

Diolase Plus™

A SOFT-TISSUE LASER



User Manual

BIOLASE®

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BIOLASE Diolase Plus™ User Manual.

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Contents

	Introduction	5
Section 1	Installation of the Diolase Plus™.....	5
	Installation Instructions	5
	Facility Requirements.....	5
	Electrical Supply	5
	Environmental Requirements	5
Section 2	Safety with the Diolase Plus™	6
	Precautions	6
	Safety Instructions.....	6
	Safety Features.....	7
	Energy Monitor	7
	Circuit Breaker.....	7
	System Monitor.....	7
	Keyswitch.....	7
	READY Button	8
	Footswitch	8
	Emergency Stop	8
	Remote Interlock	9
	Functional Display	9
	Safety Questions.....	9
	Safety Classification.....	9
Section 3	Equipment Description	10
	General	10
	Console	10
	Control Panel.....	11
	Unit Features	12
	Accessories	12
	Delivery System	15
	Delivery System Assembly	15
	Directions for Cleaving Diolase Plus™ Fiber After Each Procedure	16
Section 4	Operating Instructions	19
	Unit Setup	19
	Operation	19
	Turn On the Diolase Plus™	19
	ON/OFF Button.....	19
	READY/STANDBY Buttons	20
	LASER FIRING Icon.....	20
	MODE Buttons	20
	POWER Buttons.....	20
	PULSE DURATION Buttons.....	20
	PULSE INTERVAL Buttons	20
	FUNCTION Key.....	20
	PRESET Buttons.....	20
	Turn the Unit OFF.....	21

Section 5	SPECIFICATIONS.....	22
	General	22
	Electrical.....	22
	Laser	22
	Other Light Sources	22
Section 6	CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS ...	23
	Contraindications	23
	Warnings and Precautions.....	23
Section 7	CLINICAL APPLICATIONS	24
	Introduction	24
	Table of Indications for Use	24
Section 8	MAINTENANCE	25
	Annual Maintenance	25
	Daily Maintenance	25
	Contamination Control Procedure	25
	Cleaning	25
	High-level Disinfection Instructions for the Fiber Optic Cable	25
	Steam Sterilization for Diolase Plus Surgical Handpiece.....	26
	Transportation	26
	Storage.....	26
Section 9	CALIBRATION	27
	Calibrating Power.....	27
	Calibration Schedule:.....	27
Appendix	A - LABELS.....	28
	B - SIGNS.....	31
	C - SPARE PARTS AND ACCESSORIES	33
	D - LIMITED WARRANTY.....	34
	E - LIMITED LIABILITY.....	34

INTRODUCTION

The Diolase Plus™ Dental Soft Tissue Laser is a surgical device at the cutting edge of technology, designed for a wide variety of oral soft tissue procedures. The Diolase Plus™ utilizes a solid state diode as a laser energy source, and the energy is delivered to the operating area by means of a delivery system consisting of flexible fiber connecting the laser source and the handpiece. The device is activated by means of a footswitch.

The Diolase Plus™ is intended for use by dentists in oral soft tissue procedures. The use of this device requires proper clinical and technical training. This manual provides instructions for professionals that have completed the appropriate training.

When used and maintained properly, the Diolase Plus™ will prove a valuable addition to your practice. Please contact your authorized representative if you have any questions or require assistance.

Section 1: INSTALLATION

Installation Instructions

Upon request, your local authorized representative will unpack and install the Diolase Plus™.

The Diolase Plus™ system includes the following:

- Console
- Delivery System (Handpiece and Fiber Assembly)
- User Manual
- 3 Safety Goggles
- Footswitch
- Power Cord
- Carbide fiber scribe
- Micro fiber stripper 400um
- Laser Radiation Danger Sign
- Accessory Pouch (includes remote interlock plug, ground clip, key)

Use proper care prior to transporting the unit. Refer to Section 8 in this manual for instructions. Misalignment of optical components may occur during transportation.

Facility Requirements

Electrical Supply (100-240V)

1.5 - 3A, 50/60Hz

Environmental Requirements

Temperature: 20-25 °C

Humidity: 15-95% Relative

Section 2: SAFETY

Precautions

Failure to comply with precautions and warnings described herein may lead to exposure to dangerous voltage levels or optical radiation sources. Please comply with all safety instructions and warnings.

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

DANGER: Do not use this unit if you suspect it of functioning improperly or other than described herein.

CAUTION: This unit has been designed and tested to meet the requirements of electromagnetic, electrostatic, and radio frequency interference testing. However, the possibility of electromagnetic or other interference may still exist.

Safety Instructions

Follow these safety instructions before and during treatments:

- All operatory entrances must be marked with an appropriate warning sign. (See Appendix B.1)
- Do not operate in the presence of explosive or flammable materials.
- All persons present in the operatory must wear protective eyewear.

CAUTION: Periodically inspect eyewear for pitting and cracking.

Note: For replacement, additional or prescription protective eyewear, please contact your authorized representative.

- **Do not look directly into the beam or at specular reflections.**
- **Never direct or point the beam at anyone's eyes.**
- **Remove or cover all highly reflective items in the treatment area.**
- **Press STANDBY (Standby button) on the control panel before turning off unit.**
- **Always press STANDBY on the control panel before exchanging handpieces or removing the fiber optic connector from the unit.**
- **Move the circuit breaker (located on rear panel) to OFF (0) position and remove the key before leaving unit unattended.**

DANGER: Do not open unit housing at anytime. Danger from high voltage may exist.

NOTE: Please be aware that metal/plastic cannulas may become hot during use. Avoid contact of cannulas with tissues.

Safety Features

Energy Monitor

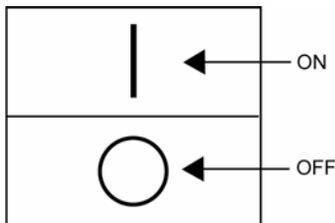
The energy monitor measures and verifies power output. Power deviations of more than 20% from the selected value will cause the display to show either error message “DIODE CALIBRATION” or “LASER POWER”.

The unit will not operate until the system is reset by pressing any key on the keypad. If error messages persist, please contact your authorized service representative.

Circuit Breaker

The circuit breaker serves as a line switch to separate the unit from the main power supply (0 = OFF, I = ON).

Figure 1: Circuit Breaker



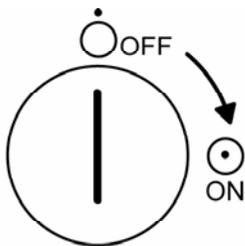
System Monitor

The system monitors the emergency stop switch, remote key, footswitch attachment, fiber attachment, and output power. An error in any one of these will stop the system, the text display will indicate the type of error. Operation will not resume until the error is cleared, and the text once again displays “Biolase Technology.”

Keyswitch

The unit can be switched ON (key in horizontal position) only with the proper key. The key cannot be removed while in the ON position. Always turn the key off (vertical position) and remove the key when not in use.

Figure 2: Keyswitch



READY Button

Once the circuit breaker, keyswitch, and ON/OFF switch are set to the ON position, the READY button on the keypad must be pressed to enable the footswitch. One beep will sound to indicate that the system is ready for use.

Footswitch

The Diolase Plus™ will not emit laser energy until the user pressed down on the footswitch. The variable footswitch works like a rheostat. The amount of energy emitted from the fiber will be proportional to the amount the footswitch is pressed. The footswitch may also be selected to function as a switch. (See Section 4: Function Key).

Figure 3: Footswitch (Domestic)



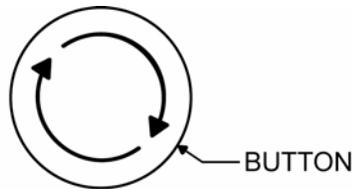
Figure 4: Footswitch (International)



Emergency Stop

Press the red emergency stop button to instantly turn off the unit. Rotate and release button to RESET. Do not use the emergency stop for normal stops.

Figure 5: Emergency Stop



Remote Interlock

This feature allows the device to be connected to the remote sensor which will prevent its operation when triggered (i.e., by opening door). This feature may be overridden by inserting the remote interlock plug.

Functional Display

The System Text Display and the Light Emitting Diode (LED) indicators on the control panel show the functional conditions of the system.

Safety Questions

Please direct any safety questions to an authorized representative.

Safety Classification

The following safety classifications are applicable to the device

- Laser Radiation – Class 4
- Type of protections against electrical shock – Class 1
- Degree of protection against electrical shock – Type B Applied Part
- Not protected against water ingress – Ordinary Equipment
- Not suitable for use in presence of flammable anesthetic mixture
- Operation Mode – Continuous Operation

Section 3: EQUIPMENT DESCRIPTION

General

The Diolase Plus™ consists of two components:

- Console
- Delivery System

Console

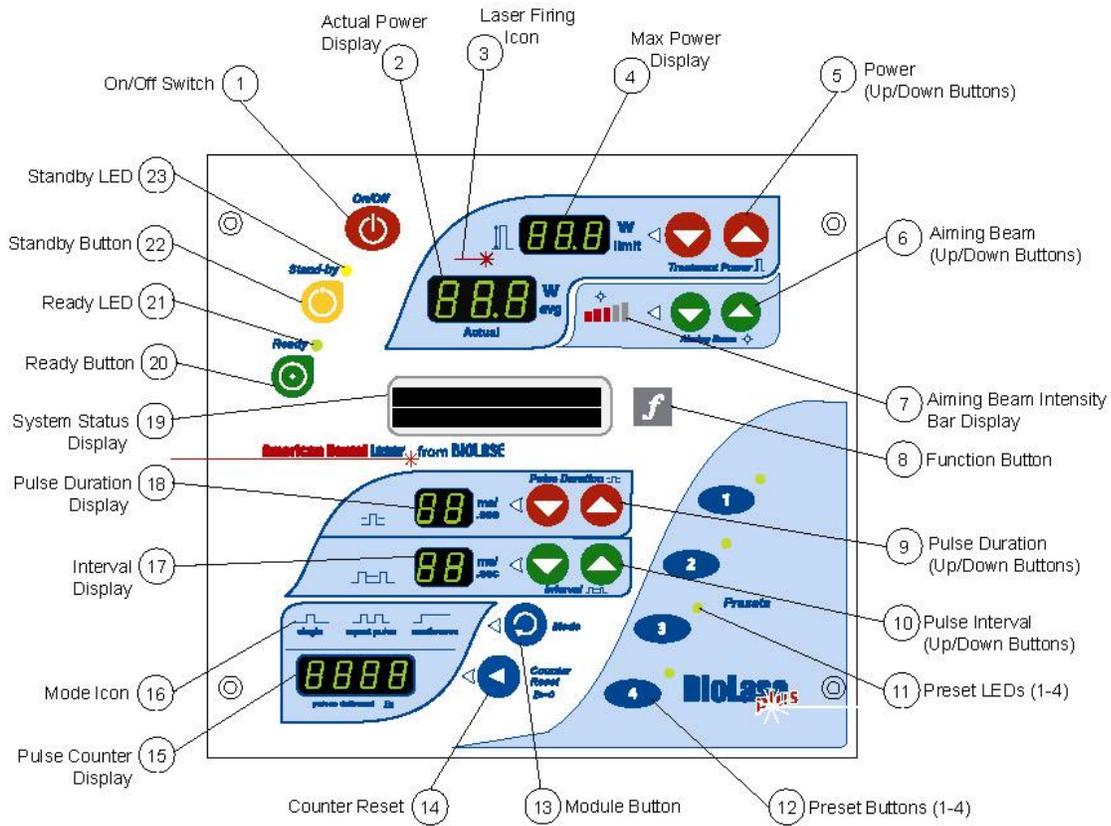
The Console Elements are the:

- Control Panel
- Unit Features
- Accessories

Control Panel (See Figure 6)

Item#	Item	Item Description
1	ON/OFF	Turns the unit on and off.
2	ACTUAL POWER DISPLAY	Indicates average power delivered.
3	LASER FIRING ICON	Flashes when laser energy is delivered.
4	MAXIMUM POWER DISPLAY	Indicates maximum allowable delivered power.
5	POWER (up/down)	Allows adjustment of maximum delivered optical power.
6	AIMING BEAM (up/down)	Allows adjustment of aiming beam intensity.
7	AIMING BEAM INTENSITY	Indicates aiming beam intensity.
8	FUNCTION	Selects user function.
9	PULSE DURATION (up/down)	Allows adjustment of pulse length.
10	PULSE INTERVAL (up/down)	Allows adjustment of pulse interval.
11	PRESET LEDs	Indicates which preset is currently selected.
12	PRESET	Allows for selection of system presets. Holding button saves selected values.
13	MODE	Toggles between continuous, repeat pulse and single emission modes.
14	COUNTER RESET	Resets pulse counter to zero.
15	PULSE COUNTER DISPLAY	Indicates total pulses delivered.
16	MODE ICON	Indicates currently selected mode (continuous, repeat pulse, single)
17	INTERVAL DISPLAY	Indicates interval between pulses.
18	PULSE DURATION DISPLAY	Indicates length of each pulse.
19	SYSTEM STATUS DISPLAY	Indicates system errors or status.
20	READY	Allows energy delivery.
21	READY LED	Indicates unit is in READY mode.
22	STANDBY	Does not allow energy delivery.
23	STANDBY LED	Indicates unit is in STANDBY mode.

Figure 6: Control Panel



Unit Features

- Base (Figure 10)
- Delivery System (Figure 10)
- Emergency stop (Figure 7, 8 and 9)
- Fiber Optic Cable (Figure 10)
- Fiber spool (Figure 9)
- Footswitch connector (Figure 8)
- Handle (Figure 9,10)
- Handpiece holder (Figure 7 and 9)
- Head (Figure 10)
- Keyswitch (Figure 8)
- Laser aperture (Figure 9 and 14)
- Main Circuit Breaker (Figure 8)
- Male Connector (Figure 10)
- Power connector (Figure 8)
- Remote Interlock connector (Figure 13)
- Ventilation channels (Figures 7 and 8)

Accessories

- Footswitch (Figure 3 and 4)
- Key (Figure 8)
- Laser Safety Glasses (Not Shown)
- Power cord (Not Shown)
- Remote interlock plug (Figure 8)

Figure 7: Side View

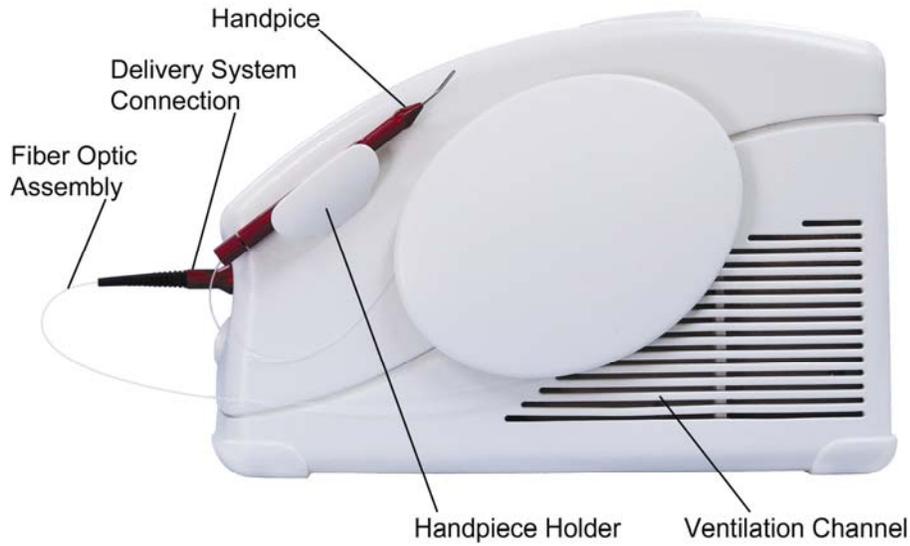


Figure 8: Back View

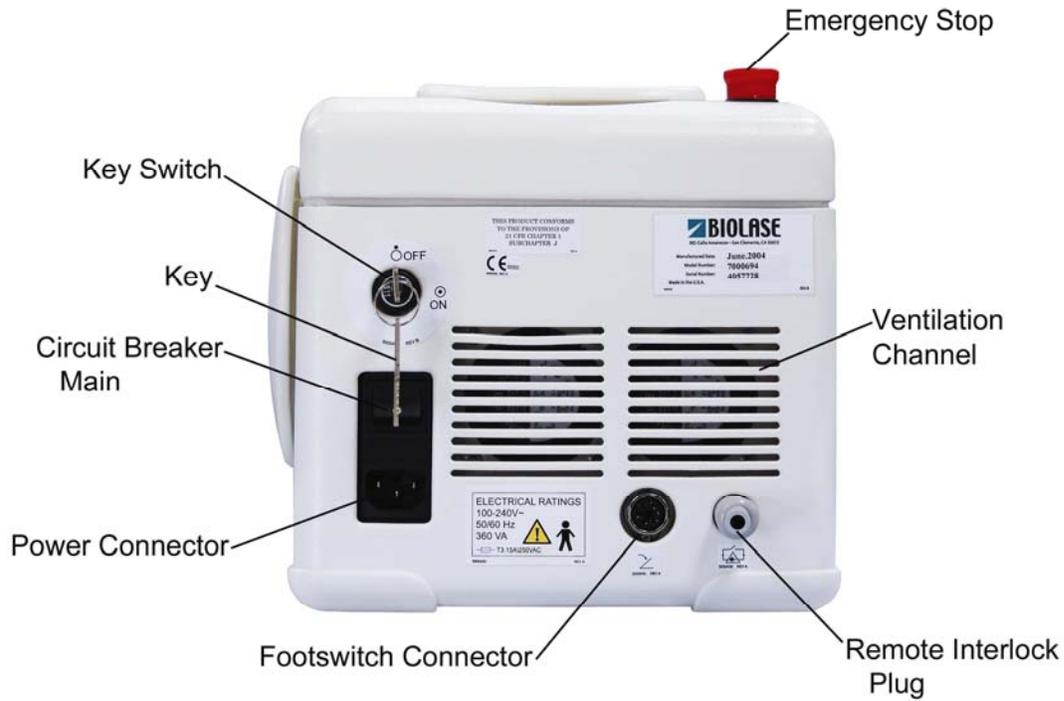
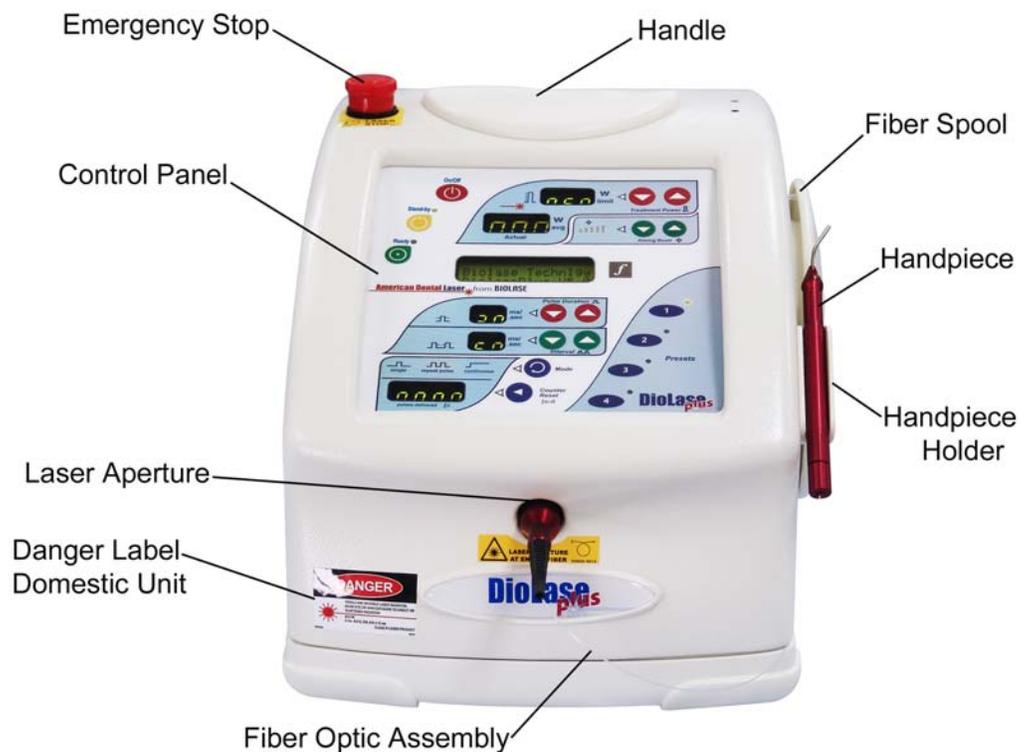


Figure 9: Front View (Domestic Unit)



Delivery System

NOTE: The fiber optic cable, handpiece, and heads (See Figure 6) are shipped non-sterile.

The Feed through Delivery System consists of:

- Fiber Optic Assembly (See Figure 10).

NOTE: The standard fiber optic cable assembly is a 400µm fiber. Other sizes are available upon request.

- Handpiece
- Base
- Handle
- Head (30P)
- Accessories: Adapter (To be used with Disposable/Bendable Tip)
- Diolase Plus™ Handpiece Kit (See Figure 11)

NOTE: The fiber optic cable, handpiece, and head are reusable accessories that require cleaning and sterilization before and after each patient treatment. For instructions on cleaning and sterilization of the fiber optic cable, handpiece and head, refer to section 8. Fiber optic cable is not autoclavable unless labeled as "autoclavable."

Diolase Plus™ Surgical Handpiece Assembly

To connect handpiece to fiber optic assembly:

1. Loosen Handpiece Base from Handpiece Handle. (See Figure 10a)
2. Slide fiber through Handpiece Base, Handle and Head.
3. Adjust fiber so it protrudes approximately 2 inches.
4. Strip and cleave fiber. (See Figure 10b)
5. Adjust to desired length. (See Figure 10c)
6. Gently tighten Handpiece Base to secure Handpiece to the Fiber Optic Assembly. (See Figure 10d)

To disassemble Handpiece from Fiber optic cable (See Figure 10):

1. Loosen Handpiece Base.
2. Slide Handpiece off of fiber optic cable.

To change Handpiece Head (See Figure 10):

1. Disassemble Handpiece from Fiber optic cable.
2. Change Handpiece head by holding handle and rotating head.

NOTE: For unit set up instructions, refer to Section 4: Operating Instructions.

Directions for Cleaving Diolase Plus™ Fiber

The Diolase Plus™ fiber should be cleaved after each procedure.

To cleave the fiber, refer to the following steps:

1. Loosen the proximal end of the handpiece (Fig.10a) by unscrewing the Handpiece Base.
2. Pull 2-3 inches of fiberoptic cable from the Handpiece Head through the Handpiece.
3. Select a fiber stripper that corresponds to the fiber diameter size.
4. Insert approximately 1 inch of the fiberoptic cable into the stripper. Squeeze the stripper handles to get a firm purchase on the fiberoptic cable, while keeping a firm grip on the fiberoptic cable, pull the stripper away from the handpiece in a smooth motion to ensure that the jacket is cleanly removed.
5. Use a diamond/carbide cleaver to cut the used end of the fiber. Place the fiber against a flat surface. Position the edge of the cleaver approximately 1/4 inch from the end of the fiber, and make a scratch around half the circumference of the fiber. Make sure that the edge of the cleaver is always perpendicular to the fiber during scratching.
6. Hold the end of the fiber above the scratch between thumb and forefinger and pull the end of the fiber away until the end section breaks off. If the fiber end is removed properly by pulling in the direction perpendicular to the end surface of the fiber, the fiber should end in a flat surface.
7. Verify the cleave quality by aiming the fiber at a flat surface and observing the shape of the spot created by the visible aiming beam. If the visible spot is a full circle, then the power output is optimal. If the circle is distorted then repeat only the cleaving procedure presented in steps 5 and 6 until you obtain a perfect circle beam.
8. After the fiber is successfully cleaved, pull the fiber back through the Handpiece, adjust fiber (See Figure 10) end to desired length. Tighten the Handpiece Base until snug. Ensure that the fiber isn't loose, by pulling lightly on the fiberoptic cable at the proximal end.

Figure 10: Feed through Delivery System

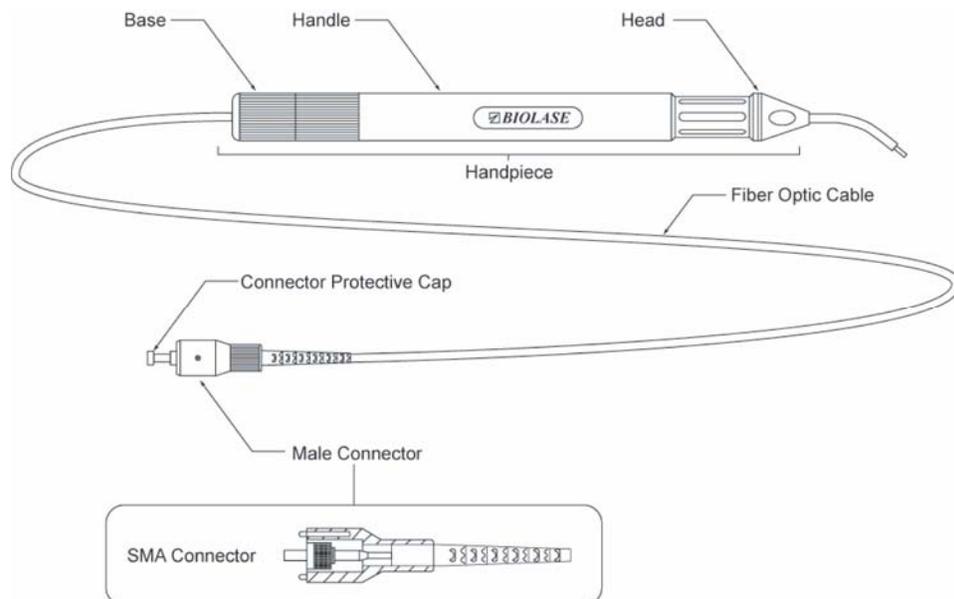


Figure 10a: Loosen Handpiece Base

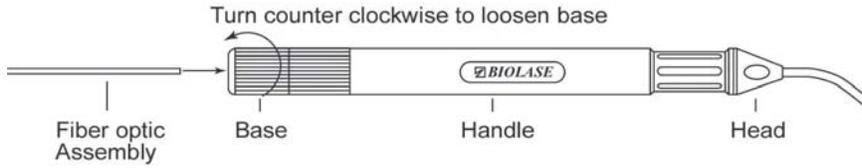


Figure 10b: Strip and Cleave

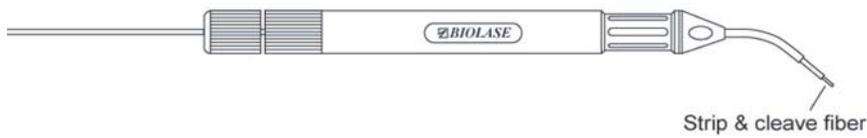


Figure 10c: Adjust Fiber Length



Figure 10d: Tighten Handpiece Base

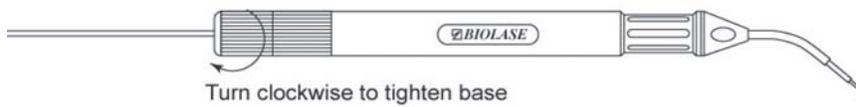
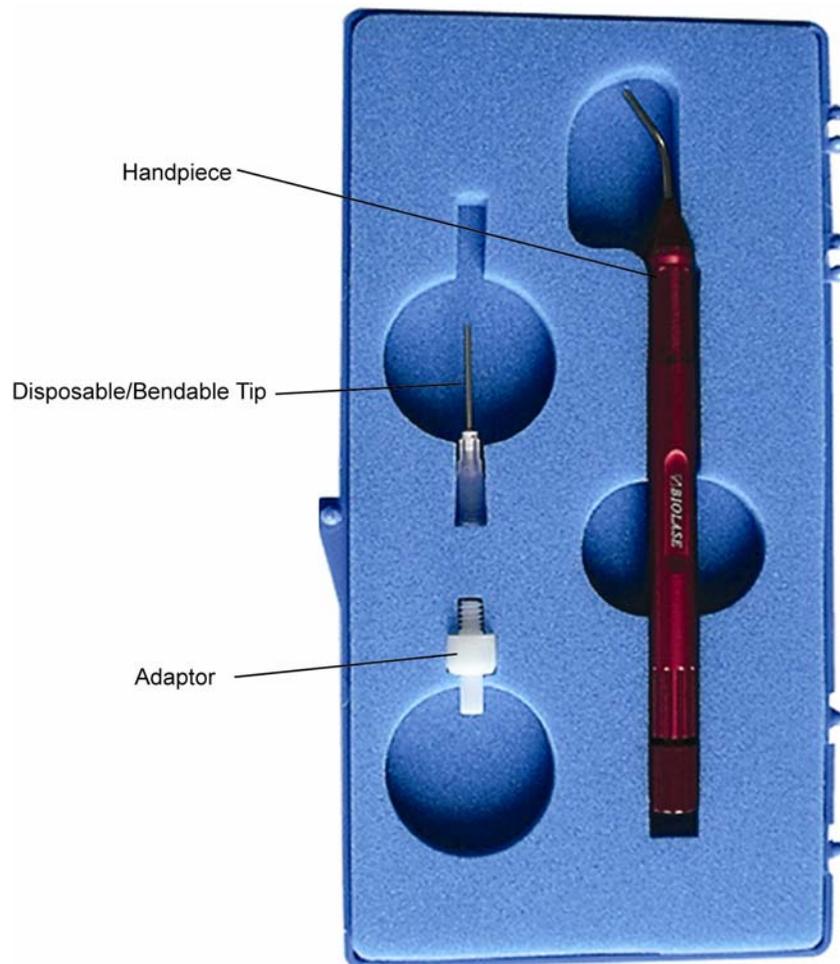


Figure 11: Diolase Plus Handpiece Kit



Section 4: OPERATING INSTRUCTIONS

Unit Setup

- Place unit in a clean, dry and well ventilated area.
- Verify circuit breaker is in OFF position.
- Connect key into key switch, verify it is in the OFF position.
- Verify Emergency Stop Button is disengaged. (Up position)
- Connect footswitch.
- Connect remote interlock.
- Connect power cord to power connector on unit and plug into wall outlet.

CAUTION: Do not cover or block ventilation channels. These channels provide air-flow path to cool unit.

WARNING: Never point fiber optic at eyes.

WARNING: All persons present in the operatory must wear protective Eyewear when laser is in operation.

Operation

Turn On the Diolase Plus™

- Turn circuit breaker to ON position.
- System Status Display shows message. Rotate key clockwise to ON position.

ON/OFF Button

Press ON/OFF button. The unit will turn on and begin a self-diagnostic routine. During this routine the following will automatically occur:

- Memory test
- Memory OK
- 3 second delay

Warm up mode

If during the self- diagnostic routine the diode laser temperature is below 18°C (64°F), the system will go into warm up mode. Follow the instructions on the display.

1. First press the READY key,
2. Press and hold the footswitch until the system stops.
3. The LASER FIRING icon will flash and beeper will sound until the system is sufficiently warmed up. It may take up to two minutes. The hand piece should be left in the holder with the fiber pointing down.

NOTE: While output power is negligible, wear protective glasses during the warm up. The warm up mode will not function at temperatures below 5°C (41°F) as a "Thermistor Error" will appear on the display. Do not leave the system in an uncontrolled environment where the temperature might drop significantly (i.e., the trunk of a car). If this happens, the system should be

left to warm up "indoors" for ten to fifteen minutes before the warm up mode is activated.

READY/STANDBY Buttons

Unit will only emit laser energy when footswitch is pressed and unit is set to READY mode. Values may be adjusted in both modes. In READY mode, values may be changed only when footswitch is released.

Press READY button.

LASER FIRING Icon

When footswitch is pressed and laser fires, the LASER FIRING icon (---*) will flash and beeper will sound, indicating that laser energy is present. When footswitch is not pressed, the LASER FIRING icon will go blank, indicating laser energy is not present.

MODE Buttons

Press the MODE button to toggle the unit between continuous, repeat pulse, and single modes.

POWER Buttons

Press POWER arrows to adjust power level. Press 'up' arrow to increase power level or press 'down' arrow to decrease power level.

PULSE DURATION Buttons

While in the repeat pulse or single pulse mode, press PULSE DURATION arrows to adjust pulse duration. Press 'up' arrow to increase pulse duration or press 'down' arrow to decrease pulse duration.

PULSE INTERVAL Buttons

While in the repeat pulse mode, press PULSE INTERVAL arrows to adjust pulse interval. Press 'up' arrow to increase pulse interval or press 'down' arrow to decrease pulse interval.

FUNCTION Key

Select Pulse Counter - "Pulse Count"

- Use Aiming Beam Up/Down buttons to Set number of pulses.
- "Pulses Delivered" Display - displays selection. When energized, counter will count down pulses as delivered.

Select Footswitch Operation - "Footswitch Oper."

- Use Aiming Beam Up/Down buttons to toggle between variable and On/Off operation of footswitch.

Select Display Brightness = "Disp. Brightness"

- Use Aiming Beam Up/Down buttons to change display LEDs brightness.

Select Beep ON/OFF

- Use Aiming Beam Up/Down buttons to turn On/Off BEEPER.

PRESET Buttons

Press a preset button to recall saved power, mode, duration and interval settings. To store values in a preset, press and hold the desired preset button for 2-3 seconds until its LED flashes.

Turn the unit OFF

- Press the STANDBY button.
- Place handpiece back on handpiece holder.

CAUTION: Verify that fiber optic tubing assembly is not twisted once handpiece is returned to holder. Fiber may break if it is twisted.

- Press the ON/OFF button.
- Turn key to OFF position.
- Switch circuit breaker to OFF position.
- Remove key from the unit and place in secured area.

Section 5: Diolase Plus™ SPECIFICATIONS

General

- Dimensions W x H x D (8.5" x 9.0" x 12.5") (22 x 23 x 32cm)
- Weight 13 lbs. (6 kg)

Electrical

- Operating Voltage 90 to 132 VAC 180 - 264 VAC
- Current Rating 3A 1.5A
- Frequency 47-63 Hz 47-63 Hz
- External Fuses None
- Main Control Circuit Breaker
- On / Off Controls Keypress, Keypad Button, Emergency Stop
- Remote Interruption Remote Interlock Connector

Laser

- Laser Classification IV (4)
- Medium GaAIs
- Wavelength 815 ± 15 nm
- Power Accuracy $\pm 20\%$
- Power Modes Continuous, Repeat Pulse, Single Pulse
- Pulse Duration 20 ms - 9.9 sec
- Pulse Interval 20 ms - 9.9 sec
- Delivery Fiber Diameter 200 - 1000 μ m
- Mode Multimode
- Max Output Power Range 7 watts out of a 600 μ m or 400 μ m fiber

Other Light sources

- Aiming Beam LED, max 5 mW, 630-670nm

Section 6: CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

Contraindications

- All clinical procedures performed with Diolase Plus™ 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, sleep apnea or an immune system deficiency. Medical clearance from patient's physician is advisable when doubt exists regarding treatment.
- Patients with snoring difficulties, possibly due to alcohol consumption or being overweight, are not candidates for Laser Assisted Uvulopalatoplasty (LAUP) unless other treatments have been attempted. NOTE: LAUP procedures should be performed by ENT trained professionals only.

Warnings

Eyewear

Doctor, patient, assistant and all others inside the operatory must wear appropriate laser eyewear protection for the diode laser wavelength of 815±15 nm.

Anesthesia

In soft tissue cases anesthesia may not be required, patients should be closely monitored for signs of pain or discomfort. If such signs are present, adjust settings, apply anesthesia or cease treatment if required.

Adjacent Structures

Diolase Plus™ is designed to remove soft tissues. Therefore, always be aware of adjacent structures and substructures during treatments. Be extremely careful not to inadvertently penetrate or ablate underlying or adjacent tissues. Do not direct energy towards hard tissues such as tooth or bone. Do not direct energy towards amalgam, gold or other metallic surfaces. Do not direct energy towards cements or other filling materials..

Suction

Use high-speed suction as required to maintain a clear field of vision during treatment. Do not use the Diolase Plus™ if you cannot clearly see the treatment site.

Training

Only licensed professionals who have successfully completed a Diolase Plus™ training seminar and have read and understood this User Manual should use this device. BIOLASE assumes no responsibility for parameters, techniques, methods or results. Physicians must use their own clinical judgment and professionalism in determining all aspects of treatment, technique, proper power settings, interval, duration, etc.

LAUP

Candidates considering LAUP treatment should be advised that this treatment could affect vocalization.

Section 7: CLINICAL APPLICATIONS

Introduction

To efficiently remove tissues it is imperative to understand the nature of the Diolase Plus™ device. Diolase Plus™ operates unlike traditional devices and the technique must be practiced and perfected to ensure efficient operation. Please study this section carefully, practice on model tissues and attend a quality diode laser training seminar before using this device in a clinical situation.

Table of Indications for Use

Use of Diolase Plus™ may be appropriate for the following indication for use:

Specialty	Application
Dental	Excisional and incisional biopsies
Soft Tissue	Exposure of unerupted teeth
	Fibroma removal
	Frenectomy
	Frenotomy
	Gingival troughing for crown impressions
	Gingivectomy
	Gingivoplasty
	Gingival incision and excision
	Hemostasis
	Implant recovery
	Incision and drainage of abscess
	Leukoplakia
	Operculectomy
	Oral papillectomies
	Pulpotomy
	Pulpotomy as an adjunct to root canal therapy
	Reduction of gingival hypertrophy
	Soft tissue crown lengthening
	Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility.)
	Treatment of aphthous ulcers
	Vestibuloplasty
ENT	Laser assisted Uvulopaletoplasty (LAUP) (For LAUP, this laser is effective for cutting, ablation, coagulating and removing oropharangeal soft tissue that has been diagnosed as anatomically abnormal or naturally occurring hypertrophic which has been identified and confirmed as being associated with chronic palatal snoring.) This procedure is for ENT professionals only.

BIOLASE assumes no responsibility for parameters, techniques, methods or results. Physicians must use their own clinical judgment and professionalism in determining all aspects of treatment, technique, proper power settings, interval, duration, etc.

Section 8: MAINTENANCE

Annual Maintenance

The Diolase Plus™ should be serviced annually by a qualified, trained, and certified technician. During the annual visit the system Diode arrays as well as all relevant electronic circuits will be calibrated.

Please contact your authorized representative to discuss Extended Service Contracts and Annual maintenance options.

Daily maintenance

Use disinfectant to wipe down the front panel of the Diolase Plus™ system after each procedure. Do not use bleach or abrasive cleansers.

Contamination Control Procedures

The contamination control suggested for the Diolase Plus™ fiber optic cable, handpiece and interchangeable heads is the steam sterilization method. However, before sterilization, the Diolase Plus™ reusable accessories (handpiece, fiber optic cable, and interchangeable heads) should be carefully cleaned per the following procedure.

NOTE: Fiber optic cable is delivered from manufacturer as non-sterile.

Cleaning Instructions for the Diolase Plus™ Surgical Handpiece and the Fiber Optic Cable

The cleaning process is intended to remove blood, protein and other potential contaminants from the surfaces and crevices of reusable accessories. This process may also reduce the quantity of particles, microorganisms and pyrogens present. Cleaning should be performed prior to sterilization and must be conducted only by qualified office personnel trained to perform the procedure and handle the Diolase Plus™ Fiber optic Delivery System.

Wear protective latex gloves when handling the contaminated delivery system. To disconnect the delivery system, follow the instruction for delivery system assembly presented in Section 3.

Together with steam sterilization, fiber optic cable can be disinfected per following instructions.

High-level Disinfection Instructions for the Fiber Optic Cable

- Transport the delivery system to a decontamination/sterilization work area.
- Take the fiber and strip 1.0" off from distal end of fiber using the fiber cleaver. Make sure that the part that has debris is removed entirely. Dispose of the contaminated fiber tip accordingly.
- Prepare the Sporox Sterilizing and Disinfecting Solution and submerge approximately 30cm(12 inches) of the fiber's distal end into the solution. For high level of disinfecting, immerse the fiber end for 30 minutes at 20°C (68°F).
- After this process is completed, thoroughly rinse and dry the fiber.
- For disposal of the Sporox, please follow the manufacture's instructions.

Steam Sterilization for Diolase Plus™ Surgical Handpiece

Before sterilization, the handpiece must be cleaned and disassembled. For cleaning, follow the procedures described above (See Section 9.3.1). To disassemble the handpiece from the fiber optic cable, carefully loosen the handpiece base and slide handpiece off of fiber optic cable (See Section 4.3.2).

The process of thermal sterilization with saturated steam under pressure is carried out in an autoclave. To perform this procedure, follow these step-by-step instructions.

- Place the handpiece, and interchangeable heads inside a single wrap self-seal autoclave pouch.
- Remove autoclave tray and place pouch(s) on the tray.
- Place tray inside the autoclave chamber and set controls to the following values:
 - Temperature: 250 °F (121 °C)
 - Pressure: 15 PSI (1 bar)
 - Time cycle: 20 minutes
- At the completion of the autoclave cycle remove the tray and let the handpiece, fiber optic cable and interchangeable heads cool and dry.
- Assemble the handpiece to the fiber optic cable and attach delivery system to unit for the next patient.

CAUTION: DO NOT place or stack other devices on top of the fiber optic cable.

Transportation

The Diolase Plus™ is susceptible to misalignment if not handled properly. The unit should ALWAYS be handled carefully and never banged, jarred, jolted, dropped or knocked.

Do not place the unit into a pick-up truck, van or other moving machine for transportation unless it is completely packaged inside of its shipping box. If you have any questions regarding transportation please call your local Dealer.

Storage

The Diolase Plus™ should be stored in a cool dry place when not in use. Cover the unit when not in use for extended periods of time. Store the system in a place where it will not be accidentally bumped or banged.

The Diolase Plus™ was shipped inside a custom shipping box. Please save and store the box in a cool dry place.

Section 9: CALIBRATION

Calibrating Power

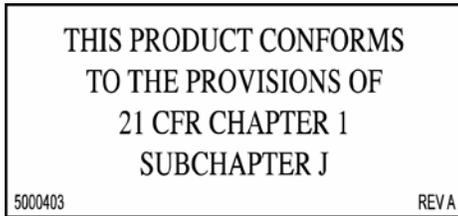
NOTE: Calibration is to be performed only by trained personnel. It is necessary periodically to calibrate the Diolase Plus™ Laser System. In order to do this, the following equipment is required:

- An Optical power meter recently calibrated
 - Diolase Plus™ Laser
 - Handpiece with polished tip
 - Service Plug
-
- Turn on the Diolase Plus™ Laser following previously described procedures.
 - Arrange a fixture such that the handpiece tip is pointing at 3" toward the optical power meter, and the beam does not overfill the sensing diameter.
 - Remove the remote plug from the rear of the Diolase Plus™ and insert the service plug.
 - Push any key to clear the "Remote Error" display, and set the output power to 0.5 watt. Be certain the pulse mode is continuous.
 - Push the "Ready" key and depress the footswitch to the maximum. The optical power meter will indicate the power delivered.
 - Use the "Aiming Beam" keys to increase or decrease the diode current until the power output displayed on the optical power meter is 0.5 watt.
 - Release the footswitch and push "Counter Reset" to store this value of diode current.
 - Set the output power to 1.0 watt, and repeat the procedure, using "Aiming Beam" keys to adjust the diode current.
 - When the optical power meter indicates 1.0 watt $\pm 10\%$, release the footswitch, push "Counter Reset".
 - Repeat at each power setting 1-10 watts.
 - Remove the service plug and re-insert the remote plug.

Calibration Schedule

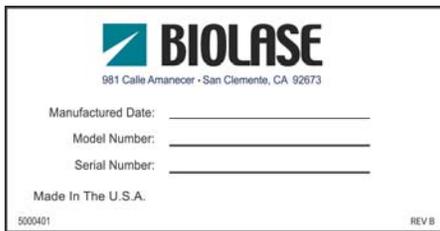
This Procedure will be required every 12 months in order to maintain the required accuracy of the output power versus displayed power.

APPENDIX A - LABELS



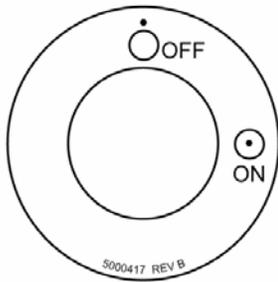
A.1 Certification

Location:
Back Panel (see figure 13)



A.2 Identification

Location:
Back Panel (see figure 13)



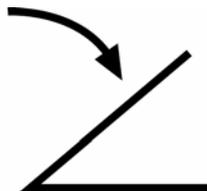
A.3 Keyswitch On/Off

Location:
Back Panel around keyswitch (see figure 13)



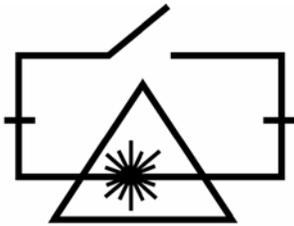
A.4 Electrical Rating

Location:
Back Panel (see figure 13)



A.5 Footswitch

Location:
Back Panel (see figure 13)



5000439 REV A

A.6 Remote Interlock

Location:
Back Panel (see figure 13)



A.7 Danger

Location:
Front Panel (see figure 9)

(Domestic use)



A.8 Laser Aperture

Location:
Front Panel (see figure 14)



A.9 Name Plate

Location:
Front Panel (see figure 14)



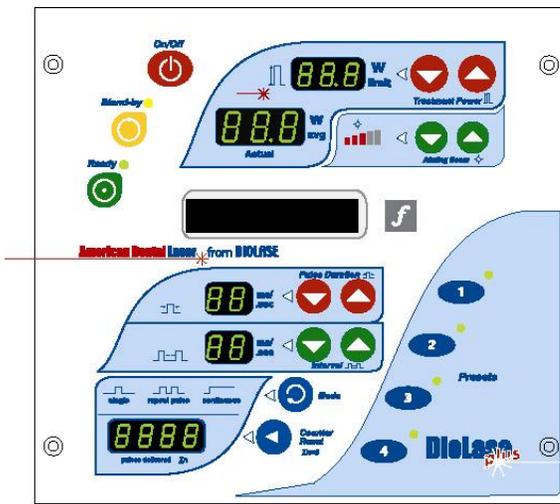
A.10 Lifting Label

Location:
On top (see figure 14)



A.11 Emergency Stop Label

Location:
On top (see figure 14)



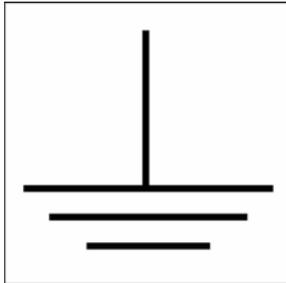
A.12 Control Panel

Location:
On top (see figure 14)



A.13 Warning label

(International Units Only)
Location:
Front Panel (see figure 14)



LB00-20-0009

A.14 Ground

(International Units Only)
Location:
Next to E1 ground terminal



A.15 CSA Certification Label

(International Units Only)
Location:
Back Panel (see figure 13)



A.16 CE Certification Label

Location:
Back Panel (see figure 13)

APPENDIX B - SIGNS



B.1 Laser Radiation Danger Sign

Location:
At Operating Entrance

Figure 13: Back View with Labels (International units)

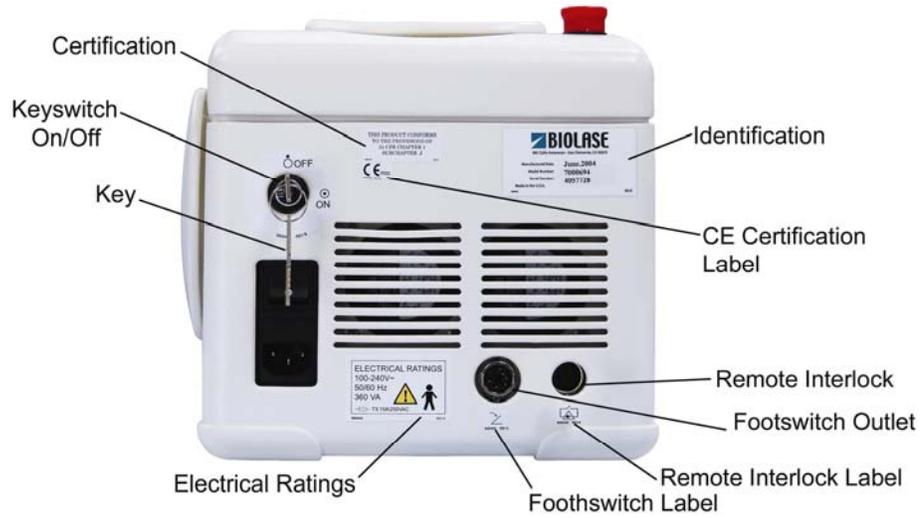
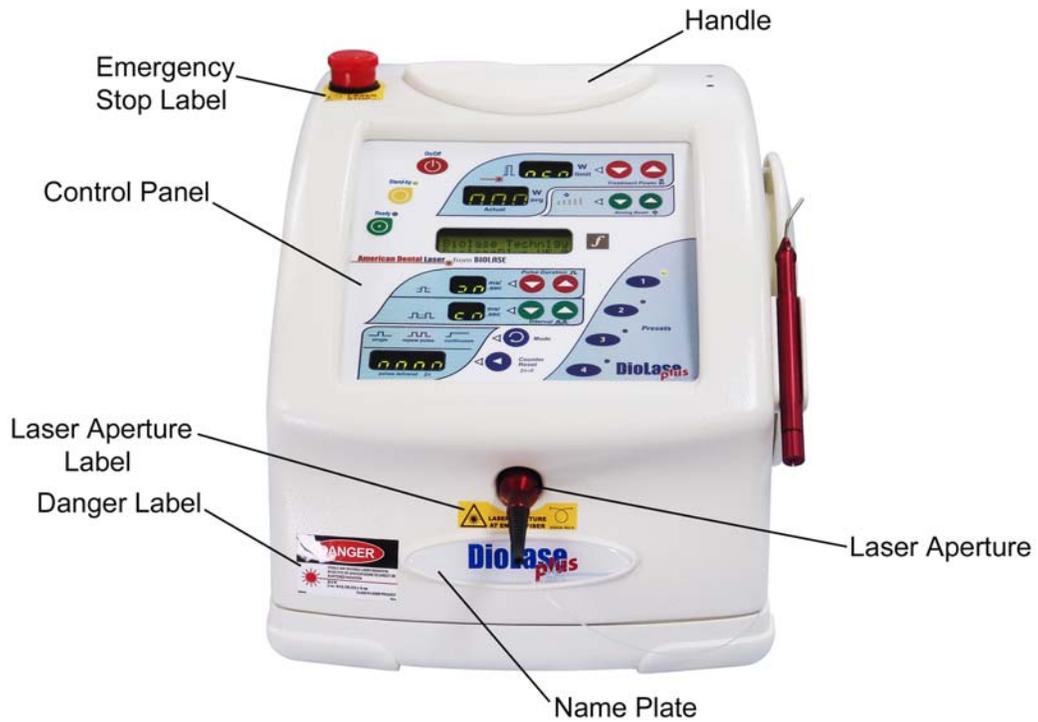


Figure 14: Front View with Labels (International units)



APPENDIX C - SPARE PARTS AND ACCESSORIES

BIOLASE DESCRIPTION

- Handpiece
 - Fiber Optic Assembly
 - Laser Safety Glasses
 - Key
 - Remote Interlock Plug
 - Power Cord
 - Footswitch
 - Laser Radiation Danger Sign
-
- Prescription eyewear may be available. Please contact your local authorized BIOLASE dealer for additional information.

APPENDIX D (LIMITED WARRANTY)

BIOLASE Technology, Inc. warrants for a period of twelve (12) months from the shipment to the original purchaser/ user the Diolase Plus™ Laser system serial number _____. It is warranted to be free from defects in materials and workmanship under normal use and service and fit for the ordinary use for which designed, if operated by a trained and competent operator and properly serviced and maintained. This limited warranty applies only to the original purchaser/user of the equipment and only so long as the equipment is used in the country to which it was originally shipped by BIOLASE Technology, Inc. or by its authorized distributor. This warranty does not cover maintenance of parts that fail due to normal use, including but not limited to the Fiber optic cable and Handpiece.

This warranty is null and void if the user attempts to service the equipment (other than performing the maintenance described in the Operator Manual) or if service is performed by persons who are not trained and authorized to do so by BIOLASE Technology, Inc. If the unit is found to be defective within the period specified above after examination by an authorized service representative and BIOLASE Technology, Inc. is satisfied that the failure was due to defective materials and/or workmanship, BIOLASE Technology, Inc. will repair or, at its option, replace the defective parts without charge. BIOLASE Technology, Inc. reserves the right to make such an examination and to make the necessary repair/replacement in its own factory, at any authorized repair station or at the purchaser/user's place of installation. In the event the user does not cooperate with BIOLASE in providing service, BIOLASE is released of all liabilities to the purchaser/user. Any shipping charges incurred shall be paid by the purchaser/user of the equipment. Disposable or consumable items are not covered by this warranty. The handpiece and fiber optic cable are warranted for 90 days against defects in workmanship and materials. BIOLASE will not be responsible or obligated to purchaser/user for loss of revenues incurred by the purchaser/user due to the product requiring service.

THE EXPRESS WARRANTY ABOVE IS THE SOLE WARRANTY OBLIGATION OF BIOLASE TECHNOLOGY, INC. AND REMEDY PROVIDED ABOVE IN LIEU OF ANY OTHER REMEDIES. THERE ARE NO OTHER AGREEMENTS, GUARANTEES OR WARRANTIES - ORAL OR WRITTEN, EXPRESSED OR IMPLIED - INCLUDING WITHOUT LIMITATION WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. BIOLASE TECHNOLOGY, INC., SHALL HAVE NO LIABILITY WHATSOEVER FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF ANY DEFECT, IMPROPER USE OR UNAUTHORIZED SERVICE OR REPAIR.

Prior to return of a unit, or any portion thereof, BIOLASE Technology, Inc. MUST be consulted to avoid unnecessary shipping. If return of the equipment is deemed necessary, a Return Authorization Number will be assigned. This number must be recorded on the outside of the shipping container.

APPENDIX E- (LIMITED LIABILITY)

BIOLASE TECHNOLOGY, INC. WILL NOT BE LIABLE FOR INCIDENTAL, CONSEQUENTIAL, INDIRECT OR SPECIAL DAMAGES OF ANY KIND INCLUDING, BUT NOT LIMITED TO, DAMAGES FOR LOSS OF REVENUE, LOSS OF BUSINESS OR BUSINESS OPPORTUNITY OR OTHER SIMILAR FINANCIAL LOSS ARISING OUT OF OR IN CONNECTION WITH THE PERFORMANCE, USE OR INTERRUPTED USE OF THE "Diolase Plus™" SYSTEM (S) OR ANY BIOLASE MATERIALS.