



# INSTRUCTIONS FOR USE

## SOL LASER

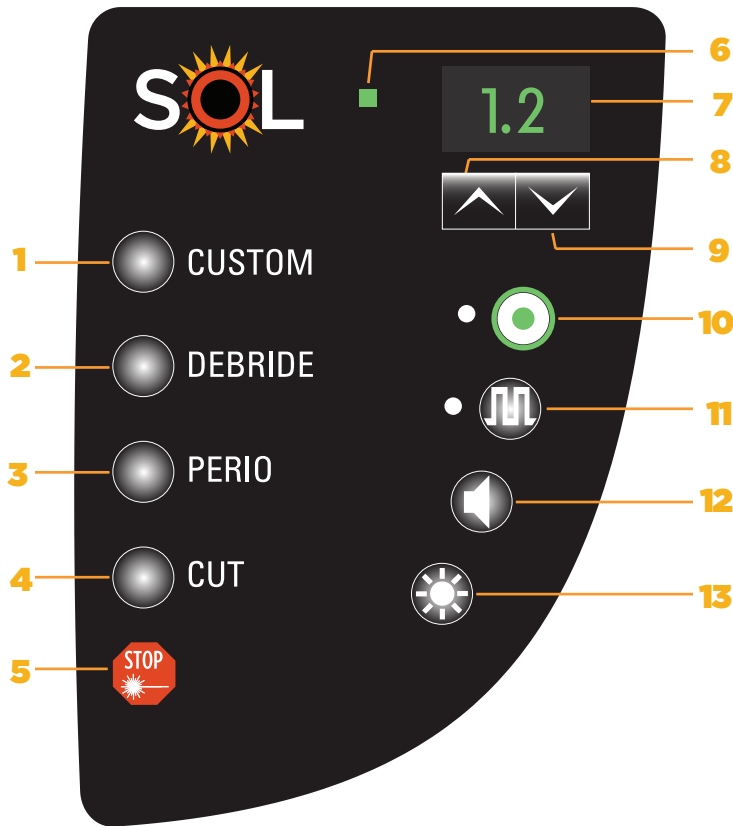


**SOL**<sup>™</sup>  
Power of light

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**FIGURE 1.0 PANEL BUTTONS**



- 1 CUSTOM** Programmable favorite setting. Default CW 1.5 Watts
- 2 DEBRIDE** Programmable favorite setting for debridement. Default preset CW 0.4 Watts
- 3 PERIO** Programmable favorite setting for the treatment of aphthous ulcers and periodontal pockets. Default preset Pulse 1.5 Watts
- 4 CUT** Programmable favorite setting for fast cutting. Default preset CW 1.2 Watts
- 5 EMERGENCY STOP** Turns active laser output OFF
- 6 BATTERY** Charge level indicator (Green, Amber, Red) flashes when battery is charging
- 7 DISPLAY** Laser power level indicator
- 8 UP** Adjusts laser power up by 0.1 watts
- 9 DOWN** Adjusts laser power down by 0.1 watts
- 10 READY** with LED Indicator – toggles between Standby and Laser Ready Modes
- 11 PULSE** Mode with illumination. Toggles between CW and Pulse modes  
NOTE: system defaults to Continuous Watt mode (not illuminated)
- 12 AUDIO** Mutes audio. Toggles between audio On/Off
- 13 AIMING BEAM** Adjusts blue aiming beam brightness up and down

NOTE: Preset labels are not intended to imply diagnosis or treatment of oral disease.

## A INTRODUCTION

The SOL Laser unit is a dental soft-tissue laser surgical/debridement device. The SOL Laser may be used for a variety of soft-tissue, gingival modification, and sulculartherapy procedures.

Safety is paramount when using any energy-based surgical instrument and your office should implement a safety program for the SOL 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 SOL Laser system. Their duties should include training office personnel in all aspects of system safety and management of the SOL Laser and all accessories.



### MANUFACTURER'S LASER IDENTIFICATION, OUTPUT AND STANDARDS LABEL

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

**MODEL: ASSY SOL LASER**  
**ITEM #: 033989100**  
**LOT #:**  
**MANUFACTURE DATE:**  
**MANUFACTURED BY:** DENMAT HOLDINGS, LLC  
 LOMPOC, CA 93436 USA  
**LASER CLASSIFICATION (PER IEC/EN 60825-1:2007):** Class 4  
**MAXIMUM LASER OUTPUT:** 3W CW; 5W P  
**FREQUENCY IN PULSED MODE:** Fixed, 10Hz  
**PULSE DURATION:** 0.05 seconds  
**WORKING BEAM WAVELENGTH:** 808 nm (±5 nm)  
**AIMING BEAM WAVELENGTH:** 405 nm (±10 nm) CW  
**POWER INPUT:** 30Watts + 12VDC supplied from 100-240 VAC 50-60 Hz Model FW7362M/12

COMPLIES WITH IEC 60601-1, IEC 60601-2-22; IEC/EN 60825-1:2007; IEC 60601-1-2, CLASS B PER EN 60601-1-2 AS WELL AS TO US FEDERAL REGULATIONS FOR LASER PERFORMANCE STANDARDS SET OUT IN 21CFR 1040.10 AND 1040.11 EXCEPT FOR DEVIATIONS PURSUANT TO LASER NOTICE 50 DATED JULY 26, 2001.


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**Attention, Consult Accompanying Documents**


## B WARNINGS & CAUTIONS



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


CLASS 4 Laser Product

Above Warning is affixed to front panel of SOL.




Symbol for: Laser aperture at the end of the handpiece.


Laser aperture warning label affixed to system hand-piece cradle.




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: US Federal Law restricts the use of this device to use by or on the order of a dentist

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 SOL Laser has been designed with several methods to terminate emission of laser energy in emergency situations. These methods include an emergency shutoff switch, a key switch and a power switch.

## C INDICATIONS FOR USE

The SOL Laser is intended for use by dental professionals in the treatment of dental patients for a variety of oral soft tissue procedures.

The SOL Laser is not intended for hard tissue procedures.

The SOL 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 aphthous 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
- Abscess incision and draining and excision
- Operculectomy
- Removal of fibromas
- Soft tissue crown lengthening

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 SOL Laser. Non-experienced users should seek appropriate training guidance before attempting clinical treatments with the SOL Laser system.

## D FACILITY & ENVIRONMENTAL CONSIDERATIONS

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

### POWER REQUIREMENTS

External AC/DC Power Supply:

**Input Power** - 110 – 120 VAC @ 60 Hz 700mA; 220-240 V AC @ 50Hz 350mA

**Output Power** – 30W + 12 VDC at 2.5A maximum

## HEATING AND VENTILATION

The optimal temperature range of 20° - 30°C (68° - 86° F). Avoid storing or transporting the lasers in temperatures below 0° Celsius (32° F).

## COMBUSTIBLE CHEMICALS AND GASES

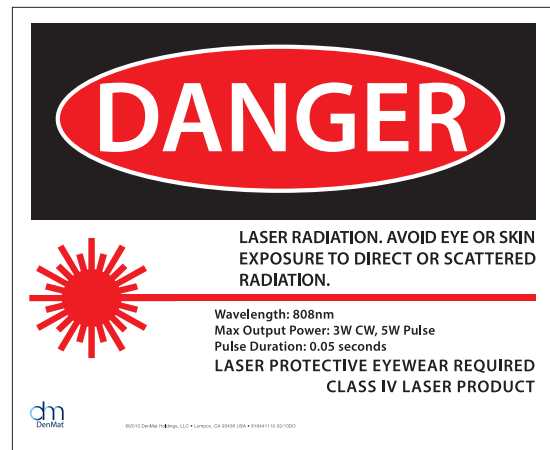
All gases that are combustible or support combustion and are used in the operatory area where the SOL Laser is being operated must be turned off during the procedure. Cleaning supplies or other flammable chemical compounds should be stored in an area away from the surgical site in order to avoid possible 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.

## OPERATORY ACCESS DURING SOL 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.



## E GENERAL SAFETY WITH THE SOL LASER

### GENERAL SAFETY CONSIDERATIONS

Safe use of the SOL Laser is the responsibility of the entire dental team including the doctor, any system operators and the dental office safety officer.

### MARKETING REQUIREMENTS REGARDING MEDICAL DEVICE SAFETY (USA)

The United States Food and Drug Administration (FDA) has control over the sale and use of the all medical devices including the SOL Laser. 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 (such as the SOL Lasersystem), 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 before the device is permitted into commercial distribution. The premarket notification (510(k)) process used for the SOL Laser system is applicable for devices that are documented to be substantially equivalent to existing legally marketed Class II devices.

### STATUTORY LICENSURE FOR DENTAL LASER USE

Usually, states or provinces do not have a specific licensure requirement for use of surgical laser devices by dentists. Many states do, however, require Hygienists who will be using lasers to attend licensure training that includes both a lecture and hands-on experience. The license applicants are then required to pass a proficiency test for certification prior to using lasers. These courses are usually taught by members of the Academy of Laser Dentistry who possess instructor credentials. Such training would be appropriate for use of the SOL Laser system.

### OSHA 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 recognizes ANSI standard Z136.1 as a source for analyzing safety with respect to medical lasers. For more information see OSHA Technical Manual (TED1-0.15A) Section III, Chapter 6, 1999. DenMat recommends implementation of a safety program for the safety of your patients and office staff in connection with the use of the SOL Laser. DenMat also recommends checking and complying with applicable state and provincial safety and health organization requirements.

### CSA PROVISIONS

This device is to be installed and operated according to the Canadian Standards Association CAN/CSA-Z386-08 provision for the safe use of the entire laser apparatus. This standard provides guidance for the Health Care Laser System (HCLS), and is intended for use by all personnel associated with the installation, operation, calibration and maintenance and service of the HCLS. This standard includes engineering, procedural and administrative controls, and laser safety training necessary for the safety of patients and health care professionals.

#### Electromagnetic Environment Guidance

(Class B (CISPR 11:2009), Group 1 per IEC 60601-1-2, sub-clause 6.8.3.201)

The SOL 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 electric equipment.

Floors should be wood, concrete, or ceramic tile. If floors are covered in synthetic material, the relative humidity should be at least 30%

Mains power quality should be that of a typical commercial or hospital environment. The SOL Laser does not require continued operation during power mains interruptions, merely it is recommended that the SOL Laser should be powered from an uninterruptible power supply (UPS) or its battery.

Power Frequency Magnetic Fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.



## EYE AND SKIN PROTECTION

While the SOL Laser is in use, doctors, system operators, auxiliary staff, patients, and anyone in the operatory must wear the appropriate safety eyewear that has been designed for use with the 800-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 of OD+4 for the wavelength range of 800nm-818nm such as NoIR Laser Company filter model D11.

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.

**TABLE 1: NOHD (INCHES/CM)**

Radiation Source	MPE mW/cm <sup>2</sup>	Divergence Angle	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

Never point the SOL 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:

- Depress the emergency “STOP” button (Fig. 1.1 Item 11)
- Remove your foot from the foot switch
- Press the “Ready” button (Fig. 1.0 Item 1)
- Turn the key counterclockwise to the “OFF” position
- Switch the power switch to the “OFF” position
- Remote interlock open circuit deactivates laser

## F INSTALLATION AND SETUP

### INSTRUCTIONS ON UNPACKING & CUSTOMER SERVICE ASSISTANCE

A DenMat customer service representative or dealer can provide assistance when you are ready to remove the SOL Laser from its shipping container. Please do not attempt to unpack the SOL Laser and install or setup the unit without reading this manual first. If you are unsure about any aspect of the assembly, call your DenMat customer service representative or dealer for assistance.

### SHIPPING CONTAINER INFORMATION

The shipping container you received with your SOL 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 SOL LASER SHIPPING CONTAINER:

The contents of the shipping container should include the following:

- SOL Diode Laser System with Hand Piece and Optical Fiber
- SOL Foot Switch
- AC/DC Power Converter
- Laser Operating Key
- Fiber Optic Tips, 400 Micron/5 pc
- Single-use Barrier Sleeves for Handpiece 25 pc
- Protective Glasses 3 pc
- Safety Sign
- SOL Laser Instructions
- Warranty Information
- Extended Warranty Offer
- Online Training Offer
- Battery Charging Notice

Each of the items listed above should be inspected and the instructions followed. Use of any cables or accessories not supplied with the system, or by DenMat, may damage the system and will void the warranty.

## LASER HAND PIECE AND FIBER



**NOTE: Avoid Exposure—Laser Radiation is emitted from this aperture.**

The detachable hand piece and fiber are installed and ready for use at the time of shipment. Uncoil the fiber and install a SOL procedure tip into the hand piece. Proper use of the system tips and fiber replacement is explained later in this manual.

## FIBER WRAP



A fiber wrap is provided to protect and store the system fiber when not in use. Gently extend the fiber by unwrapping clockwise and return in the counterclockwise direction. **TO AVOID DAMAGE TO THE FIBER**, do not bend at sharp angles or in a radius smaller than the internal diameter of the fiber wrap.

## BACK PANEL (FIG. 4)



## KEY SWITCH (FIG. 4, ITEM 1)

A removable key switch is provided as a safety feature to prevent the unauthorized operation of the laser. It is the responsibility of the laser safety officer to maintain control of the key switch and store it in a secure location when the laser is not in use. The key switch must be turned clockwise to the ON position to power the system controls and activate the laser.

## AC/DC POWER SUPPLY CONNECTOR (FIG. 4, ITEM 2)

USE MODEL FW7362M/12 ONLY. An external power supply is provided for charging the system battery and an alternate laser power source. During initial setup use the AC/DC power supply for up to four hours to fully charge the battery. Note the Battery Charge Level indicator (Fig 1, Item 6) on the system control panel, flashes to confirm that the power supply is connected and the battery is charging. **NOTE: battery does not charge when the system is in the Ready Mode or during laser activation so Charge Indicator does not flash.** Plug the power supply into an AC outlet and connect to the corresponding connector on the rear of the system. Only use the SOL Power Supply. Others may damage the system.

## POWER ON/OFF SWITCH (FIG. 4, ITEM 3)

The power switch is located on the rear of the system and must be in the ON position for the laser to be operated. Turn the power switch to the OFF position when the laser is not in use.

## FOOT SWITCH CONNECTOR (FIG. 4, ITEM 4)



The foot switch is used to activate the laser. Install the plug on the foot switch cable to the corresponding connector on the rear of the system.

## PORT FOR FUTURE EXPANSION. DO NOT USE (FIG. 4, ITEM 5)



## REMOTE INTERLOCK CONNECTOR (FIG. 4, ITEM 6)

The remote interlock is used to turn the laser OFF when the door into the room is opened. Remote interlock operation requires a Door Interlock Switch (not included) to be purchased from a local electronics store. This function is explained fully under Remote Door Interlock.

## G QUICK START INSTRUCTIONS

### SOL QUICK START INSTRUCTIONS

During initial setup use the AC/DC power supply for up to four hours to fully charge the battery. Plug the power supply into an AC outlet and connect to the corresponding connector on the rear of the system.

1. Plug the foot switch into the connector on the rear of the system.
2. Insert the key switch and turn to the ON position.
3. Turn the power switch to the ON position.
4. System powers up to default Standby Mode 0.8 Watt CW laser setting
5. Option: Adjust Power using Up and Down Arrow keys
6. Option: Enter Pulse Mode by pressing Pulse key
7. Option: Select one of four system presets with the corresponding key
8. Option: Adjust the preset as described in 5 and 6 above
9. Press Ready and note audio and visual indicator confirmations
10. Use the foot switch to activate the laser

## H CONTROLS, OPERATION & USE

### SOLSMART PRESETS (REFERENCE FIG. 1, ITEM 2-5)

SOL is delivered with five laser output settings programmed into the Default Mode when the system is turned ON and Four Preset Procedure Keys; Cut, Sterilize, Periodontal and Custom. These settings are typical for the corresponding procedures with a diode laser. All five can be reprogrammed with your favorite CW output from .10 to 3.0 watts in .10 watt increments or Pulse output from .10 to 5.0 watts in .10 watt increments. The Default Mode when the system is turned ON provides the fastest way to start lasing. After turning the system ON use the default power setting, or adjust, press READY and start lasing. SOL is smart and remembers the last mode (CW or Pulse) and power setting so the next time the system is powered up it returns to your most commonly used or Favorite Setting.

## SOL DEFAULT MODE WHEN THE SYSTEM IS TURNED ON

When the system power and key switches are placed to the ON position SOL system controls default to the factory preset Standby Mode 0.8 Watt CW laser setting. If the laser settings are changed the SOL will “remember” those settings upon exiting and they will become the default for the next session until changed again. Each subsequent change in settings becomes the new default. Adjust the laser CW power Up/Down using the Up or Down arrow keys select the Pulse Mode and adjust laser power Up/Down or enter one of four system presets to begin lasing. Press the Ready key to enter the Ready Mode. Press the Foot Switch to activate the laser. Return to the original default, or any other setting, by entering those settings.

### SOL PRESETS

See Fig 1, 1.2-1.5

The laser power and output modes, CW and Pulse, for four typical diode laser procedures are loaded into four button selections labeled Cut, Sterile, Perio and Custom. Default settings are as follows:

PRESET	POWER	DELIVERY MODE
Cut	1.2 Watts	CW
Debride	0.4 Watts	CW
Perio	1.5 Watts	Pulse
Custom	1.5 Watts	CW

Press any key to select that preset. When the preset is selected the laser power setting, (in watts), is displayed and the Pulse Mode illumination is ON if Pulse has been programmed for that preset. The laser power can be adjusted with the Up and Down Arrow keys. Pulse and CW can be selected by pressing the Pulse On/Pulse Off key. When the system is in the Pulse Mode the Pulse Icon (1.10) next to the key illuminates alerting the operator that the Pulse Mode is active. Changes to the laser output and CW/Pulse modes can be saved as a new preset by pressing and holding down the key for 3 seconds. If new settings are not saved (programmed) into the preset by holding the key for 3 seconds the original default settings will be retained upon exiting.

## READY (SOL ACTIVATION)

SEE FIG. 1

The system powers up in the Standby Mode and returns to Standby each time any key is pressed except READY. The laser cannot be activated in the Standby mode. The READY key, in either the CW or Pulse modes, prepares the system for laser activation. When the READY key is pressed there is an audio alert, unless audio is muted (see audio function), and the Ready indicator LED illuminates Green. The blue aiming beam is visible at the end of the tip. The system is ready for laser activation. When the system is in READY status pressing any key, other than the foot switch, will return the system to the Standby Mode. When the foot switch is pressed in the Ready Mode the Ready Indicator LED flashes to provide a visual indication that the laser working beam is On.

## PULSE MODE

The system Default Mode and Presets (except Perio) are programmed for CW laser delivery. The CW setting can be changed to Pulse for the Default Mode and Presets by pressing the Pulse key. When the Pulse key is pressed the Pulse Icon next to the key illuminates alerting the operator that the Pulse Mode is active. If the laser delivery is changed from CW to Pulse and saved as the Default Mode or a Preset the icon will illuminate each time that mode is used (until it is changed back to CW). SOL pulse is 10Hz 50% Duty Cycle.

## AUDIO ON/OFF

The Audio key toggles the system sound On and Off.

## AIMING BEAM

The brightness of the blue aiming beam is preset. It can be controlled by pressing the brightness key. Each time the key is pressed the brightness is increased and the selected level is displayed; A0 through A5. .

## EMERGENCY STOP

SOL can be immediately deactivated in any mode, at any power setting by pressing the STOP key. To reset the system, press and hold the STOP key for 5 seconds.

## REMOTE DOOR INTERLOCK (DOOR INTERLOCK SWITCH IS NOT INCLUDED)

The SOL diode laser provides a remote interlock feature (pg. 6 Figure 4 item 6) that enables a clinician to establish a laser treatment room with a remote interlock connector/

switch on the entrance door that is electronically wired to the system. When the door to the room is opened the connector/switch provides an electrically open circuit that deactivates laser emissions. The door must be closed with connector/switch providing an electrically closed circuit, with a manual reset by entering the Ready Mode, required to resume laser activation.

To use the remote interlock feature, an interlock connector/switch, cable and connector can be purchased from a local electronics store. Contact your Den-Mat account representative for an assembly drawing a list of parts required to use this feature.

## BATTERY POWER

The Battery Charge Indicator changes color to represent the battery capacity.

Green – 100% to 40%

Amber – Less than 40%

Red – Less than 20%

The battery should be recharged when the indicator turns amber. A long procedure should not be started when the indicator is red unless the external power supply is installed.

**NOTE:** Charge Indicator flashes when the external power supply is connected and the battery is charging.

Battery does not charge when the system is in the Ready Mode or during laser activation so Charge Indicator does not flash.

## OPERATING MODES

SOL 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) is fixed and not adjustable. Therefore, the operator will need to adjust only the laser power and mode.

## CONTINUOUS WAVE MODE

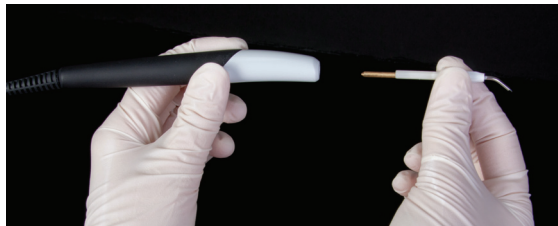
The CW mode is generally the fastest way to ablate tissues but heat can build up and cause collateral damage to adjacent tissues. Cool the tissues being treated by using periodic blasts of air from a triplex syringe and highspeed suction. You may also use water to cool in areas where there is prolonged laser exposure. 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.

### TISSUE RESPONSE 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

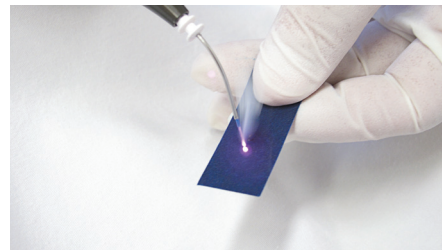


The Fiber Optic Tips conduct laser energy from the laser diodes to the tissues. These fibers are made of silica with a polymer cladding. Note that there are potential hazards when inserting, steeply bending, or improperly securing the Fiber Optics to the hand piece. Failure to follow these recommendations 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 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 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. 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 Key Switch 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 metal end of the fiber with the handpiece receptacle and firmly press the Tip onto the handpiece. To remove a worn Fiber Optic Tip, gently grip the tip body between forefinger and thumb and pull it directly out of 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.

### CLEANING INSTRUCTIONS

The SOL Diode Laser handpiece and fiber cord should be cleaned using a liquid disinfectant similar to BIREX or CIDEX. Do not spray disinfectant directly onto the handpiece as ingress of liquids may damage internal components. Apply

with a damp gauze sponge or wipe. Wear gloves and observe all other safety precautions and infection control procedures.

## ① PROCEDURAL RECOMMENDATIONS FOR USING THE SOL 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 SOL 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.

### HARD TISSUE PROCEDURES

The SOL Laser is not indicated for hard tissue procedures. The SOL Diode Laser is attracted to melanin, hemoglobin and to some extent to water. 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.

### CALIBRATION

The SOL 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 and provide an Error Message Alert to the operator. 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 DenMat Service Department. **Recalibration is recommended at a minimum of one time per year based on average usage.** The SOL may be returned to DenMat Service Department for recalibration. Alternatively, a calibrated laser power meter, approved for use with 810 nm laser devices, may be purchased to check laser output power. The power meter will also need to be calibrated at recommended intervals. SOL output should be checked at 0.5, 1.0, 2.0, and 3.0 watts. The power meter display should be within 20% of the meter reading. If not, replace the fiber tip. If the output is outside the 20% tolerance the system must be returned to DenMat Service Department for recalibration. The SOL system cannot be recalibrated by the user or service contractor and this must not be attempted.

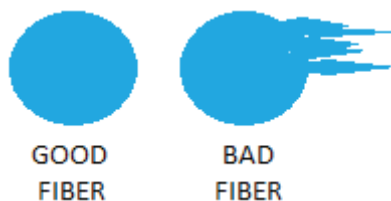
### SINGLE USE TIPS FOR INFECTION CONTROL

Fiber Optic Tips are designed for single-use only and must be changed between patients. See Section "Installing and Replacing Single-Use Fiber Optic Tips" (page 9) for details.

### CHECKING FIBER CONTINUITY

Prior to test firing and tip Initiation, illumination from the SOL aiming beam can be used to verify that there are no cracks or breaks in the system main fiber or single use tips. During this procedure use caution to prevent accidental activation of the working beam with the foot switch. It is recommended that the foot switch is unplugged to prevent laser activation. While in any system Preset or Default Mode press the Ready key to activate the aiming beam. Place the distal end of the fiber perpendicular to and about 5mm-10mm distance from a piece of white paper. Visible light should be transmitted from the tip and a well formed and focused round spot should appear. If the spot is diffused or not round in shape the single use fiber may be defective. Replace it and try again. If the spot is still diffused or not round in shape the system main fiber may need to be replaced (see Service and Troubleshooting page 15). Contact your DenMat Representative for additional assistance.

The extent to which differences in the shape of the spot will be noticed on tissue interaction is dependent on any reduction in transmission. If the spot has a small unfocused effect it may still work as expected or the fiber might need to be replaced.



### TEST FIRING THE SOL DIODE LASER

Always test-fire the SOL laser prior to using it intraorally. Use the Power On default setting or select any of the four presets. Press the Ready Key to enter the Ready Mode. Press the foot switch to activate the working beam for 1 - 2 seconds while aiming the fiber tip onto a 2 x 2 gauze sponge moistened with water. **DO NOT USE ALCOHOL OR OTHER FLAMMABLE LIQUIDS TO WET THE SPONGE.** Tip Initiation See section "Initiating the Fiber" for guidance. Not all soft tissue procedures require an initiated tip or contact with tissue. Those procedures that do not require contact will use a Fiber Optic Tip that has NOT been initiated, because to be effective in non-contactmode, laser energy must flow unimpeded from the tip.

### USING THE SOL DIODE LASER

Before using the SOL Diode Laser for patient treatment, it is recommended that a sanitary, disposable single-use Barrier Sleeve be placed over the handpiece to reduce the chance for patient-to-patient cross-contamination. Barrier Sleeves are **SINGLE USE ONLY**. Reusing these sleeves will greatly increase the chance of patient-to-patient infection. Safely dispose following use. Contact your DenMat representative for replacement packages of Barrier Sleeves.

When using the SOL Diode Laser in contact with tissue make short quick brush strokes in light contact at the lowest power setting that will remove the target tissue. Remove debris that collects on the fiber tip with a clean 2 x 2 gauze sponge moistened with water. **DO NOT USE ALCOHOL OR OTHER FLAMMABLE LIQUIDS TO WET THE SPONGE.**

When the laser is not in use and when the procedure has been completed press the Ready Key to return to the Stand-By Mode.

Turn the Key Switch counterclockwise to the "OFF" position remove and store in a safe and secure location when the laser is not in use.

### Turn the rear Power Switch to the "OFF" position to conserve battery power.

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

#### 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

## THE DENMAT HOLDINGS, LLC SYSTEM SPECIFICATION

### THE SOL LASER IS CLASS II

SOL Laser relies upon having two layers of insulation surrounding live parts or by having reinforced insulation to prevent electric shock.

### THE SOL LASER IS TYPE BF

BF  As type B but with isolated or floating (F – type) applied part or parts.

### CLASSIFICATION AGAINST FLAMMABLE VAPOS WITH AIR

SOL Laser is **NOT** suitable for use in the the presence of Flammable Anaesthetic Mixture with Air, Oxygen or Nitrous Oxide.



## K SOL LASER SPECIFICATIONS

Laser Classification: Laser diode Class 4 laser device (per IEC 60825-1:2007)  
Wavelength working beam: 808 nm +/- 5 nm  
Beam divergence: 9° +/- 1°  
Power range: 100mW to 3.0 Watts CW. 100mW to 5 Watts Pulse  
Frequency (Pulsed): Fixed, 10 Hz  
Continuous Wave (CW) Duty Cycle: Fixed 100%  
Pulse Mode Duty Cycle: Fixed 50%  
Aiming Beam Output: 2mW Maximum, adjustable  
Audible signal: Yes, adjustable On/Off  
Visual signal: Yes, adjustable  
Power Supply: 30 Watts +12VDC supplied from 100-240 VAC 50-60 Hz MODEL FW7362M/12  
Weight: 2.55 lbs.

### COMPLIES WITH

IEC 60601-1, IEC 60601-2-22; IEC 60825-1:2007; IEC 60601-1-2, Class B Per EN 60601-1-2 as well as to US Federal Regulations for laser performance standards set out in 21CFR 1040.10 and 1040.11 except for deviations pursuant to laser notice 50 dated July 26, 2001.

### HAND PIECE

Length: 4.75"  
Diameter: 0.575"  
Tip removal: Manual friction-fit  
Sanitizing: Wipe with appropriate disinfecting solution

### FIBER OPTIC TIPS

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

### ACCESSORIES

Sanitary, disposable single-use only Barrier Sleeve for Handpiece  
400 µm Single-Use ONLY Fiber Optic Tips  
Contact DenMat Sales to order accessories

## L SOL SERVICE AND TROUBLESHOOTING

**Recalibration is recommended at a minimum of one time per year based on average usage** (see Calibration page 13).

### NO VISIBLE LIGHT OR DIFFUSE LIGHT TRANSMITTED BY THE AIMING BEAM

Illumination from the SOL aiming beam can be used to verify that there are no cracks or breaks in the system main fiber or single use tips (see Checking Fiber Continuity page 13). Visible light should be transmitted from the tip and a well formed and focused round spot should be visible.

If there is NO VISIBLE LIGHT start by replacing the single use tip. If there is still NO VISIBLE LIGHT this is an indication that the system main fiber has been damaged. See Replacing The Main Fiber in the following section.



If the spot is diffuse or not round in shape the single use fiber may be defective. Replace it and try again. If the spot is still

diffused or not round in shape the system main fiber may need to be replaced

The extent to which differences in the shape of the spot will be noticed on tissue interaction is dependent on any reduction in transmission. If the spot has a small unfocused effect it may still work as expected or the fiber might need to be replaced.

### REPLACING THE BATTERY

The following procedure is provided in the unlikely event that the system battery needs to be replaced.

**WARNING FOR BATTERY REPLACEMENT:** Replace battery ONLY with SOL Replacement Battery item number authorized by DenMat. Use of a different battery may present a risk of fire or explosion. Keep away from children.

Charge battery only after it is properly installed in the SOL system and only with the SOL AD/DC Power Converter supplied with the system or Replacement SOL AC/DC Power Converter item number authorized by DenMat.

CAUTIONS FOR PROPER BATTERY DISPOSAL: The <100Wh Lithium Ion rechargeable battery used in the Den-Mat SOL is recyclable and contains 0% mercury, 0% lead, 0% cadmium.

**Battery must be recycled or disposed of properly.**

State and local regulations concerning the recycling and disposal of Lithium Ion batteries vary so it is necessary understand and remain in compliance with these regulations when replacing the SOL system battery.

Please follow the disposal and recycle symbols on the battery label to ensure that it is disposed of properly in accordance with local laws and regulations.

The manufacturer of the battery pack is a member of the Rechargeable Battery Recycling Corporation & the battery bears the RBRC symbol which includes the phone number to call to find your closest recycling location. The battery is accepted for recycling at all RBRC locations throughout North America. We encourage the use of recycling facilities for our products. For more information on Lithium Ion battery recycling:

In North America contact the Rechargeable Battery Recycling Corporation (RBRC) at:

[www.call2recycle.org](http://www.call2recycle.org) or phone 1-877-2-RECYCLE (1-877-273-2925)

In Europe contact the European Portable Battery Association (EPBA). [www.epbaeurope.net](http://www.epbaeurope.net)

**INSTRUCTIONS:**

DISCONNECT THE SYSTEM FOOT SWITCH USED FOR LASER ACTIVATION

VERIFY THE SYSTEM POWER AND KEY SWITCH ARE IN THE OFF POSITIONS

1) Place the system on its side as shown resting on a soft towel to prevent scratching. Using a 3/32 size Hex Tool remove four rubber feet from the bottom and remove the battery access panel.



2) Remove the battery. NOTE: Replace with new battery and attach bottom access panel.

**REPLACING THE FIBER OPTIC HAND PIECE**



CAUTIONS FOR OPTICAL FIBER REPLACEMENT: THE FOLLOWING REPAIR SHOULD ONLY BE PERFORMED BY A QUALIFIED LASER SERVICE TECHNICIAN.

USE THE REMOTE INTERLOCK FEATURE AS A SAFETY PRECAUTION DURING FIBER REPLACEMENT.

DISCONNECT THE SYSTEM FOOT SWITCH USED FOR LASER ACTIVATION

VERIFY THE SYSTEM POWER AND KEY SWITCH ARE IN THE OFF POSITIONS

ESD GROUNDING PRECAUTIONS SHOULD BE OBSERVED. FAILURE TO FOLLOW THESE INSTRUCTIONS MAY RESULT IN DAMAGE TO THE SYSTEM AND/OR SAFETY HAZARDS.

The following procedure is provided in the unlikely event that the system fiber optic hand piece needs to be replaced.

1) Completely unwrap the fiber from the fiber wrap and carefully store on a counter top. Remove the outer cover of the fiber wrap, using the fiber replacement tool, by

depressing two locking/release tabs located inside the wind wheel at the 10:00 o'clock and 2:00 o'clock positions while simultaneously pulling the wind cover outward from the top. Once the wind cover is loosened continue to pull outward and down until it is removed.

2) With the cover of the fiber wrap removed the optical fiber with hex nut that attaches to the diode laser assembly is exposed. Rotate the hex nut, by hand, counterclockwise to remove the fiber from the diode laser. When loose, remove the fiber from the system via the opening in the fiber wrap.



3) Install the replacement fiber in reverse order as described above. Attach fiber wrap cover by inserting bottom mounting tabs and pushing inward from the top until it snaps and locks into place. Wrap the optical fiber loosely around the fiber wrap and install hand piece into magnetic mount on the system front panel.

### ALL OTHER CONDITIONS

In the event that the SOL fails to operate correctly, and your DenMat Representative is unable to help, the unit will need to be returned to DenMat for repair. **There are no user-repairable parts found with the device.** It is recommended that the SOL is returned its their original shipping box. If not available, one can be requested at the time you discuss your return with your DenMat Representative.

### SEND RETURNS TO

Repairs  
DenMat Holdings, LLC  
1017 W. Central Ave.  
Lompoc, CA 93436 USA  
Tel.: 805-347-7990











**SOL. Everything you want in a laser.**

Call DenMat at 800.445.0345 or visit [DenMat.com](http://DenMat.com).



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