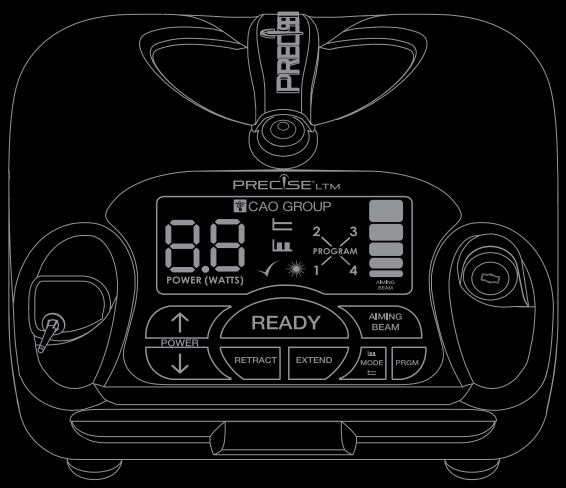
PRECISE® LTM

5 WATT SOFT TISSUE DIODE LASER.
OPERATOR'S MANUAL.



CAO GROUP, INC.
Easier · Faster · Better™

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SECTION 1: INTRODUCTION

Thank you for purchasing the Precise® LTM 5 Watt Soft Tissue Diode Laser. CAO Group (CAO) has been manufacturing diode lasers for over a decade and we are proud of our record of quality, performance, and safety. Today, the diode laser has become the standard of care in addressing the common soft tissue concerns dental professionals must address every day. Precise diode lasers treat soft-tissue to create beautiful radiant smiles. Dental visits are easier, faster, and better, by the quick and safe control of bleeding, creation of room for impression material, relieve pain or discomfort of aphthous ulcers, and a wide range of other procedures.

The Precise LTM Diode laser may reduce procedure time and potentially simplify performance of some treatments. Patients are more comfortable and tissue heals quickly compared to other common methods (e.g., scalpel, electrosurge). With well over a decade of laser manufacturing experience, practitioner and patient reports, we are confident that you too can achieve these same benefits.

As with any new tool or technique it is vital to take the time to learn how to properly use it. To shorten the learning curve and support you in becoming a Precise diode laser practitioner we provide the following training tools at no charge.

- Online quick-start videos found on our website at www.caogroup.com. These videos are a fast way to get set-up and review a few common procedures. It is recommended to practice on hot dogs or tomatoes before attempting any procedures on patients.

- One full online laser training course eligible for continuing education credits with the purchase of a Precise laser. This comprehensive course provides everything needed to start on the road to becoming a laser enthusiast with new skills that improve procedures and patient outcomes. Additional courses are available at a reduced price to Precise Laser owners.

- When available, a sales professional may conduct an in-office hands-on review of basic usage of the Precise LTM. For any technique or procedure questions please call Customer Care who may be able to refer further training.

REMINDER

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

SECTION 2: BEFORE OPERATING YOUR LASER

2.0 CONTENTS

The contents of the shipping container should include the following:

Precise LTM Complete Kit

(1)	Precise® LTM Unit
(1)	20' Fiber Cartridge
(1)	Fiber Stripper Tool
(1)	Fiber Cleaver
(1)	Package of (20) Disposable Handpiece Tips- Straight
(2)	Package of (20) Disposable Handpiece Tips- 60°
(2)	Handpiece- Autoclavable
(1)	Laser Key
(1)	Wireless Foot Pedal
(1)	9 Volt Lithium Battery
(1)	Power Supply
(1)	Power Cord
(3)	Protective Glasses
(1)	Precise LTM Operator's Manual
(1)	Precise LTM Chairside Guide
(1)	Danger - Laser in Use Signage
(1)	Procedure Guide

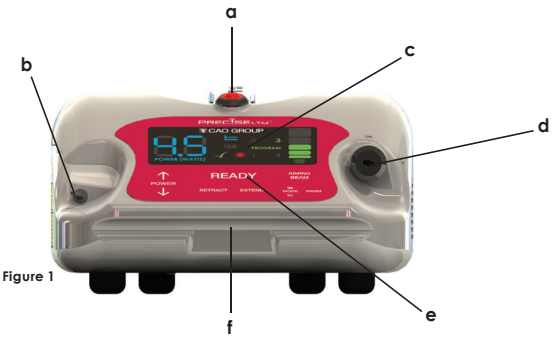


Figure 1

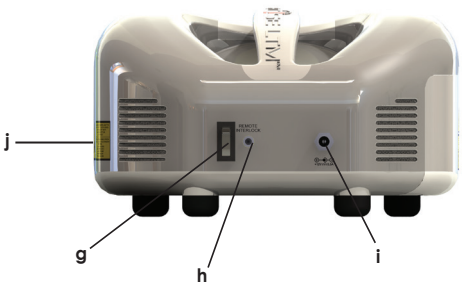


Figure 2

a. LASER STOP
b. FIBER APERTURE
c. LED DISPLAY
d. KEY SWITCH
e. CONTROL PANEL
f. MAGNETIC HANDPIECE HOLDER
g. POWER/FAN SWITCH
h. REMOTE INTERLOCK CONNECTOR
i. POWER SUPPLY RECEPTACLE
j. WARNING LOGOTYPES

2.1 REMOVING THE LASER FROM THE PACKAGING

Please 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, contact customer care at (877) 236-4408 or customercare@caogroup.com for assistance. It is highly recommended to retain the box the laser arrived in. It has been designed specifically to transport the laser and may be useful should repairs become necessary in the future.

LASER ASSEMBLY INSTRUCTIONS SUMMARY

1. Attach the laser's power cord and place the plug into the wall receptacle.
2. Install foot pedal battery. (See Section 2.2.3)
3. Attach remote interlock, if desired (not required).
4. Check the laser stop button to see that is has been pressed.
5. Turn on the power switch on the back of the unit. **NOTE**: When the power cord is plugged in, the power switch is turned on, and the laser stop is released, the key will turn the unit on.
6. Place the key into the key switch receptacle and turn the key to the right (clockwise). The control console should light up.

2.1.1 TRANSPORTATION

Precise® lasers are susceptible to misalignment if not handled properly. The unit should ALWAYS be handled carefully and never banged, jarred, jolted, dropped, or hit. Do not transport the laser unless it is completely packaged inside of the box it arrived in. Failure to properly package the laser can result in damage to the laser and accessories. When transporting or shipping your laser you must always disconnect the keys, the AC Power Adapter and fiber from the laser. If you have any questions regarding transportation, please call your authorized representative or CAO Group, Inc.

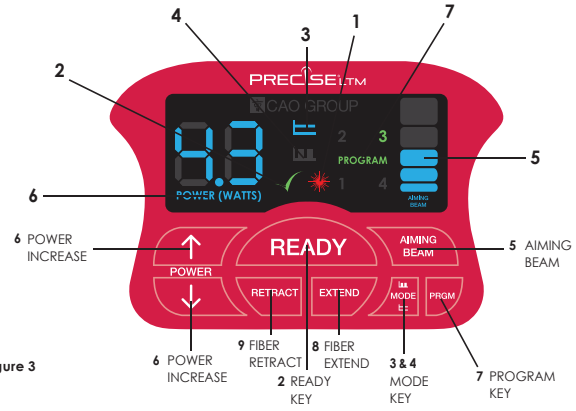


Figure 3

LED DISPLAY AND CONTROL PANEL

1. **Laser on Indicator**
   Illuminates when the foot pedal is depressed. Indicates that the working beam energy is emitted.
2. **Ready Indicator**
   Illuminates when READY key is pressed. It will blink for three (3) seconds, then remain steady. Once it is steady on, the aming beam can be activated.
3. **Continuous Mode**
   Illuminates when the unit is in Continuous Mode.
4. **Pulse Mode**
   Illuminates when the unit is in Pulse Mode.
5. **Adjustable Aiming Beam**
   The Precise LTM is actually two lasers in one, the infrared laser which performs the actual treatment and a second "laser pointer" which illuminates red and allows the user to view where the working beam is directed.. The aiming beam control allows for five (5) levels of intensity of the aiming beam. Each bar represents 20% of maximum intensity. Zero (0) bars indicates the aming beam is shut off.
6. **Working Beam Setting**
   Indicates the working beam power output setting. Use the Power Increase or Decrease key to adjust power settings from 0.5 to 5.0 Watts. Press and hold the desired key to rapidly change the value.
7. **Progam Setting Indicator**
   Indicates current program mode selected. Program key will cycle through programs in a clockwise direction (1-4).
8. **Fiber Extend**
   Press and hold to extend the fiber from the cartridge.
9. **Fiber Retract**
   Press and hold to retract the fiber into the cartridge.

2.2 ASSEMBLING THE LASER

Each of the following items should be inspected, inserted into the appropriate receptacle, and when applicable, locked using the locking hub.

2.2.1 Power Cord Installation

Remove the AC adapter and the AC power cord. Push or plug the power cord firmly into the adapter. Plug the small adapter cord into the appropriate receptacle on the back of the laser. AC adapter cord may not be flush when plugged in. When resistance is met stop insertion. To prevent power surges due to electrical storms or spikes in line voltage, we recommend that you use a power strip with a surge suppressor or unplug the laser when you are not present. Plug the power cord into a 110 Volt AC outlet rated at 60 Hz. Be sure to position the equipment such that you can quickly access and disconnect the power cord connection from the back of the unit if the need arises.

2.2.2 Power/Fan Switch and Key Switch

The Power/Fan Switch for the laser and fan is the first item you turn on each day. The switch is located on the rear panel of the laser near the lower left hand corner. The Key Switch is the major circuit breaker for your laser. It will be the second item you turn on when activating the laser each day. Place the laser key into the key receptacle located near the right-hand side on the front of the laser. (See Figure 4) Check the key switch by pushing in and turning the key clockwise, approximately 1/4 of a turn. This is the (ON) operating position for the key. The fan will start when the power/fan switch is on and the key is turned. Prior to leaving the office, the laser safety officer should check to see that the key switch has been turned off and the key removed and stored.

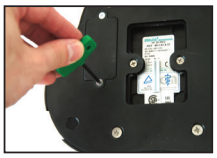
Figure 4 - OFF Position

Figure 5 - ON Position

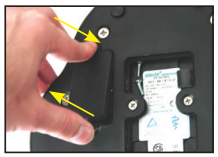
Precise® LTM Remote Interlock

The Precise LTM 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 installment is not facilitated nor required in many operatories or clinics. To that end, the Remote Interlock is available to any practitioner that requires it. The Remote Interlock Jack is located and clearly labeled on the rear of the laser. 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 to inform the local electronics store that you require a mini (1/8") phono jack wired into a normally open 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 rear of the laser.

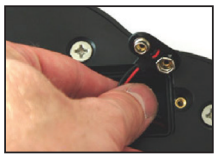
2.2.3 Wireless Foot Pedal Battery Installation/Replacement



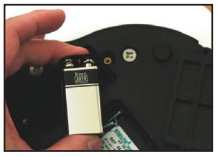
1. Insert a Philips-head screwdriver into one of the screw holding down the battery cover and twist counter-clockwise until the screw is fully removed. Repeat with the remaining screw.



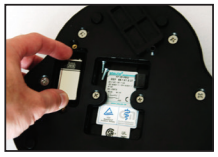
2. Push down on one end of the battery cover while simultaneously lifting up on the other end to remove it.



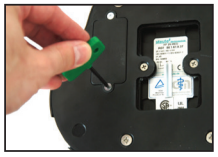
3. Locate the battery terminal inside the well and gently pull the terminal out. Do not pull excessively on the wires.



4. Remove the 9 volt lithium battery from its packaging and attach the battery to the terminal.



5. Place the battery in the well with the connector to the same side as where the wire leads emerge from the housing.



6. Replace the battery cover and replace the two screws. Tighten the screws clockwise. Be careful not to over tighten. Let foot pedal rest at least 1 minute before use.

Note A:
Only use 9 Volt Lithium batteries; alkaline batteries are insufficient. Keep an extra 9 volt Lithium battery. Replacement will be required roughly every 100 hours of use.

Note B:
Make sure the laser is completely turned off before replacing the battery in the foot pedal.

Note C:
Place the pedal face down on a hard clean surface.

2.2.4 Disposable Fiber Cartridge Replacement

A tamper sticker is in place on the fiber cartridge. Do not remove fiber cartridge without contacting Customer Care first (877-236-4408). Warranty may be voided. After cleared for removal by Customer Care, read directions thoroughly before beginning.

1. Turn system off. Remove the fiber from the handpiece and fully retract fiber into the cartridge. Place unit upside down on a hard surface.

2. Slide fiber cartridge out and gently place on hard surface next to the unit.

3. Unscrew the empty cartridge connector counterclockwise and pull straight out. Discard the empty cartridge.

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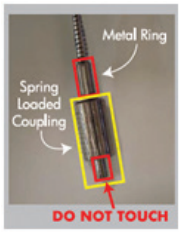
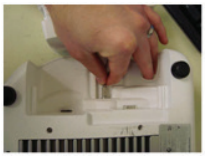


3. Place the new cartridge on its side in place of the empty cartridge. Carefully remove the dust cap. Do NOT touch the end of the connector. Grasp the metal ring at the base of the coupling to stabilize and prevent breakage.

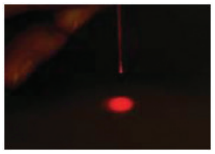


4. Gently push the coupling into the connection while maintaining your grasp on the metal ring. Continue to hold the metal right. Push the spring loaded coupling into place and twist clockwise until locked into place.

6. Position the cartridge to line up with the guide tabs on the side of the bay.

7. Slowly push the cartridge into the bay until the outside surface is flush with the side of the unit. Make sure the optical fiber coil retracts inside the cartridge as it is gently slid into place.

8. Turn on the power to the laser system. Press the Extend and Retract buttons to ensure the fiber is moving properly. If it does not, gently push the cartridge into the bay further.



9. Don't look directly at the aiming beam! Make sure the aiming beam indicator is at a value other than zero (0), and then press the Ready button. DO NOT press the foot pedal. The aiming beam should be visible from the end of the fiber.

Note: Never fire working beam if the fiber is fully retracted in cartridge.

2.2.5 Laser Stop Switch

Before activating the laser, first check the laser stop switch to ensure it's locked in the "in" position (see figure 22). The switch is the red button located on the top of the laser. The button must be "in" to operate. If the laser stop switch is "out"; engage the switch by pressing it. The display on the control panel should now be lighted. To interrupt laser emissions in an emergency, depress the button again to the "out" position.

Figure 21 - Laser Stop enabled ("OUT")

Figure 22 - Laser Stop disabled ("IN")

If you find that the display is still not operational, check all attachments, keys and switches to see that they are securely installed and, that you have an active wall plug for electricity. (See Troubleshooting Section). If the laser cannot be activated, please contact Customer Care (877-236-4408) who can help you troubleshoot.

Note: This is not a power switch.

2.3 FACILITY REQUIREMENTS

In order to insure the safe use of the laser in your facility, please check to make sure that the proposed location has the following:

2.3.1 Power Requirements

110 -120 VAC ± 10 % at 60 Hz, 1.5 Amps
Frequency Range: 45 - 63 Hz
9 Volt Lithium battery

2.3.2 Heating, Ventilation, and Humidity

The room where the laser is used should have good cooling and heating system so that the laser can be operated within the optimum range of 20 - 30°C (68 - 86°F). Avoid storing or transporting the laser in temperatures below 0° Celsius (32° F). Operating and storage humidity should be 5-95% RH.

2.3.3 Lighting

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

2.3.4 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 and ventilated 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.

2.3.5 High Speed Vacuum Systems

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 high filtration masks that are suitable for virus and bacterial control.

2.3.6 Access and Visual

Access to the treatment area should allow the dental team to restrict entry while the laser is in use. There should be a Danger Laser In Use Safety Sign placed in a designated area adjacent to the entry into the treatment area. See Figure 42.

SECTION 3: OPERATING YOUR LASER

3.0 SAFETY CONSIDERATIONS BEFORE USING YOUR LASER

The safe use of the Precise LTM® is the responsibility of the entire dental team including the doctor and the Laser Safety Officer (LSO) appointed from 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.

3.0.1 In-Office Safety Issues

Lighting & Ventilation: Always use the Precise LTM in a well lit and ventilated area. Make certain that chemicals or gases capable of supporting or causing combustion are not present when using the laser. Use high volume vacuum to remove the laser "plume" and provide high filtration masks for all people including the patient and any family or guests present in the treatment area during lasing.

Safety Eyewear: While using the Precise® LTM laser, doctors, auxiliary staff, patients, and anyone attending them in the operatory must wear the laser glasses provided with the

Precise LTM system, which is appropriate for use with this type of device. If additional glasses (part #002-00186) are obtained, they must have the same specifications for wavelength and optical density as the glasses provided with this equipment. 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.

Test Firing the Laser: Always test-fire the Precise LTM 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 2 x 2 gauze sponge moistened with water. Do not use alcohol or any other combustible material to moisten the 2 x 2 gauze as it may ignite.

Fiber Preparations: After cleaving and stripping the fiber, photo-initiation of the fiber tip will allow the operator to remove tissue more rapidly when contact procedures are indicated. Gingival debris on the tip will retain the heat and it should be removed. The tip will also begin to blacken and deteriorate as it retains the heated debris and can break if not removed by cleaving it. Clean the tip often using a 2 x 2 gauze sponge moistened with water. Do not use combustible liquids to moisten the 2 x 2.

Danger - Laser In Use Signage: Each operatory where the Precise LTM 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 reduce occurences of eye damage caused by inadvertent exposure to laser energy. See Figure 42.

Sharps Disposal and Sponge Removal: Remove cleaved fiber remnants and place them into a sharps container for disposal. All gauze used for cleanup of lasers and fibers should be disposed of in a bag for contaminated soft products.

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.

Key Switch: When the key switch is in the ON position (turn clockwise to the right so it is 90 degrees in the vertical [↑] position), the laser has been enabled and can be activated while in the READY status. When not in use, insure that the key has been turned off or that the laser is placed in the STANDBY status.

Safety Education: Provide comprehensive safety procedure training for all office personnel and including front office staff in all outside laser courses when possible. Be certain that all members of the dental team understand how the laser works and can advise patients as to their safety and advantages over conventional procedures.

Laser Security: To prevent the unauthorized use of the laser while not in use, the key should be removed from the unit and maintained by the Laser Safety Officer (LSO).

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

1. Foot Pedal – remove your foot to stop lasing
2. Engage the laser stop button
3. Key – turn off the key
4. Switch the Power to the off position (O)
5. Power Cord – unplug from the wall outlet

Hard Tissue Procedures: The Precise LTM diode is not an appropriate laser for hard tissue procedures. The diode laser is attracted to melanin, hemoglobin and to some extent, to 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.

3.0.2 Laser Safety Program and Continuing Education

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

- Selection of a Laser Safety Officer (LSO).
- Minimum Training requirements for users of the laser.
- Laser security against 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 Laser Safety Officer (LSO) can be a full or part-time employee or the laser operator and is responsible for:

- Safe use of a laser.
- Training of the staff, related training records and laser performance.
- Perform regular safety checks and prepare the laser for use on a daily basis.
- Keep records of any incidents laser failure or adverse effects and report such incidents as required by law.
- Assure a medical follow-up has been sought or has occurred following any adverse incident during treatment.
- Training of all office personnel who are involved with the laser preparation and use.
- Daily check of the facility and equipment.
- Test fire the laser prior to beginning of 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 or TR IEC 60825-8 Guidelines for the Safe Use of Medical Laser Equipment. The LSO should insure 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.

3.0.3 Food and Drug Administration

Manufacturers of products subject to performance standards under the Federal Food, Drug, and Cosmetic Act, Chapter V, Subchapter C - Electronic Product Radiation Control are required to certify compliance with the regulations and furnish various reports to the Center for Devices and Radiological Health (CDRH). For medical laser manufacturers, additional review by the FDA of the safety and effectiveness of the device is required. Companies who intend to market a medical laser today must receive authorization from the FDA to permit the device into commercial distribution. There are two forms of premarket clearance procedures. The premarket notification 510(k) procedure is principally used for those devices that are documented to be substantially equivalent to legally marketed Class I and Class II devices. For new devices not equivalent to legally marketed devices, a more complex
PMA is required.

3.0.4 OSHA and its Provisions

Worker safety is the responsibility of the employer and is regulated by OSHA (Occupational Safety and Health Administration), a division of the U.S. Department of Labor. OSHA has issued no specific standard for safe use of lasers but recognizes ANSI standard Z136.1 as a source for analyzing safety with respect to medical lasers. For more information see OSHA Technical Manual (TED 1-0.15A) Section III, Chapter 6, 1999. CAO Group, Inc. recommends implementation of a Laser Safety Program for the safety of your patients and office staff in connection with the use of the Precise® LTM 5 Watt Soft Tissue Diode Laser.

3.0.5 Statutory Licensure

State training requirements for all dental professionals vary and change from time to time. A proficiency certification may be required prior to using the laser. These courses are usually taught by members of the Academy of Laser Dentistry who possess instructor credentials. Check with your state licensing board regarding the applicable requirements for using lasers in dentistry to ensure full compliance with Federal, State, and local regulations.

3.0.6 Wireless Technology

In order to promote efficient use of the radio spectrum in various global markets the United States Federal Communications Commission (U.S. FCC) and other international government agencies have developed technical standards for devices that are capable of emitting radiofrequency energy when in use – such as wireless data cards. These products need to receive certain identification numbers in accordance with the Commission Equipment Authorization rules prior to marketing in U.S. markets. The Code of Federal Regulations, Title 47 (47 CFR), Part 15 covers the rules for the operation of unintentional, intentional or incidental radiators. Any electrical or electronic devices incorporating digital circuitry and operating with an oscillator or clock speed of greater than 9kHz requires approval to this rule. There are various types of FCC Part 15 approvals, depending on the nature of the product and its intended use. In Canada, IC-RSS 210 (Radio Standards Specification) sets out the requirements for license exempt low-power intentional radiators. This standard is very closely harmonized in terms of permitted frequencies, types of operation, and other technical requirements to the FCC requirements, but a separate certification application is required for Canada. In the European Community, compliance with several safety directives and testing to EN 300 328, EN 60950 and EN 301 489 is required for this type of device. The manufacturer is required to provide a Declaration of Conformity as evidence of its compliance with the various regulatory requirements.

3.0.7 Precise® LTM Wireless Frequency

The 2.4GHz frequency is very popular for networks and other wireless devices that share similar technology like Bluethooth® cell phones, Wi-Fi® devices, wireless networks, cordless phones, CAD/CAM machines, wireless video senders, even microwave ovens. The nature of spread-spectrum modulation in the 2.4 Ghz frequency means that a multitude of devices can co-exist in the same 2.4 GHz spectrum (as should be obvious, since many devices use 2.4 GHz and operate well on a daily basis). Bluetooth and Wi-Fi devices use multiple channels, recovering data reliably out of noise in the 2.4 GHz spectrum. They will hop around strong interference, and quickly re-try for uninterrupted operation -- and can even avoid channels or areas of the band in use by other devices by adaptive hopping. Since the Precise LTM wireless transmitters have a much lower power output, it is highly unlikely that they would "interfere" with higher-power devices. Even if this were possible, the higher-power devices would quickly switch to another channel to achieve uninterrupted operation. The Precise LTM wireless receiver use an entirely different protocol, and therefore cannot (receive) data from Bluetooth or Wi-Fi devices. The converse is also true; their protocol methods are incompatible. Precise LTM diode laser wireless technology is electronically coded. Each pedal and Precise LTM diode laser share a **UNIQUE SERIAL NUMBER INTERLOCK** protocol for reliable operation:

- A Precise LTM pedal communicates with only one Precise LTM diode laser; there is 2-way electronic code which must be verified for every transmission and acknowledge. The pedal and laser unit are interlocked to only each other's electronic codes.
- If data from another Precise LTM pedal is ever received, embedded verification measures ensure that it is always ignored and discarded.
- If data were ever received from another wireless device with a compatible protocol scheme (2.4GHz frequency), it would immediately be discarded in the same way.

In summary, the wireless transmitters in the Precise LTM 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. Precise LTM wireless receiver is incompatible with Bluetooth or Wi-Fi 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 Precise LTM diode laser except the wireless pedal which it is paired with via electronic code.

3.0.8 American National Standards Institute (ANSI) - Safety Standards

ANSI is a non-governmental, non-profit agency that has established guidelines and safety standards for the use of lasers and other electro-optics. The provisions of ANSI Z 136.3 outlines standards for lasers used in dentistry and the assessment of laser risks. ANSI also establishes guidelines for safety eyewear and classifies all lasers based on their potential for damage to eyes or tissue. See table 1 for NOHD requirements.

3.1 STARTUP AND SYSTEM CHECK

3.1.1 Selecting the Treatment Center

The laser should be placed in an area with good ventilation and lighting. The electrical service required is a 110 Volt A/C outlet - 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 chemical stored in the area should be removed.

3.1.2 Checking the Foot Pedal Installation

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. **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.

3.1.3 Checking the Key Activation and Control Panel Display
Turn the Key Switch on the front of the laser to the "On" position by turning it approximately 1/4 turn to the right (clockwise). The control panel should light up and show the laser is in Standby Mode.

3.1.4 Checking the Laser Stop Button
Check the Laser Stop Switch to see that it has not been pressed. If it has, release it by pressing it slightly. See section 2.2.5.

3.1.5 Checking the Disposable Fiber Cartridge
Do not sever tamper sticker without contacting Customer Care first. Depress the extend/retract button on the control panel to see that it is functioning properly. After checking the fiber cartridge power, extend approximately 3 feet (1 meter) of fiber. Strip, cleave and disinfect the fiber; attach the handpiece and tip (see section 4). Press the Ready button to activate the aiming beam. Aiming beam should be set above zero (0). If aiming beam still is not illuminated call Customer Care at (877) 236-4408 for further troubleshooting assistance. Do not depress the extend and retract button during laser operation.

3.1.6 Setting Modes
The Precise® LTM features two modes. Pulse mode allows some cooling of the tissue and id designated by a (insert pulse mode symbol here). Continuous mode transmits laser energy without interruption and is designated by (insert continuous mode symbol here). Review your power and mode requirements and then depress the mode button to select either Continuous or Pulse mode (see section 3.2.2 for further details) .

3.1.7 Setting Power
Select your power by pressing the up or down arrow until you have reached the desired wattage. Beginning with a low of 0.5 Watts, the power increases in increments of 100 mW up to a maximum of 5.0 Watts (Continuous Mode). By holding the up or down arrow, you can have an uninterrupted progression until you reach your desired power.

3.1.8 Setting Aiming Beam
The aiming beam can be turned on and off by pressing the aiming beam button on the laser control panel. Press this button to progressively increase the aiming beam intensity from zero (0) (off) to full intensity. Press the key once more to cycle back to zero (0). Each bar 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 working laser.

3.1.9 Programming your Precise LTM
You are able to easily set four (4) different combinations of Power, Mode and Aiming Beam Intensity. The initial Precise factory setting is 1.4 W Power + Continuous Mode + 80% Aiming Beam Intensity. To set your programs, push the Program key to display one of the program numbers. Choose the desired Power level, the desired Mode and the desired Aiming Beam Intensity. Press the READY button – your settings have been saved. Repeat for each of the four programs. You may change your settings as often as you like. The settings saved into the four programs will be retained even if the laser is turned off.
NOTE: Whenever your press the READY button, the settings displayed on the unit will be saved into the unit's memory for the program setting shown.

3.2 OPERATING YOUR LASER

3.2.1 Before Beginning Procedures
Examine the fiber tip to insure that you have not created a fiber tip shard during the cleaving process. The shard (Fig 23) can act like a miniature scalpel and cause damage while diffusing the light beam and lowering the laser's power (See section 4.0.7 for cleaving procedure). Depress the "Ready" button and the aiming beam can light after 3 seconds. Review your power and mode requirements and then depress the mode button to select either or mode.

Figure 23 - Fiber with a shard (a bad cleave)

3.2.2 During Procedures
- Test fire the laser outside the mouth by activating the laser into a 2 x 2 gauze sponge that has been moistented with water to prevent combustion. Do not use flammable liquids to wet the sponge.
- **Standby and Ready Status:** If the laser is powered on the status of the laser will be in Standby which is a non-active status. The laser will not emit energy while in Standby, even if you depress the foot pedal. On the top-center of the control panel you will see the "Ready" button (See Figure 3). Press this button to place the unit into ready status. When this button is pressed whatever settings are displayed on the unit will be saved into the unit's memory for the program setting shown. The settings saved into the four programs will be retained even if the laser is turned off. The laser will now be ready to emit energy as you depress the foot pedal.
- Depress the foot pedal and make short feather like quick brush strokes at the lowest power that you can to remove the target tissues (with initiated tip see section 4.0.8) while lightly contacting it. It is recommended to complete a training course and practice on pigmented foods such as hot dogs or tomatoes before attempting a procedure on a patient.
- **Continuous Mode ( ):** In setting up the laser while in the mode, you will deliver the amount of energy in Joules in one second equal to the value indicated in the working beam setting, i.e., set the laser for 2 Watts and while activated the laser will deliver 2 Joules per second as long as you have the foot pedal depressed. The 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 in 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.
- **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 Precise LTM 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 followed with 1 period of rest with no energy between each pulse.

The result will be an average energy 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. Two Watts of Pulsed energy will be the same average power output as 1 Watt. Remove your foot from the foot pedal and use a clean 2 x 2 gauze sponge moistened with water to remove debris from the fiber tip. Do not use flammable liquids to wet the sponge. Place the laser in Standby mode by turning "Ready" off until you are ready to start another procedure. **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 to make sure you have a good cleave of the fiber 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.

Additionally, diode lasers cut differently than other tools. Diode lasers are end cutting meaning only the very tip cuts. Use just the very tip of an initiated (see section 4.0.8) Precise® LTM fiber in light brush strokes in order to cut. Do not drag as with a scalpel or electrosurge. This technique is very efficient, damages less tissue in addition to increasing ATP production, resulting in less pain and reduced healing time.

3.2.3 After Each Procedure

- Cleave used fiber tip and discard in suitable bio-waste sharps disposal.
- Wipe the outside of the fiber using a disinfectant or sterilization solution (see section 4.1.1) and then retract the fiber by depressing the RETRACT button on the control panel. Do not retract the distal end of the fiber into the cartridge.
- Turn the key to the off position if another procedure isn't planned and remove key.
- Record the Power setting(s), mode, 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 ⊨ air cooled
#7 Lasing time	60 seconds @ 1.5 Watts ⊨ air/water spray

SECTION 4: PREPARATIONS, CARE, AND MAINTENANCE

The fiber optic element of a laser is responsible for carrying the light from the diode array to the tissue being treated. Precise laser dental laser fibers are usually made of a quartz and silica combination. Be advised about the potential hazards when inserting, steeply bending or improperly securing the fiber optics to the frame (chassis).

Laser 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. 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 an improperly working delivery system. Call Customer Care in these instances for assistance.

4.0 DISPOSABLE FIBER CARTRIDGE

The fiber cartridge is a removable assembly with a plug-in capability that provides power for the internal retraction device. This cartridge is disposable after all fiber has been used. This cartridge is not autoclavable. The fiber cartridge contains approximately 20' (6 meters +) and is wound onto a spool. Call Customer care (877-236-4408) before replacement and/or severing the tamper sticker on the bottom of the fiber cartridge.

4.0.1 Replacing the Fiber Cartridge

A white or black mark on the fiber indicates 18" of fiber remaining on the cartridge. At this point, a new fiber cartridge should be ordered. See section 2.2.4 for instructions on replacing the fiber cartridge. The spent fiber cartridge can be thrown away.

Note: Retain the fiber end cap. DO NOT discard the end cap.

4.0.2 Fiber Preparation

Prepare the fiber for use by depressing the EXTEND button on the control panel (see figure 3). Place a disposable tip onto the handpiece. Extend 3 - 4' of fiber and feed it through the fiber locking collar at the base of the handpiece after loosening the collar by twisting it counterclockwise (just till loose do not full disassemble). If using curved tips gently straighten while feeding fiber until it extends about 1' beyond the distal end of the handpiece. Tighten the locking collar by twisting clockwise until resistance is met. Strip, cleave and disinfect the fiber (see sections 4.0.6 - 4.0.9). Loosen locking mechanism again and pull fiber back until 1-2 mm of cladding is visible beyond the tip.

Do not continue to use the uncovered fiber once you have observed that it has a blackened appearance that is greater in length than 2 - 4 mm from the previous cleave spot. The protein debris of gingival tissue accumulates on the tip during surgery and retains extreme heat that can cause rapid tip deterioration and subsequent breakage.

This is especially important when using the laser for periodontal pocket debridement. During surgery, clean the tip often using a 2 x 2 sponge moistened with water. Do not use alcohol or other combustible liquids to moisten the 2 x 2 gauze sponge and do not use the sponge while the tip is hot.

Always use a cold disinfectant solution like BIREX® or CIDEX® to wipe off the fiber jacket before retracting the fiber. The fiber can be advanced or retracted by depressing the RETRACT and EXTEND buttons on the front control panel.

The fiber itself has three components:

- Jacket
- Cladding
- 400 micron quartz/silica fiber

4.0.3 Jacket

The Precise® LTM features a clear protective cover surrounding the fiber made of a synthetic material. This jacket protects the fiber from damage and microorganisms from making contact with the fiber.

4.0.4 Cladding

This is the thin material in between the outside of the quartz/silica fiber and the jacket. It is used to block the lateral escape of laser energy as it traverses the fiber. During stripping, you may "nick" the cladding and you will likely see the red aiming beam light as it escape the site of the damage. This is not a danger if all people in the area have the appropriate safety eyewear. Simply cleave and strip beyond the damage.

4.0.5 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 gingiva accumulates on the fiber and will deteriorate the tip of the fiber. It can fracture if not cleaved 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. Dispose of all small fiber remnants after you have cleaved the fiber. They should be kept in a small box with a lid until they can be properly disposed of in the "sharps" container.

4.0.6 Stripping the Fiber

The fiber's jacket is removed using a "stripper". Between each patient and once a fiber tip is initiated and begins retaining debris from the tissues during lasing, you will get a deterioration of the fiber tip. When you have a blackened tip that extends 3 - 4 mm up the fiber shaft, it is time to cleave the fiber and strip the jacket to prepare for the next procedure or patient. Begin by selecting enough jacket so that when it is removed, you will have approximately ⅜" of bare fiber exposed.

Use the measurement guide and place the end of the fiber in the stripper. Firmly grasp the adjacent fiber 2-4" from the portion fed into the stripper between your thumb nail and index finger. (See Figure 24). Grasp the fiber with the stripper by applying pressure to the handles. With a slow steady force, remove the jacket by pulling the fiber away from the stripper. (See Figure 25).

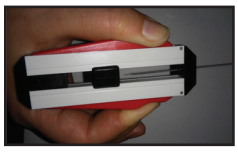


Figure 24 - Adjustable Fiber Stripping Tool

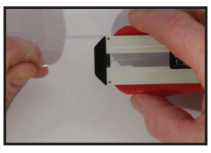


Figure 25 - Remove ¼" to ⅜" of the jacket with stripper tool

4.0.7 Cleaving the Fiber

Between patients or when the fiber deteriorates it is important to cleave the fiber. As the fiber tip deteriorates, it is more likely to fracture and could fall into the sulcus or a deep periodontal pocket. To avoid this problem, it is prudent to periodically "cleave" the discolored tip once it has become black 3-4 mm down the shaft of the fiber. A cleave is made after stripping off the jacket to expose approximately ¼" - ⅜" of bare fiber. (See Figure 27).

Cleave at a point approximately ½" (8 - 10 mm) from the site of the previous cleave so that there is no visible discoloration of the tip. The operator should place their index finger at the spot of the proposed cleave so as to stabilize the fiber. Using the pen style cleaver, draw the cleave blade across the top of the fiber with enough pressure to"score" the fiber. (See Figure 30).
Grasp the fiber with the thumb and index fingers ¼" – ½" on either side of the score mark. Apply gentle but firm pressure to cleave the fiber. (See Figure 31).

After you have cleaved the fiber, point it perpendicular to a white piece of paper and place the laser in READY mode. Hold the tip approximately ½" from the paper and you should see a near perfect circle of red light. If you have a large comet effect radiating from the circle, you have not obtained a good cleave. (See Figure 29). If the circle has just a small comet effect, it will probably work. Always dispose of the fiber tip remnants in the "Sharps" container immediately after cleaving the fiber.

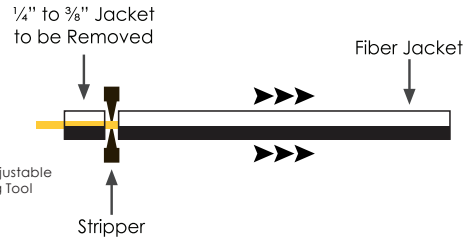


Figure 27 - Adjustable Fiber Stripping Tool

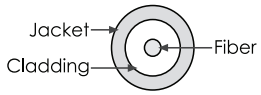


Figure 28 - Adjustable Fiber Stripping Tool

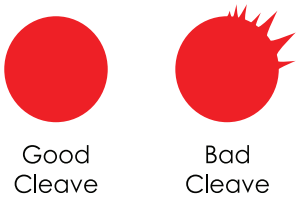


Figure 29 - Laser profile after cleaving.

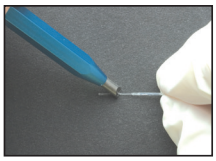


Figure 30 - Make one pass using light but steady pressure

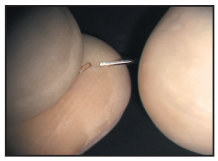


Figure 31 - Break the fiber against the cleave

Always dispose of the fiber tip remnants in the "Sharps" container immediately after cleaving the fiber.

4.0.8 Initiating the Fiber
Once successfully cleaved, prepare to cut soft-tissue. The tip of the fiber can be prepared to retain heat by introducing it to a dark pigmented material like ink, blood or cork. The easiest way to prepare the tip is to lightly move the flat surface of the tip across a piece of articulating paper or cork at about 1 Watt continuous ⎓. The tip will retain the ink and the ink will make the tip glow a yellow/white color if you exceed 1 - 2 seconds while in contact with the paper (See Figure 32). Prolonged heating will accelerate the deterioration of the tip.

4.0.9 Fiber Disinfection
The fiber and spool remain in the fiber cartridge and are not autoclavable. Once stripped, cleaved and initiated, the tip will reach temperatures of several hundred degrees centigrade, thus, as the laser emits energy, it will rid the tip of pathogens.

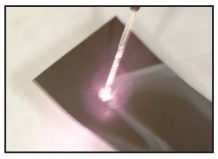


Figure 32 - Move the tip left or right while lightly touching the paper

Additionally, the tip can transfer heat up the shaft of the fiber to the edge of the jacket which may melt slightly. After your procedure, always cleave the blackened tip and damaged jacket. Wipe the jacket down using BIREX® CIDEX® or a comparable product that can disinfect the jacket. Dry the jacket using a clean 2 x 2 sponge prior to retracting the fiber into the fiber cartridge. Also see section 6.0.

4.1 LASER MAINTENANCE

4.1.1 Laser Chassis Disinfection
The exterior of the laser should be cleaned using a liquid disinfectant similar to BIREX® or CIDEX®. Do not spray the disinfectant directly on the chassis. Apply with a gauze sponge or wipe. Do not use abrasive materials or large amounts of liquid to clean the system. Place a barrier material such as parafilm® or other temporary self adhesive clear plastic sheeting over the control panel and LED screen prior to treating the next patient.

4.1.2 Calibration
The Precise® LTM 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 boots 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 in for adjustment by CAO Group, Inc., Service Department. We suggest that your practice establish an internal calibration program for your laser. Recalibration is recommended at a minimum of once per year based on average usage.

Recalibration may be performed by the manufacturer by returning the unit. Call Customer Care at (877) 236-4408 for details. Alternatively, you may purchase a calibrated hand-held power meter approved for use with 810 nm devices to check power output. The laser should be set at 1, 3, and 5 Watts with output checked at each level. The output display should be within 20% of the meter reading. If not, recleave the fiber and re-check. If the output display is still outside the 20% tolerance, return the unit to the manufacturer for recalibration. Call Customer Care at (877) 236-4408 for details. There are no methods available for the user to adjust the calibration of the unit and the unit must not be adjusted, altered, or disassembled by the user for any reason. Warranty may be voided.

4.1.3 Handpiece Preparation
The Precise® LTM handpiece is designed for easy assembly and then sterilization after each patient.

The handpiece has four (4) components:
a. Fiber locking cap (See Figure 33)
b. Plastic collet - located inside fiber locking cap (See Figure 34)
c. Body (See Figure 35)
d. Disposable tip - one time use only; not autoclavable (See Figure 36)

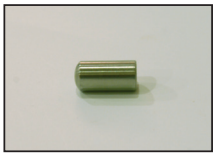


Figure 33 - Fiber locking cap

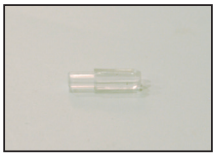


Figure 34 - Plastic collet

Figure 35 - Body

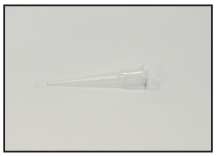


Figure 36 - Disposable straight tip (60° angle disposable tip also available)

Figure 37 - Handpiece Assembly

Assemble the handpiece with plastic collet, Fiber Locking Cap and disposable tip in place (see figure 37); only lightly tighten the Locking Cap onto the handpiece body. Extend the fiber about 3-4' from the Precise unit. Slide the end of the fiber through the Fiber Locking Cap, through the handpiece and out the disposable tip so that about 1'of fiber extends out of the handpiece. Firmly tighten the Fiber Locking Cap so that the fiber is held securely in place. Now the fiber can be prepared for lasing (Section 4.0.2 – 4.0.9). The Precise® LTM uses an autoclavable stainless steel handpiece that should be sterilized after every patient. Clean the handpiece with warm soapy water; rinse thoroughly; disassemble; place all three disassembled parts in an autoclavable bag, and then autoclave it accordingly. Set the autoclave for 250°F (121°C), at least 18 psi (124 kPa), and run for 30 minutes, followed by 30 minutes of dry time (gravity cycle method). **Note:** Do not fire working laser if handpiece is not properly attached to fiber.

4.1.4 Disposable Tips

The disposable tips are sold in two (2) different degrees of access for optimal use within fiber specifications, straight and 60° curved. Do not attempt usage of tips not manufactured by CAO. Doing so may cause undue stress damaging the fiber.
Note: Disposable tips are single use, not autoclavable.

SECTION 5: LABELS, SIGNS, WARNINGS, AND INFORMATION

5.0 FEDERAL COMPLIANCE

The Precise LTM has been designed to the latest safety standards applicable to medical lasers in the U.S. and Canada, including IEC 60825, IEC 60601-2-22, and IEC 60601-1. This laser is also designed to meet the construction and performance requirements of the Food and Drug Administration's Laser Performance Standard (21 CFR 1040.10 and 1040.11). The laser has also been certified and tested according to the telecommunications regulations for the US (FCC Part 15). Various labels are included on the laser and the wireless footswitch as evidence of conformity to these requirements. The labels on the unit are required under these standards for safety purposes and should not be removed. Please review all labels prior to using the laser. (See Figures 38 through 47). Installation and operation of this device should be made consistent with CAN/CSA-Z386-08: Laser safety in health care facilities.

5.1 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. (See Figure 42)

5.2 LASER CLASSIFICATIONS

Class 4 Laser Product (treatment laser): 810 nm, 5 Watt
Aiming Beam Laser: 630 – 660 nm, 2 mW

5.3 CAUTIONS

5.3.1 Changes or modifications not expressly approved by CAO Group could void the user's authority to operate the equipment and lead to unexpected laser exposure or electrical shock.

5.3.2 Laser Radiation – Avoid exposure to the face, eyes, or skin from direct or scattered radiation.

5.3.3 This product contains no user serviceable components within the chassis. Visible and invisible radiation may be present when the cover is removed.

5.3.4 U.S. Federal law restricts the device to sale by or on the order of a licensed professional.

5.3.5 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 corneal may be irreparable if exposed to direct, reflected or scattered radiation.

5.3.6 Use of controls, adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure. Any misuse is considered abuse of the product.

5.3.7 Do not use system if there is any visible damage to the system, including, but not limited to, cracks, wear, or damage.

5.3.8 Keep system away from liquids to prevent electrical shock and damage. Stop and power off system if exposed to liquids.

5.3.9 Do not use system in an oxygen rich environment to avoid risk of fire.

5.3.10 Consult local services to learn how to properly dispose/recycle the system.

Figure 38 - Label required under FDA laser notice 50

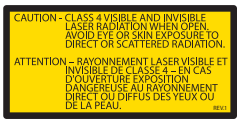


Figure 39 - Label required under FDA laser notice 50

Figure 40 - Laser Aperture label

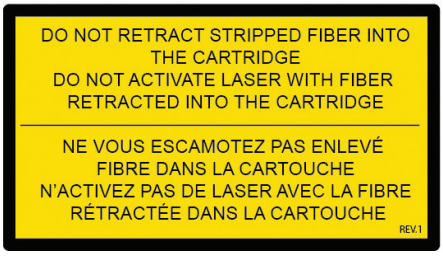


Figure 41 - Fiber Cartridge Caution Label

Figure 42 - Danger - Laser signage

5.3.11 Not indicated for patients taking Accutane (Isotretinoin) currently or within the last 6 months.

5.3.12 Use of this device is not recommended for patients who suffer from light-induced seizures.

5.3.13 Use of this device on pregnant women has not been studied. Avoid usage on pregnant women.

5.3.14 Do not use this device for procedures other than those proscribed in this manual. See Section 9.

5.3.15 Make sure the disposable tip is fully seated onto the handpiece before continuing with the procedure.

5.4 NOMINAL OCULAR HAZARD DISTANCE (NOHD)

(NOHD) Nominal Ocular Hazard Distance – The minimum distance a person without appropriate eye protection must maintain.
(MPE) The highest level of laser radiation a person may be exposed to without hazardous effects or adverse biological changes in the eyes or skin.
(NHZ) The area a laser source is within that exceeds the exposure level of MPE.

The NOHD is not to exceed the MPE. The outer limit of the NHZ is the NOHD. Eye protection within the NHZ is mandatory. See table 1 for the NOHD.

NOTE: 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. Any required correction of the interference shall be at the user's own expense).

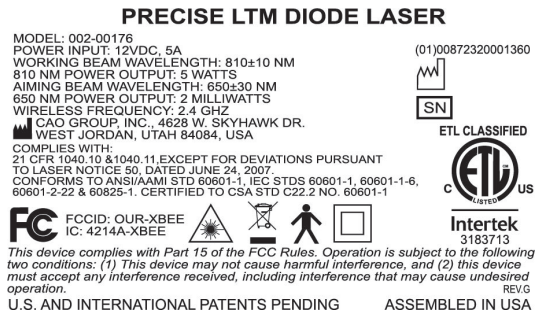


Figure 43 - Rating label with serial number

Figure 44 - CAUTION - Laser Emitting Device; Class 4 Laser

Figure 45 - Type B Applied Parts

Figure 46 - ATTENTION -- Review Operator's Manual Prior To Use

Figure 47 - Do Not Reuse

Figure 48 - Rated For 12VDC, 5A

Figure 49 - Dispose of electronics waste in a responsible manner

Figure 50 - Class II Electrical Device

SOURCE OF RADIATION	MPE (mW/cm²)	DIVERGENCE ANGLE (DEGREES)	NOHD (inches)	
			No Eyewear (inches/cm)	With Eyewear (OD=4) (inches/cm)
Fiber Optic Devices	1.66	9	154/392	1.54/3.92
Reflection from Tissue	1.66	N/A	0.04/0.12	0.0004/0.0012

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

Assumptions: Maximum Laser Power = 5 Watts, Direct Viewing Angle = 0°;
Reflectance Viewing Angle = 20°; Reflectance Coefficient of Tissue = 0.001

SECTION 6: SERVICING

6.0 LIMITED WARRANTY

The Precise® LTM Diode Laser is warranted against defective materials and workmanship for a period of two (2) years from the date of purchase; six (6) months for the fiber (excluding consumption) and cartridge. Warranted equipment will be repaired or replaced, at CAO's discretion, if returned prepaid to our factory. This warranty does not cover damage to the Precise LTM Diode Laser unit or components caused by accident, misuse or being tampered with. This warranty does not include labor, postage or delivery charges. This warranty does not apply to the external finish of the console, handpiece, fiber, power cord, foot pedal. CAO Group, Inc. reserves the right to make changes in design or to modify such previously manufactured products.

ALL RELATED ACCESSORIES USED IN CONJUNCTION WITH THE PRODUCTS INCLUDING BUT NOT LIMITED TO HANDPIECE(S), CLEAVER, FIBER STRIPPER, POWER SUPPLY, POWER CORD AND PROTECTIVE EYEWEAR, ARE WARRANTIED FOR NINETY (90) DAYS AGAINST MANUFACTURING DEFECTS. DAMAGE OCCURED OUTSIDE OF MANUFACTURING DEFECTS ARE NOT COVERED BY THIS LIMITED WARRANTY. DISPOSABLE OR CONSUMABLE ITEMS (E.G. DISPOSABLE TIPS, ETC.) ARE NOT COVERED BY THIS LIMITED WARRANTY.

THIS WARRANTY WILL BE VOIDED IF THE USER ATTEMPTS TO SERVICE THE EQUIPMENT OR IF SERVICE IS PERFORMED BY PERSONS WHO ARE NOT TRAINED OR AUTHORIZED TO DO SO BY CAO GROUP, INC. IF THE UNIT IS FOUND TO BE DEFECTIVE WITHIN THE PERIOD SPECIFIED ABOVE AFTER EXAMINATION BY AN AUTHORIZED SERVICE REPRESENTATIVE OR CAO GROUP, INC. AND THE FAILURE WAS DUE TO DEFECTIVE MATERIALS AND/OR WORKMANSHIP, CAO GROUP, INC. WILL REPAIR, OR, AT ITS OPTION, REPLACE THE DEFECTIVE PARTS WITHOUT CHARGE. CAO GROUP, INC. RESERVES THE RIGHT TO MAKE SUCH AN EXAMINATION AND TO MAKE NECESSARY REPAIR/REPLACEMENT IN ITS OWN FACTORY OR AT ANY AUTHORIZED REPAIR STATION. IN THE EVENT THE USER DOES NOT COOPERATE WITH CAO GROUP, INC. IN PROVIDING SERVICE, YOU RELEASE CAO GROUP, INC. FROM ALL LIABILITIES WITH RESPECT TO WARRANTYING ANY EQUIPMENT OR ACCESSORIES. CAO GROUP, INC. WILL NOT BE RESPONSIBLE OR OBLIGATED TO THE PURCHASER/USER FOR LOSS OF REVENUES INCURRED BY THE PURCHASER/USER DUE TO THE PRODUCT REQUIRING SERVICE. IN ORDER TO RECEIVE WARRANTY SERVICE, PRECISE LASERS MUST BE SHIPPED TO CAO GROUP, INC. IN ITS ORIGINAL TRANSPORTATION BOX. THERE ARE NO OTHER AGREEMENTS, GUARANTEES OR WARRANTIES ORAL OR WRITTEN, EXPRESSED OR IMPLIED. YOU ARE REQUIRED TO READ THE OPERATING INSTRUCTIONS MANUAL PRIOR TO USE OF THE PRODUCTS AND YOU ASSUME ALL RISKS AND LIABILITIES RESULTING FROM THE USE OF THE PRECISE LASER PRODUCTS.

6.1 REPAIRS & RETURNS

Should the laser fail to operate correctly please contact CAO Group, Inc. Customer Care at (877) 236-4408 or customercare@caogroup.com for assistance. Returns must be handled through the original authorized dealer. If needed contact Customer Care for facilitation.

CAUTION! Do not attempt to remove the housing from the laser chassis (frame) for any purpose. Serious Injury from an electrical shock or laser radiation could occur. Removing the housing on the laser chassis will void the warranty.

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

CAUTION! Do not attempt to remove the fiber cartridge and/or break the tamper sticker. Doing so will invalidate the limited warranty.

SECTION 7: TROUBLESHOOTING

PROBLEM	CORRECTIVE ACTION
Laser has no response, fan is off.	Check that the power cord is securely plugged into back of the laser unit. See section 2.1.
	Check that the power switch on the back panel is turned to the on (I) position. Make sure the key is inserted into the switch, and the key is turned on. See section 2.2.5.
Laser has no response or LED display, but fan is on.	Check that the laser stop switch is in the down position. If not, depress the button. See section 2.2.5.
	Laser will need to be returned for repair. See Section 6.1
Laser has power but no output.	Laser will need to be returned for repair. See Section 6.1
Measured power output on a power meter is different from the LED display.	Make sure the power meter is calibrated for use with 810 nm wavelength devices. If the output remains different See section 4.1.2 and/or section 6.1.
Fiber does not extend or retract from the cartridge.	Make sure the 20' of fiber cartridge still contains fiber. If some fiber remains present see section 3.1.5.
An "Er" message appears with system alert beep. Er 01 - System needs service Er 02 - System needs service Er 04 - System needs service Er 06 - System needs service	First attempt to clear the error message. Turn the laser system off and wait for 5 minutes. Turn laser back on. If the error clears from the display and the audible "beep" stops, the unit was able to make operational adjustments and the laser should perform its function. If the error message and audible "beep" continues, the laser must be sent in for adjustment. Make note of error code. See section 6.1.
Audible "beep" on Laser continually sounds when foot pedal is depressed.	Turn laser off for 5 minutes. Turn laser back on. If the audible "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. See section 6.1.
Wireless foot pedal does not activate laser.	Replace 9 Volt battery. If the pedal still fails to activate the laser with new battery, refer to section 2.2.3 for Wireless Foot Pedal Installation. Make sure there is no metal tables, chairs or surfaces between the pedal and the laser. Try repositioning the pedal to a different location or rotating it slightly on the floor.
I don't see my issue	Contact Customer Care at (877) 236-4408 or customercare@caogroup.com for assistance.

SECTION 8: ELECTROMAGNETIC COMPATIBILITY (EMC)

The Precise® LTM 5 Watt Soft Tissue Diode Laser needs special precautions regarding the EMC and needs to be installed and put into service according to the EMC information provided in this manual.
Portable and mobile RF communications equipment can affect the Precise LTM. The use of accessories, transducer, and cables other than those specified by the manufacture, CAO Group may result in increased emissions or decreased immunity of the Precise LTM. The Precise LTM should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Precise LTM should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration - electromagnetic emissioins		
The Precise LTM is intended for use in the electromagnetic environment specified below. The customer or the user of the Precise LTM laser should assure that it is used in such an environment.		
Emissions Test	Compliance	
RF emissions CISPR 11	Group 1	The Precise LTM laser uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not available	
Voltage Fluctuations/ Flicker emissions	Not available	
The Precise LTM laser is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.		

Guidance and manufacturer's declaration - electromagnetic emissioins			
The Precise LTM is intended for use in the electromagnetic environment specified below. The customer or the user of the Precise LTM should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines Not Applicable	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Main power quality should be that of a typical commercial or hospital environment. If the user of the Precise LTM laser requires continued operation during power mains interruptions, it is recommended that the Precise LTM laser be powered from an uninterruptible power supply or a battery.
(50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - electromagnetic emissions			
The Precise® LTM laser is intended for use in the electromagnetic environment specified below. The customer or the user of the Precise LTM laser should assure that it is used in such an environment.			
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Precise LTM laser, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = [3.5/V1] √ P d = [3.5/E1] √ P 80 MHz to 800MHz d = [7/E1] √ P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range. [b]Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a]Field strengths from fixed transmitters, such as base stations for radio (Bluetooth® cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Precise LTM laser is used exceeds the applicable RF compliance level above, the Precise LTM laser should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Precise LTM. [b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the Precise LTM			
The Precise LTM laser is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Precise LTM laser can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Precise LTM laser as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz d = [3.5/V1] √ P	80 MHz to 800 MHz d = [3.5/E1] √ P	800 MHz to 2.5 GHz d = [7/E1] √ P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.39
100	11.67	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

SECTION 9: LASER SPECIFICATIONS

Precise® LTM Laser Specifications

Weight	4.9 lbs
Dimensions in Inches (H x W x L)	7.6" x 8.8" x 8.75"
Laser Classification (Per IEC 60825)	Laser Diode; Class 4 Laser Device
Wavelength	Laser: 810 nm ± 20 nm Aiming Beam: 630 nm - 660 nm ± 15 nm
Beam Divergence	9 degres's ± 1 degree
Power Range	500 mW to 5 Watts
Pulse Rate (in Pulse Mode)	Fixed: 0.1 Hz
Pulse Mode Duration	Fixed: 0.05 seconds
Duty Cycle	Pulse Mode: 50% Continuous Mode: 100%
Aiming Beam (2 mW)	YES
Audible Notification	YES
Visual Notification	YES
Power Requirements	110 - 120 VAC @ 60 Hertz 220 - 240 VAC @ 50 - 60 Hertz
Amperage	1.5 Amps @ 110 - 115 VAC 0.75 Amps @ 210 - 230 VAC
Cordless Foot Pedal	Frequency: 2.4 GHz Battery: 9 Volt Lithium
Operating Temperature	0 - 30°C / 32 - 86°F
Operating & Storage Humidity	5 - 95% RH

Delivery System Specifications

Quartz/Silica Fiber	1 Cartridge - approx. 20 ft (6 meters)
Fiber Diameter	400 microns
Retractable Fiber Delivery	Non-Autoclavable - 1
Handpiece	Autoclavable - 1
Handpiece Tips	Disposable: 20 (per box)
Laser Aperture	YES

Ordering Information

Accessories

Package of (20) Disposable Handpiece Tips- Straight	002-00181
Package of (20) Disposable Handpiece Tips- Angled	002-00182
20' Fiber Cartridge Replacement	002-00206
Protective Glasses - Solid	002-00202
Danger-Laser in Use Signage	002-00034
Handpiece- Autoclavable	002-00178
Fiber Stripper Tool	002-00205
Fiber Cleaver	002-00204
Power Supply & Cord	002-00207
Handpiece Locking Mechanism (Collet)	002-00262

Indications for Uses

The Precise® LTM is approved for use by properly trained and licensed dental professionals (as applicable) for use in the removal of lesions, excision, incision, vaporization, ablation, hemostasis, photocoagulation, gingivectomy, frenectomy, operculectomy, contouring, biopsy, troughing, ulcer care, abscess care, sulcular debridement, soft tissue curettage, and removal of inflamed edematous tissue on soft tissue in the oral cavity.

Warranty

Laser	2 Years Parts and Labor
Fiber and Cartridge	6 Months Parts and Labor
Accessories	90 Days Parts and Labor

SECTION 10: GLOSSARY OF LASER TERMINOLOGY

Activate - The action that prepares the laser to emit energy.
Active Medium - The core material of a laser that is responsible for producing a source of electromagnetic energy when activated by a power supply. They can be a gas, liquid dye, semi-conductor chip or a man-made rod of Yttrium, Aluminum Garnet Scandium or Gallium, or some combination of those elements.
Amplitude - The height of an electromagnetic wave as measured from the top of one wave to the lowest point on the next wave.
Articulating Arm - A device used to deliver radiant energy
Biopsy - A tissue sample removed from an area of questionable health. Used for examination and diagnosis of a disease.
Cleave - An act of scoring an optical fiber so that it separates into two pieces.
Coherent - A property of electromagnetic waves in which every wave is of the same wave length and is in phase with the other identical waves.
Collagen - The fibrous protein that is prevalent in bone, tendons, cartilage, and connective tissue.
Collimated - A characteristic of laser wave lengths where they travel in a parallel bundle and are slow to deviate.
Continuous Wave - A temporal mode where radiant laser energy is emitted constantly without interruption. Also known as (⎓).
Electromagnetic Components of Energy - Radiation consisting of electromagnetic waves where the vertical of the wave is the electrical phase and the lateral component is a magnetic phase. Laser light is electromagnetic energy.
Electromagnetic Waves - Time varying electric and magnetic fields propagating through space. They vary in their wave lengths and frequency.
Electromagnetic Spectrum - A combination of all electromagnetic radiation arranged by wave length and frequency. Light as we know it is from the visible portion of the spectrum.
Exposure - Introducing a tissue to laser energy as measured by the intensity of the power, the frequency, and time.
Frequency - The number of complete oscillations per second of an electromagnetic wave.
Joule - A unit of energy. Expressed as milliJoules when used in dental lasers operating in the pulsed mode. 1000 milliJoules per second equal 1 Watt.
Laser - An acronym for Light Amplification by Stimulated Emission of Radiation. Lasers are devices that utilize standard electricity from a wall outlet to stimulate an active medium which will produce electromagnetic energy that is collimated, coherent, and monochromatic.
LSO - Laser Safety Officer - individual in charge of laser safety, training, and equipment operation.
Micron - One millionth of a meter. It can also be stated as 10^{-6} meter.
Mode - A stable condition of oscillation in a laser. Lasers can operate is one or more modes.
Molecule - The smallest particle of a substance that retains the property of that substance. It is composed of one or more atoms.
Nanometer - A billionth of a meter and can also be expressed as 10^{-9}. Nanometers and microns are the primary measures of a wave length used in dental lasers.
Photon - A quantum (unit) of radiant energy. A particle of light.
Power (Output Power) - Expressed as Watts where 1 Joule per second equals 1 Watt.
Power Density - A measure of exposure of the power in Watts delivered per square millimeter or square centimeter.
Pulsed - (⎍) A temporal emission of laser energy that is distributed among periods where the laser is actively emitting (on) and periods of no emission (off). The time period when the laser is not emitting energy (off) is referred to as period of thermal relaxation and is designed to allow the tissue to cool between bursts of energy.
Quantum - The smallest unit of measure for radiant (light) energy.
Radiant Energy - The vertical component of electromagnetic waves as they travel through space. It is measured in Joules or milliJoules.
Spontaneous Emission - As an electron accumulates incident energy, it is elevated to a higher energy orbit where it will become unstable and must emit a photon.
Stimulated Emission - An external source of energy from a power supply stimulates the unstable electron to return to a more stable energy level by emitting an additional photon.
Velocity - The rate of speed of an electromagnetic wave as it travels through space.
Watt - The measure of power is Watts. As used in lasers, 1 Joule per second is equal to 1 Watt.

SECTION 11: REFERENCES ON LASER DENTISTRY

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PRECISE® LTM

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