



epic[™] **V**
SERIES

User Manual

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INTRODUCTION

The EPIC™ V-Series diode laser is a surgical and therapeutic device at the cutting edge of technology, designed for a wide variety of dental and surgical soft tissue procedures, as well as for use in providing temporary relief of minor pain in domestic animals (*i.e.*, dogs, cats, birds, and horses).

The EPIC™ V-Series utilizes a solid state diode as a semiconductor source for invisible infrared radiation. The energy is delivered to the treatment site via flexible fiber connected at one end to the laser source and the other end to the Handpiece. Various types of single use, disposable tips are designed and optimized for different applications. The device is activated by means of a wireless footswitch.

The EPIC V-Series is restricted to sale by or on the order of a licensed veterinarian and its use requires proper clinical and technical training. This manual provides instructions for those professionals who have completed the appropriate training.

When used and maintained properly, the EPIC V-Series will prove a valuable addition to your practice. Please contact BIOLASE Customer Service at 1-800-321-6717 in the USA and Canada for any service needs. If you are located outside the U.S., please contact your BIOLASE-authorized distributor for any service needs.

CANADA: This device must be installed and operated according the guidelines of CAN/CSA-Z386-92 "Laser safety in a health care facility."



1. PACKAGING

1.1 SYSTEM PARTS LIST

The EPIC V-Series laser system includes the following:

1. Laser Console (lithium ion battery pack already installed)
2. Screen Protectors box (Peel-off clear screen cover - qty. 30)
3. Delivery System box
4. Tips box
5. Surgical Handpiece box (contains two (2) Surgical Handpieces)
6. Three (3) pairs of protective laser eyewear
7. DC power supply and power cord (one (1) US and one (1) International)
8. User Manual (Hard Copy only)
9. Welcome Kit (Welcome Letter, BIOLASE store information, Quick Setup Guide, Guide to Online Training & Product Registration Card, Tip User Guide, Limited Warranty Information)
10. Laser Warning Sign
11. Tip Initiation Kit
12. Remote Interlock cable
13. Philips-head screwdriver (for installing Footswitch batteries)
14. Footswitch
15. AAA batteries (2)

NOTE: The laser ships with the lithium ion battery pack already installed.

NOTE: Use proper care when transporting the unit. Refer to Section 8 in this User Manual for instructions.

WARNING: No modification of this equipment is allowed.

1.2 FACILITY REQUIREMENTS

Electrical Supply (100-240V ~):	1.5A, 50/60Hz
Environmental Requirements:	Temperature: 20-25 °C Humidity: 15-95%, Non-condensing

2. EQUIPMENT DESCRIPTION

2.1 GENERAL

The EPIC V-Series system consists of three components:

- Base Console



- Delivery System



- Wireless Footswitch



2.2 BASE CONSOLE

The Console has a Display Panel (Touch Screen and Control Button) in front. It can be powered by an external mains power supply or an internal replaceable lithium ion battery pack, 14.4V, 2.9 Ah.

2.3 CONTROL PANEL

ITEM	ITEM DESCRIPTION
CONTROL Button	Turns the controls and display on and off; places the unit into STANDBY or READY or SLEEP mode
LED Indicator	<ul style="list-style-type: none"> • <i>Amber</i> indicates unit is in STANDBY mode. • <i>Green</i> indicates unit is in READY mode. • Blinking <i>green</i> indicates the emission of laser power. • Blinking <i>blue</i> indicates pairing between the footswitch and laser console is active

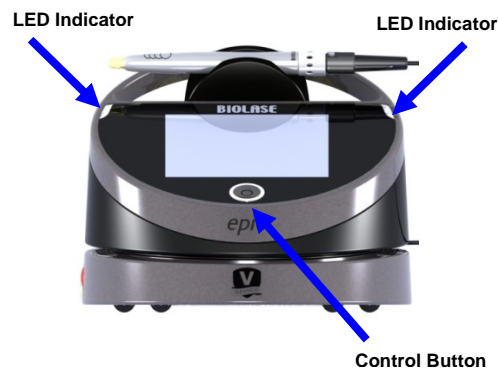


Figure 2.1: Control Panel (Front View)

2.4 SURGICAL DELIVERY SYSTEM

NOTE: All fiber optic cables, Handpieces & tips are shipped non-sterile.

The EPIC V-Series Re-Useable Delivery System with surgical Handpiece consists of:

- Re-useable Fiber Optic Assembly
- Re-useable Surgical Handpiece (Figures 2.4, 2.5)
- Disposable Tips (See Figures 2.7, 2.8, 2.9, 2.10)

NOTE: The fiber optic cable is detachable from the console. The Handpiece is a Re-usable accessory and will require cleaning and sterilization prior to each patient treatment. Tips are intended for single-use only and must be disposed of after each patient use. Proper tip disposal in a biohazard medical waste Sharps container is required. Tips must be steam sterilized prior to use. For instructions on cleaning and sterilization of the Handpiece and tips Refer to Section 8.

2.6 FIBER OPTIC CONNECTION

Only install the fiber optic cable while the laser console is turned off. The fiber optic cable is attached to the console by inserting the optical access plug (Figure 2.2) into the optical access port (Figure 2.3).

NOTE: Make sure you hear the fiber optic “click” into place; if you do not hear it “click,” remove the fiber optic and reinstall it.

CAUTION: Do not connect or disconnect the fiber while the laser console is turned on. Only connect or disconnect the fiber when the laser console is turned off.

For storage, wind the cable in the fiber storage channel around the base of the console in a counterclockwise direction (Figure 2.7).

CAUTION: Do not bend the fiber optic at a sharp angle, as it is can break. Make sure it is not caught or pinched between the housing and the fiber optic access plug.

To disconnect the fiber optic cable from the laser console, **make sure the cable is completely unwound from the console base**, grab the fiber optic access plug and slowly pull it straight back from the optical access port.

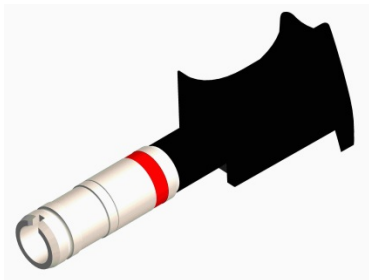


Figure 2.2: Fiber Optic Access Plug

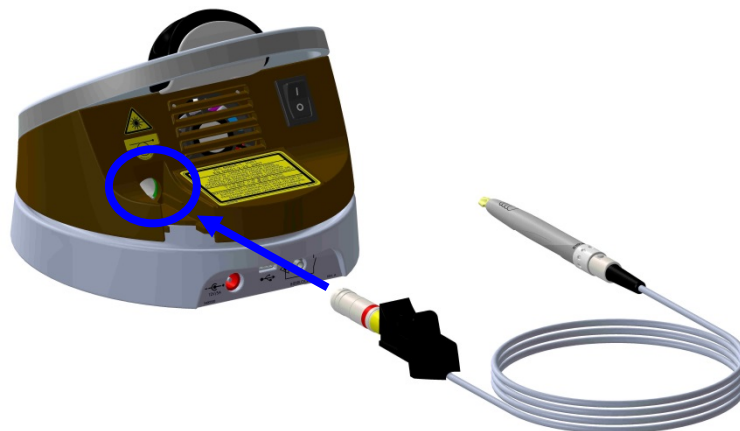


Figure 2.3: Optical Access Port

2.7 SINGLE-USE TIPS

The tips are single-use accessories and are provided in three core diameters: 200µm, 300µm, and 400µm, in different lengths (see Appendix C).

CAUTION: **Tips are single-use only** to avoid cross-contamination and are designed to withstand a single sterilization cycle; they must be disposed of after use in a biohazard medical waste Sharps container.

To connect the tip, insert it firmly into the distal end of the Handpiece as far as it will go, then tighten by turning clockwise (Figure 2.7). Bend the metal cannula according to the specific procedure requirements (Figure 2.10).

NOTE: To provide proper laser operation, do not connect tips when the Handpiece is disconnected.

2.8 SURGICAL HANDPIECE ASSEMBLY

- ▶ To connect the Handpiece to the fiber optic assembly, push the Handpiece on the fiber shaft until it clicks on and is secured at connected position.
- ▶ To disconnect the Handpiece from fiber optic assembly:
 - Take the Handpiece body in one hand and the shaft in another
 - Push the two buttons on the Fiber Shaft
 - Pull the Handpiece with the ring to separate.
- ▶ Remove the fiber tip by twisting the tip counterclockwise.

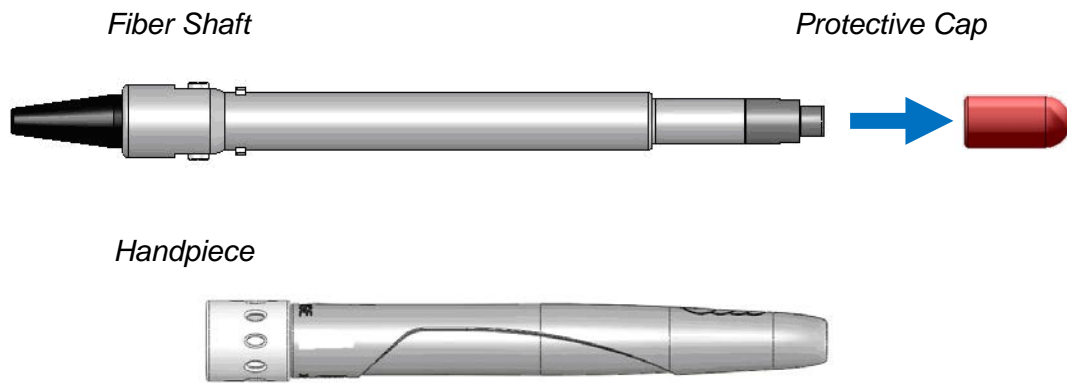


Figure 2.4: Connecting the Handpiece to the fiber optic assembly



Figure 2.5: Surgical Handpiece Assembly fully assembled

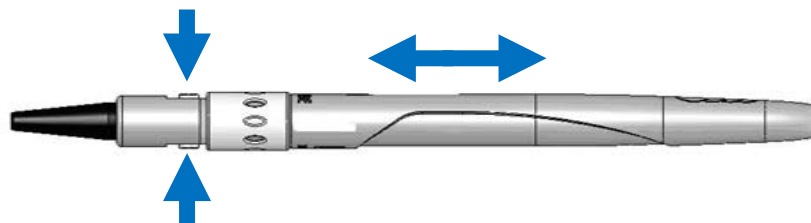


Figure 2.6: Disconnect the Handpiece from the fiber optic assembly by pressing both buttons at the base of the Fiber Shaft

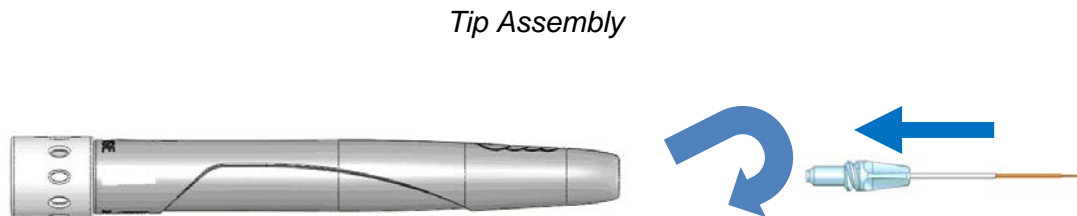


Figure 2.7: Insert the fiber tip into the Handpiece and twist **clockwise** until snug



Figure 2.8: Remove the fiber Tip by twisting the tip **counterclockwise**

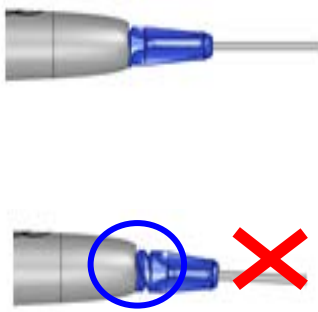


Figure 2.9: When installing the tip, make sure it is seated properly (thread correctly)

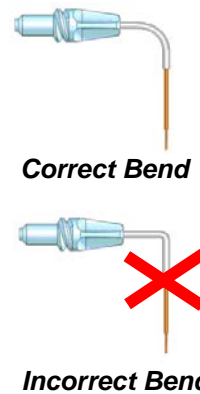


Figure 2.10: Bending the tip cannula

WARNING: When the aiming beam is not present or has a significantly different shape, change the tip.

2.9 DEEP TISSUE HANDPIECE (OPTIONAL ACCESSORY)

The Deep Tissue Handpiece is reusable and equipped with a disposable non-sterile protective shield for single patient use. The Handpiece is non-sterile and requires cleaning before and after each patient treatment. **This Handpiece cannot be sterilized in the autoclave.** For instructions on cleaning the Handpiece, refer to section 8.

NOTE:

Always wipe the disposable shield with alcohol prior to use. The disposable shield is for single-use only to avoid cross-contamination. Dispose of when treatment session is completed.

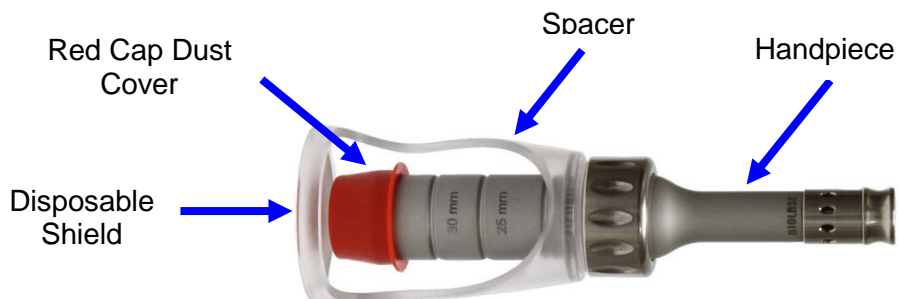


Figure 2.15: Deep Tissue Handpiece

- Remove Red Cap Dust Cover from the Deep Tissue Handpiece.
- Slide Handpiece over shaft until it clicks into place (Figure 2.16).



Figure 2.16

- Place protective shield over the adjustable spacer (Figure 2.17).



Figure 2.17

- Loosen the Lock Ring and set the Spacer at the desired spot size Detent Location (Figure 2.18). Tighten the Lock Ring.



Figure 2.18

The Handpiece is now ready to use.

To remove the Handpiece, press and hold the buttons on the side of the Fiber Shaft and pull the Handpiece away from the shaft.


3. SAFETY

3.1 PRECAUTIONS

Failure to comply with precautions and warnings described in this User Manual may lead to exposure to dangerous optical radiation sources. Please comply with all safety instructions and warnings.

3.2 SAFETY INSTRUCTIONS

Follow these safety instructions before and during treatments:

-  When the laser is in use, all operatory entrances must be marked with an appropriate warning sign (one (1) included).
- Do not operate in the presence of explosive or flammable materials. Flammable anesthetics or oxidizing gases such as nitrous oxide (N₂O) and oxygen should be avoided. Solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before laser is used. Attention should also be drawn to the danger of ignition of endogenous gases.
- All persons present in the operatory must wear protective laser eyewear.

NOTE: For replacement or additional protective laser eyewear, please contact BIOLASE.

CAUTION: Periodically inspect laser eyewear for pitting and cracking.



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

WARNING: 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 standards. However, the possibility of electromagnetic or other interference may still exist. Relocating the device may help to eliminate the interference.

CAUTION: Always ensure that the proper laser parameters are set before the EPIC V-Series laser is used in a clinical setting.



**LASER
WARNING:**

Always ensure that the protective laser eyewear is appropriate for the laser wavelength.

- Do not look directly into the beam or at specular reflections.
- Never direct or point the beam at a person's eyes.
- Always place the system into STANDBY mode (by pressing the Control Button while in READY mode) before exchanging Handpieces or disposable tips.
- Toggle the ON/OFF switch (located on the rear of the console) to the OFF (O) position before leaving unit unattended.



**LASER
WARNING:**

Do not open unit housing at any time. Danger from optical radiation may exist.



**LASER
WARNING:**

Do not aim the laser at metallic or reflective surfaces, such as surgical instruments or dental mirrors. If aimed directly at these surfaces the laser beam will reflect and create a potential hazard.

CAUTION:

Be aware that the metal / plastic cannula on the tips may become hot during use. Avoid contact of the cannula with any tissue.

3.3 SAFETY FEATURES

Energy Monitor

The energy monitor measures and verifies power output. Power deviations of more than $\pm 20\%$ from the selected value will cause the display to show the error message: "LASER CURRENT HIGH/LOW".

The laser console will not operate until the system first clears the error and then goes into READY mode. If the error message persists, please contact BIOLASE Service at 1-800-321-6717.

System Monitor

The system monitors the emergency stop switch, remote key, wireless footswitch connection, 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.

Power Switch

The laser console can be switched ON (I) or OFF (O) using the Power Switch on the back of the console.

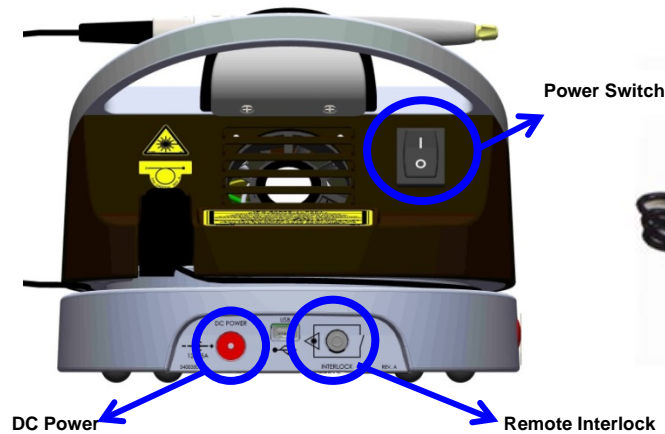


Figure 3.1: Power Switch, DC Power Input, Remote Interlock



Figure 3.2: Power Supply Module with cord

CAUTION: Use only the Power Supply Module supplied with the EPIC V-Series laser system (BIOLASE Part Number 2400129).

Access Key Code

The Access Key Code prevents unauthorized use of the system. It is activated every time system is turned on with the Power Switch (refer to Section 4 for code).

NOTE: Placing the laser in sleep mode by pressing and holding the Control button on the front panel does not re-set the Access Key Code. Turn the Power Switch OFF (O) only when the system will not be in use for a long period of time.

Control Button

Once the power switch is set to the ON (I) position, enter the access key code. After setting the desired parameters for a procedure, press the CONTROL button on the control panel to enter into READY mode. The aiming beam will illuminate to indicate that the system is ready for use.

Wireless Footswitch

The EPIC V-Series will not emit laser energy until the user presses down on the Footswitch while the laser is in READY mode. The footswitch is designed to work using wireless technology.

Two (2) AAA batteries are required to power the footswitch (included). (For instructions on how to replace the footswitch batteries, see Section 4.)



Figure 3.3: Footswitch

Remote Interlock

This feature allows the laser console to be connected to the remote sensor, preventing its operation when triggered (e.g., by opening door). The electric cable from this connector should be wired to the normally closed switch, sensing the opening of a door and turning the laser console off when the switch is open.

To override this feature, don't connect the plug.



Figure 3.4: Remote Interlock Connector

Emergency Stop

Press the red Emergency Laser Stop button to instantly turn off the laser console. The error screen will display an “Emergency Switch Error” message and the amber LED will begin flashing. To clear the error, press the Emergency Laser Stop button again; in 2 to 5 seconds the amber LED will stop flashing and the system will automatically go into STANDBY mode.

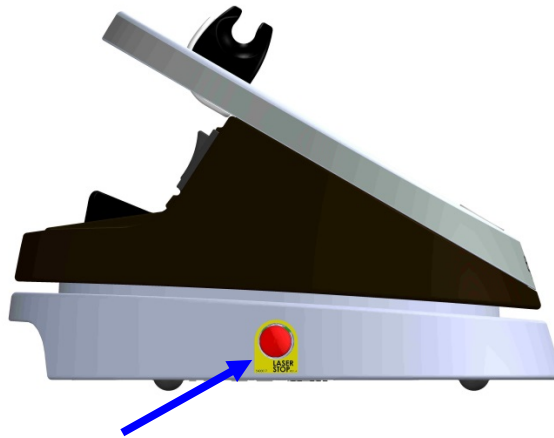


Figure 3.5: Emergency Laser Stop (Left Profile View)

Functional Display

The System Color Display with Touch Screen and LED indicators on the control panel show the functional conditions of the system.

3.4 SAFETY CLASSIFICATION

The following safety classifications are applicable to the device:

- Laser Radiation – Class 4
- Aiming Beam – Class 2
- 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
- Wireless Footswitch – IPX6

4. OPERATION INSTRUCTIONS

4.1 SYSTEM SETUP

- Place the unit in a clean, dry, and well-ventilated area.
- Verify power switch is in the OFF (O) position.
- EPIC V-Series will work using either DC power or the rechargeable battery pack:
 - *DC Power:* Connect the power cord of the power supply to the laser console and plug into a wall outlet
 - *Rechargeable Battery:* The EPIC V-Series is shipped with the battery pack already installed; to charge the battery pack, connect the power cord of the DC power supply to the laser console and plug into a wall outlet. Before first use, fully charge the battery (at least 3 hours). Once the battery is charged, unplug the power cord from the wall outlet and the laser console. The laser console will run on battery power alone.

NOTE: To fully charge the battery, plug the power supply in and then turn the laser console ON (I) at the Power Switch. The laser console will start to charge and the unit will go into sleep mode (with the screen off) after 5 minutes; if the power supply is plugged in but turned OFF (O) at the Power Switch, the battery will still charge, but at a slower rate.

- Connect the fiber to the laser console (see Section 2).

CAUTION: Do not connect or disconnect the fiber while the laser console is turned on. Only connect or disconnect the fiber when the laser console is turned off.

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

CAUTION: Do not bend the fiber optic at a sharp angle, as it can break. Make sure it is not caught or pinched between the housing and the fiber optic access plug.

- Remove protective cap from the end of the fiber shaft (see Figure 2.4).
- Carefully connect the Handpiece to the fiber optic assembly (see Figure 2.5).
- Insert the selected tip and tighten it clockwise until snug (see Figure 2.7).
- Wind any excess fiber optic cable onto the fiber spool counterclockwise around the base of the console.



- The Handpiece is now ready to use. To store the Handpiece, place it in the Handpiece holder located at the top of the laser console .



**LASER
WARNING:**

Never point the laser at a person's eyes.



**LASER
WARNING:**

Never operate the laser without a fiber tip attached.



**LASER
WARNING:**

All persons present in the operatory must wear protective eyewear when the laser is in use.

4.2 OPERATION - TURN ON THE EPIC V-SERIES

- Ensure that the battery has enough charge for operation, or connect the power supply cord to the power connector on the laser console and plug the cord into a wall outlet.
- Turn the Power Switch at the rear of the console to the ON (I) position. The “BIOLASE” logo screen will appear (Figure 4.1). After three (3) seconds the EPIC V-Series “Welcome” screen will be displayed (Figure 4.2).



Figure 4.1



Figure 4.2



Figure 4.3

- Enter the three digit access code using the touch screen. The Access Key Code is **888**. (If the incorrect code is entered, an 'X' appears briefly in the window (Figure 4.3) and then the screen reverts back to the Welcome screen; re-enter the correct code.)
- The system will go to the HOME screen which identifies three procedure categories to choose from: Soft Tissue, Whitening, Pain Therapy.

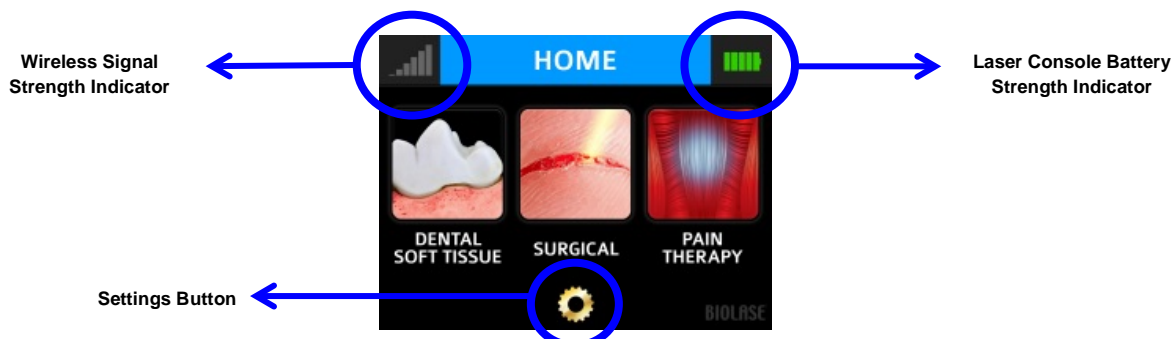



Figure 4.4: Home Screen

4.3 SETTINGS SCREEN

Pressing the Settings button  on the HOME screen accesses the Settings screen; this screen allows the user to make changes to several system settings:

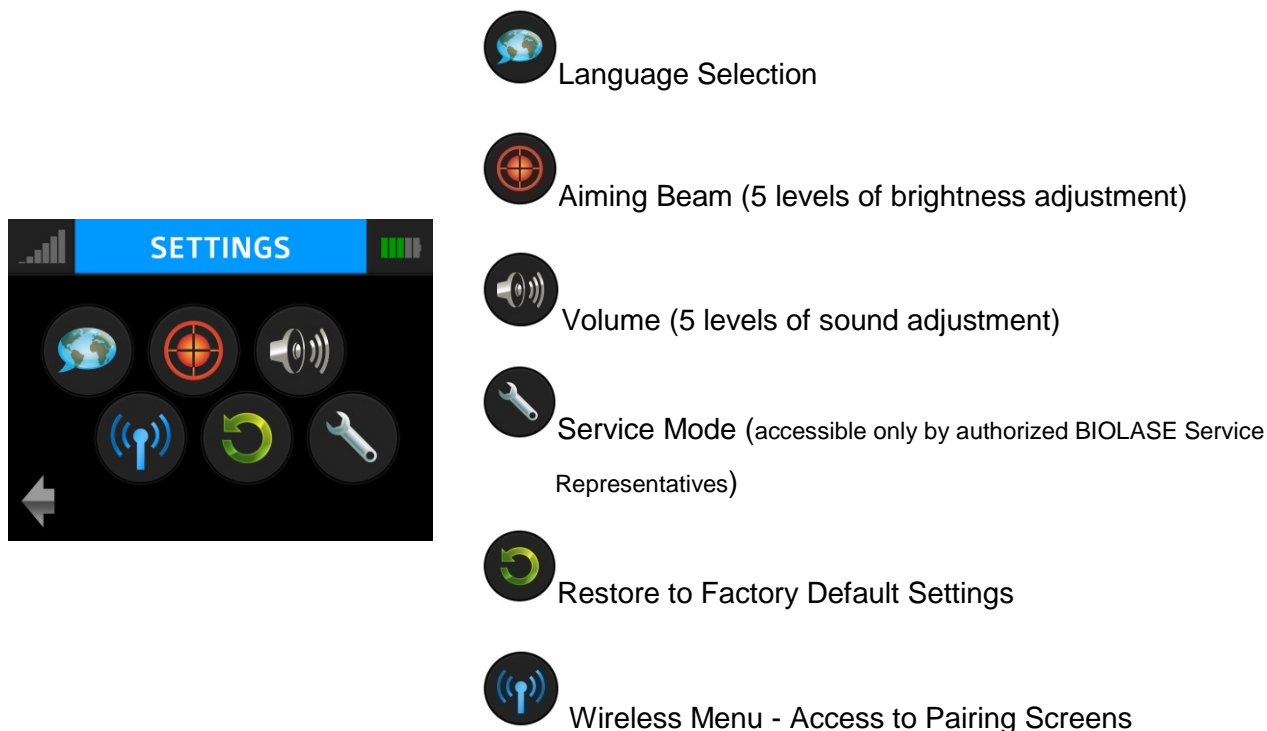



Figure 4.5

4.4 PAIRING THE FOOTSWITCH TO THE LASER CONSOLE

Verify that the footswitch and laser console are paired; a blue LED indicator light on the laser console will blink when pairing is established. The laser and footswitch are shipped already paired. However, if pairing is not confirmed, an  will appear in the pairing icon located in the upper left hand corner of the touchscreen (Figure 4.6).

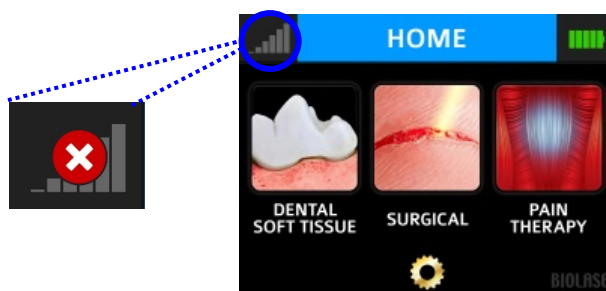




Figure 4.6

To re-establish pairing, take the following steps:

1. Go to the Settings menu on the laser console display by pressing the Settings button  and select the "Wireless" icon .



2. A screen will appear indicating that pairing of the footswitch to the laser console has been lost (Figure 4.7); press the green PAIR button. .



Figure 4.7

3. The message that "PAIRING WILL NOW BEGIN" will appear; press the green check mark to continue  (Figure 4.8).

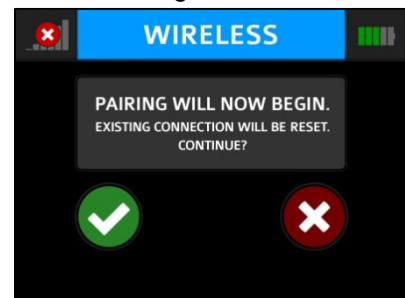


Figure 4.8

4. To complete the pairing process, turn the footswitch over and press the Pairing Button  for four (4) seconds (Figure 4.9).



Figure 4.9

- 5a. The Wireless screen will appear indicating that pairing was successful and that the footswitch and laser console are now paired (Figure 4.10). Proceed to step 6.



Figure 4.10


- 5b. If pairing has not occurred, the Wireless screen will appear again indicating that pairing was not successful (Figure 4.11); press the green button to repeat steps 3 – 5a. 



Figure 4.11

6. Press the Settings button to return to the Settings menu; press the arrow on the bottom left of the Settings screen to return to the Home screen (Figure 4.12).

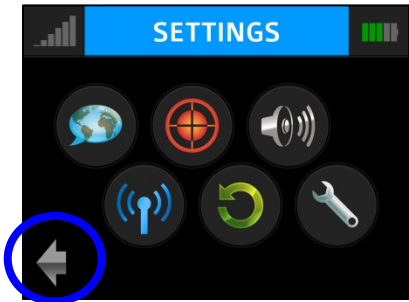


Figure 4.12

4.5 CONTROL BUTTON

The CONTROL button on the front of the laser console is a multi-functional button (Figure 2.1). Pressing and holding the Control Button for approximately two (2) seconds will allow the transition from STANDBY or READY mode to SLEEP mode. Note that you will not be allowed to go into READY mode unless you have chosen a treatment module on the HOME screen first.



4.6 ENTERING READY OR STANDBY MODES

Press and release the Control Button to place the laser console into either READY or STANDBY mode. The laser console will only emit laser energy when the footswitch is pressed and the laser console is set to READY mode. While in READY or STANDBY mode, mode setting and/or power setting values may be changed only when the laser is not firing. If the laser is firing (*i.e.*, the footswitch is engaged), the ability to change the settings is blocked. (“READY” or “STANDBY” is displayed in the lower right hand corner of the display screen).


4.7 READY MODE

When entering READY mode, the laser console fan will turn on and pressing the footswitch will activate laser radiation. There is a two (2) sec delay between switching to READY mode and the ability of the laser console to emit a laser beam.

4.8 WIRELESS FOOTSWITCH

The wireless footswitch is powered by two (2) AAA batteries.

When the wireless footswitch is pressed in READY mode and the laser fires, a beeping sound indicates that laser energy is present. A green LED will begin flashing and a blue LED will light at the top corners of the laser console, confirming the footswitch and laser are paired.

In the top left corner of most screens is a Signal Strength Indicator  which displays the signal strength between the laser console and the footswitch (strongest is five (5) bars). Pressing and releasing the footswitch while in Standby mode will update this indicator. Although the unit will work with a signal level as low as one (1) bar, a weaker signal level will make the connection between the footswitch and laser console more vulnerable to wireless (RF) interference from other sources, such as cell phones or microwaves. To improve the signal strength, reposition either the footswitch or the laser console until the signal indicator achieves the strongest possible level for optimal operation.

NOTE: When the footswitch is not in use, it will go into SLEEP mode to conserve battery power. It automatically reactivates when it is pressed.

4.9 PEAK POWER DISPLAY

This number is shown only when the system is in pulse mode and presents the value of the peak power based on the Power Setting and Pulse Mode.

4.10 PULSE MODE SELECTION

Pulse Mode selection graphically indicates whether the system is in Continuous Mode or in Pulse Mode.

In Continuous Mode, laser power is constantly delivered when the laser console is in Ready Mode and the wireless footswitch is activated.

In Pulse Mode, laser power is delivered in repetitive pulses, controlled by the Pulse Length and Pulse Interval settings.

Pressing the Pulse Mode button will allow switching between Pulsed and Continuous Modes (Figure 4.12).

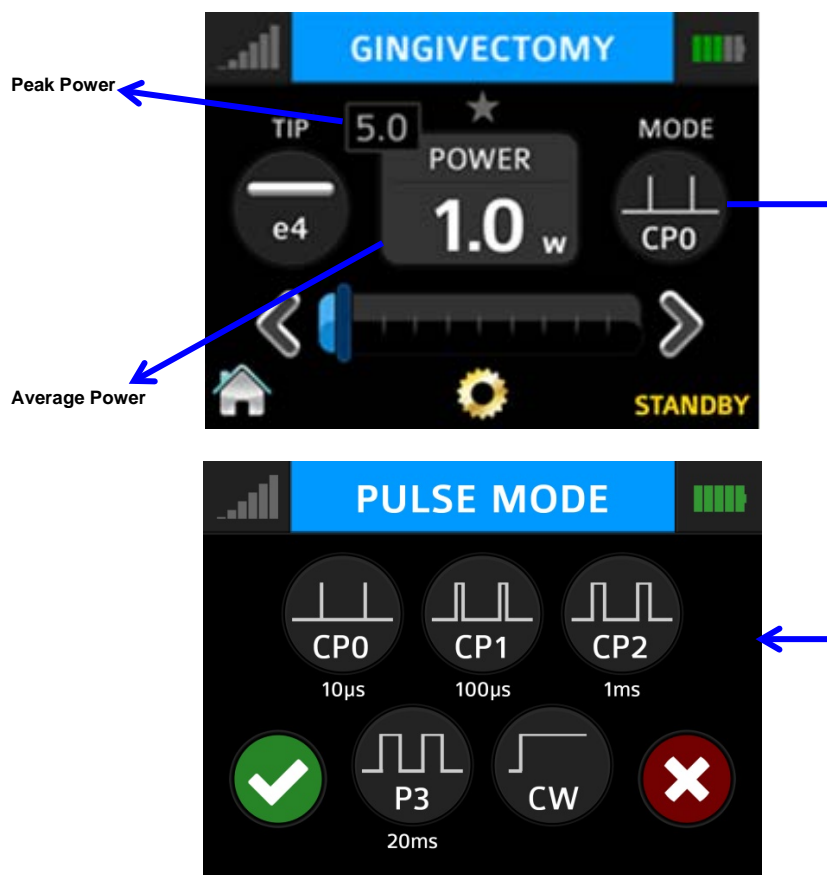


Figure 4.13

MODE*	PULSE DURATION (on)	PULSE INTERVAL (off)	Duty Cycle (Time On / Time off)
CP0	10 microseconds	40 microseconds	20%
CP1	100 microseconds	200 microseconds	33%
CP2	1 millisecond	1 millisecond	50%
P3	20 milliseconds	20 milliseconds	50%

*CP = Comfort Pulse; P3 = Pulsed Mode which is the standard for most diode lasers currently available to the dental market

Figure 4.14

NOTE: Operating the laser at a shorter pulse duration typically results in lower tissue temperature.

4.11 USING THE EPIC V-SERIES TOUCH SCREEN DISPLAY

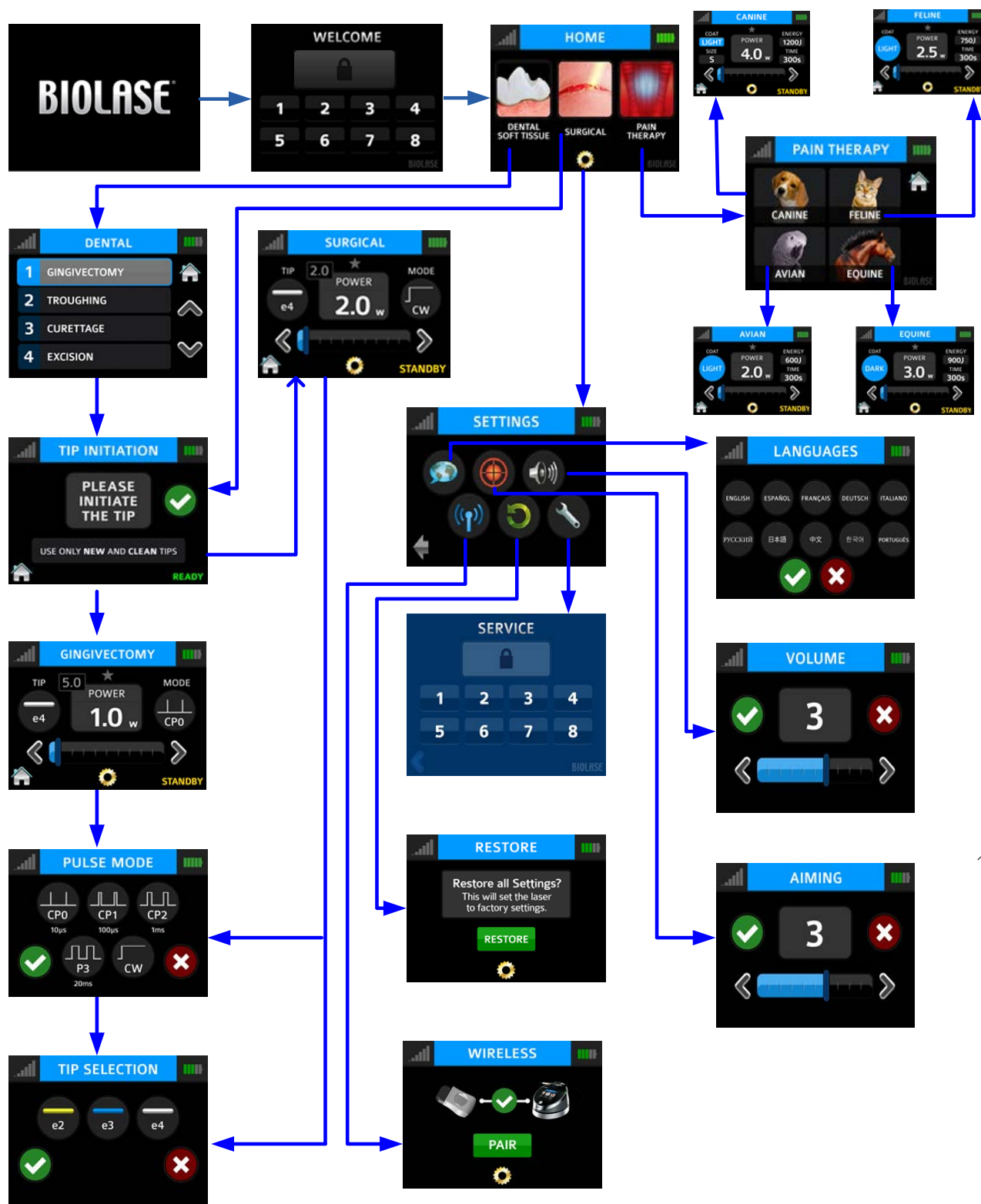


Figure 4.15

4.12 PROCEDURES BUTTON

The EPIC V-Series comes with 12 Soft Tissue procedural presets already installed and 4 empty slots for custom pre-sets, as well as one factory-installed preset for Surgical. All presets can be customized to your preference.

In order to customize the parameters for a particular clinical procedure:

1. Adjust the operating parameters of the laser (e.g., power, pulse duration, interval, etc.); select PROCEDURES Mode and scroll to the pre-set you wish to overwrite.
2. Press and hold the selected Procedure for two (2) seconds. Parameters for that procedure will be changed and saved (the laser console will beep when the adjusted settings are saved).



Figure 4.16

4.13 TURN THE LASER CONSOLE OFF

- Wind the fiber cable onto the fiber spool counterclockwise around the base of the console.
- Place the Handpiece onto the Handpiece holder.

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

- Press the CONTROL button on the front of the console for more than 2 seconds to turn the display off.
- Press the Power Switch at the rear of the laser console to the OFF (O) position if the laser system will not be used for a long period of time.

5. SPECIFICATIONS

5.1 GENERAL

Dimension	5.7 in (W) x 4.4 in (H) x 6.5 in (L) (14.5 cm x 11.2 cm x 16.5 cm)
Weight	2.5 lbs / 1kg

5.2 ELECTRICAL

Operating Voltage	100V - 240V ~ at 1.5A
Frequency	50/60Hz
External Fuses	None
Main Control	Power Switch
Remote Interruption	Remote Interlock
Disable Control	Emergency Stop Button
Battery	Lithium Ion Rechargeable, 14.4V, 2.9Ah
DC Power Supply Module	12V DC, 5A

5.3 LASER

Laser Classification	IV (4)
Medium	InGaAsP Semi-conductor diode
Wavelength	940 ± 10nm
Max Power Output	10W
Power Accuracy	± 20%
Power Modes	Continuous, Pulse Modulation
Fiber Tips Diameter	200µm, 300 µm, 400µm
Pulse Duration	0.01 ms – 20 ms

Pulse Interval	0.04 ms – 20 ms
Pulse Repetition Rate	Up to 20kHz (for reference)
Spot size	
Surgical Handpiece	400 µm (maximum in contact mode)
Deep Tissue Handpiece	30 mm diameter = 7.1 cm ² area
NOHD	4.77 meters
Beam Divergence	8 - 22° per side angle
Standard Fiber Cable Length	5 feet (1.524 meters)

5.4 OTHER LIGHT SOURCES

Aiming Beam	Laser diode, max 1 mW, 625 nm – 670 nm
-------------	--

6. CONTRAINDICATIONS, WARNINGS & PRECAUTIONS

6.1 CONTRAINDICATIONS

All clinical procedures performed with EPIC V-Series must be subjected to the same clinical judgment and care used 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 (including pacemakers), lung disease, bleeding disorders, sleep apnea or an 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.

6.2 WARNINGS AND PRECAUTIONS

Prescription Statement

Federal Law restricts this device to sale by or on the order of a licensed veterinarian; for Canine, Feline, Equine, and Avian use.

Eyewear

All personnel inside the operatory must wear appropriate laser eyewear protection for the diode laser wavelength of $940 \pm 10\text{nm}$.

Anesthesia

In soft tissue cases anesthesia may not be required, but patients should be closely monitored for signs of pain or discomfort at all times by touching the treatment area. If such signs are present, adjust settings, apply anesthesia or cease treatment if required.

Adjacent Structures

EPIC V-Series is designed to remove soft tissues. Therefore, always be aware of adjacent structures and substructures during use. Be extremely careful not to inadvertently penetrate or ablate underlying or adjacent tissues. Do not direct energy toward hard tissue 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. Exercise extreme caution when using this device in areas such as pockets, cavities or channels such as third molar sockets, where critical structures (i.e. nerves, vessels) could be damaged. Do not proceed with using the laser if visibility is limited in these areas.

Suction

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

Plume Removal

Special care must be taken to prevent infection from the laser plume generated by vaporization of virally or bacterially infected tissue. Ensure that appropriate protective equipment (including high-speed suction to remove the plume, appropriately filtered masks, and other protective equipment) is used at all times during the laser procedure.

Clinical Use

Use your clinical judgment to determine all aspects of treatment including, but not limited to, the laser treatment protocol, technique, power settings, pulse duration and interval settings, mode of operation as well as the accessories (e.g., tip type) and other procedural requirements. Closely observe and monitor clinical effects and use your judgment to determine clinical parameters and approach for the treatment. Make appropriate power, pulse length, and interval adjustments to compensate for varying tissue compositions, density, and thickness. Always start treatment at the lowest power setting for that specific indication and increase as required. BIOLASE assumes no responsibility for parameters, techniques, methods or results.

Training

Only licensed professionals who have reviewed 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.

7. CLINICAL APPLICATIONS

7.1 INTRODUCTION

To efficiently remove tissues it is imperative to understand the nature of the EPIC V-Series device. Please review this section carefully, practice on model tissues, and attend a diode laser training session before using this device in a clinical situation.

7.2 INDICATIONS FOR USE

Use of the EPIC V-Series device may be appropriate for incision, excision, vaporization, ablation and coagulation of oral soft tissues including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications:

<ul style="list-style-type: none">• Gingivectomy• Troughing• Curretage• Excision• Frenectomy• Implant Recovery• Perio Pockets	<ul style="list-style-type: none">• Pulpotomy• Crown Lengthening• Infected Pockets• Endo• Hemostasis• Surgical• Pain Relief
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7.3 SOFT TISSUE SURGERY AND DENTAL USE

Tip Initiation: Parameters and Method

Most soft tissue surgical procedures require initiation of the fiber tip. **The TIP INITIATION screen will appear (in READY mode) if tip initiation is recommended;** while in the TIP INITIATION screen, initiate the tip by following the steps outlined below.



Figure 7.1

NOTE: Sterilize the tip initiation block as described in Section 8.3 prior to tip initiation.

Tip Diameter (µm)	(Preset) Power (W)	Mode
400	1.4	CW
300	1.4	CW
200	Tip initiation not required when used for recommended procedures	

Figure 7.2

- Touch the tip to the surface of the initiation block, without activating the laser (don't press down on the footswitch (Figure 7.3).
- Press the footswitch to activate the laser, allowing the tip to sink into the block. Pull the tip out when the metal cannula touches the block, still firing until just before the tip is out of the block (Figure 7.4).
- Press the footswitch to activate the laser into the air once, you will see a white flash or the tip will glow (Figure 7.5).
- Repeat initiation process as needed to ensure the tip is initiated.

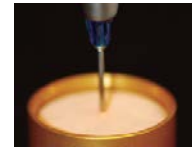


Figure 7.3

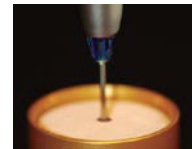


Figure 7.4



Figure 7.5

After tip initiation is completed, press the check mark to access the screen for the selected procedure.

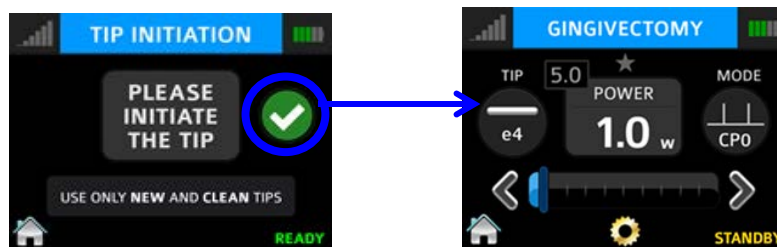


Figure 7.6

CAUTION:

If the laser console is in "READY" mode, the laser will fire if the footswitch is activated.






**LASER
WARNING:**

Never point the laser at a person's eyes. All persons present in the operatory must wear protective eyewear when the laser is in operation

Pre-programmed Settings for Dental Soft Tissue and Surgical Procedures

To access the pre-programmed procedure values:

1. Go to the Procedures menu by pressing the Soft Tissue icon  or the Surgical icon  on the Home screen.
2. Press the button associated with the desired procedure.
3. Press the up and down arrows  to scroll for additional procedures.

CAUTION:

Always use clinical judgment when selecting power, pulse, length, and pulse interval parameters to ensure optimal clinical results. The recommended settings apply only to the 300µm and 400µm tips.

To store your personal preferred settings for any procedure:

- A. Follow steps 1 and 2 above.
- B. Enter the new values.
- C. Touch and hold the Procedure name for more than 2 seconds; you will hear a beeping sound confirming the settings are saved.

NOTE:

The Procedure Pre-Sets installed at the factory are based on clinical recommendations and feedback from experienced laser dentists.

300µm tips are recommended for removing thin tissue layers. 400µm tips are recommended for removing fibrous tissue.

Always use your clinical judgment when selecting power, pulse length, and pulse interval parameters to ensure optimal clinical results. At all times observe the clinical effects on the treatment area and adjust parameters accordingly.

7.4 TABLE OF EPIC V-SERIES PRE-PROGRAMMED SETTINGS

	PROCEDURE NAME	MODE	PEAK POWER	AVERAGE POWER	PULSE INTERVAL	PULSE LENGTH	DUTY CYCLE	TIP TYPE	INITIATION
1	GINGIVECTOMY	CP0	5.0W	1.0W	0.04ms	0.01ms	20%	E4	YES
2	TROUGHING	CP2	2.0W	1.0W	1.0ms	1.0ms	50%	E4	YES
3	CURETTAGE	CP1	2.4 W	0.80W	0.20ms	0.10ms	33%	E4	YES
4	EXCISION	CP1	2.7 W	0.90W	0.20ms	0.10ms	33%	E4	YES
5	FRENECTOMY	CP2	2.0W	1.0W	1.0ms	1.0ms	50%	E4	YES
6	IMPLANT RECOVERY	CP2	2.4W	1.2W	1.0ms	1.0ms	50%	E4	YES
7	PERIO POCKETS	CP2	1.6 W	0.80W	1.0ms	1.0ms	50%	E3	NO
8	PULPOTOMY(*)	CW	0.10W	0.10W	N/A	N/A	N/A	E4	YES
9	CROWN LENGTHENING	CP1	2.7W	0.90W	0.20ms	0.10ms	33%	E4	YES
10	INFECTED POCKETS	CP2	1.60W	0.80W	1.0ms	1.0ms	50%	E4	YES
11	ENDO(*)	CW	0.10W	0.10W	N/A	N/A	N/A	E2	NO
12	HEMOSTASIS	CW	0.50W	0.50W	N/A	N/A	N/A	E4	YES
13	CUSTOM 1	CW	0.10W	0.10W	N/A	N/A	N/A	E4	YES
14	CUSTOM 2	CW	0.10W	0.10W	N/A	N/A	N/A	E4	YES
15	CUSTOM 3	CW	0.10W	0.10W	N/A	N/A	N/A	E4	NO
16	CUSTOM 4	CW	0.10W	0.10W	N/A	N/A	N/A	E4	NO
17	SURGICAL	CW	2.0W	2.0W	N/A	N/A	N/A	E4	YES

(*)Minimum defaults provided for user setting of Endodontic Procedures such as Pulpotomy and Pulpotomy as an adjunct to root canal therapy.

Figure 7.7

7.5 PAIN THERAPY

The EPIC V-Series diode laser is designed to provide near-infrared laser energy to a tissue surface for the purpose of temporary pain relief when applied with the Whitening/Contour or Deep Tissue Handpiece. The pain therapy procedure is the process by which tissue temperature is elevated for the temporary relief of minor pain, the temporary increase in local blood circulation, and the temporary relaxation of muscle, as stated in the Indications for Use.

Affected muscles and/or joints have to be exposed to an adequate level of therapeutic energy over a short period of time to provide effective therapeutic effects. Some patients may require more than one laser application or a series of treatments before significant improvement is reported. Repeat the therapy as necessary and monitor the progress of the patient's condition throughout the treatment.

The diode wavelength has increased absorption in melanin in the skin, causing greater heating of the skin surface of patients with a higher melanin concentration (darker skin types). Although patients with darker fur or coat colors may feel more discomfort during treatment, this may be alleviated by moving the Handpiece, defocusing the energy, or decreasing the power setting.

Recommended Use

There are four main variables that impact the safety and effectiveness of pain therapy procedures:

- Power output
- Distance from the skin surface
- Range of movement of the Handpiece
- Patient fur/coat color

Safety and effectiveness are described by elevating the skin temperature in the treatment area between 40°C - 45°C. Use personal clinical judgment with consideration of the fur or coat color when selecting procedure parameters; monitor the patient and adjust the settings as necessary for effectiveness and patient comfort.

CAUTION: Do not exceed a skin surface temperature of 47°C. A skin surface temperature rise above 47°C for a duration of approximately 16 minutes will cause irreversible skin damage

Patients should be monitored for discomfort and visual skin changes. Redness has been associated with increased temperature at the site of application and increased absorption properties of the skin. If discomfort or redness of the skin occurs at any time during the treatment, you have the following options:

- Move the Handpiece relative to the affected anatomy
- Defocus the energy by moving the Handpiece further away from the skin
- Decrease the power setting
- Stop treatment

Pre-Programmed Settings for Pain Therapy

The Epic V comes from the factory already programmed with 12 settings specific to the type of animal being treated. Treatment will vary depending on the type of animal, the color of its coat (light vs. dark), and in some cases, its size. You can override and store these pre-sets based on your results (see Section 7, “To store your personal preferred settings for any procedure”). Always monitor patient response; adjust power and/or distance as needed for patient comfort.

Patient	Size	Color	Setting	Time (seconds)	Energy (J)
Avian	N/A	Dark	1.0W	300	300
Avian	N/A	Light	2.0W	300	600
Equine	N/A	Dark	3.0W	300	900
Equine	N/A	Light	5.0W	300	1500
Feline	N/A	Dark	1.0W	300	300
Feline	N/A	Light	2.5W	300	750
Canine	Small	Dark	1.5W	300	450
Canine	Small	Light	3.5W	300	1050
Canine	Medium	Dark	2.0W	300	600
Canine	Medium	Light	4.0W	300	1200
Canine	Large	Dark	2.5W	300	750
Canine	Large	Light	4.5W	300	1350

Figure 7.8

Pain Therapy - Warnings and Precautions

- Scar tissue has been associated with poor circulation and reduced cooling through heat transport by blood; power settings may have to be reduced to avoid overheating.
- Patients with tender or sensitive skin may be hypersensitive to heat; reduce power as necessary to ensure comfort during treatment.
- Patients with swelling and/or inflammation may be sensitive to heat; reduce power as necessary to ensure comfort during treatment.
- Do not treat open wounds.

- Muscle tissue closer to the skin surface may experience a higher absorption of heat; carefully monitor skin temperature and reduce power as necessary.
- Excessive fatty tissue is known to transmit heat without much attenuation; reduce power.
- Different implant materials will respond differently to laser energy and heat; be aware of any implants and their location; avoid direct exposure to laser energy or heat at the site of the implant.
- Do not apply ointments, creams, lotions or heating lotion patches at, or in close proximity to, the site of treatment.
- Do not apply therapies prior to treatment that could change body temperature, such as ultrasound, ice/heat pack, electrical stimulation, or heating patches.

Using the Deep Tissue Handpiece

If holding the Handpiece in a constant location, the recommended initial power setting for therapeutic effect is 4.0W CW delivered over 10 minutes of continuous treatment, with the spacer set at a 30mm spot size. Always monitor patient response; adjust power and/or distance as needed for patient comfort.

8. MAINTENANCE

WARNING: No modification of this equipment is allowed.

8.1 DAILY MAINTENANCE

Use the peel-off clear covers for the laser console supplied with the system. Use disinfectant to wipe down the front panel and Handpiece holder of the EPIC V-Series system after each procedure. **Do not use bleach or abrasive cleansers.**

8.2 CLEANING AND STERILIZATION PROCEDURES

The contamination control suggested for the EPIC V-Series Surgical Handpiece and tips is the steam sterilization method. However, before sterilization, the EPIC V-Series reusable Handpiece should be carefully cleaned per the following procedure.

CAUTION:

Handpiece and tips must be cleaned and sterilized prior to initial use.

Tips are single-use only to avoid cross-contamination and are designed to withstand a single sterilization cycle; they must be disposed of after use in a biohazard medical waste Sharps container.

Handpieces are reusable and must be cleaned and sterilized between patients to avoid cross-contamination.

Cleaning and Disinfecting Instructions for the Surgical Handpiece, and the Reusable 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 pathogens 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 EPIC V-Series fiber optic delivery system.

Wear protective latex gloves when handling the contaminated delivery system.

To disinfect the fiber cable, wipe the entire cable, including the shaft, with an appropriate disinfecting solution, such as Cavicide™ or a similar quaternary ammonium compound product (containing 20% alcohol or less), and follow the manufacturer's instructions. Avoid getting any liquid or debris near the distal end of the fiber cable.

To Clean the Surgical Handpiece:

- Carefully remove the tip from the Handpiece and dispose of it in a biohazard medical waste Sharps container.
- Carefully remove the Handpiece from the fiber optic cable (see Section 3).
- Wipe the entire Handpiece outer surface with cotton gauze and a detergent/enzymatic cleaning solution such as Klenzyme® or similar enzymatic, presoak and cleaner.
- Soak gauze in the detergent/enzymatic cleaning solution, and then wrap the Handpiece in the gauze.
- Leave the Handpiece wrapped in the soaked gauze for 30 minutes.
- Remove the Handpiece from the soaked gauze and wipe it with dry gauze.

Steam Sterilization for Surgical Handpiece, Single Use Tips, Tip Initiation Block

Before sterilization, the Surgical Handpiece must be cleaned and disassembled. To sterilize the Handpiece, tips, and tip initiation block, follow these step-by-step instructions:

- Place the Handpiece, fiber tips, and tip initiation block in separate single-wrap, self-seal autoclave pouches.
- Remove autoclave tray and the place pouch(s) on the tray.
- Place tray inside the autoclave chamber and sterilize per the following gravity displacement sterilization cycle:

Temperature: 250°F (121°C)	Pressure: 15 PSI (1 bar)
Time cycle: 30 minutes	Drying time: 15 - 30 minutes

- Once the cycle is completed, remove the tray and let each sterilized item cool and dry.

Cleaning the Deep Tissue Handpiece

The Deep Tissue Handpiece is sold with non-sterile, disposable protective shields.

The Handpiece and clear protective shield are not autoclavable. The clear protective shields are intended for single-time use only and should never be reused.

To clean the Deep Tissue Handpiece, wipe the entire outer surface of the Handpiece with cotton gauze and isopropyl alcohol or a mild chemical disinfectant.

Always wipe the disposable shield with alcohol prior to use. Dispose of after one-time use.

8.3 INSTALLING/REPLACING THE CONSOLE BATTERY PACK

1. To install or replace the battery pack, remove the battery cover on the underside of the console using the Phillips screwdriver included with the laser system (Figure 8.1).
2. To remove the battery, grip the battery at the top and pull the cable away from the connector (Figure 8.2). Do not tug or wrench the cable from the connector.
3. To install the battery, insert the connector wire from the battery to the unit, making sure the red wire is on the left, and gently place the battery into the compartment (Figure 8.2).
4. Replace the battery cover on the bottom of the unit, using a standard Phillips screwdriver.
5. Connect the power cord of the DC power supply to the unit and plug into a wall outlet. Before first use, you should fully charge the battery (at least 3 hours). Once the battery is charged, unplug the power cord from the wall outlet and the console. The unit will run on battery power alone. (See Section 4.1)
6. Recycle the used Lithium Ion battery as regulated. Do not throw it in a trashbin.



Figure 8.1: Battery Cover/Bottom of Console



Figure 8.2: Battery Pack/Connector Wire

NOTE: Only use the battery pack supplied by BIOLASE. The battery pack is a separate accessory (BIOLASE p/n 6400457).

8.4 CHANGING THE WIRELESS FOOTSWITCH BATTERIES

The wireless footswitch is powered by two AAA batteries. When the batteries are low, a warning message will appear on the touchscreen indicating that the batteries need to be replaced. To replace the batteries, unscrew the battery cover on the underside of the footswitch (Section 3), remove the old batteries, and install the new ones, replacing the cover when done. Dispose of the used batteries as regulated; do not throw them in a trash bin.

Do not press/push/touch the Pairing Button (Figure 8.3) while changing the batteries, as this will disrupt the pairing of the laser console and footswitch.

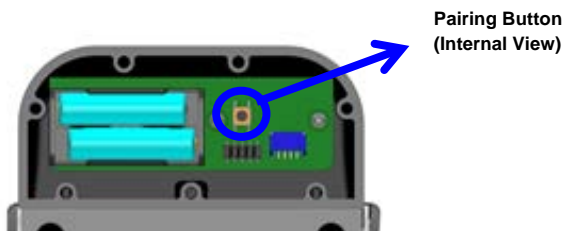


Figure 8.3

Although replacing the batteries will not disrupt the pairing of the laser console and footswitch, if you find the wireless communication has been interrupted, reestablish pairing by following the instructions provided in Section 4.

NOTE: To ensure the longevity of the battery power, only BIOLASE-supplied batteries are recommended as replacements (BIOLASE p/n 6400463); these are industrial-grade batteries which under normal use have a longer life than conventional AAA batteries.

8.5 TRANSPORTATION

The EPIC V-Series is susceptible to damage if not handled properly. The unit should ALWAYS be handled carefully and never banged, jarred, jolted, dropped, or knocked.

Do not transport the unit unless it is completely packaged inside its shipping box. If you have any questions regarding transportation please call BIOLASE Service at 1-800-321-6717.

8.6 STORAGE

The EPIC V-Series should be stored in a cool, dry place when not in use. Storage temperature 15°C-35°C (59°F-95°F), relative humidity 10%-70%, non-condensing. 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.

CAUTION: Make sure the distal end of the Handpiece shaft is protected from dirt with the protective tip plug and Handpiece.

CAUTION: Remove the batteries from the footswitch if the EPIC V-Series is not likely to be used for some time.

The EPIC V-Series is shipped inside a custom shipping box. Please save and store the box in a cool, dry place for use when transporting the laser, or for long-term storage.

9. CALIBRATION

9.1 CALIBRATION SCHEDULE

Calibration procedure is recommended to be performed every twenty-four (24) months in order to maintain the required accuracy of output power versus displayed power. Annual calibrations can be performed at a certified depot repair facility. Call BIOLASE Service at 1-800-321-6717 or your Authorized Service Representative to schedule an appointment.

10. SOFTWARE SPECIFICATION

BIOLASE respects the intellectual property of others, and we ask our users to do the same. EPIC V-Series software is protected by copyright and other intellectual property laws.

This product contains proprietary, copyrighted software developed by BIOLASE, Inc. All rights reserved in the USA and other countries.

11. TROUBLESHOOTING

Should any of the on-screen messages listed in Figure 11.1 appear, follow the troubleshooting instructions for the specific message as noted below.

NOTE: For any on-screen message not listed in Figure 11.1, re-power the laser console; if the message does not clear, call **BIOLASE Service at 1-800-321-6717** or your authorized Service Representative





























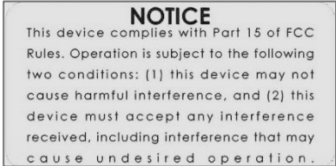





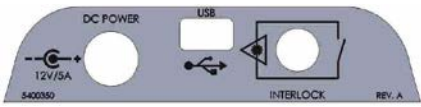


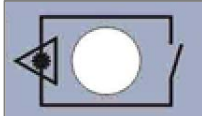
Title	Message 	Reason 	Fix 
Error 1 	Thermistor Open	Thermistor Open	Call BIOLASE Service
Error 2 	Thermistor Shorted	Thermistor Shorted	
Error 3 	Shutdown Temperature	System too hot	Allow 5-10 mins for laser to cool down
Error 4 	Laser Current High/ Low	Output is out of specs	Call BIOLASE Service
Error 5 	FS shorted in Standby	FS is partially pressed or is damaged	Press/Release FS or call Biolase Service
Error 6 	ON/OFF button Stuck	Key stuck	Press Front key
Error 7 	Flash Corrupted	Memory Corrupted	Call BIOLASE Service
Error 8 	No Fiber	Fiber not inserted	Plug in Trunk Fiber
Error 9 	Lost Footswitch Communication	Wireless Interference	Reposition console or FS to improve communication
Error 10 	Emergency Switch	E-Switch Pressed	Press E-Switch Again
Error 11 	Remote Interlock	Remote interlock open	Check Remote Interlock closed
Error 12 	Battery Critically Low	Battery Critically Low	Plug in DC supply
Warning 1 	Temp High	System is hot	Allow 5-10 mins for laser to cool down
Warning 2 	Battery Low	Battery is low	Plug in DC supply
Warning 3 	Battery Not Connected	Battery not connected	Plug in Battery
Warning 4 	FS Battery Low	Battery on FS low	Replace FS battery
Alert 1 	Wireless Not Paired	No wireless connect	Re-establish pairing (see Sec 4)
Alert 2 	System must be in READY mode to lase	System is not in READY mode	Press the Control Button in any procedure screen

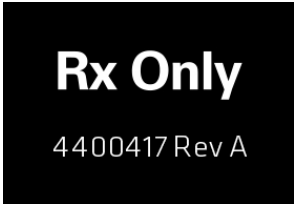
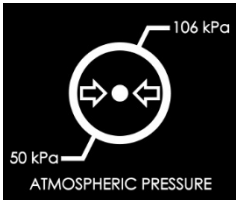


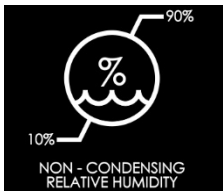
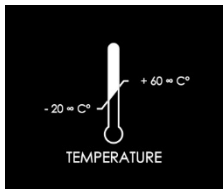
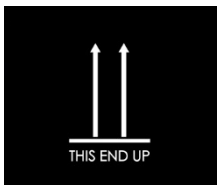
Figure 11.1

APPENDIX A – DEFINITION OF SYMBOLS ON LABELING

Symbols	Description
	Manufacturer
	Date of Manufacture
	Catalog/Part Number
	Product Serial Number
	Refer to User Manual
	Type B Applied Part: The applied part is not conductive to the patient.

<p>THIS PRODUCT COMPLIES WITH FDA PERFORMANCE STANDARDS FOR LASER PRODUCTS EXCEPT FOR DEVIATIONS PURSUANT TO LASER NOTICE NO. 50 DATED 24 JUNE 2007</p> <p>P/N: 5400341 REV. A</p>	<p>FDA Compliance Label: Indicates the device complies with FDA laser standards.</p>
	<p>Warning Label: Indicates there is the risk of possible exposure to both infrared and visible laser radiation.</p> <p>Location: Back of laser console</p>
	<p>FCC Compliance Notice: The footswitch and laser console comply with Part 15 of FCC Rules regarding unlicensed transmissions.</p> <p>Location: Bottom of Footswitch</p>
<p>MODEL: EPIC V-SERIES FCC ID: G2OEPIC</p> <p>5400452 Rev. A</p>	<p>FCC Label: Lists Federal Communication Commission and Industry Canada registration numbers.</p>
<p>IPX6</p>	<p>Ingress Protection Code: The footswitch is water-resistant, protected against splashes of water.</p>
	<p>Laser Warning: Indicates the system contains a laser.</p> <p>Location: Back of Laser Console</p>
	<p>Fiber Warning: Indicates the laser aperture is at the end of the fiber.</p> <p>Location: Back of Laser Console</p>

	<p>Emergency Laser Stop Switch: The switch used in emergencies to stop laser output.</p> <p>Location: Right side of Laser Console</p>
	<p>DO NOT REUSE For single use only.</p>
	<p>WEEE (Waste Electrical and Electronic) Recycle Lithium Ion battery as regulated. Do not throw in trash bin.</p>
	<p>DC Power, USB, Remote Interlock Label: Identifies input ports</p>
	<p>Power Input Rating: 12 Volts Direct Current, 5 amps</p>
	<p>Mini USB Input: For external programming</p>
	<p>Remote Interlock: Input for Remote Interlock Connector which, when applied to the access door of the operatory and activated, will shut off the laser.</p>

	<p>Prescription Statement: Federal Law restricts this device to sale by or on the order of a licensed veterinarian; for Canine, Feline, Equine, and Avian use.</p>
	<p>Atmospheric Pressure Limitations</p>
	<p>Fragile: Handle with care</p>
	<p>Keep Dry</p>
	<p>Humidity Limitations</p>
	<p>Temperature Limitations</p>
	<p>This End UP</p>

APPENDIX B – SAFETY PRECAUTIONS FOR LITHIUM-ION BATTERY PACKS

WHEN USING THE BATTERY

WARNING

1. Misusing the battery may cause the battery to get hot, rupture, or ignite and cause serious injury. Be sure to follow the safety rules listed below:
 - Do not place the battery in fire or heat the battery.
 - Do not install the battery backwards so that the polarity is reversed.
 - Do not connect the positive terminal and the negative terminal of the battery to each other with any metal object (such as a wire).
 - Do not carry or store the batteries together with necklaces, hairpins, or other metal objects.
 - Do not pierce the battery with nails, strike the battery with a hammer, step on the battery, or otherwise subject it to strong impacts or shocks.
 - Do not solder directly onto the battery.
 - Do not expose the battery to water or salt water, or allow the battery to get wet.
2. Do not disassemble or modify the battery. The battery contains safety and protection devices which, if damaged, may cause the battery to generate heat, rupture, or ignite.
3. Do not place the battery on or near fires, stoves, or other high-temperature locations. Do not place the battery in direct sunshine or use or store the battery inside cars in hot weather. Doing so may cause the battery to generate heat, rupture, or ignite. Using the battery in this manner may also result in a loss of performance and a shortened life expectancy.

CAUTION

1. If the device is to be used by small children, the caregiver should explain the contents of the user's manual to the children. The caregiver should provide adequate supervision to ensure that the device is being used as explained in the user's manual.
2. When the battery is worn out, insulate the terminals with adhesive tape or similar materials before disposal.

3. Immediately discontinue use of the battery if, while using, charging, or storing the battery, the battery emits an unusual smell, feels hot, changes color, changes shape, or appears abnormal in any other way. Contact your sales location or BIOLASE if any of these problems are observed.
4. Do not place the batteries in microwave ovens, high-pressure containers, or on induction cookware.
5. In the event that the battery leaks and the fluid gets into one's eye(s), do not rub the eye(s). Rinse well with water and immediately seek medical care. If left untreated, the battery fluid could cause damage to the eye.

WHEN CHARGING THE BATTERY

WARNING

1. Be sure to follow the rules listed below while charging the battery. Failure to do so may cause the battery to become hot, rupture, or ignite and cause serious injury.
 - When charging the battery, either use a specified battery charger or otherwise ensure that the battery charging conditions specified are met.
 - Do not attach the batteries to a power supply plug or directly to a car's cigarette lighter.
 - Do not place the batteries in or near fire, or into direct sunlight. When the battery becomes hot, the built-in safety equipment is activated, preventing the battery from charging further, and heating the battery can destroy the safety equipment and can cause additional heating, breaking, or ignition of the battery.
2. Do not continue charging the battery if it does not recharge within the specified charging time. Doing so may cause the battery to become hot, rupture, or ignite.

CAUTION

The temperature range over which the battery can be charged is 0°C to 45°C. Charging the battery at temperatures outside of this range may cause the battery to become hot or to break. Charging the battery outside of this temperature range may also harm the performance of the battery or reduce the battery's life expectancy.

WHEN DISCHARGING THE BATTERY

WARNING

Do not discharge the battery using any device except for the specified device. When the battery is used in devices aside from the specified device it may damage the performance of the battery or reduce its life expectancy, and if the device causes an abnormal current to flow, it may cause the battery to become hot, rupture, or ignite and cause serious injury.

CAUTION

The temperature range over which the battery can be discharged is -20°C to 60°C. Use of the battery outside of this temperature range may damage the performance of the battery or may reduce its life expectancy.

APPENDIX C - SPARE PARTS & ACCESSORIES

SYSTEM ACCESSORIES

BIOLASE p/n	Description
6400007	Surgical Handpiece
2400040	Laser Safety Glasses (Clinician)
6400058	Remote Interlock Plug
2400129	Power Cord with Power Supply
6400506	Wireless Footswitch
6400107	Tip initiation kit
6400311	Deep-Tissue Handpiece
6400310	Deep-Tissue Handpiece protective covers (qty. 20)
6400485	Peel-off clear screen covers (qty. 30)
6400457	Lithium ion battery pack for console
6400463	Battery Pack, (2 x AAA)
6400437	Trunk Fiber Assembly

SINGLE USE TIPS

Surgical:

BIOLASE p/n	Description
7400018	200 µm core diameters (qty. 30)
7400017	300 µm core diameters (qty. 30)
7400016	400 µm core diameters (qty. 30)

Perio:

BIOLASE p/n	Description
7400020	300 µm core diameters (qty. 30)
7400019	400 µm core diameters (qty. 30)

Endo:

BIOLASE p/n	Description
7400015	EZTIP Endo Kit, E2, 20mm
7400021	200 µm core diameters (qty. 30)

APPENDIX D - WIRELESS EQUIPMENT COMPLIANCE STATEMENT

This statement applies only to the wireless portion of the device:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.



Conforms to:
AAMI ES60601-1
IEC60601-1
IEC60601-2-22
IEC62366
IEC80601-2-60
IEC60825-1
Certified to:
CSA C22.2 No.
60601-1



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About **BIOLASE**

Founded in 1986, BIOLASE, Inc. specializes in lasers for medicine and dentistry that feature proprietary and patented technologies for performing minimally invasive surgeries, reducing pain and improving clinical results.

Only BIOLASE combines the leading laser technology – continuously improved through ongoing clinical R&D and engineering – with unmatched training, practice integration support and service.



Made in the USA

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