stomdevice



SOL®
Power of light

SOL. Everything you want in a laser.

Call DenMat at 800-433-6628 or visit denmat.com.

DenMat

823059600 R:7 06/22CM

©2022 Den-Mat Holdings, LLC • All rights reserved • 1017 W. Central Ave., Lompoc, CA 93436 USA

stomdevice

INSTRUCTIONS FOR USE

SOL PORTABLE DIODE LASER



SOL® Power of light

https://stomdevice.ru - стоматологическое и зуботехническое оборудование с доставкой по России и СНГ

stomdevice



IMPORTANT NOTES ABOUT YOUR SOL® PORTABLE DIODE LASER

- ❑ WARNING: Do not modify this equipment without authorization of the manufacturer.
- ❑ Read these instructions carefully prior to using your SOL Portable Diode Laser.
- ❑ Before turning power on, always apply the appropriate safety goggles and ensure all others in the operatory area are wearing the proper eye protection when laser is in use.
- ❑ Always wind the fiber optic cable in a counter clockwise manner to avoid failure.
- ❑ Ensure that all users are properly trained prior to use (refer to denmat.com or call 800-433-6628).

TABLE OF CONTENTS

	PAGE
INTRODUCTION	
Indications for Use	1
Contraindications	1
WARNINGS AND PRECAUTIONS	
Device Warnings and Cautions	1
Signage and Labels	1-2
Symbols Glossary	2
OPERATING CONDITIONS AND SAFETY CONSIDERATIONS	
Operating Conditions	2
Power Requirements	2
Combustible Chemicals and Gasses	2
Plume Evacuation	2
General Safety Considerations	2
Marketing Requirements Regarding Medical Device Safety (USA)	2
Statutory Licensure for Dental Laser Use	2
OSHA Provisions	2
CSA Provisions	2
Class A	3
SAFETY FEATURES	
Eye and Skin Protection	3
Emergency Shutdown Options	3
Remote Interlock Connector	3
Remote Door Interlock	3
INSTALLATION AND SETUP	
Contents	3
Unpacking the Container	3
Panel Buttons	4
Laser Hand Piece and Fiber	4
Fiber Wrap	4
Back Panel	4
Key Switch	4
AC/DC Power Supply Connector	4
Power On/Off Switch	5
Wireless Foot Switch	5
Optional, Wired Foot Switch	5

	PAGE
CONTROLS, OPERATIONS FOR USE	
Quick Start Instructions	5
Smart Presets	5
Default Mode	5
Ready Mode	5
Audio On/Off	5
Aiming Beam	5
Emergency Stop	5
Battery Power	6
Wireless Foot Switch Battery Power	6
Operating Modes	6
Pulsed Mode	6
Continuous Wave Mode	6
Tissue Response to Laser Energy	6
Installing and Replacing Single Use Fiber Optic Tips	6
Initiating the Fiber	6
Using the SOL Portable Diode Laser	6-7
Checking Fiber Continuity	7
Test Firing SOL Portable Diode Laser	7
MAINTENANCE INFORMATION	
Cleaning Instructions	7
Calibration	7
Troubleshooting	7-8
Repairs and Returns	8
SPECIFICATIONS	
Main Unit	8
Hand Piece	8
Fiber Optic Tips	8
Accessories	8
REGULATORY COMPLIANCE	9

DIRECTIONS FOR USE | SOL® PORTABLE DIODE LASER | 0123456789 | DENMAT.COM
https://stomdevice.ru - стоматологическое и зуботехническое оборудование с доставкой по России и СНГ

REGULATORY COMPLIANCE

IEC 60601-1-9, IEC 60601-2-22; IEC 60825-1:2007; IEC 60601-1-2, Class A 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.

FCC/Industry Canada Two Part Statement

This device complies with FCC Part 15 and Industry Canada license exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. Lexploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pasproduire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement

Per Industry Canada RSS rules:

This device complies with Health Canada's Safety Code. The installer of this device should ensure that RF radiation is not emitted in excess of the Health Canada's requirement. Information can be obtained at http://www.hc-sc.gc.ca/ewh-sem/pubs/radiation/radio_guide-lignes_direct-eng.php

Cet appareil est conforme avec Santé Canada Code de sécurité 6. Le programme d'installation de cet appareil doit s'assurer que les rayonnements RF n'est pas émis au-delà de l'exigence de Santé Canada. Les informations peuvent être obtenues:http://www.hc-sc.gc.ca/ewhsemt/pubs/radiation/radio_ guide-lignes_direct-eng.php

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Les changements ou modifications non expressément approuvés par la partie responsable de la conformité pourraient annuler l'autorité de l'utilisateur à utiliser cet équipement.

https://stomdevice.ru - стоматологическое и зуботехническое оборудование с доставкой по России и СНГ

stomdevice

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.

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 o'clock and 2 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.



REPAIRS AND RETURNS

In the event that the SOL Portable Diode Laser 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 Portable Diode Laser is returned in its 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
Den-Mat Holdings, LLC, 1017 W. Central Ave.
Lompoc, CA 93436 USA. Tel.: 805-346-3700

SPECIFICATIONS

THE SOL PORTABLE DIODE LASER IS CLASS II

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

THE SOL PORTABLE DIODE LASER HAND PIECE AND REMOVABLE DISPOSABLE FIBER OPTIC TIP IS TYPE BF APPLIED PART

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

WIRELESS FOOT SWITCH USES RF TRANSMITTER

Maximum effective output +4dBm Fixed frequency channels are within 2403MHz to 2473MHz range and are separated by 5MHz.

CLASSIFICATION AGAINST FLAMMABLE VAPORS WITH AIR

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

MAIN UNIT

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.

HAND PIECE

Length: 4.75"
Diameter: 0.575"
Tip removal: Manual friction-fit

FIBER OPTIC TIPS

Type: Removable, Single-Use Disposable
Material: Fused Silica, coated
Size: Standard 400 µm x 2 inch, 4mm cleaved
Perio 400 µm x 2 inch, 9mm cleaved
Style: Polymer-clad fiber

ACCESSORIES

Sanitary, disposable single-use only diode laser sleeves for handpiece P/N 043980902-1
Single-use fiber optic 4mm tips 25pk P/N 033980028-0
Single-use fiber optic 9mm Perio tips 25pk P/N LR1010
Wireless foot switch P/N LR1045
Wired foot switch P/N LR1004
Fiber-optic hand piece replacement kit P/N LR10006
Power cord P/N LR1005
Replacement keys P/N 033968859
Warning-laser in use sign P/N 818441110
810 diode laser safety glasses P/N LR1008
Initiating film pack P/N ZLR1020

Contact DenMat Sales to order accessories 800-433-6628.

https://stomdevice.ru - стоматологическое и зуботехническое оборудование с доставкой по России и СНГ

INTRODUCTION

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

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

INDICATIONS FOR USE

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

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

The 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 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.

Indications include: Excision and incision biopsies, hemostatic assistance, treatment of aphthous ulcers, gingivectomy, gingivoplasty, oral papillectomys, sulcular debridement, frenectomy, frenotomy, abscess incision, draining and excision, operculectomy, and removal of fibromas.

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

CONTRAINDICATIONS

Exercise caution for general medical conditions that might contra-indicate 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 contra-indicate use of certain light/laser type sources associated with this device. Medical clearance from patient's physician is advisable when doubt exists regarding treatment.

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

WARNINGS & CAUTIONS

DEVICE WARNINGS AND CAUTIONS

WARNING: Visible and Invisible Laser Radiation - Avoid eye or skin exposure to direct or scattered.

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 supplemental therapeutic oxygen supplies.

WARNING: Do not use in the presence of flammable substances.

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

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SOL Portable Diode Laser, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verity that they are operating normally.

CAUTION: Do not wind fiber optic cable clockwise.

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.

CAUTION: The SOL Portable Diode Laser is not intended for hard tissue procedures.

CAUTION: Changes or modifications not expressly approved by DenMat could void the user's authority to operate the equipment.

The SOL Portable Diode 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.

SIGNAGE AND LABELS

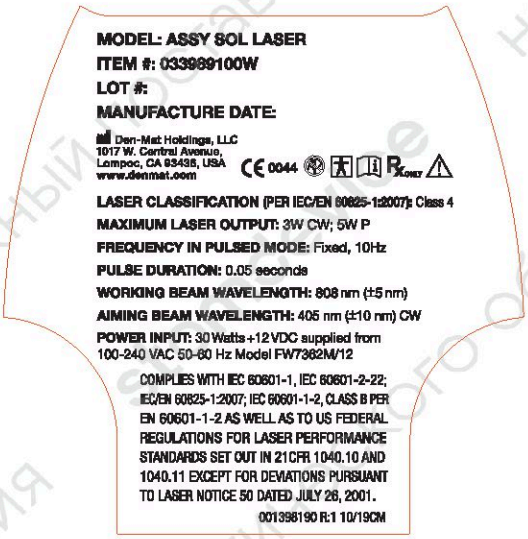
Danger warning sign:

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.



https://stomdevice.ru - стоматологическое и зуботехническое оборудование с доставкой по России и СНГ

Manufacturer's identification label:



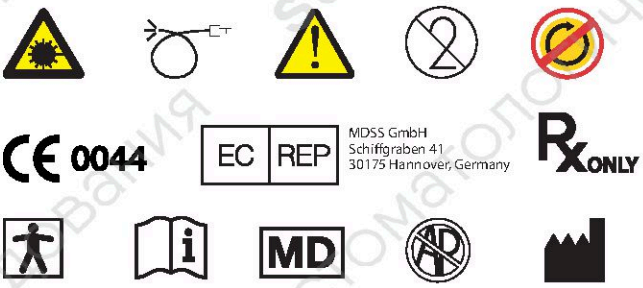
Foot pedal label:



Aperture label:



SYMBOLS GLOSSARY



Visit denmat.com/symbols for a definition of symbols.

OPERATING CONDITIONS & SAFETY CONSIDERATIONS

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

OPERATING CONDITIONS

Operating environmental conditions to be within 10° - 40°C (50° - 104°F), and 95% relative humidity or less. Transportation and storage environmental conditions to be within 0° - 40°C (32° - 104°F), and relative humidity of 95% or less. Atmospheric pressure to be within 70kPa – 106kPa in operating, transportation and storage conditions.

POWER REQUIREMENTS

NOTE: The Emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

External AC/DC Power Supply:
Input Power - 110 – 120 VAC @ 60 Hz 700mA; 220-240 V AC @ 50Hz 350mA
Output Power – 3.0W + 12 VDC at 2.5A maximum

COMBUSTIBLE CHEMICALS AND GASES

All gases that are combustible or support combustion and are used in the operatory area where the SOL 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.

GENERAL SAFETY CONSIDERATIONS

Safe use of the SOL Portable Diode 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 all medical devices including the SOL Portable Diode 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 Portable Diode Laser system), additional review by the FDA of the safety and effectiveness of the device is required. Companies who intend to market a medical laser or equivalent device must receive authorization from the FDA before the device is permitted into commercial distribution.

The premarket notification (510(k)) process used for the SOL Portable Diode 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 Portable Diode 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 Portable Diode 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, 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.

https://stomdevice.ru - стоматологическое и зуботехническое оборудование с доставкой по России и СНГ

When using the SOL Portable 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

CHECKING FIBER CONTINUITY

Prior to test firing and tip initiation, illumination from the SOL Portable Diode Laser 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 Troubleshooting). 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.

Fiber Example:



TEST FIRING THE SOL DIODE LASER

Always test-fire the SOL Portable Diode Laser prior to using intra-orally. 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. 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-contact mode, laser energy must flow unimpeded from the tip.

MAINTENANCE INFORMATION

CLEANING INSTRUCTIONS

The SOL Portable Diode Laser is not supplied in a sterile condition, nor must it be sterilized before use. The following cleaning procedures are recommended before initial use and after each subsequent use. The handpiece, fiber cord, and foot switch may be cleaned using 70/30 isopropyl alcohol. Do not spray cleaning solution directly onto the control unit or handpiece as ingress of liquids may damage internal components. Apply with a damp gauze sponge or wipe. Do not use abrasive materials to clean the laser. Wear gloves and observe all other safety precautions and infection control procedures.

CALIBRATION

The SOL 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 ± 20% of the set value, the unit will shut off power to the laser diode and provide an Error Message Alert to the operator. (See Troubleshooting). 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 the DenMat Service Department. **Re-calibration is recommended at a minimum of one time per year based on average usage.** The SOL Portable Diode Laser may be returned to the 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 Portable Diode Laser 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 the DenMat Service Department for re-calibration. The SOL system cannot be re-calibrated by the user or service contractor and this must not be attempted.

TROUBLESHOOTING

NO VISIBLE LIGHT OR DIFFUSE LIGHT TRANSMITTED BY THE AIMING BEAM

Illumination from the SOL Portable Diode Laser 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). 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. It the spot is still diffused or not round in shape the system main fiber may need to be replaced, (See Fiber Example).

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.

SYSTEM ERROR MESSAGES

E1 – Can't achieve laser output setting
E2 – Laser diode is too hot and needs time to cool down before continued use
E3 – Battery charge is too low to run the device
E4 – No power to the diode laser
E7 – Loss of battery communication

These system error messages can usually be corrected by powering the unit off and then back on again. If the problem persists, please contact your DenMat Customer Care Representative for additional trouble shooting techniques.

https://stomdevice.ru - стоматологическое и зуботехническое оборудование с доставкой по России и СНГ

stomdevice

BATTERY POWER (FIG. 1, ITEM 6)

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

Green – 100% to 40%
Amber – Less than 40%
Red – Less than 20%

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.

WIRELESS FOOT SWITCH BATTERY POWER

The Battery Indicator changes color to represent the battery capacity.

Green – 100% to 40%
Amber – Less than 40%
Red – Less than 20%

The battery should be replaced (3 AA Batteries) when the indicator turns amber. A long procedure should not be started when the indicator is red. Batteries should be removed if Wireless Foot Switch is not likely to be used for some time.

OPERATING MODES

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

PULSE MODE (FIG. 1, ITEM 11)

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 Portable Diode Laser pulse is 10Hz 50% Duty Cycle.

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 of 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 above). The tip will retain pigment from the paper and will glow. Do not exceed contact time of 1 second.

USING THE SOL PORTABLE DIODE LASER

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

https://stomdevice.ru - стоматологическое и зуботехническое оборудование с доставкой по России и СНГ

Class A

Electromagnetic Environment Guidance (Class A (CISPR 11:2009), Group 1 per IEC 60601-1-2, sub-clause 6.8.3.201)
The SOL Portable Diode Laser uses RF Energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby 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 Portable Diode Laser does not require continued operation during power mains interruptions, merely it is recommended that the SOL Portable Diode 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.
The SOL Portable Diode Laser is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

SAFETY FEATURES

EYE AND SKIN PROTECTION

While the SOL Portable Diode 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 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.

TABLE 1: NOHD (INCHES/CM)

Radiation Source	MPE mW/cm²	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 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:

- 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

REMOTE INTERLOCK CONNECTOR

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.

REMOTE DOOR INTERLOCK (FIG. 4, ITEM 4) (DOOR INTERLOCK SWITCH NOT INCLUDED)

The SOL Portable Diode Laser provides a remote interlock feature 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 DenMat account representative for an assembly drawing and list of parts required to use this feature.

INSTALLATION AND SETUP

CONTENTS

The contents of the shipping container should include the following:

- SOL Portable Diode Laser
- SOL Laser Handpiece
- AC/DC Power Converter
- Laser Operating Keys (2)
- Foot Pedal
- Disposable Fiber Tips (5)
- Single-Use Barrier Sleeves (25)
- Protective Eyewear (3)
- Laser Safety Sign
- SOL Portable Diode Laser Directions For Use
- Warranty Information

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

UNPACKING THE CONTAINER

A DenMat Customer Care Representative or dealer can provide assistance when you are ready to remove the SOL Portable Diode Laser from its shipping container. Please do not attempt to unpack the SOL Portable Diode 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 Care Representative or dealer for assistance.

The shipping container you received with your SOL 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.

https://stomdevice.ru - стоматологическое и зуботехническое оборудование с доставкой по России и СНГ

stomdevice

PANEL BUTTONS

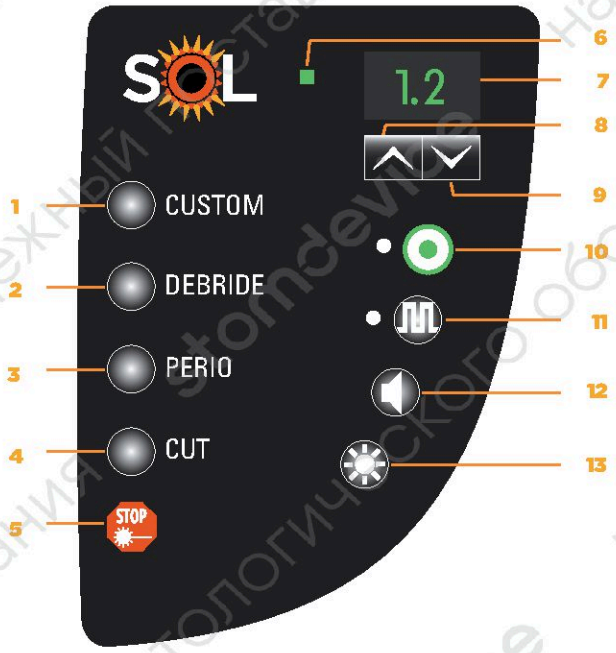


FIG. 1

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 apthous 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.

LASER HAND PIECE AND FIBER



FIG. 2

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



FIG. 3

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 (FIG1, 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.

https://stomdevice.ru - стоматологическое и зуботехническое оборудование с доставкой по России и СНГ

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.

WIRELESS FOOT SWITCH



The wireless foot switch is used to activate the laser. To use the wireless foot switch, install the (3) provided AA batteries. The SOL Portable Diode Laser unit and its wireless foot switch have been paired at the factory and are ready to use once batteries have been installed.

OPTIONAL, WIRED FOOT SWITCH



In place of the wireless foot switch, a wired foot switch option is available. To use the wired foot switch, install the plug on the foot switch cable to the corresponding USB connector on the rear of the system.

CONTROLS, OPERATIONS FOR USE

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. Install the (3) provided AA batteries to the wireless foot switch
2. Press down on the foot switch to bring out of standby mode before unit is ready to use.
3. Insert the key switch and turn to the ON position.
4. Turn the power switch to the ON position.
5. System powers up to default Standby Mode 0.8 Watt CW laser setting
6. Option: Adjust Power using Up and Down Arrow keys
7. Option: Enter Pulse Mode by pressing Pulse key
8. Option: Select one of four system presets with the corresponding key
9. Option: Adjust the preset as described in 5 and 6 above
10. Press Ready and note audio and visual indicator confirmations
11. Use the foot switch to activate the laser

SMART PRESETS (FIG. 1, ITEMS 1-4)

SOL Portable Diode Laser is delivered with four laser output settings programmed into the Default Mode when the system is turned ON and four preset procedure keys: Cut, Debride, Periodontal and Custom. These settings are typical for the corresponding procedures with a diode laser. All four 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 Portable Diode Laseris 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.

The laser power and output modes, CW and Pulse, for four typical diode laser procedures are loaded into four button selections labeled Cut, Debride, 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 (Fig. 1, Item 11) 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.

DEFAULT MODE

When the system power and key switches are placed to the ON position, SOL Portable Diode Laser system controls default to the factory preset Standby Mode 0.8 Watt CW laser setting. If the laser settings are changed the SOL Portable Diode Laser 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.

READY MODE (FIG. 1, ITEM 10)

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.

AUDIO ON/OFF (FIG. 1, ITEM 12)

The Audio key toggles the system sound On and Off.

AIMING BEAM (FIG. 1, ITEM 13)

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 (FIG. 1, ITEM 5)

SOL Portable Diode Laser 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.

https://stomdevice.ru - стоматологическое и зуботехническое оборудование с доставкой по России и СНГ