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BIOLASE

Epic T Series User Manual

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The Epic™ T Series diode laser system is a medical device that provides a therapeutic and non-invasive way to treat pain, working as a topical heating device to temporarily increase blood circulation. It is effective for chronic and acute musculoskeletal conditions, including back and neck pain, injuries from accidents, and athletic injuries to muscles and joints.

Epic T Series utilizes a solid state diode as a semiconductor source for invisible infrared radiation. The energy is delivered to the treatment site via a flexible fiber connected at one end to the laser source and the other end to the Handpiece. The device is activated by means of a wireless Footswitch.

This is a prescription device that is indicated for professional use only by licensed medical practitioners. The use of this device requires proper clinical and technical training. This manual provides instructions for those professionals that have completed the appropriate training.

When used and maintained properly, the Epic T Series will prove a valuable addition to your practice. Please contact BIOLASE customer service at **1-800-321-6717** in the U.S. for any service needs; if you are located outside the U.S., please contact your BIOLASE-authorized distributor.

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The Epic T Series diode laser is intended for topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle.

(Refer to Section 8 for Clinical procedure details.)

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3.1 CONTRAINDICATIONS

All clinical procedures performed with Epic T 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 and exercise caution for general medical conditions that might contraindicate a local procedure; such conditions may include, but are not limited to, allergy to local or topical anesthetics, heart disease (including pacemakers and implantable defibrillators), lung disease, bleeding disorders, sleep apnea, an immune system deficiency, or any medical conditions or medications that may contraindicate the use of certain light/laser-type sources associated with this device, including general neurovascular conditions which can reduce a patient's pain sensitivity while undergoing pain therapy procedures (e.g., patients with neurodegeneration associated with Type II diabetes). Medical clearance from the patient's physician is advisable when doubt exists regarding treatment.

3.2 WARNINGS AND PRECAUTIONS

PRESCRIPTION STATEMENT

U.S. Federal Law restricts this device to sale by or on the order of a dentist or other licensed dental practitioner.

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 professional knowledge to determine all aspects of treatment, including technique, power settings, pulse interval, duration, etc.

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EYEWEAR

Doctor, patient, assistand, and all others inside or entering the operatory must wear appropriate laser protective eyewear suitable for the 940 nm ± 10 nm wavelength, OD4 (DIR LB4) or greater, whenever the laser is in use. Prior to use, inspect eyewear for pitting and/or cracking. **Replace if damaged; do not use.**

CAUTION: The specifications for the protective eyewear provided with the Epic T laser system are marked on the side of the glasses. **Always check the eyewear specifications marked on the glasses to ensure they offer the required protection for the specific laser wavelength.**

For additional information, refer to the instructions for use provided with the glasses.

TREATMENT, TECHNIQUE, AND SETTINGS

Use your clinical judgment to determine all aspects of treatment including, but not limited to, the laser treatment protocol, technique, power settings, mode of operation, treatment duration, 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 the 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 the specific indication and increase as required. BIOLASE assumes no responsibility for parameters, techniques, methods, or results.

CLINICAL ENVIRONMENT

Only use this device in clinical environments that observe proper standard aseptic techniques.

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4.1 GENERAL

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

4.2 ELECTRICAL

• Operating voltage	100V - 240V ~ at 1.5A
• Frequency	50 / 60 Hz
• External Fuses	None
• Main control	Main Power Switch (ON/OFF Control Button).
• Remote Interruption	Remote interlock
• Disable Control	Emergency Stop Button
• Battery	Lithium Ion Rechargeable, 14.4 V, 2.9 Ah
• DC Power Supply Module	12V DC, 5A

4.3 LASER

• Laser Classification	IV (4).
• Medium	InGaAs Semi-conductor diode
• Wavelength	940 ± 10 nm
• Max Power Output	10W
• Power Accuracy	± 20%
• Power Modes	Continuous
• Spot Size	30 mm diameter = 7.1 cm^2 area
• NOHD (Nominal Ocular Hazard Distance)	2.71 meters
• MPE (Maximum Permissible Exposure)	30W/m^2
• Beam Divergence	7 - 22° per side angle
• Standard Fiber Cable Length	5 feet (1.5 meters)

4.4 OTHER LIGHT SOURCES

• Aiming Beam	Laser diode, max 1 mW, 625 nm – 670 nm, Class 2

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5.1 SYSTEM COMPONENTS

The Epic T laser system includes the following:

1. Laser Console
2. Screen Protectors Box (Peel-off Clear Screen Cover - qty. 25)
3. Fiber Optic Cable (Installed)
4. Laser Protective Eyewear (qty. 3)
5. Deep Tissue Handpiece (qty. 1; packaged/shipped separately)
6. Deep Tissue Handpiece Disposable Shields (qty. 20; packaged/shipped separately)
7. DC Power Supply Module
8. Power Cord (U.S.) (qty. 1)
9. Power Cord (International) (qty. 1)
10. Welcome Kit (Includes User Manual and Quick Setup Guide).
11. Laser Warning Sign
12. Remote Interlock Cable
13. Footswitch
14. Philips-Head Screwdriver (For Installing Footswitch Batteries)
15. AAA Batteries (qty. 2).

WARNING: No modification of this equipment is allowed.

5.2 GENERAL

The Epic T system consists of three components:

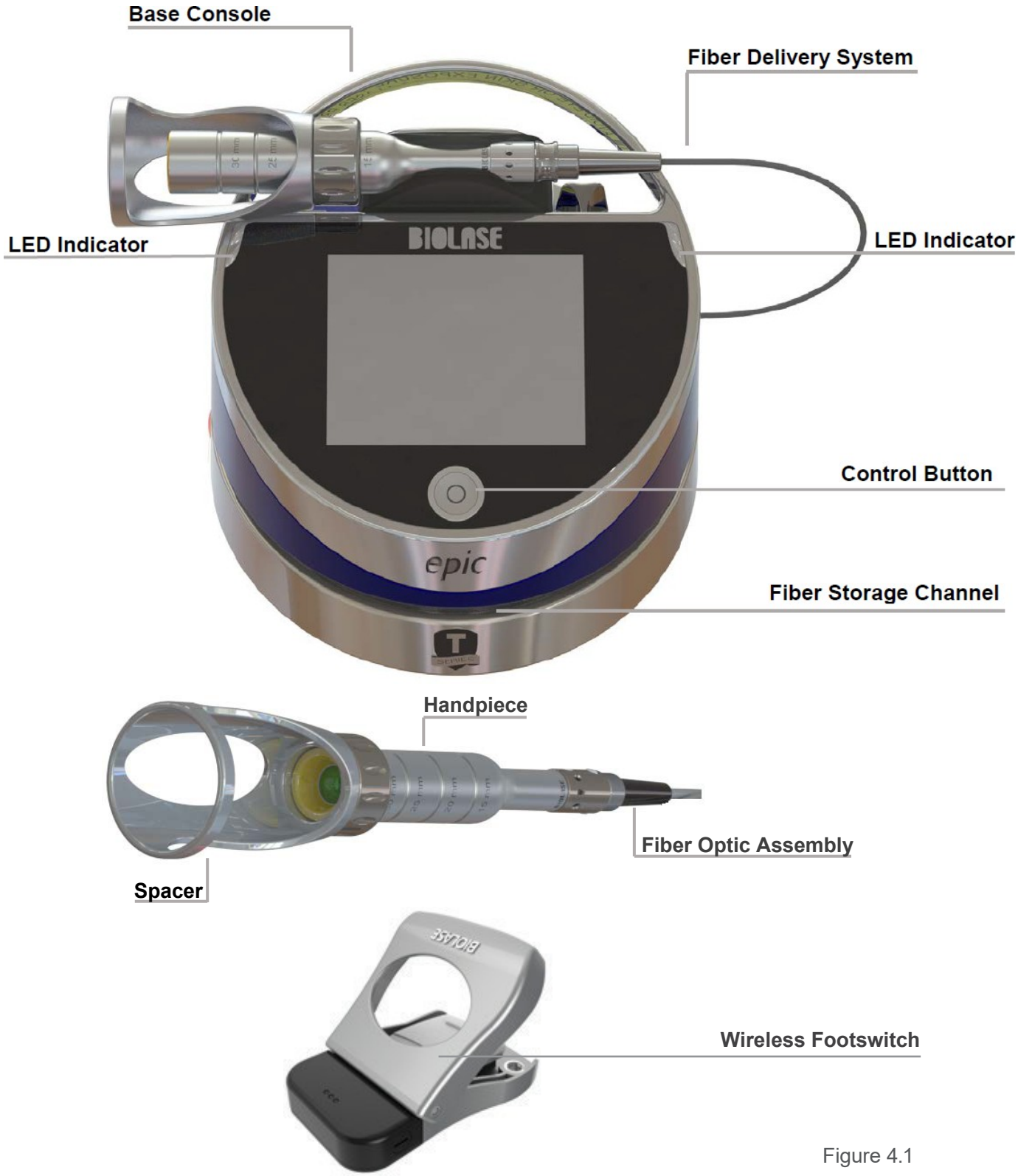

Figure 4.1

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BASE CONSOLE

The base console is portable, contains the diode laser and all the elements which power the laser, and has a touchscreen which allows the user to navigate from screen to screen, select procedures, enter and/or change settings, etc. (Figure 4.1).

CONTROL BUTTON:

Activates the controls and display; places the laser into **Standby, Ready**, or **Sleep** mode.

LED Indicators: Amber = Standby mode

Green = Ready mode

Green (blinking) = Laser is firing

Blue (blinking) = Pairing active

FIBER DELIVERY SYSTEM

The fiber delivery system consists of Fiber Optic Cable, the reusable Deep Tissue Handpiece, and transmits laser radiation from the laser console through the Handpiece to the target tissue. The laser ships from the factory with the Fiber Optic Cable already attached to the base console
(Figure 4.2).

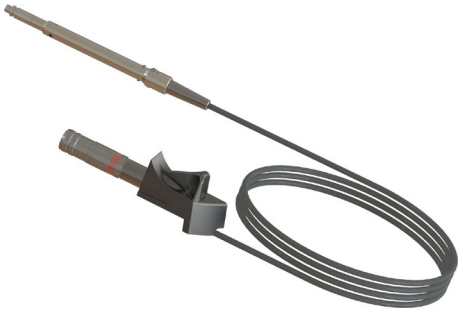

Figure 4.2

DEEP TISSUE HANDPIECE

The Deep Tissue Handpiece is a re-usable Handpiece used for pain therapy (Figure 4.3). The Handpiece is equipped with disposable non-sterile shields for single-patient use. The shields are applied to the spacer and discarded after one-time use.

Figure 4.3

WIRELESS FOOTSWITCH

The Epic T laser will only emit laser energy when the user presses down on the Footswitch while the laser is in **Ready** mode. It is designed to work using wireless technology and is powered by two AAA batteries which are installed prior to shipment from the factory; it is already paired to the base console.

The Footswitch is protected by a metal cover. To access, first press down on the cover to unlatch it, then press the Footswitch to fire the laser (Figure 4.4)

Figure 4.4

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Failure to comply with the 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.

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

6.1 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 (included - see Appendix B)
- **Do not** operate in the presence of explosive of flammable materials. Flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen (O_2) 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 laser protective eyewear**. Always ensure that the laser protective eyewear is appropriate for the laser wavelength; refer to the markings on the eyewear itself for the specifications of the protection provided.
- **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 connecting the Deep Tissue Handpiece to the Fiber Optic Cable.
- **Always** ensure that the proper laser parameters are set before the Epic T laser is used in a clinical procedure.
- Toggle the ON/OFF switch (located on the rear of the console) to the OFF (O) position before leaving the unit unattended.
- **Do not** use the laser if the Fiber Optic cable is damaged or broken.
- **Do not use** the laser if there's a suspicion it is not functioning properly or other than as described in this User Manual.

LASER WARNING: DO NOT open the console housing at any time. Danger from optical radiation may exist.
DO NOT aim the laser at metallic or reflective surfaces, such as surgical insturments or mirrors. If aimed directly at these surfaces the laser beam will reflect creating a potential hazard.

CAUTION: DO NOT position this equipment so that it is difficult to pull the plug from the power source.

CAUTION: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

CAUTION: High temperatures produced in the normal use of this laser equipment may ignite some materials (e.g., cotton wool when saturated with oxygen); solvents or adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used.

CAUTION: This laser system 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.

6.2 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 and pulse mode.
- Wireless footswitch – IPX6.

6.3 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 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 or your BIOLASE-authorized service representative.

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 cannot 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. Turn the power switch OFF (O) only when the system will not be in use for a long period of time.

ACCESS KEY CODE

The Access Key Code (888) prevents unauthorized use of the system. It is activated every time the system is turned ON with the power switch.

Placing the laser in Sleep mode by pressing and holding the Control button on the front panel of the console does not re-set the access key code.

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.

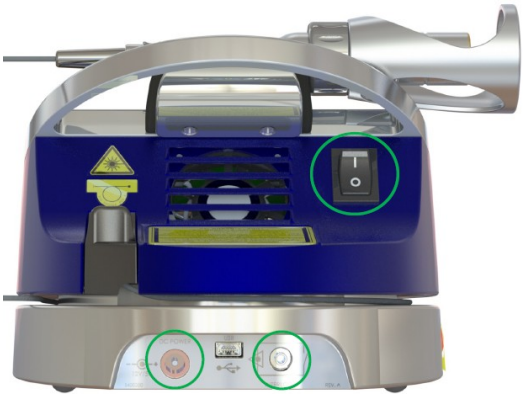

Figure 6.1:
Power Switch, DC Power Input, Remote Interlock

Figure 6.2:
DCPower Supply Module

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WIRELESS FOOTSWITCH

The Epic T 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 (Figure 6.3).

Figure 6.3:
Wireless Footswitch

REMOTE INTERLOCK

This feature allows the laser to be connected to a remote sensor which prevents it from firing when the sensor is triggered. To install the remote interlock (Figure 6.4), insert the plug at the end of the connector into the rear of the laser console and attach the two wires at the other end to a door switch; the laser will stop immediately when the connection to the door switch is deactivated, i.e., when the door is opened.

Figure 6.4:
Remote Interlock Connector

EMERGENCY STOP

Press the red emergency laser stop button to instantly turn off the laser console (Figure 6.5). The message “Emergency Switch Error” will appear on the console display 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.

FUNCTIONAL DISPLAY

The system color display with touch screen and LED indicators on the control panel shows the functional conditions of the system.

Figure 6.5:
Emergency Laser Stop

CAUTION: Use only the DC Power Supply Module supplied with the Epic T laser system. (BIOLASE P/N 2400075)

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

FACILITY REQUIREMENTS

Electrical Supply: 100V-240V ~ at 1.5A, 50/60Hz

Environmental: Temperature 15-35 ºC (59-95 ºF), Humidity 10-90%, non-condensing

- Place the unit in a clean, dry, and well-ventilated area; **do not** cover or block the ventilation channels. These channels provide an air-flow path to cool the unit.
- Verify the power switch is in the OFF (O) position.
- Epic T will work using either DC power or its rechargeable battery pack
  - **DC Power:** Connect the DC power supply module to the laser console, attach one end of the power cord to the DC power supply module and plug the other end of the power cord into a wall outlet.
  - **Rechargeable Battery:** The Epic T is shipped with the battery pack already installed; to charge the battery pack, connect the power cord of the DC power supply module 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. To fully charge the battery, plug the DC power supply module 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 (the screen is dark) after 5 minutes; if the DC power supply module is plugged in but the console is turned OFF (O) at the power switch, the battery will still charge, but at a slower rate.

7.2 CONNECTING THE FIBER OPTIC CABLE

The Epic T ships with the Fiber Optic Cable already connected to the laser console.

CAUTION: Do not connect or disconnect the fiber cable while the laser console is turned ON. Only connect or disconnect the fiber when the laser console is turned OFF.

Figure 7.1: Fiber Optic Cable Access Plug

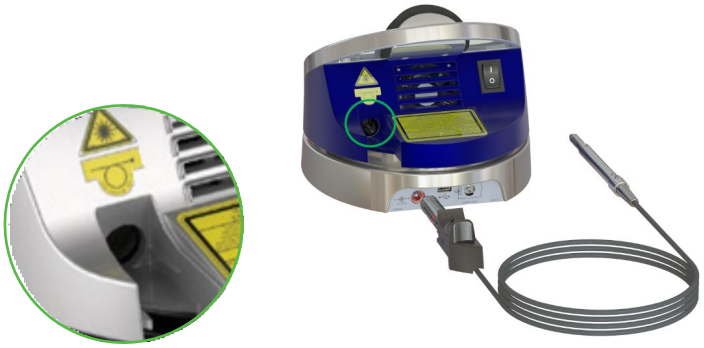

Figure 7.2: Optical Access Port

To disconnect the Fiber Optic Cable from the laser console, **make sure the laser console is turned off and the cable is completely unwound from the console base**, grab the Fiber Optic Cable access plug and slowly pull it straight back from the optical access port (Figure 7.1).

To re-install the Fiber Optic Cable, **make sure the laser console is turned off**. The Fiber Optic Cable is attached to the console by inserting the optical access plug (Figure 7.1) into the optical access port (Figure 7.2).

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

CAUTION: Do not bend the Fiber Optic Cable 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.

7.3 CONNECTING/DISCONNECTING THE DEEP TISSUE HANDPIECE

The Deep Tissue Handpiece is a reusable accessory and is provided with disposable non-sterile protective shields designed for single patient use. The Handpiece is non-sterile and requires disinfection before and after each patient use. **This Handpiece cannot be sterilized in the autoclave, as doing so will damage its internal optics.** For instruction on how to clean and disinfect the Handpiece, please refer to Section 9.

Always wipe the disposable shield with alcohol prior to use. These shields are for single-use only to avoid cross-contamination and must be discarded after one-time use.

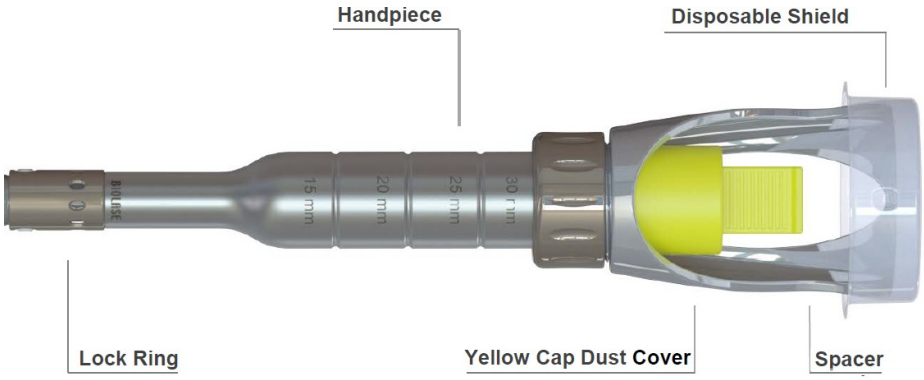

Figure 7.3: Deep Tissue Handpiece

To connect the Handpiece to the Fiber Optic Cable:

- Make sure the laser is turned OFF.
- Make sure the Fiber Optic Cable is connected to the laser console (Section 7.2).
- Remove yellow cap dust cover from the distal end of the Deep Tissue Handpiece (Figure 7.4).

Figure 7.4

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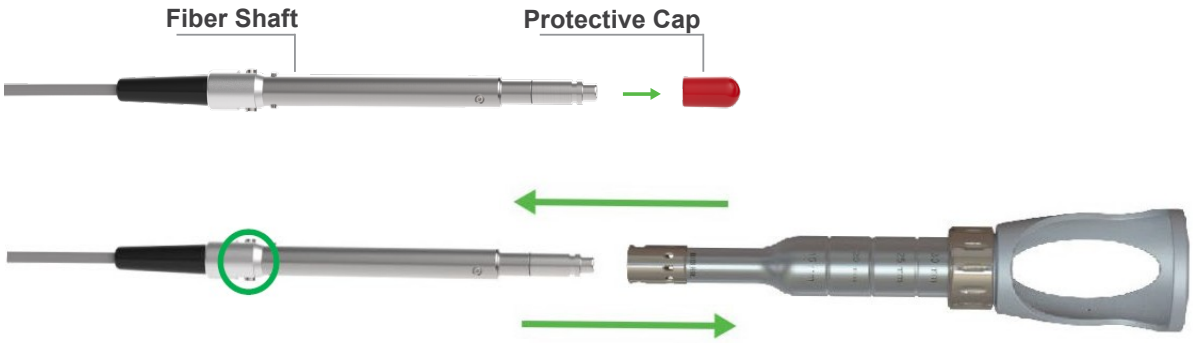

Figure 7.5

- Connect the Deep Tissue Handpiece to the Fiber Optic Cable by sliding it over the fiber shaft until it clicks into place and is secured (Figure 7.5). If no click is audible, disconnect the Handpiece and then re-install it.
- Set the spot size to 30mm by loosening the lock ring and sliding the spacer to the 30mm spot size detent location (Figure 7.6); tighten the lock ring to prevent the spacer from moving during treatment.
- Place the protective shield over the spacer (Figure 7.7).

The Handpiece is now ready to use.

To disconnect the Handpiece from the Fiber Optic Cable, press and hold both buttons at the base of the fiber shaft and gently pull the Handpiece to separate (Figure 7.5).

Figure 7.6

Figure 7.7

NOTE: When not in use, protect the lens of the Handpiece from debris; store in a safe and clean environment. Clean any debris that appears on the lens using a cotton swab moistened with isopropyl alcohol.

NOTE: Refer to the individual Instructions for Use included with the Deep Tissue Handpiece packaging for additional details.

7.4 OPERATION - TURN ON THE EPIC T

Operate with the battery or connect the DC power supply module 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. After three (3) seconds the Epic T “Welcome” screen will be displayed.

- 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; press the ‘X’ or wait 3 seconds to revert back to the welcome screen; re-enter the correct code.
- The system will go to the HOME screen.

Figure 7.8

7.5 HOME SCREEN

The Home screen offers the following access and information:

- **Settings icon** (bottom center): Accesses the settings screen; allows the user to make changes to several system settings, including language.
- **Laser console battery indicator** (upper right corner): Displays console battery charge level.
- **Wireless signal strength indicator** (upper left hand corner): Displays the strength of the wireless connection between the Footswitch and laser console.

Figure 7.9

7.6 SETTINGS SCREEN

Pressing the Settings button on the HOME screen accesses the Settings screen; the user may make changes to the following system settings:

Figure 7.10

7.7 PAIRING THE FOOTSWITCH TO THE LASER CONSOLE

Verify that the Footswitch and laser 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 "x" will appear over the pairing icon located in the upper left hand corner of the touchscreen (Figure 7.11).

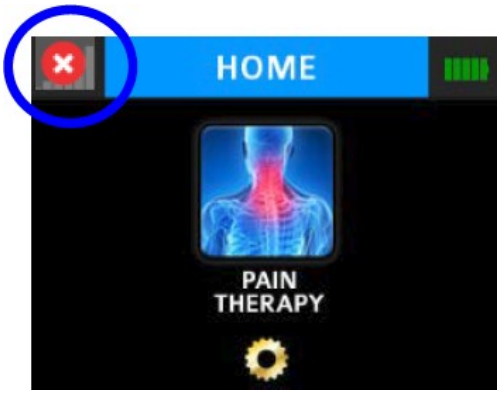

Figure 7.11

To re-establish pairing, take the following steps:

1. Go to the settings menu on the laser console display by pressing the settings icon; select the “Wireless” icon.

2. A screen will appear indicating that pairing of the Footswitch to the laser console has been lost (Figure 7.12); press the green PAIR button.

3. The message that “PAIRING WILL NOW BEGIN” will appear (Figure 7.13); press the green check mark to continue.

4. To complete the pairing process, turn the Footswitch over and press the pairing button for four (4) seconds (Figure 7.14).

5. The wireless screen will appear indicating that pairing was successful and that the Footswitch and laser console are now paired (Figure 7.15). Proceed to step 6.

6. If pairing has not occurred, the wireless screen will appear again indicating that pairing was not successful (Figure 7.16); press the green button to repeat steps 3 and 4.

7. 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 7.17).

Figure 7.12

Figure 7.13

Figure 7.14

Figure 7.15

Figure 7.16

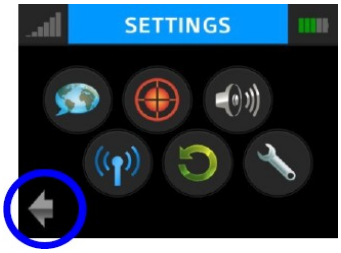

Figure 7.17

7.8 CONTROL BUTTON

The CONTROL button on the front of the laser console is a multi-functional button. 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.

7.9 ENTERING READY OR STANDBY MODES

Press and release the Control button to place the laser console into either **Ready** or **Standby** mode (the mode is displayed in the lower right hand corner of the display screen). 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.

7.10 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) second delay between switching to **Ready** mode and the ability of the laser console to emit a laser beam.

NOTE: The aiming beam is on only when the laser is in **Ready** mode or when adjusting the brightness of the beam while in Settings. If the aiming beam is not visible in either instance, remove the Handpiece and confirm the beam is actually on by shining the end of the Fiber Optic Cable on a plain, non-reflective surface. **DO NOT** look directly at the output end of the Fiber Optic Cable. If the aiming beam is not on, turn off the laser console, then remove and re-install the Fiber Optic Cable assembly. If the aiming beam is still not on, turn off the laser console and call a Biolase-authorized service representative.

7.11 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: If the Footswitch is pressed while the system is in **Standby** mode, the screen will display **ALERT 2**, indicating the system is not in **Ready** mode. Press the control button to switch to **Ready** mode.

When the Footswitch is not in use, it will go into **Sleep** mode to conserve battery power. It automatically reactivates when pressed.

7.12 USING THE EPIC T TOUCH SCREEN DISPLAY

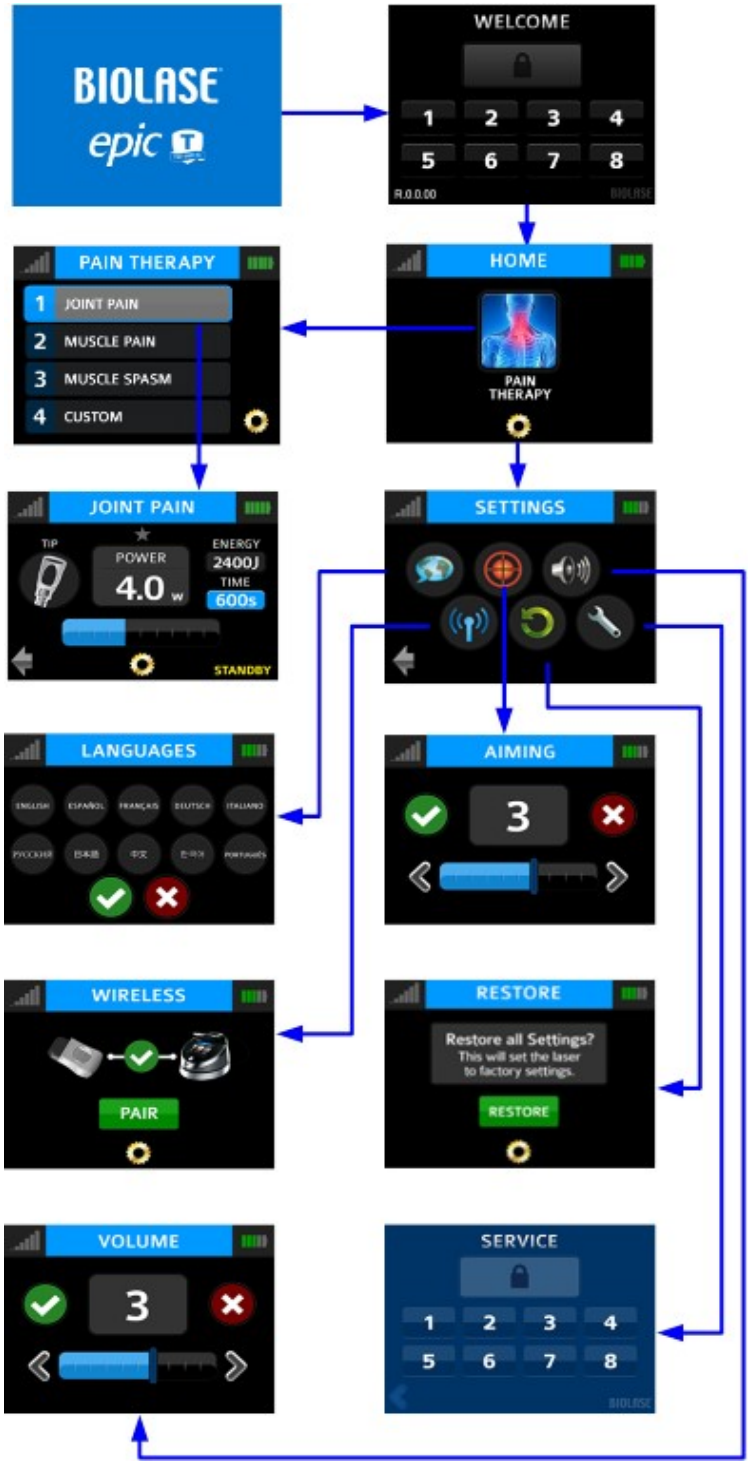

Figure 7.18

7.13 TURN THE LASER CONSOLE OFF

- Wind the fiber Optic 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 Cable 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.

8

8.1 OVERVIEW

Please review this section carefully before using this device in a clinical situation.

The Epic T 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 Deep Tissue Handpiece. The pain therapy procedure elevates tissue temperature 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 ameliorative 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.

Refer to the Fitzpatrick Skin Type Scale when performing pain therapy procedures. The diode wavelength has increased absorption in melanin in the skin, causing greater heating of the skin surface of patients with a higher melanin concentrations (darker skin types). Patients with higher melanin content in their skin may feel more discomfort during treatment, which may be alleviated by moving the Handpiece to defocus the energy, or decreasing the power setting

PAIN THERAPY PRESET VALUES

The default settings for pain therapy are 2.75W, 10 minutes, with the spot size set at 30mm. Power can be adjusted from 2.75W to 4W max, as appropriate, based on the Fitzpatrick Skin Type Scale. Always start at the lowest power setting and increase as necessary. The Handpiece can be used in a constant location or moved around the treatment area. If holding the Handpiece in a constant location, adjust the settings on the screen to the recommended initial power settings for therapeutic effect. Always monitor patient response; adjust power and/or distance as needed for patient comfort.

NOTE: To adjust the power, press the power indicator window in the center of the screen, then use the scroll bar to adjust the power level up or down.

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 skin type.

Safety and effectiveness are described by elevating the skin temperature in the treatment area utilizing the recommended settings (Figure 8.1). Use personal clinical judgment with consideration of the Fitzpatrick Skin Type Scale when setting the procedure parameters; monitor the patient and adjust the settings as necessary for effectiveness and comfort.

NOTE: To avoid potential patient discomfort and/or skin damage, it is advisable to use a test spot prior to the initial treatment to assess the suitability of the selected settings for the individual patient.

Fitzpatrick Skin Type Scale		Maximum Recommended Power / Exposure
TYPE I	Always burns, never tans (pale white; blond or red hair; blue eyes; freckles).	Not recommended for laser therapy
TYPE II	Usually burns, tans minimally (white; fair; blond or red hair; blue, green, or hazel eyes).	3.25W / 10 minutes
TYPE III	Sometimes mild burn, tans uniformly (cream white; fair with any hair or eye color).	4.00W / 10 minutes
TYPE IV	Burns minimally, always tans well (moderate brown).	3.50W / 10 minutes
TYPE V	Very rarely burns, tans very easily (dark brown).	3.25W / 10 minutes
TYPE VI	Never burns, never tans (deeply pigmented dark brown to darkest brown).	2.75W / 10 minutes

Figure 8.1

PAIN THERAPY – ADVERSE EFFECTS

Some reddening of the skin at the treatment site is normal due to increased circulation; however, in very rare cases burning or blistering of the skin may occur. Immediately stop treatment, rinse the area with cool water or place a cold pack to the affected area for at least 5 minutes, then apply a burn ointment or spray. **DO NOT USE ICE.**

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.

Patients suffering from general neurovascular conditions, such as neurodegeneration associated with Type II diabetes, may have reduced sensitivity to pain affecting their response to discomfort during treatment. Refer to Section "Contraindications, Warnings, and Precautions" for additional information.

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.
- **Avoid** treatment of sites that have tattoos.
- **Do not** apply ointment, creams, lotions or heating lotion patches at, or in close proximity to, the treatment area.
- **Do not** apply therapies prior to treatment that could change body temperature, such as ultrasound, ice/heat pack, electrical stimulation, or heating patches.
- **Do not** apply treatment over articles of clothing.
- **Do not** apply any numbing agents to the affected area as they could reduce the patient's pain sensitivity and response to any treatment discomfort.

9

CAUTION: This device contains no user-serviceable parts other than what is described in this manual. Any attempt to modify or repair the laser by anyone other than an authorized BIOLASE technician or BIOLASE-trained representative may lead to exposure to laser radiation and collateral radiation and will void the product warranty.

9.1 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 T system after each procedure. **Do not use bleach or abrasive cleansers.**

9.2 DISINFECTING THE FIBER OPTIC CABLE

Always disinfect the fiber between patients by wiping it completely 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. **DO NOT AUTOCLAVE.**

CAUTION: The Fiber Optic Cable cannot be autoclaved; doing so will make it unusable. However the Fiber Optic Cable must be disinfected between patients by following the procedure outlined in his section.

9.3 DISINFECTING THE DEEP-TISSUE HANDPIECE

The Deep-Tissue Handpiece is a reusable accessory. It is shipped non-sterile and requires disinfection before and after each patient use. **DO NOT AUTOCLAVE**, as doing so will damage its internal optics and make it unusable.

This Handpiece is sold with non-sterile, disposable protective shields. The shields are intended for single-use only and should never be reused to prevent cross-contamination.

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

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

9.4 FIBER CABLE LENS INSPECTION AND CLEANING

LENS INSPECTION PROCEDURE

The lens is at the distal end of the Fiber Optic Cable (Figure 9.1); this is where debris may accumulate over time with use. To inspect the lens, take the following steps:

CAUTION: DO NOT inspect the lens while the laser system is powered on; the aiming beam or laser beam can permanently impair vision if aimed at the eye.

1. Remove the Handpiece from the fiber shaft.
2. Inspect the distal end of the fiber using a magnifier or loupes with at least 10X magnification (Figure 9.2).
3. Inspect the lens.

Figure 9.1

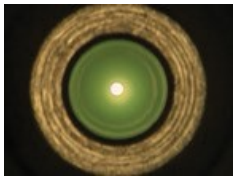

Figure 9.2

CLEANING THE LENS

If debris or dark spots are observed on the lens, clean the window using the procedure outlined below.

1. Always use a new, unused Microbrush (provided) to clean the lens (Figure 9.3).
2. Dip the Microbrush in isopropyl alcohol.
3. Gently rub the lens surface to remove debris or dark spots (Figure 9.4).
4. Repeat as needed using a new Microbrush each time until no residue appears on the swab.

Figure 9.3

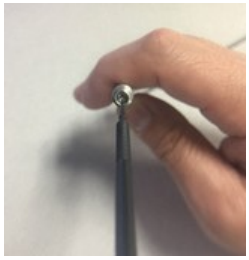

Figure 9.4

9.5 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 9.5)
2. To remove the battery, grip the battery at the top and pull the cable away from the connector. Do not tug or wrench the cable from the connector. (Figure 9.6)
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.
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 module to the unit and plug into a wall outlet. Before first use, it is recommended to fully charge the battery for 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.

6. Recycle the used Lithium Ion battery as regulated. Do not discard in a trash bin.

Figure 9.5

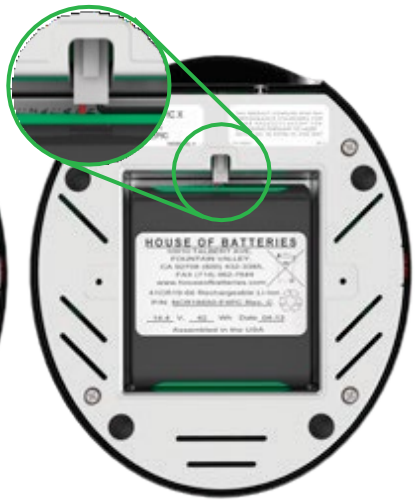

Figure 9.6

NOTE: Only use the battery pack supplied by BIOLASE. The battery pack is a seperate accessory (BIOLASE P/N 6400457).

9.6 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, remove the 3 screws on the underside of the Footswitch to remove the battery cover (Figure 9.7); take out the old batteries, and install the new ones, replacing the cover when done. Discard the used batteries as regulated; do not throw them in a trash bin.

Figure 9.7
Battery Cover Screws

Do not press/push/touch the pairing button (Figure 9.8) while changing the batteries, as this will disrupt the pairing of the laser console and Footswitch.

Replacing the batteries may disrupt the pairing of the laser console and Footswitch. If you find the wireless communciation has been interrupted, reestablish pairing by following the instructions provided in Section 7.

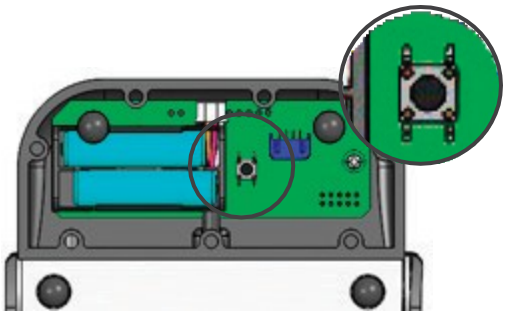

Figure 9.8
Pairing Button (internal view)

NOTE: To ensure the longevity of the battery power, only BIOLASE-supplied batteries are recommended as replacements (BIOLASE p/n 2400203); these are industrial-grade batteries which under normal use have a longer life than conventional AAA batteries.

9.7 TRANSPORTATION

The Epic T 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**.

9.8 STORAGE

The Epic T should be stored in a cool, dry place when not in use under the following environmental conditions:

- Storage temperature: 15°C-35°C (59°F-95°F).
- Relative humidity: 10%-90%, 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.

The Epic T 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.

NOTE: At end-of-life, final disposition of the laser must be done as required by local waste elecrical and electronic equipment (WEEE) laws.

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Calibration is recommended every twenty-four (24) months in order to maintain the required accuracy of output power versus displayed power and 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.

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BIOLASE respects the intellectual property of others, and we ask our users to do the same. Epic T 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.

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Should any of the on-screen messages listed in Figure 12.1 and Figure 12.2 appear, follow the troubleshooting instructions for the specific message, as noted.

NOTE: For any on-screen message not listed in Figure 12.1, re-power the laser console; if the message does not clear, call BIOLASE Service at **1-800-321-6717** or your Authorized Service Representative.

Screen	Message	Reason	Fix
Warning 1	Temperature high	System is hot	Allow 5-10 minutes for laser to cool down
Warning 2	Battery is low	Battery is low	Plug in DC supply
Warning 3	Battery is not connected	Battery is not connected	Plug in the battery
Warning 4	Footswitch battery is low	Battery on the Footswitch is low	Replace Footswitch battery
Warning 5	Footswitch	Footswitch held	Release Footswitch
Alert 1	Wireless not paired	No wireless connection	Re-establish pairing (see sec. 7)
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 12.1

12

Screen	Message	Reason	Fix
Error 1	Thermistor open	Thermistor open	Call BIOLASE service
Error 2	Thermistor shorted	Thermistor shorted	Call BIOLASE service
Error 3	Shutdown temperature	System too hot	Allow 5-10 minutes for laser to cool down
Error 4	Laser current high/low	Output is out of specs	Call BIOLASE service
Error 5	Footswitch shorted	Footswitch is partially pressed or damaged	Press/release Footswitch 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 Fiber Optic Cable
Error 9	Lost Footswitch communication	Wireless interference	Reposition console/Footswitch 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 is critically low	Plug in DC supply
Error 13	Internal error	Internal error occurred	Restart unit
Error 14	Footswitch battery	Footswitch battery critically low	Replace Footswitch battery

Figure 12.2

Appendix A

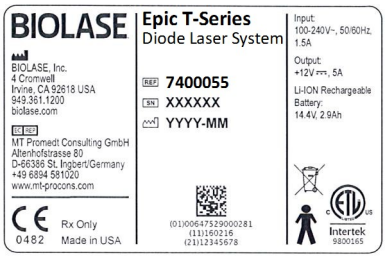
PART NO.	DESCRIPTION
2400277	Laser Safety Glasses
6400058	Remote Interlock Plug
2400075	DC Power Supply Module
2400043	Power Cord (U.S.)
2400055	Power Cord (International)
6400522	Wireless Footswitch
6400311	Deep-Tissue Handpiece
6400310	Deep-Tissue Handpiece Disposable Shields (qty. 20)
6400465	Peel-off Clear Screen Covers (qty. 20)
6400457	Lithium-ion Battery Pack for Console
2400203	Battery pack (2 x AAA)
6400437	Fiber Optic Cable
5400386	Laser Warning Sign

Appendix B

PRODUCT IDENTIFICATION

LABEL: LOCATION:

Bottom of laser console.



MANUFACTURER

CATALOG/PART NUMBER

PRODUCT SERIAL NUMBER

DATE OF MANUFACTURE

LASER WARNING:

Symbol warns of laser beam hazard. Always wear appropriate eye protection.

LOCATION:

Back of Laser Console.

TYPE BF APPLIED PART:

The applied part is not conductive to the patient.

EMERGENCY LASER STOP SWITCH:

The switch used in emergencies to stop laser output.

LOCATION:

Left side of laser console.

LASER APERTURE WARNING:

Indicates visible and/or invisible laser radiation is emitted from this aperture.

LOCATION:

Back of laser console.

Appendix B

CERTIFICATION:
This device complies with FDA laser standards.

LOCATION:
Bottom of laser console.

Complies with FDA performance standards for laser products except for conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1, as described in Laser Notice 56, dated May 8, 2019.

5400341 Rev. C

WARNING LABEL:
Indicates there is the risk of possible exposure to both infrared and visible laser radiation.

LOCATION:
Back of laser console

FCC AND IC LABEL:
Federal Communication Commission and Industry Canada registration numbers.

LOCATION:
Bottom of laser console.

MODEL: EPIC T-SERIES
FCC ID: G2OEPIC-1

5400567 Rev. A

REFER TO USER MANUAL

FCC COMPLIANCE NOTICE:
The Footswitch and laser console comply with Part 15 of FCC Rules regarding unlicensed transmissions.

LOCATION:
Bottom of Footswitch.

NOTICE
This device complies with Part 15 of FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

INGRESS PROTECTION CODE:

The Footswitch is water-resistant, protected against splashes of water.

IPX6

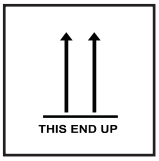
Appendix B

SINGLE USE ONLY – DO NOT REUSE

WEEE (WASTE ELECTRICAL AND ELECTRONIC):
Recycle lithium ion battery as regulated. Do not throw in trash bin.

THIS END UP

LOCATION: Outer carton (shipping box).



FRAGILE: HANDLE WITH CARE

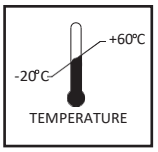
LOCATION: Outer carton (shipping box).

KEEP DRY

LOCATION: Outer carton (shipping box).

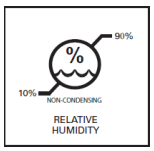
TRANSPORTATION TEMPERATURE LIMITATIONS

LOCATION: Outer carton (shipping box).



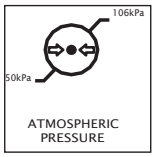
HUMIDITY LIMITATIONS

LOCATION: Outer carton (shipping box).



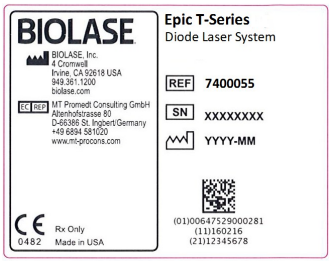
ATMOSPHERIC PRESSURE LIMITATIONS

LOCATION: Outer carton (shipping box).



SYSTEM SHIPPING LABEL:

LOCATION:
Outer carton (shipping box).



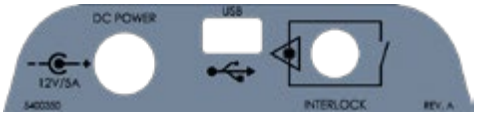
Appendix B

LASER WARNING SIGN

Included in the Welcome Kit; must be placed **outside of the operatory** whenever the laser system is in use.

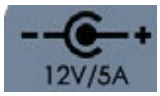
DC POWER, USB, REMOTE INTERLOCK LABEL:

Identifies input ports



POWER INPUT RATING:

12 Volts Direct Current, 5 amps

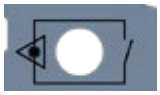


MINI USB INPUT:

For external programming

REMOTE INTERLOCK:

Input for Remote Interlock Connector



Appendix C

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 cards 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'smanual.

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.

Appendix C

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. Changing 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 D

CAUTION: Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the following tables.

Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment.

Accessories: Medical grade power cord, maximum length 3ft (1 meter), BIOLASE p/n 2400043
DC Power Supply Module, BIOLASE p/n 2400075
Wireless Footswitch, BIOLASE p/n 6400522

WARNING: The use of accessories other than those supplied or sold by BIOLASE, Inc. as replacement parts for internal or external components may result in increased EMISSIONS or decreased IMMUNITY of the Epic T diode laser system.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS		
The Epic T diode laser is intended for use in the electromagnetic environment specified below. The customer or the user of the Epic T diode laser should assure it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF radiated emissions CISPR 11	**Group 1, Class A/B**	The Epic T uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF conducted emissions CISPR 11	**Group 1, Class A/B**	The Epic T is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	**Class A**	
Voltage fluctuations/flicker emissions IEC 61000-3-3	**Class A**	

Appendix D

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The Epic T diode laser is intended for use in the electromagnetic environment specified below. The customer or the user of the Epic T diode laser should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Continuous level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±2, ±4, ±8 kV contact ±2, ±4, ±8, ±15 kV air	±2, ±4, ±8 kV contact ±2, ±4, ±8, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 50%.
Electrical fast transient/burst IEC61000-4-4	100 kHz repetition ± 2 kV for power supply lines 100 kHz repetition ± 1 kV for input/output lines	100 kHz repetition ± 2 kV for power supply lines N/A	Main power quality should be that of a typical commercial or hospital environment. Input/output that does not apply because the footswitch cable length is less than 3 meters.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2kV common mode	± 1 kV differential mode ± 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	0% U_T for 0.5 cycle 0% U_T for 1.0 cycle 70% U_T for 25 cycles (50 Hz/60 Hz) 0% U_T for 250 sec/300 cycles (50 Hz/60 Hz)	0% U_T for 0.5 cycle 0% U_T for 1.0 cycle 70% U_T for 25 cycles (50 Hz/60 Hz) 0% U_T for 250 sec/300 cycles (50 Hz/60 Hz)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model Epic T requires continued operation during power mains interruptions, it is recommended that the Epic T diode laser be powered from an uninterrupted power supply.
Power frequency (50-60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the A.C. mains voltage prior to applications of the test level.			

Appendix D

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY *(Continued)*			
The Epic T is intended for use in the electromagnetic environment specified below. The customer or the user of the Epic T should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Continuous level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 GHz 6Vrms At the standard specified ISM band	3 Vrms 150 kHz to 80 GHz 6Vrms At the standard specified ISM band	Portable and mobile RF communications equipment should be used no closer to any part of the model Epic T, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC61000-4-3	9 V/m to 28 V/m 385 to 5785 MHz		**Recommended separation distance** d = 1.2√P d = 1.2√P 80 MHz to 800 MHz d = 2.3√P 800MHz to 2.5GHZ Where **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and **d** is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 - At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 – These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephone and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Epic T is used exceeds the applicable RF compliance level above, the Epic T should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Epic T. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.			

Appendix D

RECOMMENDED SEPARATION DISTANCE BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE EPIC T			
The Epic T is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Epic T can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Epic T as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter (m)**		
	150kHz to 80Mhz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 – At 80 MHz and 800 MHZ, the separation distance for the higher frequency range applies.			
NOTE 2 – These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Appendix E

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.

Intertek
9000165

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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