiber tip has to be completely inserted into the handpiece assembly. Make sure that the serrations at the end of the handpiece sleeve engage with the inner part of the plastic housing of the fiber tip. The gap between handpiece sleeve and plastic housing of the fiber tip should not be significantly greater than 1/32 inch or less than 1mm when fully inserted. Fig 6.3.4a.

Proper fit can be tested by a simple shake test as shown in Figure 6.4.3b. Pick up the handpiece at the end of the sleeve and shake the handpiece in two or three abrupt downward movements.

If the tip slides out, re-insert it and try again or use a new fiber tip and follow the same procedure. Please call your Pioneer representative if the tip is not properly retained as intended. This is a safety measure to ensure proper seating of the tip during the intra oral procedure and to maintain the selected power output.

6.5 Proper Handpiece Care

6.5.1 Preventing Contamination

Your optical fiber handpiece will become contaminated and the energy output of your laser will decrease if the end of the handpiece is left exposed. Leaving the lens exposed for even a short time can lead to contamination of the lens. By leaving the end of the handpiece exposed, dust could settle on the lens. This dust will burn onto the lens when the laser is fired, causing the lens to become permanently contaminated. Fig. 6.5.1a and b. Once the lens is contaminated, the energy output of your laser will decrease and the cutting efficiency will degrade.



Figure 6.5.1a

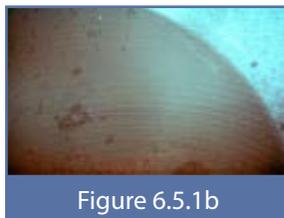


Figure 6.5.1b

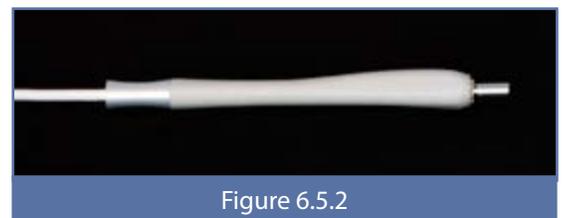


Figure 6.5.2

A unit dose tip or metal protective cap must be on the end of the handpiece at all times to prevent dust from settling on the lens. Fig 6.5.2.

6.5.2 Protecting the Glass Core

A glass core (at the center of the fiber cable) delivers the laser energy. Fig 6.4.2. This glass core can become cracked or broken if excessive weight or impact is applied to the cable. If the glass core becomes cracked or broken, the amount of laser energy delivered to the tip will be drastically reduced. Please ensure that everyone in your practice follows these simple instructions to prevent the glass core from cracking or breaking:

1. Keep the cable off the floor.
2. If the Pioneer Elite is stored in a drawer or cabinet, ensure that the cable does not become jammed or pinched.
3. If the cable is wound up for storage, slightly wind the cable so the circle is no smaller than the size of a CD.

6.6 Therapy Handpiece (Sleeve)

The Therapy Handpiece consists of a single specialized handpiece sleeve that is designed for performing the therapeutic procedures indicated for this laser (Pain Relief to increase Circulation, treat Tissue, and treat Muscle and Joints). This sleeve is sterilized and prepared the same as the surgical sleeve as described in Section 6.4.2. Once this sleeve is attached to the handpiece, the assembly is ready for use. No disposable tip is associated with the use of the therapy tip assembly.



Figure 6.6

6.7 Whitening Handpiece (Sleeve)

The Whitening Handpiece consists of a specialized handpiece sleeve and reusable dispersion cone that together are designed for performing the tooth whitening procedure indicated for this laser. The sleeve and cone should be cleaned and sterilized the same as the surgical sleeve as described in Section 6.4.2. Once this sleeve is attached to the handpiece, attach the reusable cone to the whitening sleeve. The cone will snap onto the sleeve, indicating it is fully attached.

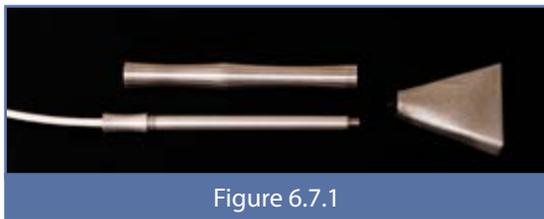


Figure 6.7.1



Figure 6.7.2

SECTION 7 – LABELING, WARNINGS, AND MANUFACTURER'S INFORMATION

7.1 Regulatory Compliance

The Pioneer ELITE Diode Laser is designed to be compliant to the latest safety standards applicable to medical lasers in the US and Canada including IEC 60825, IEC 60601-2-22, IEC 60601-1, CSA/CAN C22.2 No. 601.1 and the Food and Drug Administration's Laser Performance Standard (21 CFR 1040.10 and 1040.11) except for deviations pursuant to Laser Notice 50, date June 24, 2007. The laser has also been tested according to the telecommunications regulations for the US (FCC Part 15) and Canada (IC RSS 210). Various labels are included on the laser and the wireless foot switch as evidence of conformity to these requirements. The labels on the units are required under these standards for safety purposes and should not be removed. Please review all labels prior to using the laser.

7.2 Labels

7.2.1 Danger Laser in Use

Each treatment area should have a "Laser in Use" warning sign posted at the entrance to the treatment area. This signage serves to warn people to not enter the treatment area without proper safety eyewear and protective clothing when the laser is in use.

7.2.2 Class 4 Laser Product

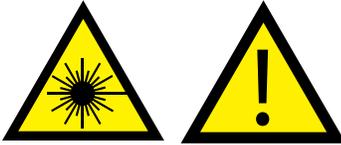
810 nm ± 10 nm 3 W

7.2.3 Aiming Beam Laser

650 nm ± 10 nm 2 mW

7.2.4 Interference with Wireless Signals

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. (Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense).



7.3 Device Cautions

- Changes or modifications not expressly approved by Pioneer Lasers, LLC could void the user's authority to operate the equipment.
- Laser Radiation - Avoid exposure to the eyes or skin from direct or scattered radiation
- This product contains no user serviceable components within the chassis. Visible and invisible radiation may be present when the cover is removed. Do not open the laser chassis under any circumstances.
- US Federal law restricts this device to sale by or on the order of a licensed dentist.
- Eyewear that protects your eyes from wavelengths other than 810 nm do not provide proper protection for use with this laser. Damage to the retina or cornea may be irreparable if exposed to direct, reflected or scattered radiation. Always wear protective eyewear when operating the laser.
- Use of controls or adjustments, or performance of procedures other than those specified herein may result in hazardous radiation exposure.
- The 810 nm wavelength of the working beam is not visible to the human eye.
- Do not attempt to remove the cover from the laser chassis for the purpose of repairing the laser. Serious Injury from an electrical shock or laser radiation could occur. Removing the cover on the laser chassis will void the warranty.
- Avoid prolonged exposure of the energy when working in and around the cervical areas of the tooth. Due to the thin layer of enamel in this area, the laser's energy may be absorbed by the hemoglobin in the pulp and pulpal hyperemia may occur. Extended exposure to laser energy could lead to pain and possible pulpal necrosis.
- Treatments performed with this device are subject to the same clinical assessment as with traditional techniques. Consider the patient's medical history and risks prior to treatment. Patient conditions may exist that may contraindicate use of this device. Consult the patient's general physician if doubts exist.



Figure 7.2.1b



Figure 7.2.1a

7.4 Nominal Ocular Hazard Distance (NOHD)

The NOHD is the distance beyond which the exposure during normal operation is not to exceed the appropriate Maximum Permissible Exposure (MPE). The NOHD for persons wearing safety glasses is shown in Table 1 below. The Nominal Hazard Zone (NHZ) is the area where the laser source within which exposure levels exceeds the MPE (which is the highest level of laser radiation to which a person may be exposed without hazardous effects or adverse biological changes in the eyes or skin). The outer limit of the NHZ is the NOHD.

APPROPRIATE EYE PROTECTION MUST BE WORN BY ALL INDIVIDUALS WITHIN THE NOMINAL HAZARD ZONE.

| Source of Radiation | MPE (mW/cm ²) | Divergence Angle (degrees) | NOHD (inches/cm) | |
|-----------------------|---------------------------|----------------------------|------------------|---------------------|
| | | | No Eyewear | With Eyewear (OD=4) |
| Fiber Optic (Direct) | 1.66 | 9 | 119.72/304.8 | 1.2/3.04 |
| Reflected from Tissue | 1.66 | N/A | 0.023/0.059 | 0.00023/0.00059 |

Assumptions: Maximum Laser Power = 3 Watts, Direct viewing angle =0, Reflectance viewing angle =20°, Reflectance coefficient of tissue = 0.001

Table 1 - Nominal Ocular Hazard Distance (NOHD) for various viewing conditions while wearing eye protection.

SECTION 8 – SERVICING

8.1 Limited Warranty

The Pioneer Elite diode laser is warranted against defective materials and workmanship for a period of:

- 2 years for the laser
- 1 year for battery
- 6 months for handpiece and fiber assembly

from the date of purchase, and will be repaired or replaced, at our discretion, if returned prepaid to our factory. This warranty does not cover damage to the Pioneer Elite diode laser unit or components caused by accident, misuse, or being tampered with. This warranty does not include postage, or delivery charges. This warranty does not apply to the external finish of the console, handpiece, fiber, power cord or foot pedal. Pioneer Lasers, LLC reserves the right to make changes in design or to modify such previously manufactured products. Warranty coverage of your Pioneer Elite diode laser is facilitated by registering your laser, either online at www.pioneerlasers.com or with the completed and mailed in registration card supplied with your laser.

8.2 Repairs & Returns

Should the laser fail to operate correctly, please call the Pioneer Customer Service at (877) 236-4402 to obtain a Return Material Authorization (RMA) number for shipping purposes. No lasers will be accepted without an RMA. Please ensure that the RMA number is clearly marked on the box used to return the laser. It is recommended that you return your laser in its original shipping box. Please clearly state the reasons for return.

8.3 Troubleshooting

| Problem | Corrections |
|--|---|
| Unit has no signs of power or activity. | <ul style="list-style-type: none"> • Check that the power cord is securely plugged into back of the laser unit. • Check that the power switch on the side panel is turned to the on () position. • Check that the Laser Stop button is depressed. If not, depress the button. • Check the fiber/handpiece attachment and verify that it is properly engaged. • The laser battery is not charged. THE LASER BATTERY MUST BE FULLY CHARGED BEFORE INITIAL USE. Allow the battery to charge overnight before use. |
| Unit has power, but no laser output. | <ul style="list-style-type: none"> • Check the battery in the wireless foot pedal. • Depress the reset button on the wireless foot pedal. • Check that handpiece and fiber tip are properly initiated. • The aiming beam is set too low. Increase the intensity of the aiming beam. • Check that handpiece and fiber tip are properly initiated. |
| Measured power output is different from the displayed setting. | <ul style="list-style-type: none"> • Make sure the power meter is calibrated for use with 810 nm wavelength devices. • Take a new fiber tip and insert tip according to instructions. |
| Repeated audible beep when the laser is firing. | <ul style="list-style-type: none"> • Turn laser off for 5 minutes. Turn laser back on. If beep stops, the unit was able to make operational adjustments and the laser should perform its function. If the beep continues, the laser must be sent in for adjustment. |
| Repeated audible beep when the laser is not firing. | <ul style="list-style-type: none"> • Turn laser off for 5 minutes. Turn laser back on. If beep stops, the unit was able to make operational adjustments and the laser should perform its function. If the beep continues, the laser must be sent in for adjustment. |
| The laser beam doesn't fire when the pedal is pressed. | <ul style="list-style-type: none"> • Replace the 9 Volt battery (PP3, ANSI 1604A) in the foot pedal if the green light to the left of the actual foot pedal does not light up when the pedal is being depressed. A 9V lithium battery will last considerably longer than a regular alkaline battery. • Depress the black reset button in the front part of the wireless foot pedal for three seconds. • This laser uses wireless transmission technology at a frequency of 2.4GHz. This is a popular frequency used by other devices such as cordless phones and computer equipment such as wireless peripherals and network connections. Place the laser system in an area away from these types of devices. Also, large metal surfaces may disrupt wireless communications as well. Make sure there are not large metal surfaces between the laser unit and the foot pedal when setting these items in place. • The laser is not in "Ready" mode. |
| There is a "Safety Alert" pop-up on the screen. | <ul style="list-style-type: none"> • Tighten the nut that connects the handpiece assembly to the bottom of the unit so that it can make contact with the outer ring of the femaler adapter. • Depress the red "Laser Stop" button on the faceplate of the unit. • In case you use a separate Remote Interlok assembly (3.1.7), make sure it works properly. |

| | |
|--|---|
| <p>The laser doesn't cut as expected (low output).</p> | <ul style="list-style-type: none"> • Your handpiece assembly is a precision instrument and may be contaminated. Unit should be serviced. The handpiece assembly is a consumable item and should be replaced when laser output is consistently low. • Do not remove your handpiece assembly from the Elite unit unless it requires replacement. Optical connectors can be polished during service intervals to make sure your fiber assembly performs as expected. |
|--|---|

SECTION 9 – SELECTED REFERENCES

1. Leo Meserindino, D.D.S. and Robert Pick, D.D.S. *Lasers in Dentistry*. Quintessence Books, 1995 .
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3. The Institute for Advanced Dental Technologies, Southfield, MI: "Lasers Dentistry: Clinical Training Seminars". 1966.
4. D.J. Coluzzi, "An Overview of Laser WaveLengths Used in Dentistry". Chapter in *The Dental Clinics of North American*: Convissar, Robert A. editor, "Lasers and Light Amplification in Dentistry", W.B. Saunders Company, 44 (4). October 2000. 753 - 765
5. Andreas Moritz, et.al. "Treatment of Periodontal Pockets with a Diode Laser". *Lasers in Surgery and Medicine*, Vol 22. 1998. 302- 311
6. M. Kreisler, et.al., "Effects of Diode Laser Irradiation on the Survival Rate of Gingival Fibroblast Cell Cultures", *Lasers Surg Med*, Volume 28 (5). 2001. 445 - 450.
7. P. Spencer et.al. "Change of Temperature in Subjacent Bone During Soft Tissue Laser Ablation", *Journal of Periodontology*, Volume 69 (11). 1998.
8. Nora Raffetto and Terri Gutierrez, "Lasers in Periodontal Therapy, a Five Year Retrospective", *California Dental Hygiene Association Journal*, Volume 16 (2). Redondo Beach, CA, 2001. 17-20
9. "Safe Use of Lasers in Health Care Facilities". *American National Standard Institute Standard Z136.3*.

SECTION 10 – REORDERING

| | |
|-----------|-----------------------------------|
| 002-00276 | Barrier Sleeves, pack of 250 |
| 002-00275 | Laser Protective Glasses |
| 002-00263 | Fiber Cable - 4ft Length |
| 002-00264 | Fiber Cable - 6ft Length |
| 002-00258 | Battery Pack |
| 002-00130 | Power Supply w/cord |
| 002-00259 | Disposable Fiber Tips, pack of 50 |
| 002-00124 | Surgical Handpiece Sleeve |
| 002-00277 | Pain Relief Sleeve |
| 002-00278 | Whitening Sleeve |
| 002-00279 | Whitening Cone |
| 002-00280 | Charging Cradle |
| 002-00108 | Operator Warning Sign |

**CONGRATULATIONS ON YOUR PURCHASE
LEARN MORE ABOUT US AND OUR LASERS AT:**



4628 West Skyhawk Drive
West Jordan, UT 84084
www.pioneerlasers.com

Call us toll free at 1-877-236-4402 in the U.S.