

# Sapphire<sup>®</sup>



PORTABLE DIODE LASER

CE 0459



## Sapphire<sup>®</sup> Portable Diode Laser Instructions for Use

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**MANUFACTURER INFORMATION**

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## 1. INTRODUCTION

The Sapphire® Portable Diode Laser unit is a dental soft-tissue laser surgical/debridement device. The Sapphire Portable Diode Laser may be used for a variety of soft-tissue, gingival modification, and sulcular therapy procedures.

Dental professionals and staff who will use the Sapphire Portable Diode Laser should receive proper laser use training prior to patient treatment with these devices. Applicable training programs for dental Laser use are available through the Academy of Laser Dentistry, dental schools, and many dental continuums. Your authorized Den-Mat Holdings, LLC Representative can also provide the names of local dentists who have a Sapphire Portable Diode Laser and may be able to provide additional guidance for new Sapphire Portable Diode Laser users.

Safety is paramount when using any energy-based surgical instrument and your office should implement a safety program for the Sapphire Portable Diode Laser. If your office does not already have a safety officer, one should be appointed to be responsible for understanding proper use, safe operation, and maintenance of the Sapphire Portable Diode Laser system. Their duties should include training office personnel in all aspects of system safety and management of the Sapphire Portable Diode Laser and all accessories.

### **Manufacturer's Laser Identification, output and standards label**

The Sapphire Portable Diode Laser carries the Manufacturer's identification label affixed to the bottom panel of the Control Module.

**MODEL: Sapphire® Portable Diode Laser**

**MODEL NO.: 033981000-0**

**MANUFACTURED BY: DEN-MAT HOLDINGS, LLC. SANTA MARIA, CA 93455 USA**

**LASER CLASSIFICATION: (PER IEC 60825-1): Class 4**

**MAXIMUM LASER OUTPUT: 3W Continuous Wave, 5W Pulsed**

**FREQUENCY IN PULSED MODE: Fixed, 10 Hz**

**PULSE DURATION: 0.05 seconds**

**WORKING BEAM WAVELENGTH: 808 nm ( $\pm 5$ nm)**

**POWER INPUT: 15W, 5 VDC supplied from 110 - 120 VAC**

**@ 60 Hz, or 220 - 240 VAC @ 50 Hz**

**COMPLIES WITH IEC 60601-1, 60601-2-22; IEC 60825-1; IEC 60601-1-2,  
CLASS B PER IEC 60601-1-2.**

## 2. WARNINGS AND CAUTIONS



Warning: Visible and Invisible Laser Radiation – Avoid eye or skin exposure to direct or scattered radiation

CLASS 4 Laser Product

Above Warning is affixed to the front panel of the Sapphire Portable Diode Laser Control Module.



LASER APERTURE  
at the end of handpiece

Above Warning is affixed to the cover overhanging the power/communications cord receptacle.



Warning: Laser Safety Eye Protection **MUST BE WORN** by the Operator, Patient, Assistant, and anyone present when the laser is activated. Eye Protection must conform to Specification DIN EN207 Annex II of the Directive 89/686/EEC with optical density in 800nm-818nm of OD 4+ such as NoIR Laser Company filter model DII



Warning: Do not use in the presence of combustible or combustion supporting gases



Warning: Do not use in the presence of supplemental therapeutic oxygen supplies



Warning: Always test activate the device outside the mouth before using on a patient.

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

### **Emergency Termination of Laser Emissions:**

The Sapphire® Portable Diode Laser has been designed with several methods to terminate emission of Laser energy if the operator wishes to deactivate the system in an emergency situation. These include an emergency shutoff switch, a key switch, a power switch, and pressing the READY button on the control pad. Any of these may be used to terminate laser emissions from the Sapphire Portable Diode Laser System.

## **3. SAPPHIRE PORTABLE DIODE LASER INDICATIONS FOR USE**

The Sapphire Portable Diode Laser is indicated for use in dental intraoral soft tissue general, oral maxilla-facial and cosmetic surgery including ablating, incising, excising, vaporizing and coagulation of soft tissues using a fiber optic delivery system. Indications include:

- Excision and incision biopsies
- Hemostatic assistance
- Treatment of apthous ulcers
- Gingival incision and excision
- Gingivectomy
- Gingivoplasty
- Gingival troughing
- Gingival recontouring
- Tissue retraction for impressions
- Oral papillectomy
- Sulcular debridement
- Sulcular tissue removal
- Removal of granulation tissue
- Frenectomy
- Frenotomy
- Abcess incision and draining and excision
- Operculectomy
- Removal of fibromas
- Soft tissue crown lengthening
- Vestibuloplasty

General guidelines for some of these procedures may be found in section 9 of this user instruction manual. In addition to receiving proper training in the use of dental Lasers, users should be familiar and experienced with these procedures using electrosurgical devices or traditional instruments before performing them on patients with the Sapphire Portable Diode Laser. Non-experienced users should seek appropriate training or guidance before attempting clinical treatments with the Sapphire Portable Diode Laser system.

## 4. SAPPHIRE PORTABLE DIODE LASER FACILITY AND ENVIRONMENTAL CONSIDERATIONS

In order to insure the safe use of the Sapphire Portable Diode Laser in your facility, please check to make sure that the proposed location is compatible with the specifications listed below.

Power requirements for the Sapphire Portable Diode Laser follows:

Input Power - 110 – 120 V AC @ 60 Hz, 3A; 220-240 V AC @ 50 Hz, 1.5A (switchable)

Output Power - 24W, +5 V DC at 6A maximum

### Heating and Ventilation:

The room where the Sapphire Portable Diode Laser is used should have an appropriate cooling and heating system so that the lasers can be operated within the optimal temperature range of 20° - 30°C (68° - 86° F). Avoid storing or transporting the lasers 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 Sapphire Portable Diode Laser intra-orally.

### Combustible Chemicals and Gases:

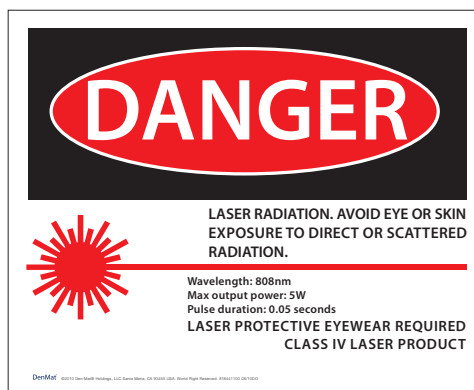
All gases that are combustible or support combustion and are used in the operatory area where the Sapphire Portable Diode Laser is being operated must be turned off during the procedure. Cleaning supplies or other flammable chemical compounds should be stored in an area away from the surgical site in 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 should be addressed when vaporizing tissues. A high volume vacuum system should be used and 0.1 micron or less 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 Sapphire Portable Diode Laser system.

### Operatory Access during Sapphire Portable Diode Laser Use:

Access to the treatment area should be restricted while the lasers are in use. A sign indicating "LASER IN USE" should be placed in a designated area adjacent to the treatment area entry location.



## **5. GENERAL SAFETY WITH THE SAPPHIRE® PORTABLE DIODE LASER**

### **General Safety Considerations:**

Safe use of the Sapphire Portable Diode Laser is the responsibility of the entire dental team including the doctor, any system operators and the dental office safety officer. Protocols for the safe use of Lasers have been developed by medical and dental professionals, scientists and laser manufacturers. These protocols should be followed when using the Sapphire Portable Diode Laser system. Dental professionals have also developed protocols and guidelines for Laser use on oral soft tissues which should be employed when using the Sapphire Portable Diode Laser system. Den-Mat® Holdings, LLC recommends implementation of a safety program for the safety of your patients and office staff in connection with the use of the Sapphire Portable Diode Laser. Den-Mat Holdings, LLC also recommends checking and complying with applicable local safety and health organization requirements.

### **Conformance to Medical Device Regulations**

The Den-Mat Holdings, LLC Sapphire Portable Diode Laser is in conformity with the Essential Requirements spelled out in the Medical Device Directive (MDD), 93/42/EEC, dated 14 June 1993 as amended by Directive 2007/47/EC.

The device follows the conformity assessment procedure for CE marking described in Annex II, point 3 (Full Quality Assurance) of the MDD.

Den-Mat Holdings, LLC's Notified Body is LNE/G-MED, number 0459.

The Company's Authorized Representative to the European Community is:

GLS GLOBAL LEGAL  
16, boulevard Saint-Germain  
75005 PARIS, FRANCE



**Eye and Skin Protection:**

While the Sapphire Portable Diode Laser is in use, doctors, system operators, auxiliary staff, patients, and anyone attending them in the operatory must wear the appropriate safety eyewear that has been designed for use with the 700-plus nm wavelengths associated with Lasers. Eye Protection must conform to Specification DIN EN207 Annex II of the Directive 89/686/EEC with optical density in 800nm-818nm of OD 4+ such as NoIR Laser Company filter model DI1.

Nominal Ocular Hazard Distance (NOHD) is the distance from the source of laser emission to the point where it no longer exceeds its Maximum Permissible Exposure (MPE – highest level of laser radiation to which a person may be exposed without hazardous effects or adverse biological changes in the eyes or skin). The Nominal Hazard Zone (NHZ) is the space within which the level of direct, reflected, or scattered radiation during normal operation exceeds the appropriate MPEs. The outer limit of the NHZ is equal to the NOHD. The NOHD for persons wearing recommended safety glasses is shown in Table 1 below.

Radiation Source	MPE mW/cm <sup>2</sup>	Divergence Angle	NOHD (inches/cm)	
			Without eye protection	With Recommended Eye Protection
Fiber Optic Tip (direct)	1.66	9° (± 1°)	155/393.7	1.55/3.94
Reflected from tissue	1.66	n/a	0.25/0.63	0.0025/0.0063

Table 1 NOHD

Never point the Sapphire Portable Diode Laser tip directly at the face, eyes or skin of anyone while emitting energy.

**Emergency Shutdown Options:**

Perform any of these actions to terminate laser emissions in the event of a real or perceived emergency:

1. Release the handpiece activation button.
2. Depress the emergency “STOP” button.
3. Remove your foot from the foot switch.
4. Turn the key counterclockwise to the “OFF” position.
5. Switch the power switch to the “OFF” (O) position.
6. Press the READY button to go to Standby mode.

**6. SAPPHIRE PORTABLE DIODE LASER INSTALLATION AND SETUP**

**Instructions on Unpacking & Customer Service Assistance:**

A Den-Mat Holdings, LLC Authorized Distributor can provide assistance when you are ready to remove the Sapphire Portable Diode Laser from its shipping container. Please do not attempt to unpack the Sapphire Portable Diode Laser and install or setup the unit without reading this section first. If you are unsure about any aspect of the assembly, call your Den-Mat Holdings, LLC Authorized Distributor for assistance.

### **Shipping Container Information:**

The shipping container you received with your Sapphire® Portable Diode Laser was specially designed to safely transport the Laser. In the unlikely event that you need to return the Laser for service or repair, please retain the original shipping container.

#### **Contents of Sapphire Portable Diode Laser Shipping Container:**

The contents of the shipping container should include the following:

- Sapphire Portable Diode Laser Control Module with Laser Handpiece
- AC/DC Power Converter
- Laser Operating Key
- Fiber Optic Tips, 400 µm/5 pc
- Single-use Barrier Sleeves for Handpiece 25 pc
- Protective Glasses 3 pc
- Safety Sign
- Sapphire Portable Diode Laser Instructions
- Warranty Information

Please check to insure that all items are accounted for.

### **Installing the Sapphire Portable Diode Laser:**

Each of the items listed below should be inspected and the instructions followed. Use of any cables or accessories other than those provided by Den-Mat Holdings, LLC may damage the device and may result in increased RF emissions or decreased immunity of the equipment.

Sapphire Portable Diode Laser control module – Plug the AC/DC Power Converter into the wall outlet and attach the small, low-voltage plug to the jack on the rear of the Control Module.

Power Switch – The power switch for the Sapphire Portable Diode Laser is located on the rear panel of the Control Module. This switch must be in the “ON” position when the Sapphire Portable Diode Laser unit is to be used.

Sapphire Portable Diode Laser Handpiece – When the operating key is turned on, the Sapphire Portable Diode Laser unit will default to STANDBY status, indicated by 0.8 showing in the LASER POWER display and the CW icon glowing green.

Operating Key Switch – In order to operate the Sapphire Portable Diode Laser unit, the Laser Operating Key must be inserted into the key switch in the Sapphire Portable Diode Laser Control Module and turned clockwise to the “ON” position to place the unit in STANDBY status. Prior to leaving the office, your safety officer should check to see that the key switch has been turned off, removed and stored in a safe place.

Footswitch (optional) – A footswitch may be purchased, if desired. To use, insert the plug into the jack on the side of the Control Module. When the footswitch is attached, the Handpiece ON/OFF button will not function and the footswitch controls the working beam’s emission.

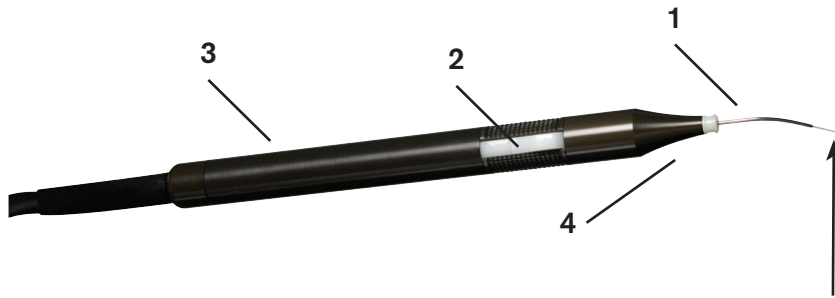
**Sapphire Portable Diode Laser Assembly Instructions Summary:**

1. Plug the Power Converter into the wall outlet and the low voltage plug into the jack on the rear of the Control Module.
2. Switch the Power Switch on the Control Module to "ON."
3. Insert the Operating Key into the key switch on the Control Module and turn the switch to the "ON" position.
4. Attach the foot switch (optional)
5. The display on the Sapphire Portable Diode Laser unit will show the default output 0.8 W in the CW Mode. The CW icon will glow green.
6. If the battery power level for the Sapphire Portable Diode Laser unit is low (identified by a blank "LASER POWER" display and a red Battery Indicator), the unit will need to charge its batteries before use. Wait until the Battery Indicator has turned to green, indicating that the batteries are fully charged.

## 7. SAPPHIRE® PORTABLE DIODE LASER CONTROLS AND DISPLAYS

### Sapphire Portable Diode Laser Handpiece:

The Sapphire Portable Diode Laser Handpiece includes the components and functions as shown below:



Avoid Exposure-Laser Radiation is emitted from this aperture

### Sapphire Portable Diode Laser Handpiece Components

1. Removable, Disposable single-use Tip
2. ON/OFF Actuator Switch
3. Main Handle Barrel of Handpiece
4. Collar for Removable Tip
5. Sanitary, disposable single-use Barrier Sleeve (not shown).

### Sapphire Portable Laser Control Panel:

The Sapphire Portable Laser Control Panel has the following features and control functions:

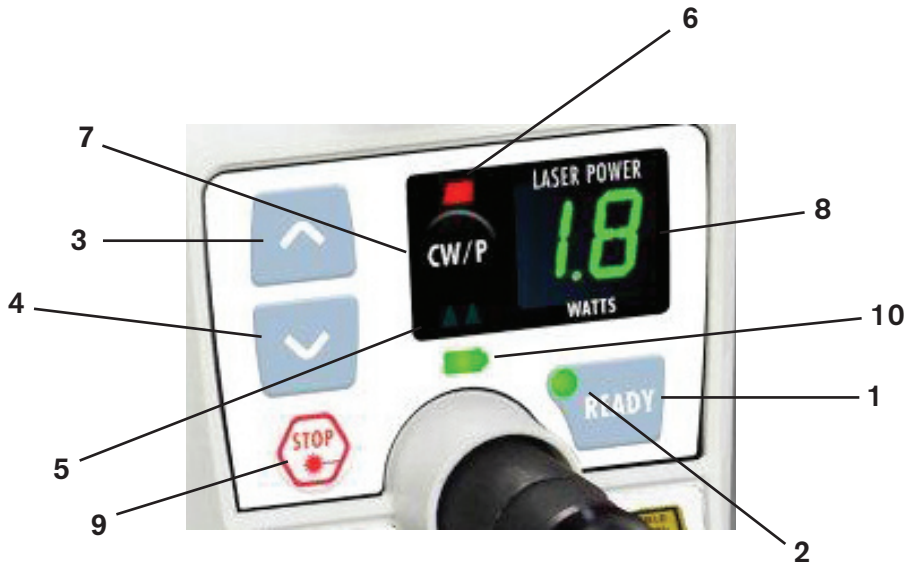





Figure 1

1. "READY" Button
2. "READY" Indicator Light
  - Green in "READY" status
  - Unlit in "STANDBY" status
3. "UP" adjustment for Laser Power
4. "DOWN" adjustment for Laser Power
5. "PULSE"  mode indicator
6. "CW" (CONTINUOUS WAVE)  mode indicator (glowing RED, indicating working beam firing)
7. "CW/P" (CONTINUOUS WAVE/ PULSE) Mode Toggle Button
8. Laser Power Level Indicator
9. "STOP" (LASER EMERGENCY STOP) Button
10. Battery power level indicator

### **Sapphire® Portable Diode Laser Power Level Adjustment:**

Power can be adjusted by using the UP and DOWN arrow keys to increase (UP) or decrease (DOWN) the power setting. The power level setting will be displayed by the Laser Power Level Indicator. Upon initial power-up, the unit defaults to the CW mode and the CW icon  on the control panel glows green. The power setting will default to 0.8 Watts and will be displayed in the LASER POWER window.

### **Continuous Wave and Pulse Mode:**

Continuous Wave (CW) or 10 Hz Pulse modes for Laser power delivery may be selected by pressing the “CW/P” toggle key. The icon for the selected mode will glow green.

### **READY Activation of Sapphire Portable Diode Laser Unit:**

Press the READY button in either CW or PULSE to change from STANDBY to READY status and prepare the unit for Laser activation. The LED embedded on the READY button will glow green indicating that the Laser is in “READY” status. Changing the mode or power level releases the unit from “READY” status requiring the user to select the new setting by pressing the READY button again. Settings may not be changed when the laser is activated. Pressing the READY button without changing the Laser power level or mode toggles the system back to STANDBY status.

When the unit is placed into READY mode, the LED in the READY button glows green, offering a visual indication that the unit is READY to fire the working beam.

### **Target-Indicating Device**

The disposable Fiberoptic Tips point to where the Laser working beam will perform its surgical or therapeutic purpose and, therefore, functions as the Sapphire Portable Diode Laser’s target-indicating device.

### **Laser Activation and Laser “ON” Indication:**

The Sapphire Portable Diode Laser working beam can be activated using either the handpiece ON/OFF actuator or the (optional) footswitch, but not both at the same time. If the footswitch is installed, it overrides the handpiece ON/OFF switch. Unplug the footswitch from the Sapphire Portable Diode Laser Control Module if it will not be used.

When the Sapphire Portable Diode Laser is in READY and the ON/OFF button on the Handpiece is held down, or the footswitch is depressed and held down, the active mode icon will turn from GREEN to RED and an audible “chirp” will be heard, indicating that the laser working beam has been activated. After a 100 micro-second delay, the Handpiece will begin delivering laser working beam emissions to the target tissue by means of the disposable 400 micrometer fiberoptic delivery tip. Releasing the Handpiece ON/OFF button or the footswitch will immediately terminate the working beam’s emission.

#### **EMERGENCY DEACTIVATION OF LASER:**

The Sapphire Portable Diode Laser may be deactivated at any time by pressing the Emergency “STOP” button (Page 13, #9, Figure 1). This action deactivates the unit function in any mode, at any power setting, and whether or not Laser power is activated.

Other means of terminating laser working beam emissions:

1. Release the handpiece activation button
2. Depress the emergency “STOP” button
3. Remove your foot from the Foot Switch
4. Turn the key counterclockwise to the “OFF” position
5. Switch the Power switch to the “OFF” (O) position
6. Press the READY button to go to Standby mode.

To reset the unit for use, depress and hold down the “STOP” button for 5 seconds.

#### **Remote Door Interlock Jack (Door Interlock Switch not included)**

The Sapphire Portable Diode Laser footswitch jack doubles as a remote interlock jack when the ‘Y’-shaped bifurcated door interlock cord (not provided) is installed. This feature enables a clinician to establish a separate laser treatment room with an entrance door that is electronically wired to the Sapphire Portable Diode Laser. When the remote interlock is installed, the laser will turn off anytime the door to the room is opened, hypothetically to protect the eyes of the person entering the room. Without the remote interlock installed, the Sapphire Portable Diode Laser will operate normally.

To use the remote interlock feature, an interlock loop will need to be purchased from a local electronics store. Call your Den-Mat Holdings, LLC Authorized Distributor for a list of parts needed to install the remote door interlock switch. Install the switch on the door and plug the jack into the end of the bifurcated cord marked ‘Remote Door Interlock.’ Plug the male end of the Y-shaped cord into the Sapphire Portable Diode Laser footswitch jack.

If you intend to use the optional footswitch to control the Sapphire Portable Diode Laser, plug the footswitch cord into the end of the door interlock cord marked ‘Footswitch.’

If you don’t require this feature in your operatory and you wish to control laser emissions with the optional footswitch, the footswitch jack can be inserted directly into the footswitch jack without use of the ‘Y’-shaped bifurcated door interlock cord. Call your Den-Mat Holdings, LLC Authorized Distributor if you’d like to receive this connector to use the door interlock feature.

### **Portability of the Sapphire® Portable Diode Laser:**

The Sapphire Portable Diode Laser does not need to be attached to the wall outlet to function. A rechargeable lithium-ion battery powers the Sapphire Portable Diode Laser. When fully charged, the Sapphire Portable Diode Laser can be operated for up to 40 minutes, for most procedures, before needing to be recharged. So, the Sapphire Portable Diode Laser can be taken from operator to operator as needed. (Be certain that all safety considerations are followed wherever the Laser is operated, including protective glasses for operator, assistants, and patients as well as signs warning others that laser procedures are taking place.)

### **Battery Power Level Indicator:**

If the battery charge drops below 3.4V, the Battery Power Indicator will change from green to amber. This is usually not cause for concern unless the unit is intended to be used for an especially extended procedure (greater than 40 minutes), particularly if the procedure requires for the laser to be operated in the continuous wave mode at outputs greater than 2.0W. If the battery is discharged below 2.5V, the Battery Power Level Indicator changes from amber to red. This indicates that very limited power remains and that the Laser should be reconnected to the Power Converter and recharged before using. If the battery continues to discharge, “E 4” will appear in the Laser Power display window and the READY LED will flash red, indicating that there is not enough power to initiate lasing. The unit will need to be plugged into the wall outlet and allowed to recharge before it can be used.

### **Error Codes:**

- E 1 – Output power Not in Calibration: Exceeds  $\pm 20\%$  of indicated output
- E 2 – Over temp; Diode base temperature  $>50\text{ }^{\circ}\text{C}$
- E 3 – Low battery; Recharge or replace battery (Battery indicator RED)
- E 4 – No power; No output or drive current (READY LED blinks RED, too)
- E 5 – Handpiece communication error

## **8. SAPPHIRE PORTABLE DIODE LASER OPERATION AND USE**

### **Operating Modes:**

The Sapphire Portable Diode Laser will deliver energy in either continuous wave (CW) or Pulsed (P), “temporal emission mode” (time related mode). 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 (0.05 seconds) and the number of pulses per second (10) have been fixed by the manufacturer. Therefore, the operator will need to adjust only the laser 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 Sapphire Portable Diode Laser 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 resulting from air captured within the tissue during the cooling process.



### **Pulsed Energy Mode**

Pulsing the Sapphire Portable Diode Laser energy will allow some cooling of the tissue between emissions of energy. The “duty cycle” is the percentage of the time that the system is emitting energy. The pulses per second, the duty cycle and the energy intensity per pulse determine the average power.

In the pulsed mode, the Sapphire Portable Diode Laser is programmed to deliver 10 pulses per second with a duty cycle of 50%. It produces 1 energy pulse with 1 period of rest with no energy between each pulse. The result is an average power per second that will be 50% of the laser’s setting. Therefore, when using pulsed energy, you will have to adjust your power upward in order to achieve the same rate of work at the same power set in CW.

### **Tissue Responses to Laser Energy:**

Maximum results will be achieved by regulating the power and the speed that the operator moves the Fiber Optic Tip. Tissue charring is an undesirable after-effect of too much power, or of 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 will result in 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 808 nm laser 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 target tissue.

### **Installing and Replacing Single-Use Fiber Optic Tips**



Installing the Fiber Optic Tip

The Fiber Optic Tips conduct laser energy from the laser diodes to the tissues. These fibers are made of silica with a polymer cladding.

Note that there are potential hazards when inserting, steeply bending, or improperly securing the Fiber Optics to the handpiece. Failure to follow these recommendations may lead to damage to the fiber or delivery system and/or harm to the patient, staff, or laser operator.

The fiber is relatively flexible, but can be broken if bent at an angle that is too sharp or a radius that is too small. Protein debris from gingival tissue accumulates on the fiber during surgery and the extreme heat that develops will deteriorate the Tip. Fibers can fracture if a blackened area greater than 3 - 4 mm develops. This is especially important when using the Sapphire® Portable Diode Laser for periodontal pocket debridement. Stop lasing and regularly wipe off the tip with a 2 x 2 gauze sponge that has been wet with water to avoid the accumulation of protein debris. Do not use flammable solvents such as alcohol when cleaning a hot tip. The Sapphire Portable Diode Laser disposable Fiber Optic Tips are designed so that they typically won't need to be stripped or cleaved. Replace the disposable, single-use Tip as necessary and for each new patient.

The disposable, single-use Fiber Optic Tips are provided in a sealed package. Each Fiber Optic Tip contains a pre-cleaved, pre-stripped piece of fiber. They are designed for single-use only and must be discarded after use. Confirm the integrity of the package before use; if damaged, do not use the Tips. Special care should be taken not to break or snap the fiber when removing Tips from packaging. Do not touch the ends of the fiber.

Re-using Fiber Optic Tips will greatly increase the chance of patient-to-patient infection. Dispose used Fiber Optic Tips in a Sharps Container.

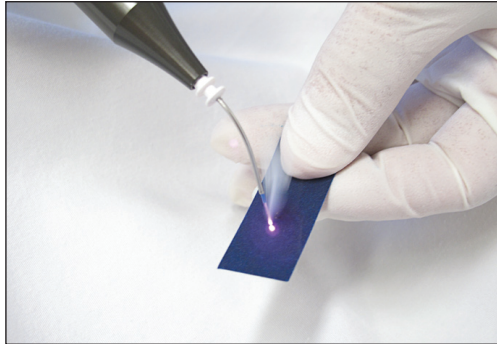
Confirm that the unit's Operating Key is turned to 'OFF' when changing Fiber Optic Tips.

To install a new Tip, hold the collar of the Tip between your thumb and forefinger, align the polished end of the fiber with the Handpiece receptacle and firmly press the Tip onto the Handpiece. We recommend that you set the Sapphire Portable Diode Laser to READY with the aiming beam at default (0.4 mW) after installing a new Fiber Optic Tip to evaluate the shape and the intensity of the beam to ensure the integrity of the fiber Optic system: the aiming beam spot should be round and the beam should be focused and not diffuse. If the beam is not round or is diffuse, try another Fiber Optic Tip and if the problem persists, the unit's Fiber Optic system will need to be evaluated by the manufacturer. Reset the aiming beam to desired output (page 14) following this evaluation.

To remove a worn Fiber Optic Tip, gently grip the Sapphire Portable Diode Laser Fiber Optic Tip between forefinger and thumb and pull it directly away from the Handpiece.

### **Initiating the Fiber**

Some procedures call for the Fiber Tip to be 'initiated.' 'Initiation' prepares the tip of the fiber to retain heat by fusing a thin layer of pigment on the end. The easiest way to initiate a tip is by lightly moving the end of the fiber across a piece of articulating paper with the unit set to 1W CW (see below). The tip will retain pigment from the paper and will glow. Do not exceed contact time of 1 second.



Tip Being Initiated

### **Setting Parameters:**

Review your power and mode requirements and then depress the mode toggle button to select either Continuous (CW) or Pulsed (P) mode operation. The mode you have selected will be identified by the corresponding icon glowing green.

Select power output by pressing the up or down arrow buttons until you have reached the desired level. The default power setting is 0.8 Watts and will be displayed in the LASER POWER window when the unit is powered-up.

### **Hard Tissue Procedures:**

The Sapphire Portable Diode Laser is not indicated for hard tissue procedures. The Sapphire Portable 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, energy may be absorbed by the hemoglobin in the pulp and pulpal hyperemia may occur. Extended exposure to such energy could cause patient discomfort and even lead to possible pulpal necrosis.

### **Cleaning Instructions:**

The Sapphire Portable Diode Laser Handpiece and power/communication cord should be cleaned using a liquid disinfectant similar to BIREX or CIDEX. Do not spray disinfectant directly onto the Handpiece as this may damage the ON/OFF switch or penetrate into the microprocessor or laser optics. Apply with a gauze sponge or wipe. Please wear gloves.

### **Calibration:**

The Sapphire Portable Diode Laser uses solid-state circuitry to continuously monitor power output and adjusts the power supplied to the laser diode to maintain the output at the user defined setting. If the output levels are more than  $\pm 20\%$  of the set value, the unit will shut off power to the laser diode. If this happens, the unit should be turned off and allowed to sit for about five (5) minutes, then turned on again. If the laser performs when retried, the microprocessor has been able to make adjustments and the unit will function. If the unit fails to fire when retried, the device will need to be sent for re-calibration by Den-Mat® Holdings, LLC Service Department.

We suggest that your practice establish an internal calibration program for your laser. Recalibration is recommended at least once per year based on typical usage.

Recalibration may be performed by Den-Mat® Holdings, LLC by returning the unit. As an alternative, you may purchase a calibrated hand-held power meter approved for use with 808 nm devices to check power output. The laser should be set at 1, 2, and 3W in CW with output checked at each level. Similarly, the output should be set 1, 3, and 5W in P with output checked at each level. The output display on the hand-held meter should be within 20% of each setting. If not, replace the Fiber Optic Tip and recheck power outputs. If output displays are still outside the  $\pm 20\%$  tolerance, return the unit to Den-Mat Holdings, LLC for recalibration. There are no methods available for the user to adjust the calibration of the unit and the Handpiece must not be opened by the user for any reason.

## 9. PROCEDURAL RECOMMENDATIONS FOR USING THE SAPPHIRE® PORTABLE DIODE LASER

Following procedure guidelines are provided as a guide only and have been developed based on information provided by experienced laser users and educators. Always review the patient's history to evaluate possible contra-indication for use of local anesthesia or other complications. All clinical procedures performed with the Sapphire Portable Diode Laser must be subjected to the same clinical judgment and care as with traditional techniques. Patient risk must always be considered and fully understood before clinical treatment. The clinician must completely understand the patient's medical history prior to treatment.

### **Contraindications**

Exercise caution for general medical conditions that might contraindicate a local procedure. Such conditions may include allergy to local or topical anesthetics, heart disease, lung disease, bleeding disorders, and immune system deficiency, or any medical conditions or medications that may contraindicate use of certain light/laser type sources associated with this device. Medical clearance from patient's physician is advisable when doubt exists regarding treatment.

Fiber Optic Tips are designed for single-use only and must be changed between patients. See Section **"Installing Single-Use Fiber Optic Tips"** (page 17) for details.

### **Test Firing the Sapphire Portable Diode Laser:**

Always test-fire the Sapphire Portable Diode Laser prior to using it intra-orally. Set working beam power to 1.0W CW, and place the Sapphire Portable Diode Laser in the READY mode. Activate the working beam for 1 - 2 seconds while aiming the Fiber Optic Tip onto a 2 x 2 gauze sponge moistened with water. Do not use alcohol or any other combustible material to wet the 2 x 2 sponge, as it may ignite.

### **Tip Initiation (when indicated):**

Not all soft tissue procedures require contacting tissue with the Fiber Optic Tip. Those procedures that do not require contact will use a Fiber Optic Tip that has NOT been initiated, because to be effective in non-contact mode, laser energy must flow unimpeded from the Tip. See section "Initiating the Fiber" (page 19) for guidance.

### **Sapphire Portable Diode Laser Use:**

NOTE: Before using the Sapphire Portable Diode Laser for patient treatment, it is recommended that a sanitary, disposable single-use Barrier Sleeve be placed on the Handpiece to minimize soiling the Handpiece and reduce the chance for patient-to-patient cross-contamination. Reusing these sleeves will greatly increase the chance of patient-to-patient infection. Safely discard following use. Contact your Den-Mat Holdings, LLC Authorized Distributor for replacement packages of Barrier Sleeves.

Depress the Handpiece actuator switch (or the Foot Pedal, if installed) and make short quick strokes at the lowest power that you can to remove the target tissues while lightly contacting it. Release the Handpiece actuator switch (or the Foot Pedal) and use a clean 2 x 2 gauze sponge moistened with water to remove debris from the Fiber Optic Tip. Do not use flammable liquids to wet the sponge.

Place the Sapphire® Portable Diode Laser in Standby Mode until you are ready to start another procedure.

Turn the Operating Key counterclockwise to the "OFF" position if you are not going to be starting another procedure.

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

Patient Name: Mary Jones

Procedure: Gingivectomy # 6 and # 7

#6 procedure time 90 seconds @ 1.0 Watts CW air cooled

#7 procedure time 60 seconds @ 1.1 Watts CW air / water spray

## Gingival Contouring with the Sapphire® Portable Diode Laser:

Tip: Initiated

Mode: Continuous Wave

Power: 0.8 W

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 the 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 soft tissue contouring 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, Gingivoplasty and Papillectomy with the Sapphire Portable Diode Laser:

Tip: Initiated

Mode: Continuous Wave

Power: 1.0 W

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 establish.
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 Fiber Optic 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 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 power settings used and treatment times in the patient's chart.



## **Gingival Troughing & Tissue Retraction for Impressions with Sapphire® Diode Portable Laser:**

Tip: Initiated

Mode: Continuous Wave

Power: 0.8 W

Anesthesia: Topical or Local, as required

Technique: Contact

1. Following preparation of the tooth, cleanse the area (optional) with H<sub>2</sub>O<sub>2</sub> 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 gingiva, angling the tip away from the tooth.
4. Using very light pressure, begin lasing 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 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.





## **Sulcular Debridement with the Sapphire Portable Diode Laser:**

(Including removal of sulcular tissue and granulation tissue)

Tip: Initiated

Mode: Pulsed

Power: 0.8 W

Anesthesia: Topical or Local, as required

Technique: Contact

Time: 30 seconds

Technique: Contact

1. After conventional instrumentation has been completed, insert the Fiber Optic Tip to the full pocket depth.
  2. Gently probe the pocket to get a sense of its geometry.
  3. Begin lasing onto 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 tissue.
  5. Keep the Fiber Optic 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 Fiber Optic Tip in contact with the epithelium, move the Fiber Optic 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 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 Sapphire® Portable Diode Laser:**

(and Frenotomy procedures)

Tip: Initiated

Mode: Continuous Wave

Power: 1.0 W

Anesthesia: Local, as required

Technique: Contact

The procedures to relieve the frenum will differ for three basic areas: 1) Mandibular frenum – labial or buccal; 2) Mandibular frenum – lingual (tongue-tied relief); 3) Maxillary frenum – labial and buccal.

Mandibular labial frenum attachments:

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 Sapphire Portable Diode 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 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.

Lingual frenum:

Lingual frenum relief must be approached with caution to ensure that you do not inadvertently rupture or incise the rich vascular beds in the floor of the mouth and the inferior border of the tongue.

- Grasp the frenum with a hemostat near the attachment to the tongue and use a hemostat to protect the vascular complex as the incision is made and the frenum released.

Maxillary labial frenum:

- Grasping the lip, place tension on the frenum and begin to make a perpendicular incision at the most coronal aspect of the attachment to the gingiva.
- With continued tension, release the frenum fibers as you are moving apically.

NOTE: Do not perforate or incise the periosteum.

Release all fibers down to the frenum attachment to the periosteum.

- A diamond shaped surgical area will indicate that you have released the attachment.
- Use warm saline rinses to clean the area.

## **Abcess Excision with the Sapphire Portable Diode Laser**

Tip: Initiated

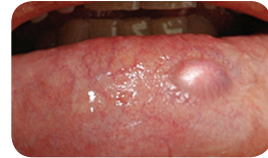
Mode: Continuous Wave

Power: 1.0 W

Anesthesia: Topical or Local, as required

Technique: Contact

1. Determine the status of the lesion, chronic or acute, and select a site to enter the parulis of the infection.
2. Based on the lesion status, enter the lesion by placing the fiber tip at the most coronal spot on the parulis and with short strokes, make an incision to establish a drainage path.
3. Using high volume suction, irrigate the area with saline solution as the exudate appears.
4. Insert the Tip into the incision site without emitting energy and lightly probe the area inside the parulis as you advance the tip apically.
5. Once you have established the base of the parulis, back the Fiber Optic Tip out approximately 2 mm and activate the Sapphire Portable Laser as you slowly withdraw the tip.
6. Remove the Tip briefly and allow any exudate to drain.
7. After draining has slowed, re-enter the parulis and insert the Fiber Optic Tip just short of the base and then withdraw the Tip as the laser is activated.
8. Repeat the process until you have established a clear path for completing the remaining drainage.
9. Administer oral antibiotics as needed and give the patient instructions on using warm saline to cleanse and irrigate the oral environment.
10. If you are not able to complete the drainage procedure without pain, review basic protocols before administering a local anesthetic into the infected area.



## **Hemostasis with the Sapphire® Portable Diode Laser**

Tip: Uninitiated

Mode: Continuous Wave

Power: 1.0 W

Anesthesia: Topical or as required

Technique: Non-Contact

Place the Fiber Optic Tip 2 mm above the gingival sulcus, in non-contact with tissue. Direct energy into sulcus and away from the dentin and cementum.

- Active the laser as you make a series of 2 – 3 mm strikes while circling the tooth. This should take about 30 – 40 seconds.

NOTE: Do not stop the movement of the Fiber Optic Tip until you have reached the starting point again and do not contact the tissue.

- Examine the sulcus and see if you have hemostasis or if the 'oozing' has slowed.
- Repeat in 30 second intervals if hemorrhage persists.
- If bleeding continues after the second attempt, clean any excessive hemorrhage and lase for a third time. Do not exceed 1½ minutes of lasing care.

NOTE: Continued bleeding indicates that you may have a larger arteriole that requires other hemostatic assistance in order to control.



# 10. SAPPHIRE PORTABLE DIODE LASER SPECIFICATIONS

Laser Classification:	Laser diode Class 4 laser device (per IEC 60825)
Wavelength working beam:	808 nm $\pm$ 5 nm
Beam Divergence:	9° $\pm$ 1°
Power Range:	100 mW to 3 W, CW; 100mW to 5W, P
Frequency (Pulsed):	fixed, 10 Hz
Pulse Duration:	fixed 0.05 seconds
Duty Cycle:	Pulsed mode 50% Continuous wave 100%
Audible signal:	Yes
Visual signal:	Yes
Power Supply:	15W, 5 VDC supplied from 110 - 120 VAC @ 60 Hz, or 220 - 240 VAC @ 50 Hz Power Adapter (switchable)

## Complies with:

IEC 60601-1, IEC 60601-1-2, IEC 60601-2-22, IEC 60825-1.

## Handpiece:

Length:	5.20 in
Diameter:	0.65 in
Tip removal:	Manual friction-fit
Activation method:	Electrical contact on Handpiece/ Footswitch control (optional)
Power cable:	60 in. x 0.26 in.
Sanitizing:	Wipe with appropriate disinfecting solution

## Fiber Optic Tips:

Type:	Removable, Single-Use Disposable
Material:	Fused Silica, coated
Size:	400 $\mu$ m x 2 inch
Style:	Polymer-clad fiber

## Accessories:

Foot Switch (EN 60529, IP 38 compliant; includes contact guard)  
Sanitary, disposable single-use only Barrier Sleeve for Handpiece  
400  $\mu$ m Single-Use ONLY Fiber Optic Tips  
Contact Den-Mat Holdings, LLC Authorized Distributor to order Accessories.

## **11. SERVICING THE SAPPHIRE® PORTABLE DIODE LASER**

In the event that the laser fails to operate correctly and your Authorized Representative is unable to help, the unit will need to be returned to Den-Mat® Holdings, LLC for repair, there are no user-repairable parts found with the device.

It is recommended that lasers be returned in their original shipping box. If not available, one can be requested at the time you discuss your return with your Authorized Representative.

## **12. SYSTEM WARRANTY**

When used under normal operating conditions as described in this Manual, the Sapphire Portable Diode Laser system is warranted to be free of defects in workmanship and materials for one (1) year from the date of original shipment.

Within the warranty period, all parts and service charges for repairs to the Sapphire Portable Laser System are covered by Den-Mat Holdings, LLC.

If service is required, the System must be returned to the manufacturer for diagnosis and repair. Contact your Authorized Den-Mat Holdings, LLC Distributor to arrange returns. Repairs may be made with new or refurbished parts, at the manufacturer's discretion.

Returned units that are outside the Warranty period will be evaluated for the cause and extent of failure or damage by Den-Mat Holdings, LLC Service Representatives. Subject to the results of this evaluation, Den-Mat Holdings, LLC will contact the customer through the Authorized Den-Mat Holdings, LLC Distributor with a price quotation for the cost of repairs.

This is a limited warranty and the liability of Den-Mat Holdings, LLC is to repair or replace the system. Den-Mat Holdings, LLC has no liability to refund any part of the purchase price and no liability for consequential damages, loss of profits, and damages to person or injury by reasons of any defects in said system from any cause whatsoever. Any buyer who purchases said system acknowledges their familiarity with the terms, conditions, and provisions of this limited warranty and purchases said system agreeing to such terms, conditions, and provisions.

Buyer purchases the Sapphire Portable system from Den-Mat Holdings, LLC on the terms, conditions, and provisions of this limited warranty and waives all other rights and claims against Den-Mat Holdings, LLC for any damages or remedies exceeding said limited warranty.

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