epic 10™

User Manual

Contents

INTRODUCTION

The ***EPIC 10*** Dental Soft Tissue Laser is a surgical and therapeutic device at the cutting edge of technology, designed for a wide variety of oral soft tissue procedures and dental whitening, as well as for use in providing temporary relief of minor pain.

The ***EPIC 10*** 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 the single use tips were designed and optimized for different applications. The device is activated by means of a wireless footswitch.

The ***EPIC 10*** is a prescription device that is indicated for professional use by dentists and hygienists (where local law allows) under the supervision of a dentist. The use of this device requires proper clinical and technical training. This manual provides instructions for dental professionals that have completed the appropriate training.

When used and maintained properly, the ***EPIC 10*** will prove a valuable addition to your practice. Please contact Biolase Service at 1-800-321-3717 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.”

Section 1: INSTALLATION

Installation Instructions

The ***EPIC 10*** system includes the following:

- Console (includes rechargeable battery pack)

NOTE: For instructions on how to install or change the battery pack, see Section 8.

- Re-usable Delivery System (1 surgical handpiece; 1 whitening handpiece, 1 re-usable, detachable fiber assembly, *(optional)* 1 deep tissue handpiece) *or*
- *(optional)* Classical Delivery System (1 "feed-through" fiber assembly, 1 corresponding handpiece, 1 fiber stripper, 1 fiber scribe)
- User Manual CD
- 3 pairs of protective laser eyewear
- Wireless Footswitch with two AAA batteries (FCC I.D. No. G20EPIC)
- Power Supply with Cord
- Remote interlock assembly
- Peel-off clear cover pack (qty. 30)
- Tip Initiation Kit
- Tips Starter Kit (single-use)
- Quick Reference DVD
- Window Cleaning Kit
- Warning Sign

NOTE: Use proper care prior to transporting the unit. Refer to section 8 in this Manual for instructions.

Facility Requirements

Electrical Supply (100-240V)

- 1.5 - 3A, 50/60Hz

Environmental Requirements

- Temperature: 20-25 ºC
- Humidity: 15-95%, Non-condensing

Changes or modifications not expressly approved by Biolase Technology, Inc. could void the user's authority to operate the equipment.

Section 2: SAFETY

Precautions

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

CAUTION:	Federal Law restricts this device to sale by or under the order of a dentist or physician or other licensed practitioner.

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

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

CAUTION:	This unit has been designed and tested to meet the requirements of electromagnetic, electrostatic, and radio frequency interference 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 10 product is used in a clinical setting.

Safety Instructions

Follow these safety instructions before and during treatments:

- All operatory entrances must be marked with an appropriate warning sign (included with shipment).
- 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.

CAUTION:	Periodically inspect laser eyewear for pitting and cracking.

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

NOTE: For replacement or additional protective laser eyewear, please contact your authorized dealer

- Do not look directly into the beam or at specular reflections.
- Never direct or point the beam at anyone's eyes.
- Always place the system into STANDBY mode (by pressing the control button on the control panel while in READY mode) before exchanging handpieces or disposable tips.

- Move the toggle switch (located on rear of console) to OFF position before leaving unit unattended.

DANGER:	Do not open unit housing at anytime. Danger from optical radiation may exist.

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

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

Safety Features

Energy Monitor

The current 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: “DIODE CALIBRATION”.

The unit will not operate until the system is reset by pressing the “Next” button on the touchscreen and then going into READY mode. If the error messages persist, 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 unit can be switched ON or OFF using a toggle switch at the back panel.

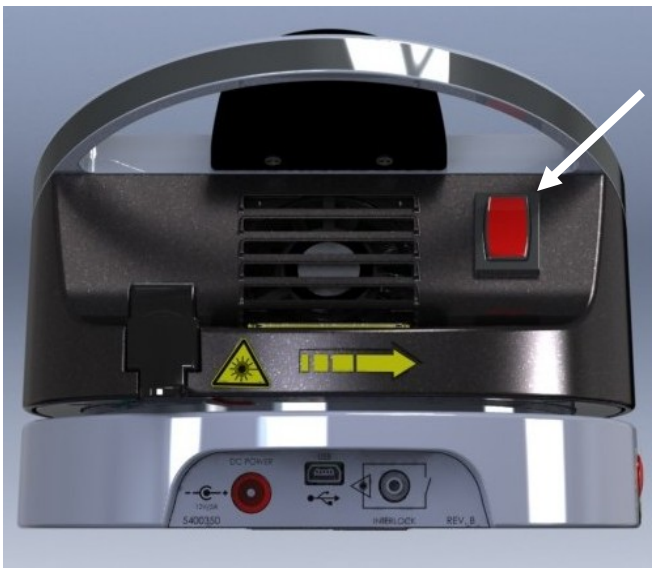


Figure 1: Power Switch

Figure 2: Power Supply with cord

CAUTION: Use only the Power Module supplied with the ***EPIC 10*** system (Biolase Part Number 6400142).

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.

NOTE: Turning the laser off by pressing and holding the Control button on the front panel does not re-set the Access Key Code. Turn the Power Switch OFF 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 position the access key code is activated. The CONTROL button on the control panel must be pressed to enable the footswitch. The aiming beam will illuminate to indicate that the system is ready for use.

Wireless Footswitch

The ***EPIC 10*** will not emit laser energy until the user presses down on the footswitch in READY mode. The footswitch is designed to work using wireless technology. Two AAA batteries are required to power the footswitch (operating voltage – 2 to 3.2 volts).

Figure 3: Footswitch

Remote Interlock

This feature allows the device to be connected to the remote sensor which will prevent 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 OFF when switch is open.

This feature is overridden when the plug is not connected.

Figure 4: Remote Interlock connector

Emergency Stop

Press the red Emergency Laser Stop button to instantly turn off the unit. The error screen will display an “Emergency Switch Error” message. Press the “√” icon to clear the error and automatically set the system into STANDBY mode.

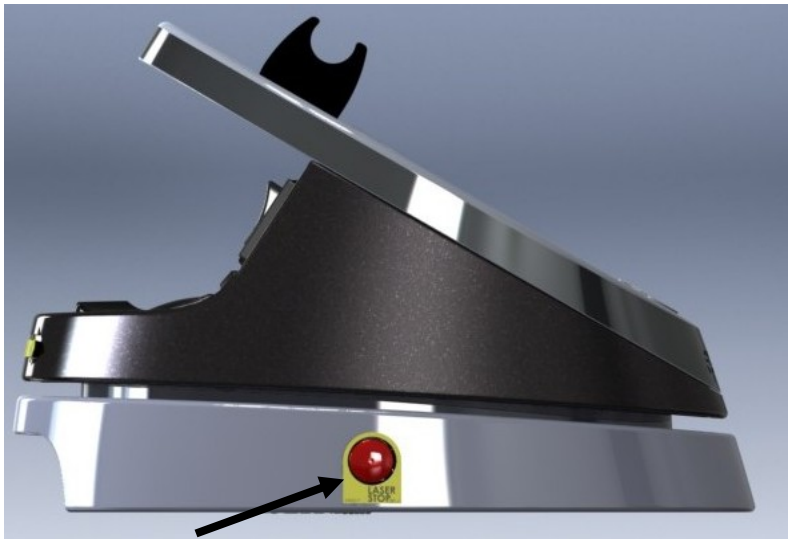


Figure 5: Emergency Laser Stop

Functional Display

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

Safety Classification

The following safety classifications are applicable to the device:

- Laser Radiation – Class 4
- Type of protections against electrical shock – Class 1
- Degree of protection against electrical shock – Type B Applied Part
- Not protected against water ingress – Ordinary Equipment
- Not suitable for use in presence of flammable anesthetic mixture
- Operation Mode – Continuous Operation
- Wireless Footswitch – IPX6

Section 3: EQUIPMENT DESCRIPTION

General

The ***EPIC 10*** system consists of three components:

- Console
- Delivery System
- Wireless Footswitch

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, 14.8V, 2.9 A/h

Control Panel (See Figure 7)

ITEM #	ITEM	ITEM DESCRIPTION
1	CONTROL BUTTON (a)	**Turns the controls and display on and off** **Places unit into STANDBY or READY mode**
2	LED INDICATOR (b)	***Amber* indicates unit is in STANDBY or READY mode.** **Blinking *green* indicates emission of laser power.** **Blinking *blue* indicates wireless connection is active**

Figure 7: Control Panel

Main Menu and Procedures Screen (See Figure 8)

ITEM #	ITEM	ITEM DESCRIPTION
1	HOME	Selects procedure categories
2	PROCEDURES SCREEN	Selects pre-set procedures parameters

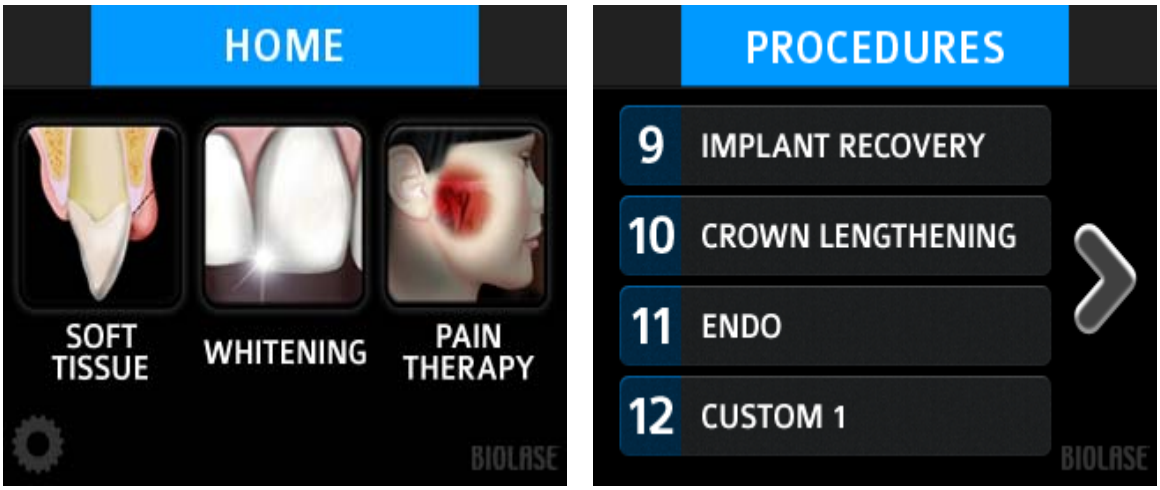


Figure 8: Main Menu and Procedures Screen

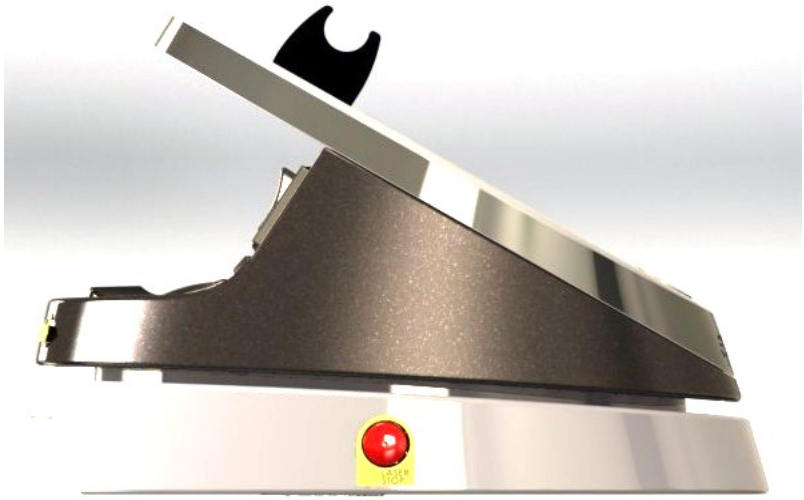


Figure 9: Left Side View

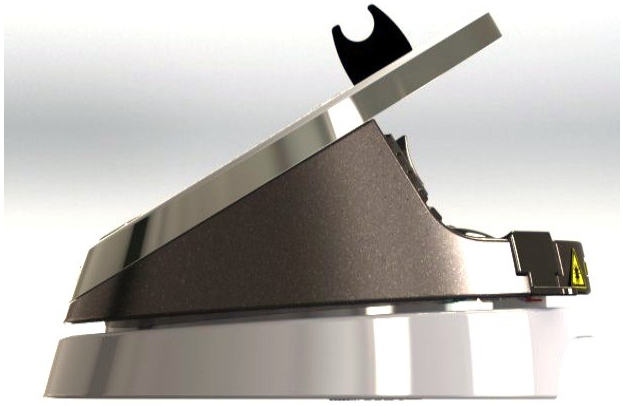


Figure 10: Right Side View

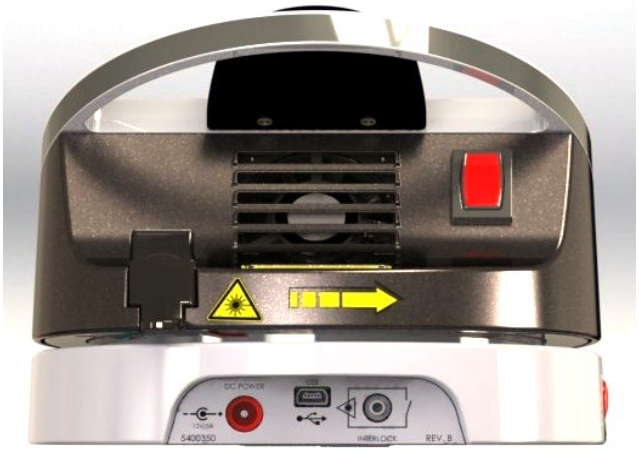


Figure 10: Back View

Figure 12: Front View

Re-usable Surgical Delivery System

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

The ***EPIC 10*** Re-Useable Delivery System with surgical handpiece consists of:

- Re-Useable Fiber Optic Assembly
- Surgical Handpiece (Figures 13, 14)
- Disposable Tips (See Figures 15, 16, 17)

NOTE: The fiber optic cable is detachable from the console. The Handpiece is a reusable accessory. The Handpiece 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.

Fiber Optic Connection

The fiber optic cable is attached to the console by inserting the optical access plug (Figure 13) into the optical access port (Figure 14).

For storage, the cable can be wound in the fiber storage channel around the base of the console in either a clockwise or counterclockwise direction (Figure 15).

Figure 13: Optical Access Plug

Figure 14: Optical Access Port

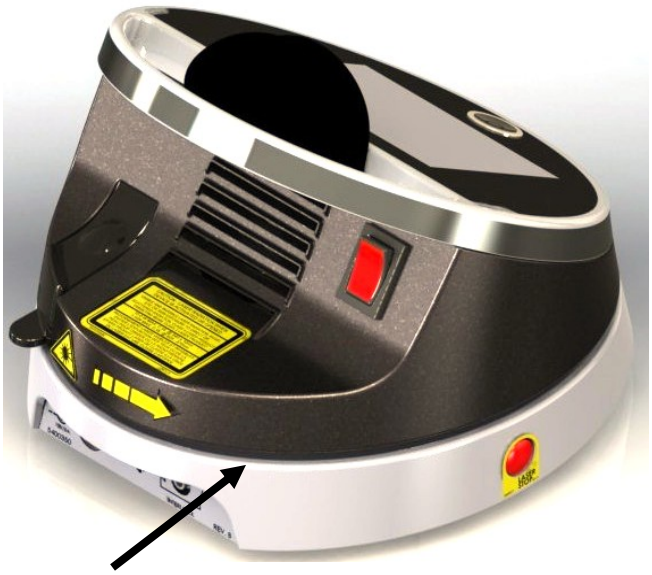


Figure 15: Fiber Storage Channel

Single-use Tips

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

WARNING: Always autoclave before tip initiation. Do not autoclave more than once. Tips are single-use only.

To connect the tip, insert it into the handpiece orifice and tighten by turning clockwise. Bend the metal cannula according to the specific procedure requirements.

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

CAUTION: Do not bend tips with sharp angle - it will break the tip (Figure 17). If the red aiming beam is not present in READY mode - replace the tip.

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 handpiece from fiber optic assembly:
  1. Take handpiece body in one hand and the shaft in another (See Figure 14)
  2. Push two buttons on the handpiece shaft
  3. Pull handpiece with the ring to separate.

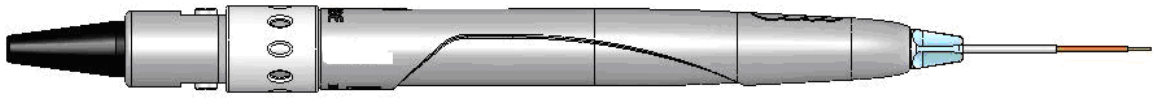


Figure 16: Surgical Handpiece Assembly

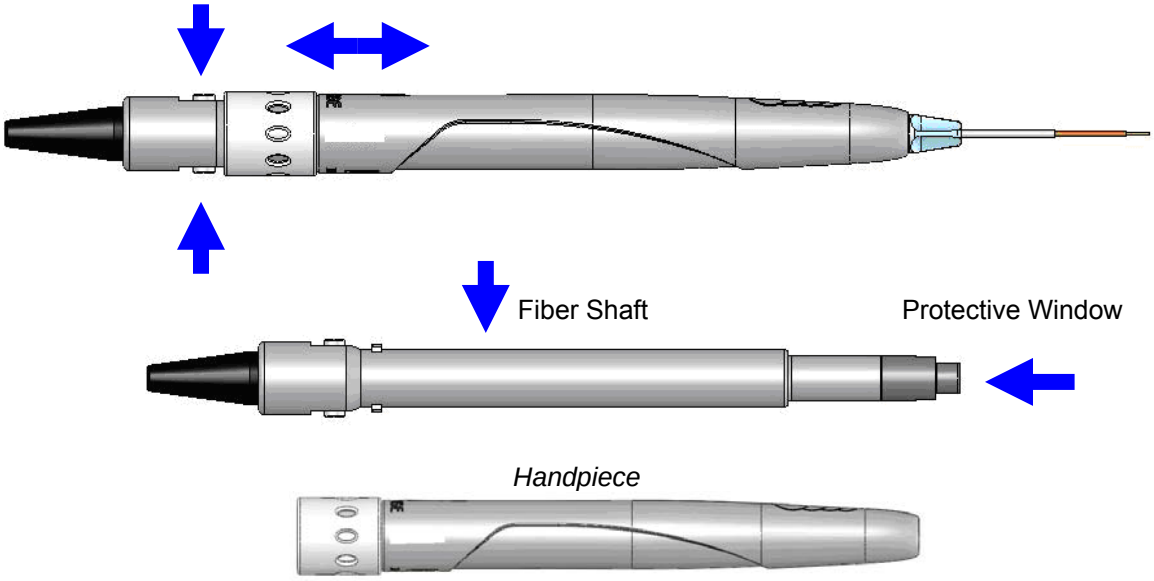


Figure 17: Disconnecting the Handpiece(push both buttons)

Figure 18: Disconnecting the fiber Tip (twist first counter clockwise)

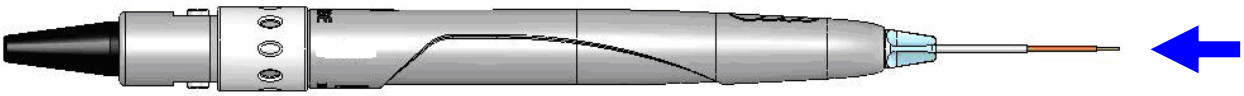


Figure 19: Tightening the fiber tips twist (only when Handpiece is connected to fiber)

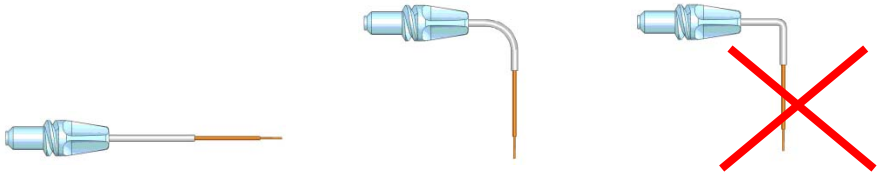


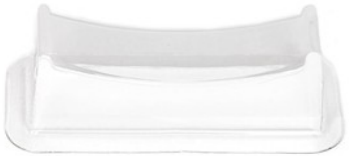
Figure 20: Bending the tip cannula

Whitening/Contour Handpiece

NOTE: The handpiece is reusable and equipped with a disposable non-sterile protective shield for single patient use. The handpiece requires cleaning before and after each patient treatment. For instructions on cleaning the the handpiece, refer to section 8.

NOTE: The Whitening/Contour Handpiece is compatible only with the Re-useable Fiber Optic Cable Assembly. It is not compatible with the Classical (Feed-Through) Fiber.

Whitening/Contour Handpiece



Disposable Shield

The area of Laser Energy Output is 35mm x 8mm = 2.8cm^2 Spot Size.

To disconnect the handpiece from the fiber optic assembly:

1. Take the handpiece body in one hand and the shaft in another.
2. Push two buttons on the handpiece shaft.
3. Pull handpiece with the ring to separate.

To connect the Handpiece to the fiber optic cable, push the handpiece on the fiber shaft until it clicks on and is secured.

Deep Tissue Handpiece (Optional)

NOTE: The handpiece is reusable and equipped with a disposable non-sterile protective shield for single patient use. The handpiece requires cleaning before and after each patient treatment. For instructions on cleaning the the handpiece, refer to section 8.

NOTE: The Deep Tissue Handpiece is compatible only with the Re-useable Fiber Optic Cable Assembly. It is not compatible with the Classical (Feed-Through) Fiber.

Deep Tissue Handpiece

1) Remove Red Dust Cover from Deep Tissue Handpiece

2) Slide handpiece over monocoil shaft until it clicks into place.

3) Place protective cover over the adjustable spacer

4) Loosen the Lock Ring and set the spacer at the desired spot size detent location. Tighten the Lock Ring.

5) Place handpiece into the handpiece holder.

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

Classical "Feed-Through" Fiber Handpiece (Optional)

Classical "Feed-Through" Delivery System

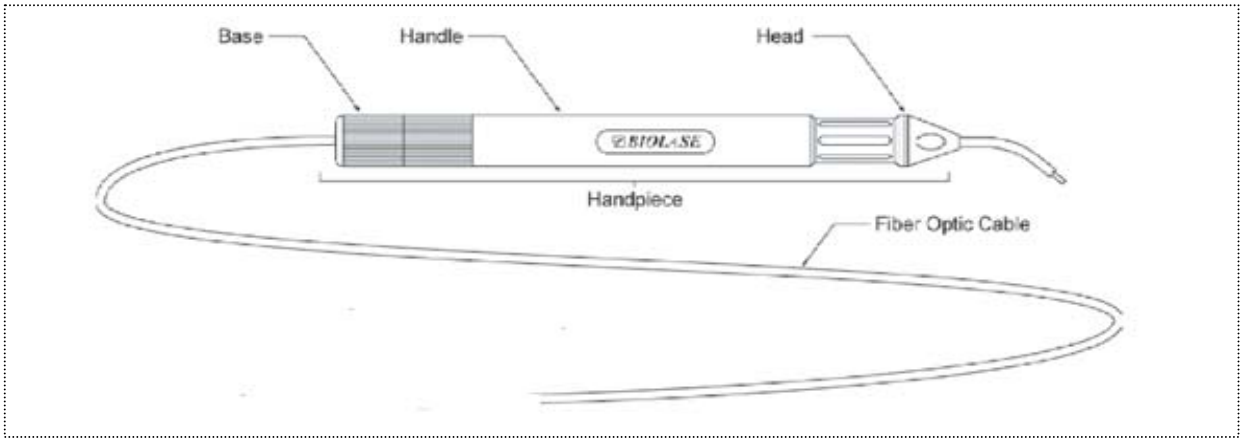
The Feed-Through Delivery System with Surgical Handpiece consists of a Fiber Optic Assembly with the following:

► Handpiece

► Base

► Handle

► Head (30°)



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

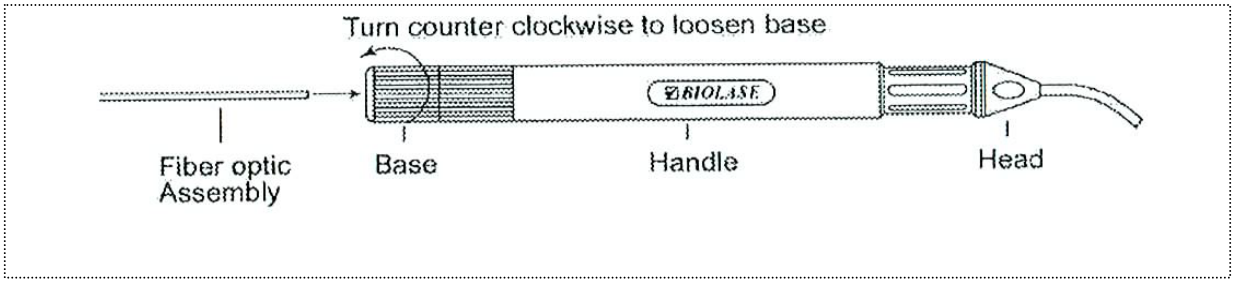
WARNING: All fiber optic cables, handpieces, and heads are shipped non-sterile. These are reusable accessories that require cleaning and sterilization before and after each patient treatment. For instructions on cleaning and sterilization of the fiber optic cable, handpiece, and head, refer to Section 8. Fiber optic cable is not autoclavable unless it is labeled as "autoclavable."

Cleaving the Fiber

The fiber should be cleaved after each procedure.

1) Loosen the proximal end of the handpiece by unscrewing the handpiece base.

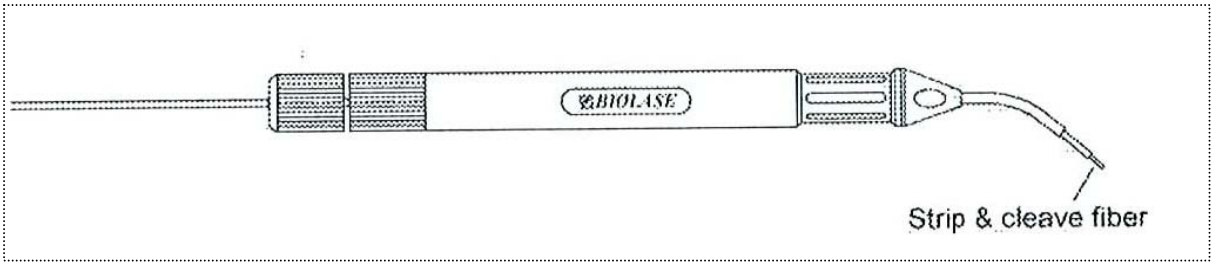
2) Pull 2-3 inches of fiber optic cable from the handpiece head through the handpiece.



3) Select a fiber stripper that corresponds to the fiber diameter size.

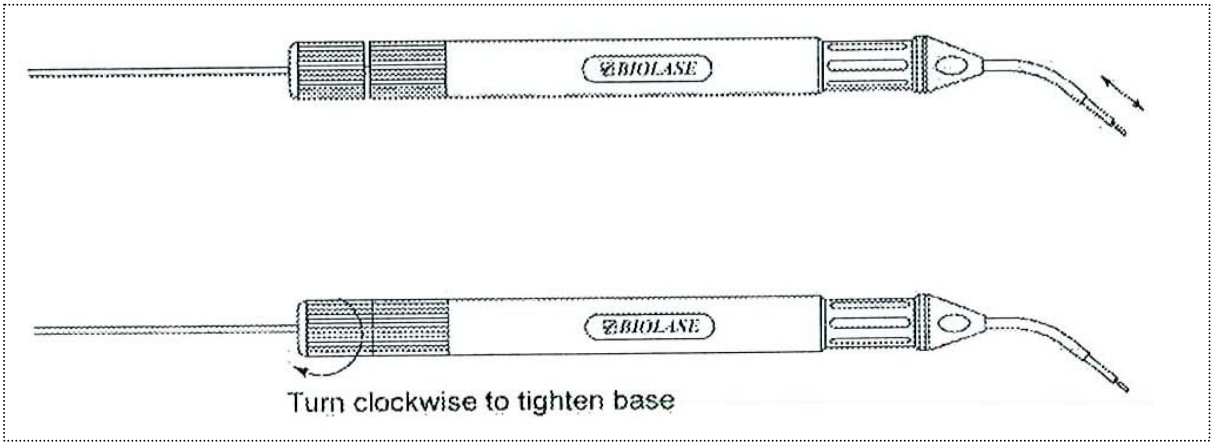
4) Insert approximately 1 inch of the fiber optic cable into the stripper. Squeeze the stripper handles to get a firm purchase on the fiber optic cable, and while doing so pull

the stripper away from the handpiece in a smooth motion to ensure that the jacket is cleanly removed.



5) Use a diamond/carbide cleaver to cut the used end of the fiber. Place the fiber against a flat surface. Position the edge of the cleaver approximately ¼ inch from the end of the fiber, and make a scratch around half the circumference of the fiber. Make sure that the edge of the cleaver is always perpendicular to the fiber during scratching.
6) Hold the end of the fiber above the scratch between thumb and forefinger and pull the end of the fiber away until the end section breaks off. If the fiber end is removed properly by pulling in the direction perpendicular to the end surface of the fiber, the fiber should end in a flat surface.
7) Verify the cleave quality by aiming the fiber at a flat surface and observing the shape of the spot created by the visible aiming beam. If the visible spot is a full circle, then the power output is optimal; if the circle is distorted, then repeat only the cleaving procedure presented in steps 5 and 6 until you obtain a perfect circle beam.

8) After the fiber is successfully cleaved, pull the fiber back through the handpiece until just the fiber tip protrudes from the fiber end of the handpiece head. Tighten the handpiece base until snug. Ensure that the fiber isn't loose by pulling tightly on the fiber optic cable at the proximal end.



Tip Initiation: Parameters and procedures

■ **Laser Parameters:**

Tip Diameter (µm)	Power (W)	Mode
400	1.4	CW
300	1.0	CW

■ **Procedural Steps:**

Step 1)

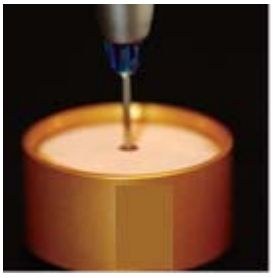
Set the ***EPIC 10*** to the appropriate setting for the particular tip, using the table above as a guide.

Step 2)

Touch the tip to the surface of the initiation block, without firing

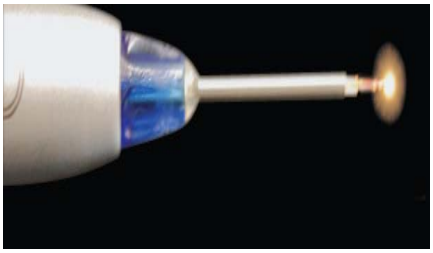
Step 3)

Fire the laser, allowing the tip to sink into the block. Pull the tip out when the metal canula touches the block, still firing until just before



Step 4)

Fire the laser into the air once, you will see a white flash or the tip will glow.



Repeat steps 1 – 4 to ensure the tip is initiated.

Section 4: OPERATING INSTRUCTIONS

System Setup

- Place unit in a clean, dry and well-ventilated area.
- Verify power switch is in OFF position
- Connect power cord to power connector on the unit and plug into wall outlet to charge the rechargeable battery. Before first use, it is recommended to fully charge the battery (at least 2 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.
- Connect chosen fiber to the console

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

CAUTION: Do not bend fiber optic cable sharply or fiber will break.

- Remove protective tip and handpiece from fiber shaft (See Fig. 14)
- Verify visually that protective window is clean. If not – blow off any residue or dirt with compressed air. For better results, use a non-linting cotton swab soaked with alcohol.
- Carefully connect the Handpiece (See Figure 13)
- Insert the selected tip and tighten it clockwise until snug.
- Wind excess fiber optic cable onto the fiber spool around the base of the console.
- Place handpiece in handpiece holder. (See Figure 12)
- If using the classical "feed-through" fiber handpiece, make sure the fiber connector is free of dirt and dust. If not – clean with a cotton swab soaked with alcohol.

WARNING: Never point fiber optic at eyes.

WARNING: Never operate the laser without a fiber tip attached.

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

Operation

Turn On the *EPIC 10*

- Ensure that the battery has enough charge for operation, or connect power cord to power connector on the unit and plug into wall outlet.
- Turn power switch at the rear of the base of the console to ON position. The ***EPIC 10*** Welcome screen will be displayed.

Figure 21

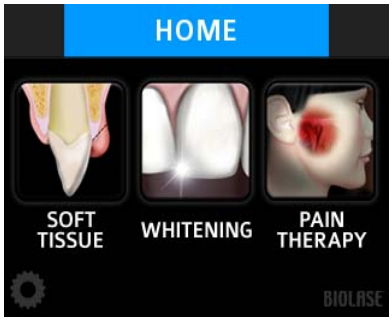


Figure 22

- Enter the three digit key access code using the touch screen. The Access Key Code is **888**. (If the proper code is not entered, re-enter the correct code.)
- The system will go to the HOME screen, which identifies three procedure categories to choose from.
- Verify wireless communication with the footswitch; a blue LED indicator light on the console will blink when communication is established. The laser and footswitch are shipped already paired. However, if the wireless communication is not confirmed by the indicator light, take the following steps to establish pairing:

  1. Go to the Settings menu on the console display and select “Wireless” icon.
  2. In the “Wireless” menu, press “Connect” to initiate pairing; blue LED will start blinking, indicating that the laser console and footswitch are communicating.
  3. While holding the footswitch, press and hold the Reset switch on the bottom of the footswitch.
  4. While holding the footswitch, press and hold the foot pedal.
  5. Release the Rest switch.
  6. Release the foot pedal.
  7. A message will appear on the console display indicating that pairing has been successful, or unsuccessful. If unsuccessful, repeat steps 1-6.

CONTROL Button

Pressing and holding the Control Button for 2 seconds will cause the system to enter SLEEP mode, or move out of SLEEP mode to STANDBY mode, or go from STANDBY mode to READY mode; this button will also turn the system ON.

Entering READY or STANDBY Modes

A quick press of the Control Button will place the system into either READY or STANDBY mode. The unit will only emit laser energy when the footswitch is pressed and the unit is set to READY mode. Values may be adjusted in both modes. In READY mode, values may be changed only when footswitch is released.

READY Mode

When entering READY mode, the system fan will turn ON and pressing the footswitch will activate laser radiation. There is 2 sec delay between switching to READY mode and the ability of the system to emit a laser beam. This is evidenced by the delay in the appearance of the red aiming beam.

Figure 23 ***When the tip is straight, the aiming beam will look like a circle, outlining the area where main laser power is applied.*** 	*Figure 24* ***When the tip is bent, the aiming beam will look like a spot, and the main laser power is applied in the middle area of the spot.*** 

WARNING: When aiming beam is not present or has significantly different shape, change the tip and inspect / clean the protective window.

Wireless Footswitch

The wireless footswitch is powered by 2 standard AAA batteries.

When the wireless footswitch is pressed in READY mode and the laser fires, a beeper will sound indicating that laser energy is present. A green LED will be visible on the top right of the front panel. When the footswitch is not pressed, the green light will not appear.

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.

PEAK POWER Display

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

PULSE Mode Selection

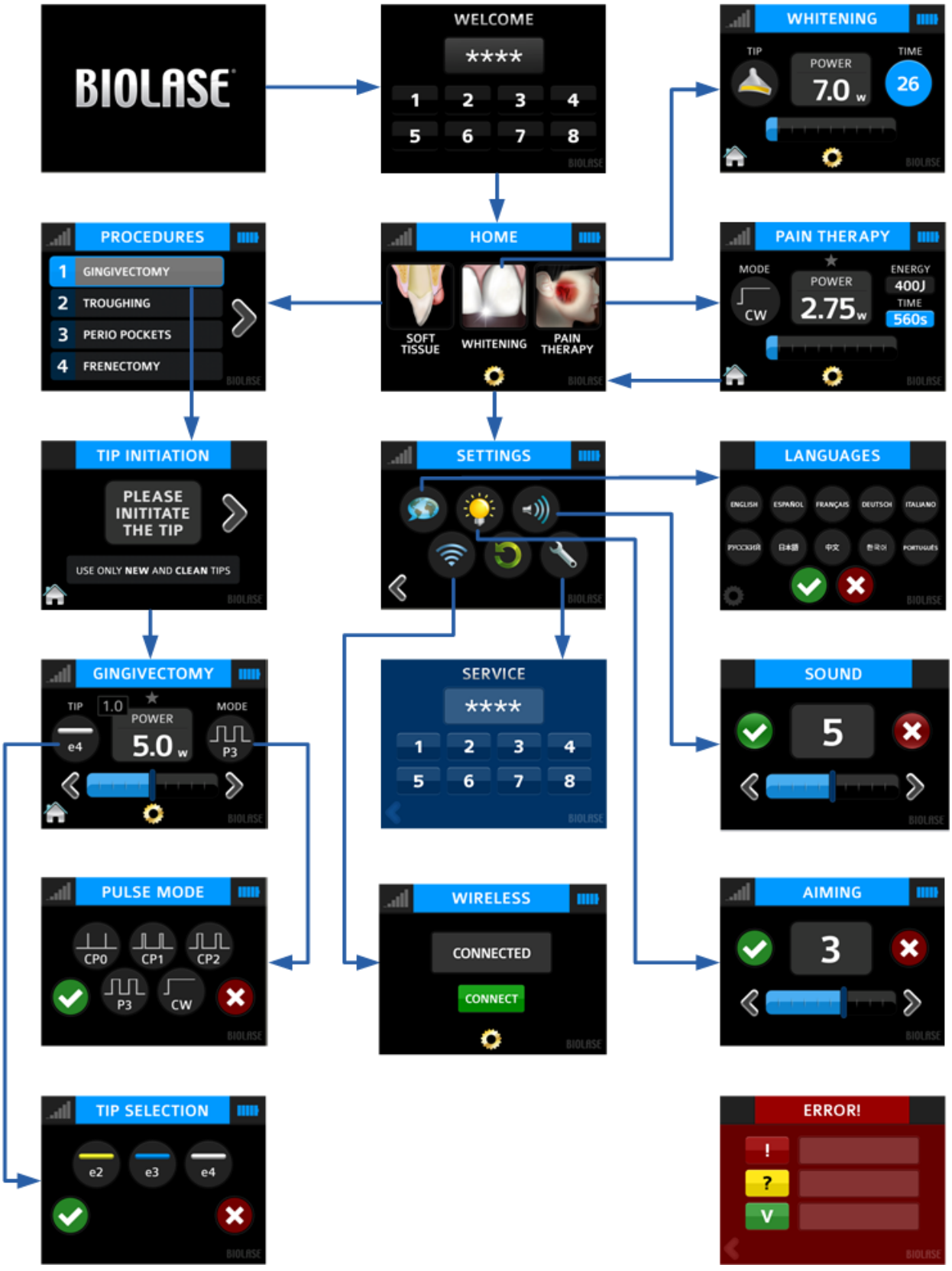
Pulse Mode selection graphically indicates whether the system is in Continuous Mode or in Pulsed Mode.

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

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

Pressing the Pulse MODE button will allow switching between Pulsed and Continuous Modes.

Operational Algorithm of the *EPIC 10*



PROCEDURES Button

The ***EPIC 10*** has 20 pre-set procedures, 14 with pre-programmed procedural presets and 6 empty slots for custom pre-sets. All of them can be customized to your preference.

In order to customize parameters for the particular clinical procedure:

- Adjust parameters on the main Pre-Programmed Procedure menu
- Select PROCEDURES Mode
- Press and hold the selected Procedure for 2 seconds. Parameters will be changed and saved for that Procedure (you will hear a beeping sound when the adjusted settings are saved).

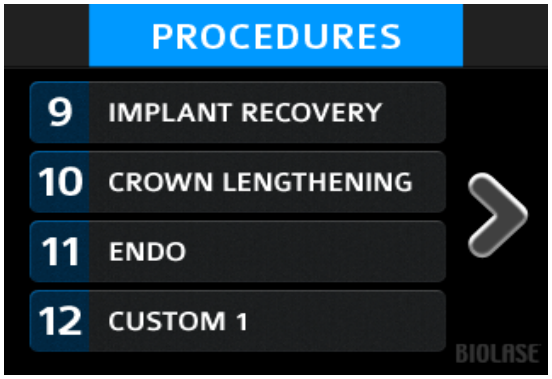


Figure 25

SETTINGS Screen

By pressing the Settings icon on the main screen, you can access several system settings:

- Language Selection
- Aiming Beam (5 levels of brightness adjustment)
- Beep Sound (3 levels of sound adjustment)
- Service Mode (accessible only by authorized Biolase Service Representatives)
- Restore Factory Default Settings

Turn the Unit OFF

- Place handpiece back on handpiece holder.

CAUTION: Verify that 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 to turn display OFF.
- Switch the Power Switch at the rear of the base of the console to OFF position, if the laser system will not be used for a long period of time.
- Wind the fiber cable onto the fiber spool around the base of the console.

Section 5: SPECIFICATIONS

General

- Dimensions — 5.7 in (W) x 4.4 in (H) x 6.5 in (L)
- Weight — 2.5 lbs / 1kg

Electrical

- Operating Voltage — 100V ± 10% and 230V ± 10% ~ at 2A
- Frequency — 50-60Hz
- External Fuses — None
- Main Control — Power Switch
- On / Off Controls — Control Button, Emergency Stop
- Remote Interruption — Remote Interlock

Laser

- Laser Classification — IV (4)
- Medium — InGaAsP
- Wavelength — 940 ± 10nm
- Max Output Power — 10 Watts
- Power Accuracy — ± 20%
- Power Modes — Continuous, Pulse Modulation
- Pulse Duration — 0.01 ms – 10 sec
- Pulse Interval — 0.01 ms – 10 sec
- Pulse Repetition Rate — Up to 20KHz (for reference)
- Fiber Tips Diameter — 200, 300, 400 µm
- Spot size
  - Surgical Handpiece — Maximum 400 µm
  - Deep Tissue Handpiece — 30 mm diameter = 7.1 cm^2 area
  - Whitening Handpiece — Rectangular 35 mm x 8 mm = 2.8 cm
- NOHD — 4.77 meters
- Beam Divergence — 8 – 22 degrees per side angle
- Standard Fiber Cable Length — 5 feet (1.524 meters)
- Feed-Through Fiber Cable Length — 8 feet (2.438 meters)

Other Light Sources

- Aiming Beam — Laser Diode, max 1 mW, 635 nm ± 10nm

Section 6: CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

Contraindications
All clinical procedures performed with ***EPIC 10*** must be subjected to the same clinical judgment and care as with traditional techniques. Patient risk must always be considered and fully understood before clinical treatment. The clinician must completely understand the patient's medical history prior to treatment. Exercise caution for general medical conditions that might contraindicate a local procedure. Such conditions may include allergy to local or topical anesthetics, heart disease (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.

Warnings and Precautions

Prescription Statement
Federal law restricts this device to sale by or under the order of a licensed medical or dental practitioner.

Eyewear
Doctor, patient, assistant and all others inside the operatory must wear appropriate laser eyewear protection for the diode laser wavelength of 940 ± 10nm.

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. If such signs are present, adjust settings, apply anesthesia or cease treatment if required.

Adjacent Structures
EPIC 10 is designed to remove soft tissues. Therefore, always be aware of adjacent structures and substructures during treatments. Be extremely careful not to inadvertently penetrate or ablate underlying or adjacent tissues. Do not direct energy towards hard tissues such as tooth or bone. Do not direct energy towards amalgam, gold or other metallic surfaces. Do not direct energy towards cements or other filling materials. Exercise extreme caution when using this device in areas such as pockets, cavities or channels such as 3rd 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 10*** 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 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.

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

Section 7: CLINICAL APPLICATIONS

Introduction
To efficiently remove tissues it is imperative to understand the nature of the ***EPIC 10*** 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.

Table of Indications for Use
Use of the ***EPIC 10*** 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:

►Excisional and incisional biopsies

►Exposure of unerupted teeth

►Fibroma removal

►Frenectomy

►Frenotomy

►Gingival troughing for crown impressions

►Gingivectomy

►Gingivoplasty

►Gingival incision and excision

►Hemostasis

►Implant recovery

►Incision and drainage of abscess

►Leukoplakia

►Operculectomy

►Oral papillectomies

►Pulpotomy

►Pulpotomy as an adjunct to root canal therapy

►Reduction of gingival hypertrophy

►Soft tissue crown lengthening

►Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa

►Vestibuloplasty

►Tissue retraction for impression

►Laser soft tissue curettage

►Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket

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

►Light activation for bleaching materials for teeth whitening

►Laser-assisted whitening/bleaching of teeth

►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.

DENTAL

Pre-programmed Settings for Dental Procedures

WARNING: 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 300 µm and 400 µm tips.

To access the pre-programmed procedure values:

1) Go to the Procedures menu by pressing the Procedures button
2) Press the button associated with the chosen procedure

To store your personal preferred settings for any procedure:

a) Follow steps 1 and 2 above
b) Enter the new values
c) Press and hold the Procedure button for 2 seconds; you will hear a beeping sound confirming the settings are saved.

NOTE:

1. These pre-sets are recommendations based on clinical feedback from experienced laser dentists.
2. 300µm tips are recommended for removing thin tissue layers. 400µm tips are recommended for removing fibrous tissue.
3. Always use your clinical judgment when selecting power, pulse length, and pulse interval parameters to ensure optimal clinical results. At all times observe clinical effects and adjust parameters accordingly.

PRE-PROGRAMMED SETTINGS

	PROCDURE NAME	MODE	PEAK POWER	AVERAGE POWER	PULSE INTERVAL	PULSE LENGTH	DUTY CYCLE	TIP TYPE	INITIATION
1	GINGIVECTOMY	CP0	5.0W	1.0W	0.04 ms	0.01 ms	20%	E4	YES
2	TROUGHING	CP2	2.0 W	1.0 W	1.0 ms	1.0 ms	50%	E4	YES
3	CURETTAGE	CP1	2.4 W	0.8 W	0.2 ms	0.1 ms	30%	E4	YES
4	EXCISION	CP1	2.7 W	0.9 W	0.2 ms	0.1 ms	30%	E4	YES
5	FRENECTOMY	CP2	2.0 W	1.0 W	1.0 ms	1.0 ms	50%	E4	YES
6	IMPLANT RECOVERY	CP2	2.5 W	1.25 W	1.0 ms	1.0 ms	50%	E4	YES
7	PERIO POCKETS	CP2	1.6 W	0.8 W	1.0 ms	1.0 ms	50%	E3	NO
8	PULPOTOMY(*)	CW	0.10W	0.10W	N/A	N/A	N/A	E4	YES
9	CROWN LENGTHENING	CP1	2.7 W	0.9 W	0.2 ms	0.1 ms	30%	E4	YES
10	INFECTED POCKETS	CP2	1.6 W	0.8 W	1.0 ms	1.0 ms	50%	E4	YES
11	ENDO(*)	CW	0.10 W	0.10 W	N/A	N/A	N/A	E2	NO
12	HEMOSTASIS	CW	0.50W	0.50W	N/A	N/A	N/A	E4	YES
13	APHTHOUS ULCERS	CW	0.70W	0.70W	N/A	N/A	N/A	E4	NO
14	EXPOSURE OF UNERUPTED TEETH	CP2	1.80W	0.90W	1.0ms	1.0ms	50%	E4	YES
15	CUSTOM 1 - 6								

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

Tooth Whitening Procedure

The following items are required to perform teeth whitening with the ***EPIC 10*** laser:

- ***EPIC 10*** diode laser
- Whitening/Contour Handpiece
- LaserWhite™ 20 Whitening Gel Kit (p/n 7400030 sold separately in packs of 5)

Detailed step-by-step instructions, contraindications, precautions, and warnings for tooth whitening are provided with the LaserWhite™ 20 Whitening Gel Kit. Please read the instructions carefully before proceeding.

PAIN THERAPY

NOTE: Follow the *Fitzpatrick Skin Type Scale* noted below when performing pain therapy procedures. Select the appropriate clinical parameter and reduce power as necessary for patient comfort.

Fitzpatrick Skin Type Scale

TYPE I	Highly sensitive, always burns, never tans. Example: Red hair with freckles
TYPE II	Very sun-sensitive, burns easily, tans minimally. Example: Fair-skinned, fair-haired Caucasians
TYPE III	Sun-sensitive skin, sometimes burns, slowly tans to light brown. Example: Darker Caucasians
TYPE IV	Minimally sun-sensitive, burns minimally, always tans to moderate brown. Example: Mediterranian-type Caucasians
TYPE V	Sun-insensitive skin, rarely burns, tans well. Example: Some Hispanics, some Blacks
TYPE VI	Sun-insensitive, never burns, deeply pigmented. Example: Darker Blacks

Using the Whitening/Contour Handpiece: Recommended Clinical Settings

The ***EPIC 10*** diode laser, in conjunction with the Whitening/Contour Handpiece, is designed to provide near-infrared laser energy to tissue for the purpose of elevating tissue temperature and providing for temporary relief of pain conditions 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 be effective. Two main therapeutic power settings are recommended for these treatments:

- 2.75W CW: place the handpiece in contact with the skin and apply laser energy for 10 minutes continuously.
- 5.50W CW: place the handpiece approximately 2 – 3mm away from the skin surface (non-contact). Exposure time remains the same at 10 minutes continuously.

Patients should be monitored for discomfort. If discomfort is reported at any time during the treatment, there are several options:

a) Decrease the power setting to 2.75W; or
b) Defocus the energy by moving the handpiece further away from the sking; or
c) Stop treatment.

Using the Deep Tissue Handpiece: Recommended Clinical Settings

TYPE II	Set Power to 4.0W CW for 2 minutes, followed by Power at 3.25W for 3 minutes and then set Power to 2.75W for the remaining 5 minutes
TYPE III	Set Power to 4.5W CW for 2 minutes, reduce Power to 4.0W for the remaining 8 minutes
TYPE IV	Set Power to 4.0W CW for 2 minutes, reduce Power to 3.5W for the remaining 8 minutes
TYPE V	Set Power to 3.5W CW for 2 minutes, reduce Power to 3.0W for the remaining 8 minutes.
TYPE I	Less common, settings are not available
TYPE VI	Less common, settings are not available

NOTE: Some patients may require more than one laser application or a series of treatments before significant improvement is reported. Repeat this therapy as necessary and monitor progress of the patient's condition throughout the the treatment.

Section 8: MAINTENANCE

Annual Maintenance

The *EPIC 10* should be serviced annually by a qualified, trained, and certified technician. 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.

Please contact Biolase Service at 1-800-321-6717 or your Authorized Representative to discuss Extended Service Contracts and Annual maintenance options.

Daily Maintenance

Use peel-off clear covers supplied with the system. Use disinfectant to wipe down the front panel and handpiece holder of the ***EPIC 10*** system after each procedure. **Do not use bleach or abrasive cleansers.**

Check and clean the protective window of the fiber optic shaft with cotton swab wet in alcohol.

Contamination Control Procedures

The contamination control suggested for the ***EPIC 10*** surgical handpiece and tips is the steam sterilization method. However, before sterilization, the ***EPIC 10*** reusable handpiece should be carefully cleaned per the following procedure.

NOTE: The fiber optic cable and Handpiece are delivered from the manufacturer as non-sterile.

NOTE: Tips are designed to withstand a single sterilization cycle and must be disposed of after single use in a biohazard medical waste sharps container.

Cleaning Instructions for the Surgical Handpiece, the Classical (Feed-Through) Fiber 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 pyrogens present. Cleaning should be performed prior to sterilization and must be conducted only by qualified office personnel trained to perform the procedure and handle the

EPIC 10 Fiber optic Delivery System.

Wear protective latex gloves when handling the contaminated delivery system.

To clean the fiber cable, wipe the entire cable, including the shaft, with cotton gauze and chemical disinfectant. Keep the window intact. If the window is dirty, clean with a cotton swab wet with alcohol.

To clean the handpiece:

- ► Carefully remove tip from the handpiece and dispose of in a biohazard medical waste sharps container.
- ► Carefully remove the handpiece from the fiber optic cable (see Section 3).
- ► Wipe entire handpiece outer surface with cotton gauze and chemical disinfectant.
- ► Soak gauze in a chemical disifectant, and then wrap the handpiece in the gauze.
- ► Leave the handpiece wrapped in the soaked gauze for 10 minutes.
- ► Remove the handpiece from the soaked gauze and wipe with dry gauze.

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

Before sterilization, the handpiece must be cleaned and disassembled.

The process of thermal sterilization with saturated steam under pressure is carried out in an autoclave. To sterilize the handpiece, tips, and tip initiation block, follow these step-by-step instructions:

- ► Place the handpiece, tips, and tip initiation block in **separate** single wrap, self-seal autoclave pouches.
- ► Remove autoclave tray and place pouch(s) on the tray.
- ► Place tray inside the autoclave chamber and sterilize using a clinic-validated cycle. The recommended autoclave cycle for the ***EPIC 10*** is:

Temperature:	250°F (121°C)
Pressure:	15 PSI (1 bar)
Time cycle:	20 minutes

- ► At the completion of the autoclave cycle, remove the tray and let each item sterilized cool and dry.

Although Biolase Technology has validated the parameters for the recommended autoclave sterilization procedure, it is the responsibility of the customer/user to properly validate his or her autoclave sterilizer.

Cleaning the Whitening/Contour Handpiece

The Whitening Handpiece is sold together with disposable protective caps. The handpiece and protective cap are **not autoclavable**.

The protective cap is intended for one-time use only and therefore cannot be cleaned and reused.

To clean the Whitening Handpiece, wipe down the handpiece with gauze and isopropyl alcohol.

Cleaning the Deep-Tissue Handpiece

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

The protective covers are intended for one-time use only and therefore cannot be cleaned and 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.

Disinfection of the Classical (Feed-Through) Fiber Optic Cable

► Take the fiber and strip 1.0" off from the distal end using the fiber cleaver. Make sure that the part that has debris is removed entirely. Dispose of the contaminated fiber tip in a properly labeled biohazard medical waste sharps container.

► Prepare a Sporox Sterilizing and Disinfecting Solution and submerge approximately 30cm (12 inches) of the fiber's distal end into the solution. For a high level of disinfection, immerse the fiber end for 30 minutes at 20° C (68° F).

► After this process is completed, thoroughly rinse and dry the fiber. For disposal of the Sporox, follow the manufacturer's instructions.

Changing the Wireless Footswitch Batteries

The wireless footswitch is powered by two standard AAA batteries. To replace the battery, unscrew the battery cover on the underside of the footswitch, remove the old battery, and install the new one, replacing the cover when done. Dispose of the used battery as appropriate.

Installing/Replacing the Console Battery Pack

NOTE: Only use the battery pack suppled by Biolase. The battery pack is a separate accessory (see Appendix B).

1. To install or replace the battery pack, remove the battery cover on the underside of the console using a Phillips screwdriver (Figure 26).

Figure 26: Battery Cover/Bottom of Console

2. To remove the battery, grip the battery at the top and pull the cable away from the connector (Figure 27).

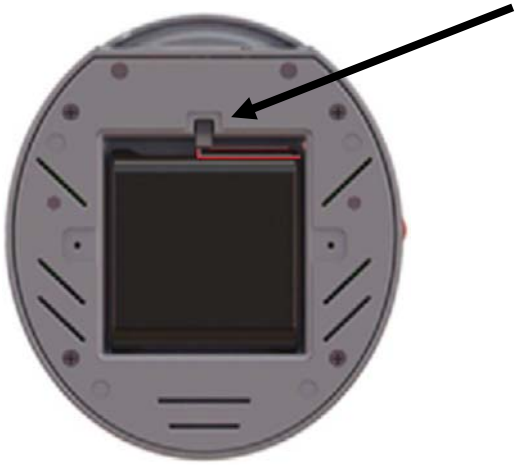


Figure 27: Battery Pack/Connector Wire

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 drop the battery into the compartment (Figure 27).

4. Replace the battery cover on the bottom of the unit, using a Phillips screwdriver (Figure 26).

5. Connect power cord to power connector on the unit and plug into wall outlet to charge battery (at least 2 hours). Once the battery is charged, unplug the power cord from the wall outlet and the console.

6. Dispose of the used battery pack as appropriate for your location.

Transportation

The ***EPIC 10*** 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 of its shipping box. If you have any questions regarding transportation please call your local Representative.

Storage

The ***EPIC 10*** 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 battery pack if the ***Epic 10*** is not likely to be used for some time

The ***EPIC 10*** was shipped inside a custom shipping box. Please save and store the box in a cool dry place.

Section 9: CALIBRATION

Calibration Schedule
Calibration procedure is recommended to be performed every 12 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.

Section 10: SOFTWARE SPECIFICATION

Biolase respects the intellectual property of others, and we ask our users to do the same. EPIC 10 software is protected by copyright and other intellectual property laws.

This product includes software developed by Biolase Technology Copyright ©2012 Biolase Technology.

Section 11: TROUBLESHOOTING

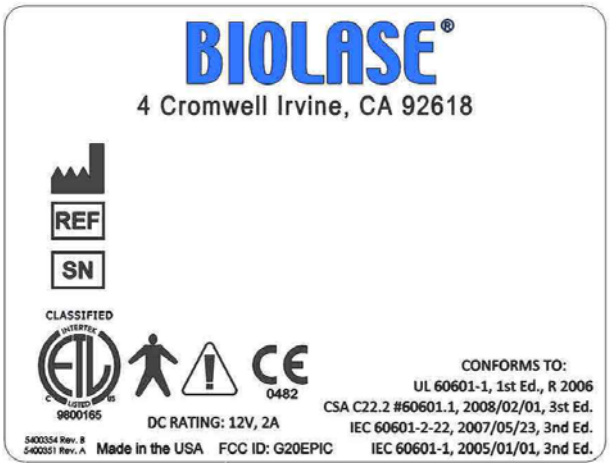
Below is the list of the Error messages, which in most cases can be fixed by the user.
If Corrective Action did not help, re-power the laser.

If Error is not cleared after re-powering, please call for system Service.

NOTE: For all Error Messages not listed in the table, re-power the system and if Error is not cleared, call for system Service.

Error/Warning Description	Reason	Fix
Thermistor Open	Thermistor Open	Call Biolase Service
Thermistor Shorted	Thermistor Shorted	
Shutdown Temperature	System too hot	Allow 5-10 mins for laser to cool down
Laser Current High/ Low	Output is of specs	Call Biolase Service
FS shorted in Standby	FS not in Ready mode	Enter Ready mode
ON/OFF button Stuck	Key stuck	Press Front key
Flash Corrupted	Memory Corrupted	Call Biolase Service
No Fiber	Fiber not inserted	Plug in Trunk Fiber
Lost Footswitch Communication	No wireless connect	Re-establish pairing (see Sec 4)
Emergency Switch	E-Switch Pressed	Press E-Switch Again
Remote Interlock	Remote interlock open	Check Remote Interlock closed
Warning Temp High	System is hot	Allow 5-10 mins for laser to cool down
Warning Battery Low	Battery is low	Plug in DC supply
Warning Battery Not Connected	Battery not connected	Plug in Battery

APPENDIX A - LABELS

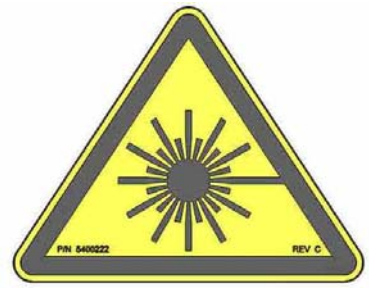


A.1 Identification

Location: Bottom of laser console

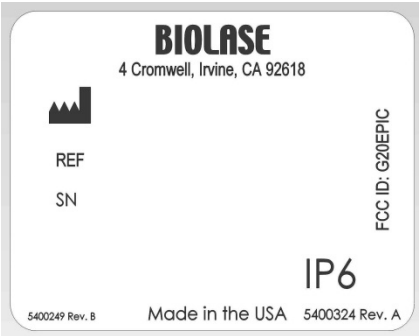
A.2 Footswitch

[Engraved]



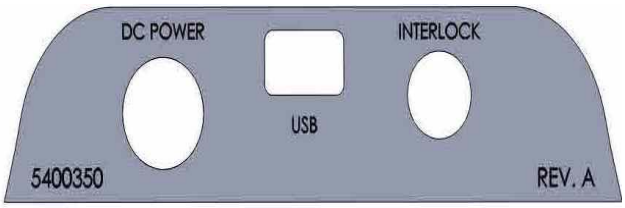
A.3 Laser Aperture

Location: Rear of laser console



A.4 FCC Compliance Notice

Location: Bottom of footswitch



A.6 Remote Interlock

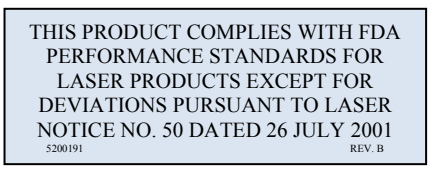
Location: Rear of Laser Console

A.7 Emergency Laser Stop Switch

Location: Left side of laser console

A.8 Warning label

Location: Rear top cover of laser console



A.9 Compliance label

Location: Bottom of laser console

APPENDIX B - SPARE PARTS AND ACCESSORIES

DESCRIPTION

6400007	Surgical Handpiece
2400040	Laser Safety Glasses (Clinician)
2400078	Laser Safety Glasses (Patient)
6400058	Remote Interlock Plug
6400005	Power Cord with Power Supply
6400xxx	Wireless Footswitch
6400107	Tip initiation kit
7400022	Whitening/Contour Handpiece (Optional)
6400180	Whitening Handpiece clear handpiece covers (30-pack)
7400030	LaserWhite 20 Whitening Gel Kit (pack of 5)
6400311	Deep-Tissue Handpiece (Optional)
6400310	Deep-Tissue Handpiece protective covers (qty. 20)
TBD	Peel-off clear covers (qty. xx)
6000562	Classical (Feed-Through) Fiber Handpiece (Optional)
TBD	Classical (Feed-Through) Fiber
6400457	Lithium ion battery pack for console

SINGLE-USE TIPS:

Surgical:

7400018	200 μm core diameters (qty. 30)
7400017	300 μm core diameters (qty. 30)
7400016	400 μm core diameters (qty. 30)

Perio:

7400020	300 μm core diameters (qty. 30)
7400019	400 μm core diameters (qty. 30)

Endo:

7400015	EZTIP Endo Kit, E2, 20mm
7400021	200 μm core diameters (qty. 30)

APPENDIX C – LIMITED WARRANTY

For warranty information, refer to separate equipment warranty.

This note applies only to the wireless portion of our 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.

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5400321 Rev. X: DRAFT