

Lucerna

Instructions For Use (IFU)
Model VDL980-1

030-0001_D

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1. Introduction

The Viax Dental Lab LUCERNA model VDL980-1 diode laser is a surgical and therapeutic device at the cutting edge of technology; it is designed for a wide variety of oral soft tissue procedures, dental tooth whitening, and dental restorations requiring the photoinitiation (curing) of dental composite and adhesives.

The Viax Dental Lab LUCERNA model VDL980-1 laser utilizes solid state laser diodes as a semiconductor source for invisible infrared radiation as well as visible spectrum blue energy for material curing. The energy is delivered to the treatment site via flexible fiber connected at one end to the laser source(s) and the other end to the Handpiece. Various types of single use, disposable tips are designed and optimized for different applications and procedures.

The device is activated by means of a touch screen display and/or a footswitch. The Viax Dental Lab Lucerna Model VDL980-1 contains a 5-Watt 980nm Diode laser and a 1 Watt 450nm diode laser, focused into a small point at the treatment tip. For safety, the Viax Dental Lab Lucerna Model VDL980-1 features several ways to stop energy flow if the operator wishes to deactivate the Laser source. These include an emergency shutoff switch (on front panel), a power switch, a removable energy source (Battery). Any of these may be used to terminate power emissions from the Viax Dental Lab Lucerna Model VDL980-1 System.

The battery design and wireless technology used in the Viax Dental Lab Lucerna Model VDL980-1 allows the dentist or hygienist to transport the device between different operatories. The lightweight and durable chassis is designed to use a 110 - 220 Volt wall mounted power supply for recharging the battery. It further allows the practitioner the latitude to perform a thorough compliment of treatment procedures utilizing functional menus in the LCD display for all the functions available.

Training for the dental professional and staff is highly recommended and opportunities for such are available through VIAX Dental Lab continuing education programs, please visit our web site for training dates and locations at www.viaxdental.com. Training programs are also available through the Academy of Laser Dentistry, dental schools, and many dental continuums. You may also ask your authorized VIAX representative for the names of dentists in your area who have a laser or Viax Dental Lab Lucerna Model VDL980-1 and who could help you in a mentoring capacity. Proper training will allow for a thorough appreciation of the results than can be achieved with the Viax Dental Lab Lucerna Model VDL980-1 system and its many applications for use.

Safety is paramount in importance and each dental office should immediately develop and implement a safety program for the Viax Dental Lab Lucerna Model VDL980-1 and appoint a “safety officer” to be responsible for the use, operation, and maintenance of the Viax Dental Lab Lucerna Model VDL980-1. Their duties should include management of the Viax Dental Lab Lucerna Model VDL980-1 and all accessories as well as training of office personnel in all aspects of system safety.



WARNING: Always test fire the device outside the mouth before using it on a patient.



WARNING: Do not use in the presence combustibile or combustion supporting gases.



WARNING: The operating doctor or hygienist, the patient and any staff member present in the operatory should be wearing the appropriate safety eyewear whenever the Viax Dental Lab Lucerna Model VDL980-1 is being used. Strict adherence to protocols for safe use is essential.



WARNING: OPTICAL RADIATION SOURCE
Avoid direct eye exposure.
Avoid exposure to scattered beams without proper protective eyewear.

2. Viax Dental Lab Lucerna Model VDL980-1 Facility and Environmental Considerations (Americas)

In order to insure the safe use of the Viax Dental Lab Lucerna Model VDL980-1 in your facility, please check to make sure that the proposed location has the following:

Power Requirements:

100-240 VAC $\pm 10\%$ at 50/60 Hz

1.5 - 0,7 Amps

Frequency range 47 - 63 Hz

Heating and Ventilation:

The room where the Viax Dental Lab Lucerna Model VDL980-1 is used should have an appropriate cooling and heating system so that the laser can be operated within the optimal temperature range of 20° - 30°C (68° - 86° F). Avoid storing or transporting the laser in temperatures below 0° Celsius (32° F).

Lighting:

Overhead lighting and/or dental unit light should provide enough illumination to allow proper operator visibility of the surgical site when activating the Viax Dental Lab Lucerna Model VDL980-1 intra-orally.

Combustible Chemicals and Gases:

All gases that are combustible or support combustion and are used in the operatory area where the Viax Dental Lab Lucerna Model VDL980-1 is being operated 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. Do not use in the presence of supplemental therapeutic oxygen supplies for patients with respiratory or related diseases.

Plume evacuation:

Plume evacuation is a priority when vaporizing tissues. A high volume vacuum system should be used and high filtration masks that are suitable for virus and bacterial control should be worn by Clinicians, operators and auxiliary staff in the vicinity of procedures being performed with the Viax Dental Lab Lucerna Model VDL980-1 system.

Operatory Access during Viax Dental Lab Lucerna Model VDL980-1 Use:

Access to the treatment area should be restricted while the laser is in use. A sign indicating "Class IV Laser In Use" should be placed in a designated area adjacent to the treatment area entry location. A door interlock cable is available from VIAX as an accessory.

3. General Safety Information About The Viax Dental Lab Lucerna Model VDL980-1

General Safety Considerations:

Safe use of the Viax Dental Lab Lucerna Model VDL980-1 is the responsibility of the entire dental team including the doctor, system operators and the dental office safety officer. 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 and should be employed when using the Viax Dental Lab Lucerna Model VDL980-1 system. Dental professionals have also developed protocols and guidelines for laser on oral soft tissues, which should also be employed when using the Viax Dental Lab Lucerna Model VDL980-1 system. Sound judgment and the concern for patient safety should be a priority in all patient care.

Marketing Requirements Regarding Medical Device Safety (United States):

The United States Food and Drug Administration has influence over the use of the Viax Dental Lab Lucerna Model VDL980-1. 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 manufacturers of medical lasers and equivalent devices (such as the Viax Dental Lab Lucerna Model VDL980-1 system), additional review by the FDA of the safety and effectiveness of the device is required. Companies who intend to market a medical laser or equivalent device 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 existing legally marketed Class I and Class II devices.

Statutory Licensure:

Usually, states or provinces do not have a specific licensure requirement for use of a laser or equivalent device by a dentist. Most states require hygienists who will be using lasers or an equivalent device 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. Such training and licensure would be appropriate for use with the Viax Dental Lab Lucerna Model VDL980-1 system.

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OSHA Provisions (United States)

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 high-energy output lamps, 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. Viax Dental Lab recommends implementation of a Safety Program for the safety of your patients and office staff in connection with the use of the Viax Dental Lab Lucerna Model VDL980-1. Viax Dental Lab also recommends checking and complying with applicable state and provincial safety and health organization requirements.

Protective Eyewear:

While the Viax Dental Lab Lucerna Model VDL980-1 is in use, doctors, auxiliary staff, patients, and anyone attending them in the operatory must wear the appropriate safety eyewear that has been designed for use with the 980nm and 450nm wavelengths. Never point the Viax Dental Lab Lucerna Model VDL980-1 tip directly at the face, eyes or skin of anyone while emitting energy. The aiming beam is also capable of causing eye damage.

Emergency Shutdown Options:

ANY OF THESE MECHANISMS MAY BE USED TO SHUT DOWN THE EMISSION OF PHOTONIC ENERGY IN A REAL OR PERCEIVED EMERGENCY.

1. Touch the Red Lase indicator on the LCD touchscreen interface
2. Depress the emergency shutdown button
3. Foot Pedal – Remove your foot or other weight to stop emissions
4. Switch the Power switch to the “OFF” (O) position
5. Battery – Remove Battery from its compartment at rear of the Viax Dental Lab Lucerna Model VDL980-1 unit

4. Viax Dental Lab Lucerna Model VDL980-1 Installation and Setup

Instructions on Unpacking & Customer Service Assistance:

A VIAX customer service representative can provide assistance when you are ready to remove the Lucerna Model VDL980-1 from its shipping container. Please **do not attempt to unpack the Viax Dental Lab Lucerna Model VDL980-1 and install the various components without reading this section first**. If you are unsure about any aspect of the assembly, call your VIAX customer service representative for assistance.

Shipping Container Information:

The shipping container you received with your Viax Dental Lab Lucerna Model VDL980-1 was specially designed to safely transport the Viax dental Lab Lucerna Model VDL980-1. In the unlikely event that you need to return the Viax Dental Lab Lucerna Model VDL980-1 for service or repair, please retain the original shipping container.

Contents of Shipping Container:

THE CONTENTS OF THE SHIPPING CONTAINER SHOULD INCLUDE THE FOLLOWING:

- (1) Viax Dental Lab Lucerna Model VDL980-1
- (1) VDL980-1 laser Handpiece (Non Sterile)
- (1) Viax Laser Accessory Kit (Country Specific)
- (1) Fiber Optic Patch Cord (Whitening)
- (1) Viax Dental Lab Lucerna Model VDL980-1 Owner's Manual
- (1) Viax Dental Lab Lucerna Model VDL980-1 Instructions for Use (IFU)
- (1) Quick Start Guide
- (1) Laser Safety Sign
- (1) Warranty Information

Please check to insure that all items are accounted for.

5. Assembling the Viax Dental Lab Lucerna Model VDL980-1:

Each of the items listed below should be inspected and the instructions followed:



Power Adapter - Used for recharging battery.

Remove the power Adapter from the Viax Dental Lab Lucerna Model VDL980-1 package and insert the appropriate end into the receptacle on the back of the system. Then plug the power adapter into a 100/240 Volt AC outlet rated at 50/60Hz. To prevent power surges due to electrical storms or spikes in line voltage from damaging the Viax Dental Lab Lucerna Model VDL980-1 System, use a sufficiently rated surge protected power strip with a circuit breaker and unplug the Viax Dental Lab Lucerna Model VDL980-1 when you are not present. *Note: Battery is shipped in charged state and should be ready for use.*

Foot Pedal

A wired footswitch (or optional wireless footswitch) is available for use with the Viax Dental Lab Lucerna VDL980-1. The wireless footswitch is code matched to your Viax Dental Lab Lucerna Model VDL980-1 and is ready for use with the paired unit. *Note: The wireless footswitch uses a 9V battery that will require periodic replacement.*

Viax Dental Lab Lucerna Model VDL980-1 Remote Interlock (Installation and use optional) -

The Viax Dental Lab Lucerna Model VDL980-1 is equipped with a Remote Interlock Jack. The Remote Interlock Jack is provided so that a clinician may install the Viax Dental Lab Lucerna Model VDL980-1 in a dedicated treatment room where the Lucerna Model VDL980-1 is interlocked with the entrance door of the room. In an interlocked installation, the Viax Dental Lab Lucerna Model VDL980-1 will shut off anytime that the door is opened. While this type of installation is not facilitated in most dental operatories or clinics, the Remote Interlock is still available to any practitioner who desires it. The Remote Interlock Jack is located and clearly labeled on the rear of the Viax Dental Lab Lucerna Model VDL980-1. The mini-phono jack is wired in the normally closed position so that no special action is required to operate the Viax Dental Lab Lucerna Model VDL980-1 without the interlock loop. If the interlock loop is desired, you may purchase the loop from VIAX customer service. To install the loop, mount a (user-provided) switch on the operatory door and connect it to the Remote Interlock Jack on the Viax Dental Lab Lucerna Model VDL980-1. VIAX customer service can provide assistance if needed.



Power Switch -

The power switch for Viax Dental Lab Lucerna Model VDL980-1 is located on the rear of the chassis.

Operating Security Code (PIN) -

The Security Code (PIN) is required for operation of your Viax Dental Lab Lucerna Model VDL980-1. After placing the power switch in the "ON" position, the LCD touchscreen will illuminate, proceed to the second screen, you will notice keypad. Select the icons that you have set up on installation to enter the program for operating the Viax Dental Lab Lucerna VDL980-1. The Security Code will remain active as long as the system is powered and only needs to be set when the system is either shut down from the LCD touchscreen display, Power Switch, or battery Removal (or depletion).



**VIAX DENTAL LAB LUCERNA MODEL VDL980-1 ASSEMBLY
INSTRUCTIONS SUMMARY:**

1. Attach the Viax Dental Lab Lucerna Model VDL980-1 power adapter and place the plug into a 110/220VAC power source using a surge protector.
2. Locate the foot pedal in a location that is accessible and convenient for use.
3. Attach remote interlock (optional).
4. Place the Fiber optic patch cord and handpiece into the receptacle on the rear panel.
- 5.. Place the power switch in the “ON” position
6. Enter the Security code (PIN).
7. The user interface will advance to the Main Menu Screen.
8. The Viax Dental Lab Lucerna Model VDL980-1 will be in standby mode.

6. Viax Dental Lab Lucerna Model VDL980-1 Controls and Displays

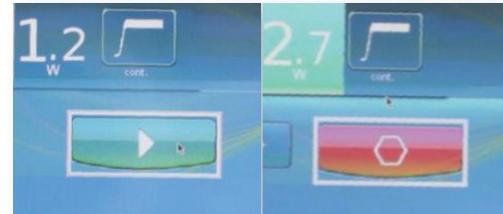


LCD Touchscreen Display (GUI):

Increase and Decrease: Use these to adjust the power settings from 0 to 5 watts. Hold the desired key to increase or decrease the power in 5% increments from 0% to 100%

Emitted radiation On (Laser):

The display indicator will go from Green to RED on the power setting screen when the GUI button or foot pedal is depressed. This indicates that the working beam energy is being emitted.



Continuous and Pulse Mode:

This illuminates to display when the unit is in continuous or pulse mode. Use the MODE key to toggle back and forth between Continuous and Pulse. Note: The pulse mode is indicated when the Hz indicator is illuminated. *Note: In CW operation the power setting is indicated on the display (indicated as actual power); in the pulse mode the pulse rate is displayed as a percentage of the duty cycle.*

Aiming Beam:

The Viax Dental Lab Lucerna Model VDL980-1 provides a visible (Blue) light that illuminates the direction where the working beam will be used, allowing the operator to aim during the working beam during activation.

7. Viax Dental Lab Lucerna Model VDL980-1 Operation and Use

Operating Modes:

The Viax Dental Lab Lucerna Model VDL980-1 will deliver energy in either continuous wave (CW) or pulsed modes, which are called temporal emission modes (time related modes). Selection of the appropriate mode will allow the operator to optimize control of target tissue temperatures and the efficiency of energy delivered. The pulse duration (.1 seconds) and the number of pulses per second (10) have been fixed by the manufacturer using a adjustable duty cycle and the operator will therefore need to adjust only the power and mode.

Continuous Wave (CW) Mode:

The CW mode is generally the fastest way to ablate tissues but heat can build up and cause collateral damage to adjacent tissues. Cool the tissues being treated by using periodic blasts of air from a triplex syringe and high-speed suction. You may also use water to cool in areas where there is prolonged exposure to the Viax Dental Lab Lucerna Model VDL980-1's beam. Avoid using the air syringe when you have an opening in soft tissue adjacent to or within the surgery site as an air embolism may occur as a result of air captured within the tissue during the cooling process.

Pulsed Energy Mode:

Pulsing the laser energy will allow some cooling of the tissue between emissions of energy. The “duty cycle” is the percentage of the time 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 Viax Dental Lab Lucerna Model VDL980-1 is programmed to deliver 10.0 equal pulses per second with a duty cycle of 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.

Tissue Responses to Photonic Energy:

Maximum results will be achieved by regulating the power and the speed that the operator moves the therapy 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 that is required to complete your procedure. The ideal tissue response will show little or no discoloration after treatment and there will be less residual damage and faster healing. Avoid penetrating or

damaging the periosteum, and do not attempt to use the laser on alveolar bone. Because the photonic energy is attracted to melanin and hemoglobin, power must be reduced when treating patients with darker soft tissue. Always begin with the lowest power you can use to remove or modify the target tissues.

Handpiece and therapy tip care:

The handpiece is delivered as new clean material in NON STERILE condition. It must be High Level Disinfected prior to use. High Level Disinfection instructions are provided in the Viax Dental Lab Lucerna VDL980-1 user manual. The procedure tips are delivered as NON Sterile single use product.

Do not continue to use the therapy tip once you have observed that the therapy tip has a blackened appearance that is greater in length than 2-4 mm. The protein debris of gingival tissue accumulates on the tip during surgery and retains extreme heat that can cause rapid tip deterioration. This is especially important when using the Viax Dental Lab Lucerna Model VDL980-1 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. Do not use the sponge while the tip is hot.

Setting Parameters:

Review your power and mode requirements and then depress the mode button to select either Continuous (CW) or pulsed mode operation. The mode you have selected will be displayed just below the display screen and will be designated by a small light in the corner of either the pulse or CW panel display.

Select your power by pressing the up or down arrow until you have reached the desired level. Beginning with a low of 50% of the deliverable power range, the power increases in increments of 5% to a maximum power of about 3.0 Watts (CW).

Hard Tissue Procedures:

The Viax Dental Lab Lucerna Model VDL980-1 is not indicated for hard tissue procedures. The Viax Dental Lab Lucerna Model VDL980-1 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.

8. Viax Dental Lab Lucerna Model VDL980-1 Recommended Procedural Guidelines

Test Firing the Viax Dental Lab Lucerna Model VDL980-1:

Always test-fire The Viax Dental Lab Lucerna Model VDL980-1 prior to using it intra-orally. Using a power of 50% continuous wave, place the Viax Dental Lab Lucerna Model VDL980-1 in the ready mode. Then, activate for 1-2 seconds while aiming the therapy tip 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.

Viax Dental Lab Lucerna Model VDL980-1 Use:

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. Release the foot pedal and use a clean 2 X 2 gauze sponge wetted with water to remove debris from the therapy tip. Do not use flammable liquids to wet the sponge.

Place the Viax Dental Lab Lucerna Model VDL980-1 in Standby Mode until you are ready to start another procedure.

Record the Powers and total procedure times used for each procedure in the patient's chart. For example:

Patient Name: Jane Doe

Procedure: Gingivectomy # 6 and # 7

#6 procedure time 90 seconds @ 2.0 Watts CW air cooled

#7 procedure time 60 seconds @ 1.5 Watts CW air / water spray

Gingival Contouring with the Viax Dental Lab Lucerna Model VDL980-1 System:

Tip: Initiated 1mm

Mode: Continuous Wave

Power: 50% (TBD may revise)

Anesthesia: Local, as required

Technique: Contact

1. After anesthesia is profound, insert a periodontal probe into the sulcus down to the crest of the bone.
2. Measure that depth from the crest of the gingiva to the bone. Note that reading and reduce it by 2.5 mm.
3. Make a stick mark in the facial gingiva at a point 2.5 mm above the crest of the bone.
Always leave 2.5 mm or more of gingival tissue above the crest of the bone when performing a crown lengthening procedure, so as to not infringe upon the biological width of the tooth.
4. Angle the tip slightly toward the incisal and make a series of 2-3 mm quick strokes with the fiber tip as you remove tissue and establish the new line for the crestal gingiva.

Gingivectomy with the Viax Dental Lab Lucerna Model VDL980-1 System:

Tip: Initiated 1mm

Mode: Continuous Wave

Power: 1.2W (nom) or as required

Anesthesia: Local, as required

Technique: Contact

1. Using a periodontal probe, record the depth of the pocket to be treated and evaluate its condition, either acute or chronically inflamed.
2. If there is no apparent exudate present, use the periodontal probe to define the height of contour that is to be established.
3. With the patient anesthetized, carefully place a stick mark along the facial aspect of the gingiva to create a reference for the incision path.
4. With the therapy tip angled slightly toward the occlusal or incisal, remove the diseased tissue down to the previously marked incision line.
5. If necessary to achieve desired results, increase power level but always use the lowest amount of power necessary to reach the treatment objectives and avoid charring of tissue.
6. Taper and festoon the crestal gingiva as needed and then quickly remove the diseased epithelium and restore anatomical contour.
Note: Remember to avoid touching the root whenever possible and move quickly while near the bone or root.
7. Flush the pocket using a warm saline solution or hydrogen peroxide.
8. Record powers used and treatment times in the patient's chart.

Gingival Troughing with the Viax Dental Lab Lucerna Model VDL980-1 System:

Tip: Initiated 1mm

Mode: Continuous Wave

Power: 1.2W (or as required)

Anesthesia: Topical or Local, as required

Technique: Contact

1. Following preparation of the tooth, cleanse the area with H₂O₂ and then rinse with a light spray of water.
2. Air dry with low volume flow of air.
3. Lightly contact the sulcus lining just inside the crest of the gingival angling the tip away from the tooth.
4. Using very light pressure, begin emitting as you make small paint brush like strokes tracing the area of the tooth that needs to be exposed or where the restoration margins are not completely visible.
5. If necessary to achieve desired results, increase power level but always use the lowest amount of power necessary to reach the treatment objectives and avoid charring of tissue.
6. Create a small trough between the tooth and gingiva. This will allow you to achieve a high quality optical image, scan or impression.
7. You may also choose to recontour abnormal gingival tissue to achieve better esthetics in a fraction of the time with greater precision for outstanding results.

Sucular Debridement with the Viax Dental Lab Lucerna Model VDL980-1 System:

Tip: Initiated 0.4mm Debridement Tip

Mode: Continuous Wave

Power: 50% (TBD may revise)

Anesthesia: Topical or Local, as required

Technique: Contact

Time: 30 seconds

1. After conventional instrumentation has been completed, insert the fiber tip to the full pocket depth.
 2. Gently probe the pocket to get a sense of its geometry.
 3. Begin to emit photonic energy the diseased epithelial lining.
 4. If necessary to achieve desired results, increase power level but always use the lowest amount of power necessary to reach the treatment objectives and avoid charring of tissue.
 5. Keep the therapy tip parallel to the root surface or tilted slightly toward the gingival tissue during treatment in order to maximize ablation of the inflamed tissue.
 6. While keeping the therapy tip in contact with the epithelium, move the therapy tip in both horizontal and vertical directions, covering the epithelium and adjacent inflammatory connective tissue. Move the tip smoothly and at a moderate speed. Debride all granulation tissue.
- You may use a fine water spray during laser treatment for rinsing.
 - Remove plume and debris with the high volume evacuation.
 - The total amount of time for this procedure is a function of the extent of the diseased soft tissue. In general, treat pockets 6 millimeters or less for approximately 30 seconds and pockets greater than 6 millimeters for 45 seconds.
 - If the patient experiences noticeable discomfort, lower the power setting.
 - Anesthetic may be administered as required.

Labial Frenectomy with the Viax Dental Lab Lucerna Model VDL980-1 System:

Tip: Initiated 1mm

Mode: Continuous Wave

Power: As deemed necessary

Anesthesia: Local, as required

Technique: Contact

1. Place tension on the frenum by retracting the lip or cheek.
2. Beginning at the base of the attachment to the gingival tissue, make an incision with the Laser that is perpendicular to the length of the frenum.
3. If necessary to achieve desired results, increase power level but always use the lowest amount of power necessary to reach the treatment objectives and avoid charring of tissue.
4. Using continued tension, extend the incision until you are nearing the periosteum.
Note: Do not cut into or damage the periosteum.
5. The incision may need to extend laterally when there is a wide attachment.
6. Wipe the debris from the hard and soft tissues using hydrogen peroxide or warm saline solution.
Note: Sutures are usually not required.

Biopsy with the Viax Dental Lab Lucerna Model VDL980-1 System:

Tip: Initiated 1mm

Mode: Continuous Wave

Power: As deemed necessary

Anesthesia: Local, as required

Technique: Contact

1. Depending on the location of the lesion, establish a perimeter around the lesion that is 2mm+ outside its border.
2. If necessary to achieve desired results, increase power level but always use the lowest amount of power necessary to reach the treatment objectives and avoid charring of tissue.
3. Grasp the lesion with the beaks of a hemostat or tissue forceps and pull the lesion away from its base.
4. With the laser tip contacting the tissue at the base of the lesion, activate the laser as you make an incision to remove the lesion.
5. Limit the amount of power you use and move in quick strokes of 2-3 mm each so that you do not accumulate excessive energy.
6. Place the lesion in a specimen bottle and send it to a diagnostic lab.

Note: If you have maintained the 2mm boundary around the lesion, the pathologist should be able to compare the healthy tissue with the diseased specimen.

9. Electromagnetic Compatibility



CAUTION: Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the following tables.

Portable and mobile Radio Frequency (RF) communications equipment can affect medical electrical equipment.

Accessories: Medical grade power cord, maximum length 3ft (1 meter)



WARNING: The use of accessories, other than those specified, except those supplied or sold by Viax Dental Lab as replacement parts for internal or external components, may result in increased EMISSIONS or decreased IMMUNITY of the Viax Dental Lab VDL980-1 diode laser system.

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS

The Viax Dental Lab VDL980-1 diode laser is intended for use in the electromagnetic environment specified below. The customer or the user of the laser should assure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions	Group 1	The Viax Dental Lab Lucerna VDL980-1 diode 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.
CISPR 11 RF emissions CISPR 11	Class A	
Immunity test Electrostatic discharge (ESD) $\pm 6k$	Class A	The Viax Dental Lab Lucerna VDL980-1 diode 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.
Voltage fluctuations/ flicker emissions $\pm 8k$ IEC 61000-3-3	Class A	

10. Guidance and Manufacturer’s Declaration – Electromagnetic Immunity

The Viax Dental Lab Lucerna VDL980-1 laser is intended for use in the electromagnetic environment specified below. The customer or the user of the Viax Dental Lab Lucerna VDL980-1 diode laser should assure that it is used in such an environment.

NOTE: Ur is the A.C. mains voltage prior to applications of the test level.

The Viax Dental Lab Lucerna VDL980-1 is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Continuous level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 GHz	3 V 3Vm	Portable and mobile RF communications equipment should be used no closer to any part of the Viax Dental Lab Lucerna VDL980-1, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3Vm 80 MHz to 2.5 GHz		

Recommended separation distance

$d = 1.2\sqrt{P}$

$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz

$d = 2.3\sqrt{P}$ 800MHz to 2.5GHZ

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 meters (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 (cellular/cordless) telephone 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 Viax Dental Lab Lucerna VDL980-1 is used exceeds the applicable RF compliance level above, the Viax Dental Lab Lucerna VDL980-1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Viax Dental Lab Lucerna VDL980-1.

B. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

11. Recommended Separation Distances Between Portable And Mobile Rf Communications Equipment

The A. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephone 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 Viax Dental Lab Lucerna VDL980-1 is used exceeds the applicable RF compliance level above, the communications equipment (transmitters) and the Viax Dental Lab Model VDL980-1 diode 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		
	150kHz to 80Mhz	80 MHz to 800 MH	800 MHz to 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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.

12. Wireless Equipment Compliance Statement:

This statement applies only to the wireless portion of the device:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- *Reorient or relocate the receiving antenna.*
- *Increase the separation between the equipment and receiver.*
- *Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.*
- *Consult the dealer or an experienced radio/TV technician for help.*



CAUTION: Federal Law restricts this device to sale by or on the order of a dentist or physician or other licensed medical practitioner

NOTES



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