



DENTALAZE[®]

WIRELESS DIODE LASER

INSTRUCTIONS FOR USE

DENTAL DIODE LASER

FOR LICENSED TRAINED DENTAL OR MEDICAL PROFESSIONAL USE ONLY



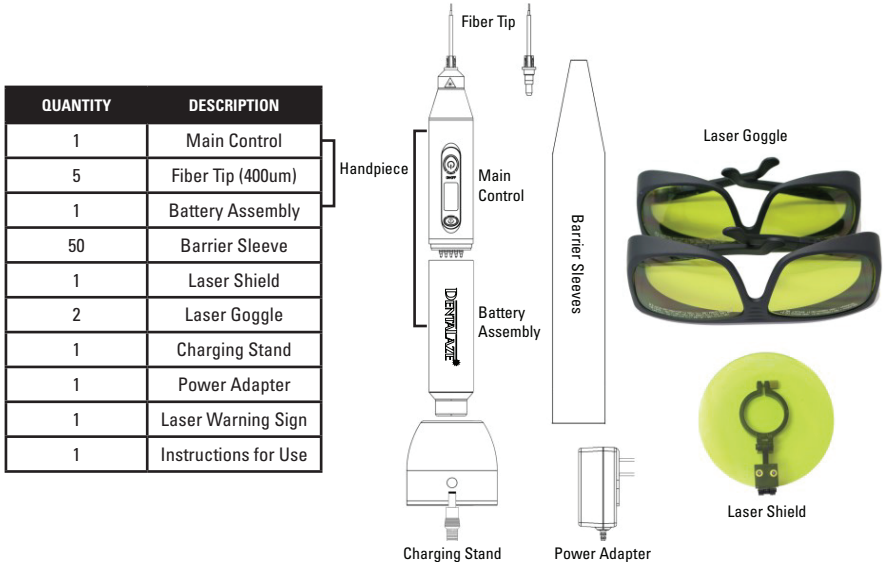
PRODUCT INFORMATION

DESCRIPTION

DentalLaze is a dental diode laser system designed for a wide variety of dental soft tissue procedures. The energy from the invisible infrared radiation out of the diode laser is delivered to the treatment site via a single-use Fiber Tip. These operating instructions provide recommendations and guidelines for the intended use. Please read them carefully.

SYSTEM COMPONENTS

DentalLaze kit consists of Laser Handpiece, Laser Shield, Laser Goggle, Charging Stand, Power Adapter, Barrier Sleeves, and Instructions for Use. The Laser Handpiece contains a disposable Fiber Tip, Main Control and Battery Assembly. It delivers laser energy, under user control, to the treatment site.



INDICATIONS FOR USE

DentalLaze laser is generally indicated for incision, excision, vaporization, ablation and coagulation of oral soft tissue including the following:

- Gingival troughing for crown impression
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis and coagulation
- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy and frenotomy
- Implant recovery
- Incision and drainage of abscess
- Leukoplakia
- Operculectomy
- Oral papillectomies
- Vestibuloplasty
- Soft tissue crown lengthening
- Tissue retraction for impression
- Reduction of gingival hypertrophy
- Treatment of canker sores, herpetic and ulcers
- Pulpotomy and Pulpotomy as an adjunct to root canal therapy

For laser periodontal procedures, including:

- Sulcular debridement (curettage, removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss, and tooth mobility).
- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket.

CONTRAINDICATIONS

All clinical procedures performed 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. 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.

SAFETY INFORMATION

SAFETY PRECAUTIONS

Prior to installation and activation of the laser, please read these instructions carefully and follow safety procedures as well as the specific safety comments and recommendations presented throughout the instructions for use. The manufacturer accepts no liability for any damage resulting from the improper use of this unit and/or for any purpose other than those covered by these instructions.

PRESCRIPTION REQUIRED: Federal law restricts this device to sale by or on the order of a dentist or physician or licensed practitioner.

TRAINING REQUIRED: Only licensed professionals who have reviewed and understood this User Manual should use this device. Additional training from a Certified Laser Training Representative is strongly recommended.

CLINICAL USE: Use your clinical judgment to determine all aspects of treatment including, but not limited to, the laser treatment protocol, technique, power settings, mode of operation as well as the tip type and other procedural requirements. Always start treatment at the lowest power setting for that specific indication and increase as required. Closely observe and monitor clinical effects and use your judgment to determine clinical parameters and approach for the treatment. Make appropriate power and settings adjustments to compensate for varying tissue compositions, density and thickness. Cutting with the DentaLaze is a thermal process and any transfer or accumulation of heat into adjacent structures may result in a burn and tissue damage. Be aware of the underlying and adjacent structures such as nerves and blood vessels when cutting with this device. Do not direct laser energy towards hard tissues such as tooth or bone. Do not direct laser energy towards metallic restorations, cements or other dental materials. Exercise extreme caution when using this laser inside the pocket, 3rd molar sockets, channels and other openings where visibility is limited.



DANGER: LASER RADIATION – Do not look directly into the beam or at specular reflections. Never direct or point the beam at anyone's eyes!



WARNING: Do not use this device if you suspect it is functioning improperly!



CAUTION: All persons present in the operatory must wear/use protective laser eyewear.



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



CAUTION! Fiber Tip marked "Single Use" on the labelling are intended for single use only. Discard properly after each patient use.

The equipment should be routinely inspected and maintained in accordance with the instructions given in the maintenance section of this manual. Unauthorized accessories not provided by the manufacturer may result in potential hazard. Safety operation of laser electronic devices requires prevention of the unauthorized use of the devices. An electronic key is implemented for that purpose.



Always use the laser in a well-lit and ventilated area. The area around the laser must be free of standing water.



CAUTION! The laser plume may contain viable tissue particulates. Use a high-volume vacuum to remove the laser "plume." Provide high filtration masks for all personnel in the treatment area. Chemicals or gases that could cause combustion must not be present when using the laser.



WARNING: Nominal Ocular Hazard Distance (NOHD) is 6m from the distal end of the Fiber Tip.



Do not clean the device when in use or while not in SLEEP or SAFELOCK mode. Keep solvents, flammable liquids, and sources of intense heat away from DentaLaze. A risk of fire and/or explosion exists when the LASER OUTPUT is used in the presence of flammable materials, solutions or gases, or in an oxygen enriched environment. The high temperatures produced in NORMAL USE of the laser equipment may ignite some materials, for example cotton wool when saturated with oxygen.

- DO NOT autoclave or immerse unit in any kind of ultrasonic bath, disinfectant, cleaning solution or any kind of liquid. Do not spray liquids directly onto the light and prevent liquids from entering DentaLaze open area such as Keypad, Charging Stand, and its connectors as this may damage or short-circuit the device and can cause potential hazard for operator and/or patient.
- DO NOT position the device charging stand and power adapter to make it difficult to disconnect the power adapter from a wall plug or power plug.

NOTE: Opening this unit or adjusting components inside the unit will void the warranty since such actions may compromise the performance of the laser system.

Failure to comply with the stated precautions and warnings may lead to exposure to electrical shock and/or exposure to radiation sources. Please comply with all safety instructions and warnings.

SAFETY INSTRUCTIONS

Follow these safety instructions before and during treatments:

- All operatory entrances must be marked with the appropriate danger warning sign.
- Do not operate the laser in the presence of explosive or flammable materials.
- Near infrared light (808nm) from the laser can pass through the transparent components of the unprotected eye and may focus on the retina at the back of the eye. This can cause permanent retinal burns and blindness. Patients and operating room personnel should wear protective eyewear with an optical density (OD) of at least 4+ in the range of laser wavelengths during all procedures.



PERIODICALLY INSPECT EYEWEAR FOR PITTING AND CRACKING.

NOTE: For replacement, additional or prescription protective eyewear, please contact DentaLaze.

- Do not look directly into the beam or at specular reflections.
- Never direct or point the beam toward the eyes.
- Remove or cover all highly reflective items in the treatment area.
- Operation Mode: See Specifications

SETTING UP YOUR LASER

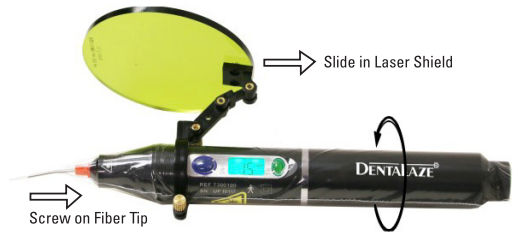
START UP

Assemble Handpiece

Upon receiving your DentaLaze, remove all components from the package and examine them. If damage is apparent, please contact Shofu Dental Corporation.

Attach the Battery Assembly to the Main Control by screwing the Battery Assembly clockwise into the Main Control. A short

beep upon connection indicates that the light is battery powered. Attach a Fiber Tip by screwing it all the way into the laser head. Slide in barrier sleeves and then attach the Laser Shield by sliding it into the handpiece. The device is now ready for use.





Barrier Sleeves and Fiber Tips must only be used for a single procedure and then properly disposed.

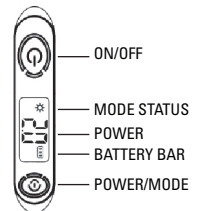
SAFELOCK Mode and UNLOCK the device

The device is electronically safe locked at the start with “EP” displayed on the LCD. **PRESS THE BOTTOM GREEN MODE BUTTON 4 TIMES TO UNLOCK THE DEVICE.** LCD will now display the default power setting 0.5W with a green backlit screen.

STANDBY Mode

Once the device is unlocked, it goes into the STANDBY Mode (green LCD screen). The user now can select the power mode. The device has 2 power modes: Continuous Wave (CW) and Pulse Mode. Default is set at CW. Single press the mode button to set the operating power levels from 0.5W to 3.0W in increment of 0.5W. To change to Pulse mode or vice versa, press and hold the mode button for 3 seconds until a pulse or constant power symbol (mode status) is displayed on the corner of the LCD screen. In Pulse Mode, operating power can be set from 1.0 to 5.0 as listed below. Cross reference the standard procedures and suggested power settings for optimum cutting and operation.

MODE	CW						Pulse				
											
Power (WATT)	0.5	1.0	1.5	2.0	2.5	3.0	1.0	2.0	3.0	4.0	5.0
Switch Mode	Press and Hold Power/Mode Button for 3 seconds then release										



Below is a list of suggested power settings for common clinical soft-tissue procedures. These settings are provided for your guidance only. It is at your discretion as the operator to modify these settings on a patient-by-patient basis, in order to deliver the safest and most effective treatment.

PROCEDURE	MODE	POWER	TECHNIQUE	TIP
Aphthous Ulcer/Canker Sores	CW	0.5	Non-contact	Non-initiated
Biopsy	CW	1.5	Contact	Initiated
Crown Lengthening	Pulse	2.0	Contact	Initiated
Excision/Incision	CW	1.5	Contact	Initiated

PROCEDURE	MODE	POWER	TECHNIQUE	TIP
Expose Teeth	CW	1.0	Contact	Initiated
Fibroma	CW	1.5	Contact	Initiated
Frenectomy	CW	1.5	Contact	Initiated
Gingivectomy	CW	1.5	Contact	Initiated
Gingivitis	CW	1.5	Non-Contact	Non-Initiated
Gingivoplasty	CW	1.5	Contact	Initiated
Hemostasis	CW	1.0	Contact	Initiated
Herpetic Lesion	Pulse	1.5	Non-Contact	Non-Initiated
Hyperplasia	CW	1.0	Contact	Initiated
Implant Recovery	CW	1.5	Contact	Initiated
Periodontal Sulcular Debridement	Pulse	1.0	Non-Contact	Non-Initiated
Pulpotomy	Pulse	1.0	Non-Contact	Non-Initiated
Recontouring	CW	1.0	Contact	Initiated
Troughing	CW	1.0	Contact	Initiated

Pulsed mode uses a 50% on and off duty cycle with a pulse duration of 0.225 seconds and pulse frequency of 2.2Hz. Pulsing the laser energy allows tissue cooling between energy emissions for better heat control and less lateral tissue damage. The average power in the pulse mode is half of its peak power. Therefore, when using pulsed energy, you must adjust your power upward to achieve the same rate of output as the same power set in CW mode. For example, 2 watts of pulsed power is the same average power output as 1 watt in CW.

READY MODE

When the device operating power/mode is selected, place the system into READY Mode by pressing and holding the ON/OFF button for 4 seconds. The LCD screen background will turn white in READY Mode. Only in this mode the green aiming beam is activated, and the laser can be fired. To switch from READY to STANDBY Mode, press and hold POWER/MENU button for 4 seconds. To switch from READY to SAFELock Mode, turn the battery counterclockwise until the screen is off then screw the battery back on.



FIRING THE LASER

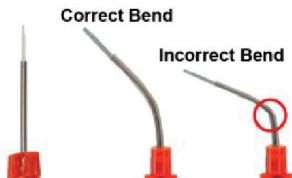
EMERGENCY STOP: The laser has multiple laser stop features in case the laser needs to be shut down immediately. Release the ON/OFF button or remove the battery from the main control by turning it counterclockwise.

- 1) Make sure a Fiber Tip is inserted all the way into the main control.
- 2) Make sure that all personnel in the operatory are wearing laser protective eyewear and the operator is protected viewing through the Laser Shield.
- 3) After the user enters READY Mode, the LCD screen is white. The green aiming beam will also appear at this time. The laser is now ready to fire.
- 4) **Tip Initiation:** set the power to 1.0W (CW). Touch the Fiber Tip to a dental articulating paper. Depress (press and hold) the ON/OFF button to fire and initiate the tip. Move the tip back and forth on the articulating paper during firing. You will see a white flash or a glowing tip. A glowing tip indicates the tip is ready for use.
- 5) Test the laser before inserting into the patient's mouth. Depress (press and hold) the ON/OFF button to activate the laser. Use short, quick, brush-like strokes and test the laser on sample objects (e.g., fruits, sausage).

6) Performing the Procedure: position the tip over the treatment spot at the center target of the aiming beam. View the tip through the Laser Shield. Depress (press and hold) the ON/OFF button using your thumb or index finger to fire. Using the left hand to hold and anchor the Laser Shield while dragging the Fiber Tip slowly over the target tissue for stability and to ensure the eye safety. The Laser Shield blocks the reflected laser beam and eases the operation of the procedures, which is particularly helpful when using magnified loupes to see the laser tissue interaction. There is a brief delay between depressing the ON/OFF button and the onset of the laser activation. This allows the user adequate time to react. When firing the laser, there is an audible beep per second indicating the invisible infrared laser in action.

INSTALLING AND REPLACING SINGLE-USE FIBER TIP

The Fiber Tip conducts laser energy from the laser diodes to the tissues. These fibers are made of silica with a polymer cladding. To install, first inspect and make sure the Fiber Tip has not been used before or shows no damage/imperfection. Take off the fiber dust cap from the proximal (polished) brass end. Then hold the collar of the tip between your thumb and forefinger, align the proximal end of the fiber with the handpiece receptacle (laser aperture) and gently tighten (do not force) the Fiber Tip by turning it clockwise and make sure that there is no gap between the laser aperture and the Fiber Tip. The Fiber Tips come with the kit are straight and they are self-bendable. Once properly installed, bend the metal cannula as appropriate for the planned procedure.



CAUTION: Do not bend the tip at a sharp angle (close to or more than 90°) as it may break the fiber or significantly reduce the optical performance.

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. Cut the Fiber Tip when necessary to adjust the tip length using a Fiber Scriber. 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 DentaLaze 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 the Fiber Tip. Replace the disposable, single use Fiber Tip as necessary and for each new patient. Each Fiber Tip contains a pre-cleaved, pre-stripped piece of fiber. They are designed for single-use only and should be discarded after use. **CONFIRM THE INTEGRITY OF THE PACKAGE BEFORE USE:** if damaged, do not use the Tips. Special care should be taken not to break or snap the fiber when removing Tips from packaging. Do not touch the ends of the fiber.

To remove a worn Fiber Tip, gently grip the Fiber Tip between forefinger and thumb and unscrew it from the handpiece. Do not force push or pull the Fiber Tip!

LASER EMISSIONS

As the aiming beam passes down the same fiber delivery system as the working beam, it provides a good means of checking the integrity of the delivery system. If the aiming beam spot is not present as a target full circle at the distal end of the delivery system, its integrity is reduced, this is a possible indication of a damaged or malfunctioning delivery system. If the issue is not resolved by replacing the Fiber Tip, return the system to Shofu Dental Corporation for repair.

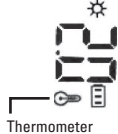

Use minimum power to enable cutting in order to avoid unnecessary lateral damage to the tissue for speedier cutting, less pain and faster recovery for the patient. Minimum power will extend the laser lifetime as well.

SLEEP MODE & AUTOMATIC CHANGE OF MODES

When the laser is inactive for more than 3 minutes from READY Mode, it will switch to STANDBY Mode for safety. When the laser is inactive from STANDBY Mode for 2 minutes, it will switch to SAFELock Mode and further switch to SLEEP Mode in another 2 minutes. The LCD screen will turn off in SLEEP Mode.

BUILT-IN SELF-PROTECTIONS

DentaLaze has built in self-protections on low battery and overheating. Low battery is indicated with low Battery Bars (one or no bars) on the LCD screen. Low battery triggers audible warning and self-protection shutdown. Light will go to Sleep Mode when the battery is low. Overheating is indicated with an audible warning beep together with a red backlite and thermometer flash. Laser shuts off when overheat is triggered. The operator needs to wait at least a minute or direct an air stream from an air syringe or high-speed vacuum tip to the laser head to cool it down before the laser can be ready to use again.

Temperature Overheat	Battery Protection
Allow Cool Down	Check Connection
 Thermometer	

BATTERY CARE

Always keep DentaLaze charged in the office. Connect DC Power Plug to Plug Receptor on the Charging Stand. Place the Handpiece into the Charging Stand. Secure Charging Stand on a table counter by peeling off the white self-stick paper at the bottom of the Charging Stand for ease of operation. Alternatively connect DC Power Plug directly to the back end of Handpiece to charge and power on the unit. Separate Battery Assembly from Main Control for long-term storage. LCD screen lights green while charging and has no light when fully charged. Battery Bar displays three full bars in Digital Control models when the battery is fully charged. In normal operation, Battery Bar drops from 3 to 2 bars while running and returns to full bar upon completion of a cycle.



Battery Replacment: Use only original battery assembly from the manufacturer as incorrect replacement, inappropriate handling and mechanical damage may result in hazards such as explosion, fire or smoke development.

LASER APERTURE/WINDOW CARE

Keep an Aperture Dust Cap or a Fiber Tip (not for clinical use) at the laser aperture to prevent dust and dirt from degrading laser window inside the laser head while not in use. Fiber tips are one time use only. CONTAMINATED FIBER TIP OR FAULTY FIBER TIP WILL DAMAGE THE LASER WINDOW INSIDE THE LASER APERTURE, WHICH WILL VOID THE WARRANTY.



DISPOSAL

BATTERY DISPOSAL: The Battery Assembly contains a Lithium ion (Li-ion) battery. When the battery is at the end of its life, recycle or dispose it according to national, state and local regulations.

FIBER TIPS & BARRIER SLEEVES: Disposal in a biohazard medical waste container is required. Do not reprocess the items.

DEVICE AND PARTS: DentaLaze is a medical device subject to regulations governing its disposal. Contact Shofu Dental Corporation for instructions on returning the device to DentaLaze for disposal. Do not dispose of an DentaLaze or its parts in landfills or incinerators.

CLEANING & DISINFECTION

DentaLaze must be cleaned prior to use and used with Barrier Sleeves on each patient. Cleaning should be performed prior to sterilization and must be conducted only by qualified office personnel trained to perform the procedure and handle the DentaLaze System. Manual cleaning is recommended.

Wear protective gloves and eyewear. Prepare a sterilizing and disinfecting solution of a CaviCide™ or equivalent product. Follow the instructions for disposal of used solution.

- **Fiber Tip**

- Submerge the fiber end of the Fiber Tip into the solution for 5 minutes
- After this process is completed, thoroughly rinse and dry the fiber

- **Laser Handpiece**

- Set the device in SLEEP or SAFELOCK mode. Apply the solution with a damp gauze sponge or wipe to thoroughly clean and disinfect Laser Handpiece. Do not spray, soak, or autoclave

STERILIZATION

- Take off fiber dust cap. Place the Fiber Tips inside FDA-cleared single-wrap, self-sealed sterilization pouches
- Place the pouches on an autoclave tray. Do not stack other instruments on top of the pouches
- Place the tray into the autoclave chamber and set controls to the following values:

STERILIZER TYPE	GRAVITY DISPLACEMENT	PRE-VACUUM
Temperature	121°C	132°C
Min Time Cycle (minutes)	20	4
Pressure (PSI)	15	15
Drying Time (minutes)	0	0

- When cycle is complete, the Fiber Tips must remain in the sterilization pouches until used to maintain sterility
- To assemble the components when ready to use, install the Fiber Tip as detailed in above of this User Manual

MAINTENANCE INFORMATION



CAUTION! This product contains no user serviceable components within the device. Visible and invisible radiation may be present when the cover is removed. Do not open the laser assembly under any circumstances.

- Disposable Fiber Tips are supplied non-sterile and must be discarded in an infectious waste container after each use. Fiber Tips are designed to be used one time only and must be sterilized prior to each use. Place the Fiber Tips inside a single-wrap self-sealed sterilization pouch and autoclave the Fiber Tips prior to use. Sponges used for cleaning fibers should be disposed of in a bag for contaminated soft products. There is no reuse or re-sterilization procedure indicated.
- Avoid dirt from the Fiber Tip butt end. Only use new and clean Fiber Tip.
- Safeguard Handpiece opening area, Metal Keypad, Charging Plug, and Laser Aperture against dirt, liquid and sharp objects as this may cause electrical short-circuit, permanent optical damage or malfunction.















REGULAR MAINTENANCE

- Place the laser handpiece back to the Charging Stand when not in use and/or overnight to maintain the battery and extend its usable lifetime.
- **Laser Calibration:** We suggest that your practice establish an internal calibration program for your laser and recommend that a laser calibration be performed every 12 months to ensure that the laser output power corresponds accurately to the displayed power. You may purchase a calibrated hand-held power meter approved for use with 808nm devices to check power output. The laser should be set in continuous wave (CW) mode at 1.0, 2.0 and 3.0 Watts with the output checked at each level. The output display should be within 20% of the meter reading. If not, replace the Fiber Tip and re-check. If the output display is outside the 20% tolerance, return the unit to the manufacturer for recalibration. Call 1-678-296-4191 or send online request to set up the service procedure.

TYPE OF INFORMATION		SPECIFICATIONS	
Wavelength ($\pm 10\text{nm}$)	DentaLaze	808nm	
Max. Power ($\pm 20\%$; Watt)	DentaLaze	CW	3
		Pulse	5 (Pulse duration 0.225 seconds; Pulse frequency 2.2Hz)
Duty Cycle		CW 100%; Pulsed 50%	
Audible Notification		Yes	
Aiming Beam		525 \pm 10nm (peak), Max. 0.6mW, Class I	
Power Adapter		Input: 100-240V – 50/60Hz; Output: 5V 2A	
Battery performance		Output: 3.7V nominal and 1.4AH. Running time ~ 45 minutes (1.5W); 90 minutes full recharging time. Expected life: 500 full charge/discharge cycles.	
Operation		Continuous operation patient application	
Shutoff		Timer auto shutoff; User shut off anytime by releasing ON/OFF button; Low battery auto shutoff; Overheat auto shutoff. Self-protection shutoff.	
Overcurrent Protection		Auto	
Dimension (mm, without Fiber Tip)		Length: 163; Width: 22; Height: 22	
Charging Dock Dimensions (mm)		Height: 45; Diameter: 44	
Weight (grams):		Handpiece: 100; Charging Stand: 88	
Laser Classification		4	
Safety		IEC 60601-1:2014; IEC 60825-1:2014; IEC 60601-2-22:2013	
EMC Compliance		IEC 60601-1-2:2014	
Protection from Electric shock		Type B	
Protection from ingress of liquids		IPX0	
Service Lifetime		Lifetime of the device is approximately 20,000 hours based on laser diode and battery life or typically 5 service years in normal office use.	
Operating environment		Ambient temperature: 50°F to 79°F (10°C to 26°C) Relative humidity: 10%-80%, non-condensing, Atmospheric pressure: 0.85-atm to 1.0-atm (86 kPa - 106 kPa)	
Storage environment		Ambient temperature: 14°F to 104°F (-10°C to 40°C) Relative humidity: 10%-70%, non-condensing, Atmospheric pressure: 0.85-atm to 1.0-atm (86 kPa - 106 kPa)	

LABELS & SYMBOLS

Symbols and labels are used on the device, accessories and throughout this manual, it is important that the user/operator of DentaLaze understands the meaning of each symbol to avoid possible injury to the operator or/and patient.

	Symbol is used to alert you to consult instructions for use. Understand all safety messages that follow this symbol to avoid injury to the operator and/or patient.		
	Aperture/Laser Warning		Attention, consult accompanying documents
	Waste Electrical & Electronics Equipment (WEEE)		
	Type B Applied Medical Equipment		Protection Class II- Double insulated
	Date of Manufacturing		Atmospheric Pressure Limitation
	DC Voltage		Humidity Limitation
	Single Use Only		Keep Dry
	Temperature Limitation		For Licensed Trained Dental Professional Use Only!
SN	Serial Number	REF	Product Number

DENTALAZE DIODE LASER	
	REF 7500083B SN 3B1001 LOT 8948PL
	Wavelength: 808nm Power Class: 3W (2W) Input: RV — 2A 2020010 Designed by Shofu Dental Corporation 1225 Stone Drive San Marcos, CA 92078 US

Product Label

DANGER	CLASS 4 LASER RADIATION WHEN OPEN AND INTERLOCKS DEFEATED
	Visible and invisible laser radiation. Avoid eye or skin exposure to direct or scattered radiation. Continuous wave and pulsed Pulse duration: 200ns; Pulse Frequency: 3.5KHz 3W Max, CW; 5W Max, Pulsed 800 ~ 110nm 100W Max, CW @2000 nm

Caution Label

REF 7500083B	CONFORMS TO IEC 60825-1:2014 IEC 60601-2-22:2013 INPUT: 5VDC, 2A
SN 3B1001	Shofu Dental Corporation 1225 Stone Drive San Marcos, CA 92078 US
DENTALAZE	

Charging Stand Label

LIMITED TWO-YEAR WARRANTY

Register your product at www.shofu.com/en/product/dentalaze/. Shofu Dental Corporation extends a two-year warranty against defects in material and workmanship (one-year battery and charging stand). This warranty is valid providing factory inspection indicates that any such defect was developed during normal and proper use. Dentalaze shall under no circumstances be liable for incidental, special, consequential damages and damage from misuse including the following expressed or implied:

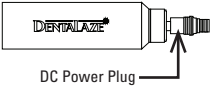
- Improper operation, accident or neglect, misuse or abuse, such as reusing Fiber Tips or physical damage (dents, scratches, dirty window etc.)
- Liquid, water, rain, extreme humidity, ultrasonic, autoclaving
- Tampering, improper repairs or modifications that have not been carried out by a certified Service Center
- Use of other spare parts and accessories other than from the manufacturer such as incorrect power adapter
- Other acts which are not the faults of DentaLaze

For service, call 1-678-296-4191 (in US) to obtain RMA number. Fill out RMA form online and return as instructed. In case of a warranty claim, the complete apparatus must be returned.

LASER WARNING SIGN

Please post the enclosed **Danger Sign** at the entrance of the laser operating room.

TROUBLESHOOTING GUIDE

PROBLEM	ERROR INDICATION	POSSIBLE SOLUTIONS	
Laser not turning on	1) LCD is blank 2) Buzzing noise when charging 3) Thermometer alarm	1) Push any button 2) Charge Battery Assembly alone by directly plugging DC Power Plug (bypassing Charging Stand) for 5 hours 3) Wait to cool down or direct an air stream	
	1) Not in Ready Mode 2) Power setting cannot be changed	1) Set to Ready Mode 2) Contact manufacturer or your local dealer for service	
Laser not cutting	1) Laser aperture window dirty or damaged 2) Power calibration incorrect	1) Clean laser window with alcohol damped mini-Q-tip 2) Contact manufacturer or your local dealer for service	
Laser not staying on	1) One or no Battery Bars 2) Bad connection or contacts 3) Battery out-of-capacity	1) Charge handpiece directly (bypass Charging Stand) 2) Check connection pins to make sure that they are not damaged 3) Replace battery	
Battery not charging	1) Broken pins in Charging Stand 2) Electronic defect in Battery Assembly	1) Bypass, replace or service Charging Stand 2) Replace or service Battery Assembly	

REORDER ITEM NUMBERS

PN	DESCRIPTION	PN	DESCRIPTION
DL001	DentaLaze Diode Laser Kit	DL005	DentaLaze Laser Shield
DL002	DentaLaze Fiber Tips (25/box, 400um)	DL006	DentaLaze Battery Assembly
DL003	DentaLaze 50 Laser Barrier Sleeves	DL007	DentaLaze Charging Stand
DL004	DentaLaze Laser Goggles	DL008	DentaLaze Power Adapter

**Distributed by
Shofu Dental Corporation**

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San Marcos, CA 92078, USA
(800) 827-4638
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