

Epic *Hygiene*



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1 Introduction

The Epic Hygiene™ is a dental laser intended for the treatment of specific soft-tissue conditions, reduction of bacteria in periodontal pockets, ablation, vaporization and coagulation of oral soft-tissue, including marginal and interdental gingival and the epithelial lining of free gingiva.

Epic Hygiene 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. Various types of single use, disposable tips are designed and optimized for different applications. The device is activated by means of a wireless footswitch.

This is a prescription device that is indicated for professional use only by dentists and other licensed dental professionals, such as dental hygienists, where permitted by state or local practice regulations. 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 Hygiene 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.

This device must be installed, operated, and maintained according to the guidelines of CAN/CSA-Z386-14.

2 Indications for Use

Use of the Epic Hygiene device may be appropriate for the following:

- Hemostasis and coagulation
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa
- 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).
- Laser soft tissue curettage
- Reduction of bacterial level (decontamination) and inflammation
- Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium

3 Contraindications, Warnings, and Precautions

3.1 CONTRAINDICATIONS

All clinical procedures performed with Epic Hygiene 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. 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. BIOLASE assumes no responsibility for parameters, techniques, methods, or results.

EYEWEAR

Doctor, patient, assistant, and all others inside or entering the operatory must wear appropriate laser protective eyewear suitable for the 980 nm \pm 10 nm wavelength, OD4 (DIR LB4) or greater, whenever the laser is in use. Prior to use, inspect the eyewear for pitting and/or cracking. **Replace if damaged; do not use.**



CAUTION: The specifications for the protective eyewear provided with the Epic Hygiene 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.

3 Contraindications, Warnings, and Precautions

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 noted, adjust settings, apply anesthesia, or cease treatment if required.

ADJACENT STRUCTURES

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

SUCTION

Use high-speed suction as required to maintain a clear field of vision during treatment. Do not fire the laser 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.



CAUTION: Laser plume may contain viable tissue particulates.

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, pulse duration and interval settings, mode of operation, as well as the accessories utilized (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 with all oral procedures.

4 Specifications

4.1 GENERAL

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

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, 14.6V, 2.75Ah
- DC Power Supply Module 12V DC, 5A

4.3 LASER

- Laser Classification IV (4)
- Medium InGaAs Semi-conductor diode
- Wavelength $980 \pm 10\text{nm}$
- Max Power Output 1.5W Max Average Power, 10W Max Peak Power
- Power Accuracy $\pm 20\%$
- Power Modes Continuous, Pulse Modulation
- Fiber Tip Diameter $400\mu\text{m}$
- Pulse Duration 0.01ms – 20ms
- Pulse Interval 0.04ms – 20ms
- Pulse Repetition Rate Up to 20kHz (for reference)
- NOHD (Nominal Ocular Hazard Distance) 5 ft. 4 in (1.625 meters)
- MPE (Maximum Permissible Exposure) 36.31W/m^2
- Beam Divergence 25.4° full angle
- Standard Fiber Cable Length 6 ft. 5 in (2 meters)

4.4 OTHER LIGHT SOURCES

- Aiming Beam Laser diode, max 5 mW, 625nm – 670nm, Class 2

5 Equipment Description

5.1 SYSTEM COMPONENTS

The Epic Hygiene laser system includes the following:

1. Laser Console with Fiber Optic Cable
2. Peel-off Screen Protectors (qty. 30)
3. Assorted Tips
4. Handpiece (qty. 2)
5. Laser Protective Eyewear (qty. 3)
6. DC Power Supply Module
7. Power Cord (one [1] US, one [1] international)
8. Welcome Kit (Includes User Manual and Quick Setup Guide)
9. Laser Warning Sign
10. Tip Initiation Kit
11. Remote Interlock Cable
12. Wireless Footswitch
13. Philips-Head Screwdriver (for installing Footswitch batteries)
14. AAA Batteries (qty. 2)



WARNING: No modification of this equipment is allowed.

5 Equipment Description

5.2 GENERAL

The Epic Hygiene system consists of three components:

Base Console



Handpiece



Figure 5.1

5 Equipment Description

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 5.1).

CONTROL BUTTON:

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

LED Indicators:

Solid Amber = Standby mode	Blinking Blue = Pairing active
Solid Green = Ready mode	Blinking Green = Laser is firing
Blinking Amber = System error	

FIBER DELIVERY SYSTEM

The fiber delivery system (Figure 5.2) consists of the Fiber Optic Cable, the reusable Handpiece, and the fiber Tips, and transmits laser radiation from the laser console through the Handpiece and fiber Tips to the target tissue. The Fiber Optic Cable is permanently attached to the base console.



Figure 5.2

HANDPIECE

The Handpiece (Figure 5.3) is a re-usable Handpiece. It is a conduit for delivering the optical energy produced by the laser to the treatment site and must be cleaned and sterilized between patients to avoid cross-contamination (See Section 9).



Figure 5.3

WIRELESS FOOTSWITCH

The Epic Hygiene 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 ships 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 5.4).



Figure 5.4

6 Safety

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 C).
- **Do not** operate in the presence of explosive or flammable materials. Flammable anesthetics or oxidizing gases such as nitrous oxide (N₂O) and oxygen (O₂) should be avoided. Solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the 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.
- Prior to use inspect the eyewear for pitting and/or cracking; do not use if damaged; for replacement or additional laser protective eyewear, please contact BIOLASE.
- **Do not** look directly into the beam or at specular reflections.
- **Never** direct or point the beam at a person's eyes.
- **Do not** aim the laser at metallic or reflective surfaces, such as surgical instruments or dental mirrors. If aimed directly at these surfaces the laser beam will reflect, creating a potential hazard
- Always place the system into **Standby** mode (by pressing the control button while in **Ready** mode) before exchanging Handpieces or disposable Tips.
- Always ensure that the proper laser parameters are set before the Epic Hygiene 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 Epic Hygiene 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 described in this User Manual.

6 Safety



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 instruments or dental 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: Be aware that the metal/plastic cannula on the Tips may become hot during use. Avoid contact of the cannula with any tissue.

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 wave and pulse mode
- Wireless Footswitch – IPX6

6 Safety

6.3 SAFETY FEATURES

ENERGY MONITOR

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

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

6 Safety

WIRELESS FOOTSWITCH

The Epic Hygiene 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 and is paired to the laser console at the factory.

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, insert the plug (a) at the end of the connector (Figure 6.4) into the rear of the laser console and attach the two wires (b) 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.

EMERGENCY STOP

Press the red emergency laser stop button to instantly turn off the laser console. 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 (Figure 6.5); 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.



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



Figure 6.3: Wireless Footswitch



Figure 6. 4: Remote Interlock Connector



Figure 6. 5: Emergency Laser Stop

7 Installation and Set-Up

7.1 SYSTEM SETUP

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 °C (59-95 °F), 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 Hygiene will work using either DC power or its rechargeable battery pack:
 - DC Power Supply Module: 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 Hygiene 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 power supply 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 THE FIBER OPTIC CABLE

The Epic Hygiene ships with the Fiber Optic Cable built into the laser console and cannot be disconnected from the console. For storage, wind the Fiber Optic 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 output plug.

7 Installation and Set-Up

7.3 HANDPIECE ASSEMBLY



CAUTION: The Handpiece is not sterile when shipped and **MUST** be sterilized prior to initial use and cleaned and sterilized between patients.

To connect the Handpiece to the Fiber Optic Cable, push the Handpiece onto the fiber shaft, without twisting, until it clicks into place and is secured (Figures 7.2, 7.3). If no click is audible, disconnect the Handpiece and then re-install it.

Figure 7.1: Removal of the Protective Cap

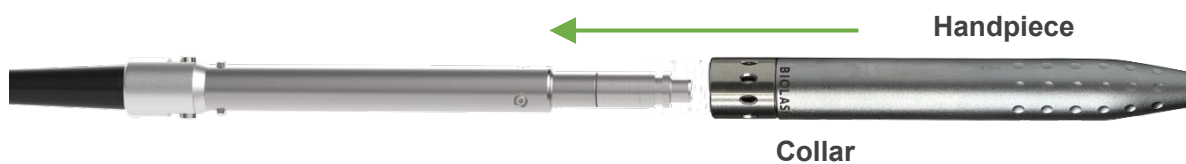


Figure 7.2: Connecting the Handpiece to the Fiber Optic Cable



Figure 7.3: Handpiece Assembly fully assembled

7 Installation and Set-Up

To disconnect the Handpiece from the Fiber Optic Cable (Figure 7.4):

1. Take the Handpiece body in one hand and the shaft in the other,
2. Pushing the two buttons on the fiber shaft,
3. Gently pull the Handpiece by the collar to separate it from the fiber shaft, without twisting.

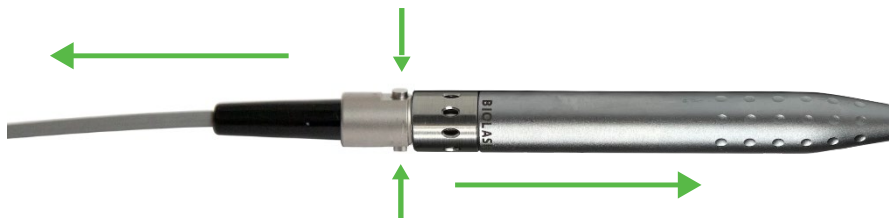


Figure7.4: Disconnecting the Handpiece from the Fiber Optic Cable

7.4 SINGLE-USE TIPS

The Tips are single-use accessories and are provided in 400µm core diameter and in different lengths (see Appendix A).



CAUTION: Tips are single-use only to avoid cross-contamination and are designed to withstand only a single sterilization cycle; they must be disposed of after use in a biohazard medical waste sharps container. Always visually inspect the Tip prior to use to make sure it is free of debris or damage.

To connect the Tip, remove the protective cap from the end of the fiber shaft, connect the Handpiece to the Fiber, then insert the tip firmly into the distal end of the Handpiece as far as it will go and tighten by turning clockwise (Figure 7.5). Bend the metal cannula according the specific procedure requirements (Figure 7.8).



Figure 7.5: Insert the fiber Tip into the Handpiece and twist clockwise until snug



Figure 7.6: Remove the fiber Tip by twisting the Tip counterclockwise.

7 Installation and Set-Up

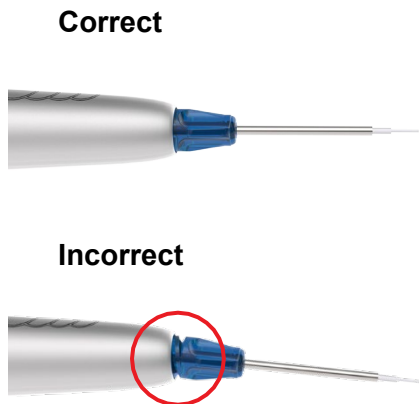


Figure 7.7: Installing the Tip

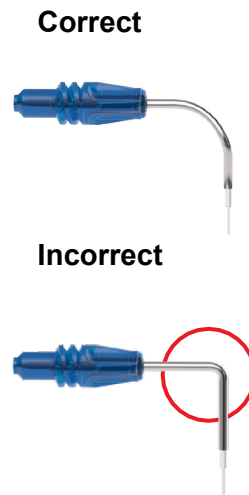


Figure 7.8: Bending the Tip cannula



CAUTION: For proper laser operation, do not connect the Tip when the Handpiece is not connected to the fiber.

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

Wind any excess Fiber Optic Cable onto the fiber spool counterclockwise around the base of the console.



CAUTION: Be aware that the metal cannula on the Tips may become hot during use. Avoid touching the cannula to any tissue. Should the Tip become excessively hot, make sure it is properly installed (Figure 7.7), or, if the bend radius of the tip is too acute, the fiber tip inside the cannula may be broken. Replace the tip.



CAUTION: When using uninitiated tips, if the aiming beam is not present or has a significantly asymmetrical shape, the tip may be broken or damaged; change the tip.

If using a *pre-initiated* tip, the aiming beam may not be visible, or may be fuzzy; this is normal. The tip does not need to be replaced.



WARNING: Never operate the laser without a fiber Tip attached to the Handpiece. Never point the laser at a person's eyes. All persons present in the operatory must wear protective eyewear when the laser is in use.

7 Installation and Set-Up

7.5 OPERATION - TURN ON THE EPIC HYGIENE

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 Hygiene “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, then re- enter the correct code.
- The system will go to the Procedure screen which identifies 6 procedures available for Hygiene, as well as "custom" slots; select whichever procedure is applicable for the patient's condition.
- The Procedure screen also displays how much charge is left in the console battery (upper right corner), and whether the wireless connection between the Footswitch and console is at full strength (upper left corner).

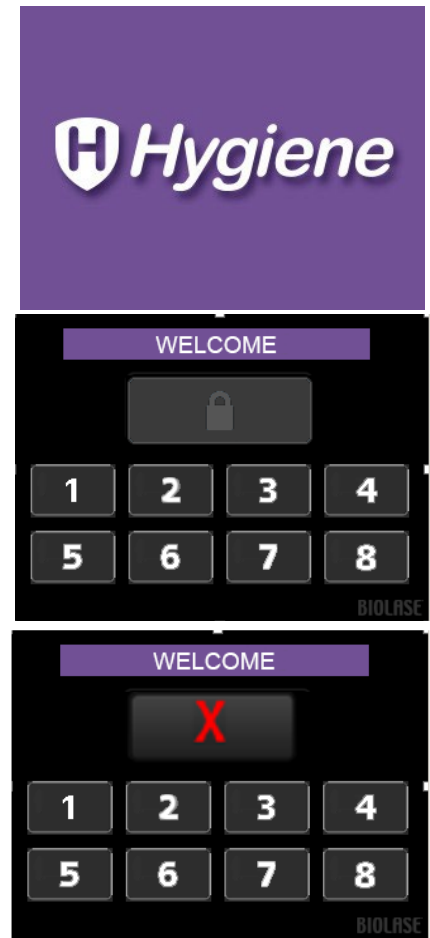


Figure 7.10

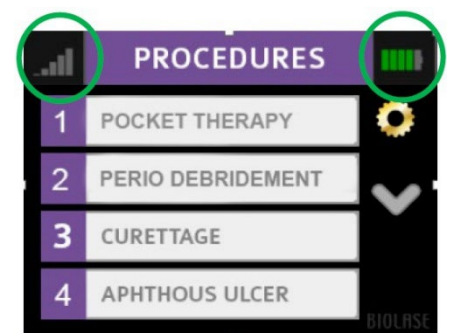


Figure 7.11

7 Installation and Set-Up

7.6 SETTINGS SCREEN

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

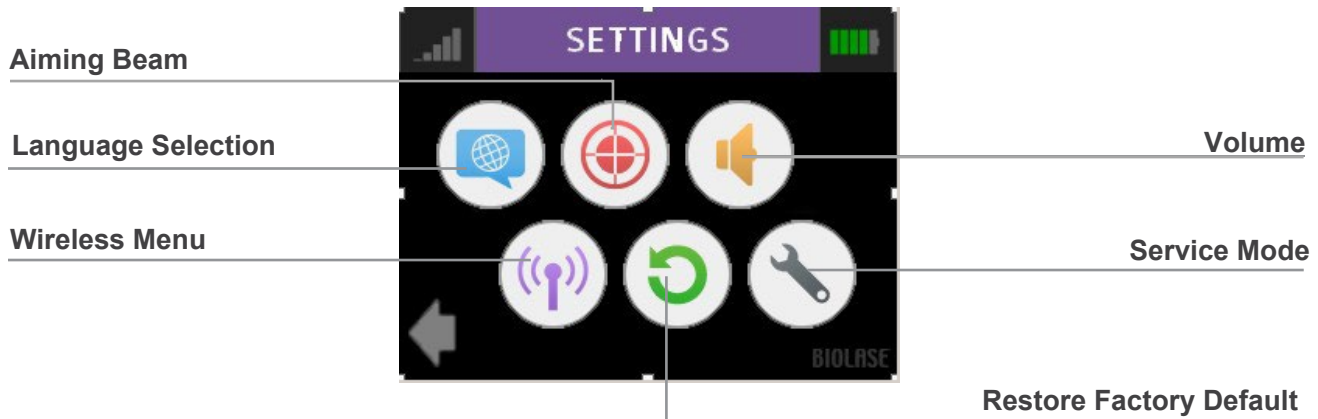


Figure 7.12

7.7 PAIRING THE FOOTSWITCH TO THE LASER CONSOLE

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

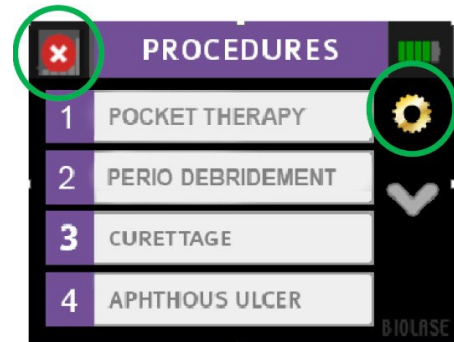


Figure 7.13

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 7.14); press the green CONNECT button.



Figure 7.14

7 Installation and Set-Up

3. The message that “PAIRING WILL NOW BEGIN” will appear (Figure 7.15); 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 7.16).
5. The wireless screen will appear indicating that pairing was successful and that the Footswitch and laser console are now paired (Figure 7.17). Proceed to step 7.
6. If pairing has not occurred, the wireless screen will appear again indicating that pairing was not successful (Figure 7.18); 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 Procedures screen (Figure 7.19).

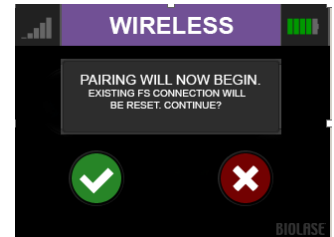


Figure 7.15



Figure 7.16



Figure 7.17



Figure 7.18

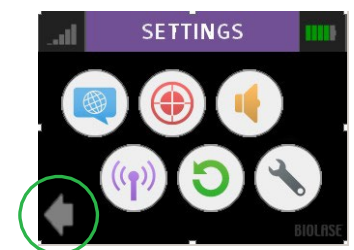


Figure 7.19

7.8 CONTROL BUTTON

The CONTROL button on the front of the laser console is a multi- function 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 Procedure screen.

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 console). 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; pressing the Footswitch will activate the emission of 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 mode. 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 your authorized service representative.

7 Installation and Set-Up

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 Installation and Set-Up

7.12 PEAK POWER DISPLAY

This number is displayed above and to the left of the Power (average power) and presents the value of the peak power based on the power setting and Pulse mode.

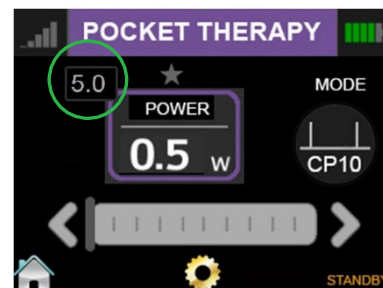


Figure 7.20

7.13 PULSE MODE SELECTION

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

In Continuous mode (CW), laser power is constantly delivered when the laser console is in **Ready** mode and the wireless Footswitch is activated.

In Pulse mode (CP, or Comfort Pulse), laser power is delivered in repetitive pulses, controlled by the Pulse Length and Pulse Interval settings. Pressing the Pulse mode button will allow switching between Pulsed and Continuous modes (Figure 7.21).

Mode	Pulse Duration (on)	Pulse Interval (off)	Duty Cycle ($\frac{\text{Time on}}{\text{Time on} + \text{Time off}}$)
CP10	10 microseconds	90 microseconds	10%
CP20	10 microseconds	40 microseconds	20%
CP33	100 microseconds	200 microseconds	33%
CP50	20 milliseconds	20 milliseconds	50%

Figure 7.21

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

NOTE: Use Procedures only as permitted by individual State practice regulations. Always use clinical judgment when selecting power, pulse length, and pulse interval parameters to ensure optimal clinical results.

7 Installation and Set-Up

7.14 USING THE EPIC HYGIENE TOUCH SCREEN DISPLAY

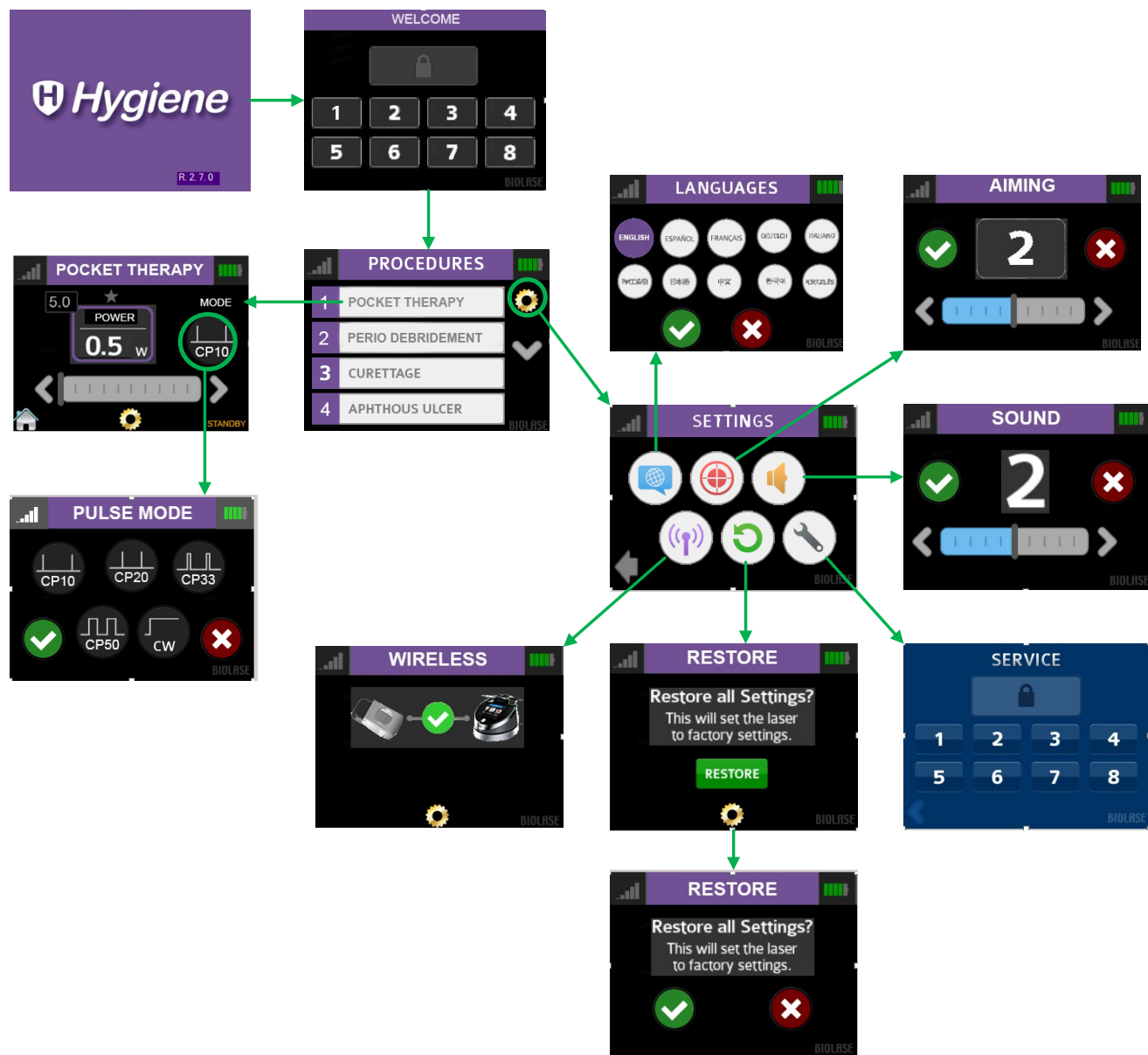


Figure 7.22

7 Installation and Set-Up

7.15 PROCEDURES BUTTON

The Epic Hygiene has the ability to store up to 12 pre-set procedures; Epic Hygiene is factory-installed with 6 pre-programmed procedural presets and 6 empty slots for custom pre-sets. All of them can be customized to your preference.

To customize the parameters (e.g., power, pulse duration, interval, etc.) for a particular clinical procedure:

1. From the PROCEDURES screen scroll to and select pre-set you wish to overwrite.
2. Press and hold the banner on the selected procedure for two seconds. The parameters for that procedure will be changed and saved (the laser console will beep when the adjusted settings are saved).

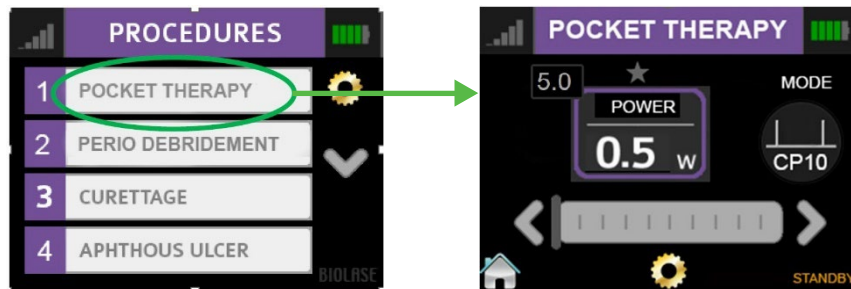


Figure 7.23

7.19 TURNING THE LASER CONSOLE OFF

- Wind the Fiber Optic Cable onto the fiber storage channel counterclockwise around the base of the console
- Place the Handpiece onto the Handpiece Holder



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

- Press the CONTROL button on the front of the console for more than 2 seconds to turn the console 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 an extended period of time

8 Clinical Applications

8.1 OVERVIEW

To efficiently treat tissues, it is imperative to understand the nature of the Epic Hygiene 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.

8.2 PRE-PROGRAMMED SETTINGS

NOTE: Use Procedures only as permitted by individual State practice regulations. Always use clinical judgment when selecting power, pulse length, and pulse interval parameters to ensure optimal clinical results.

The procedure pre-sets installed at the factory are based on clinical recommendations from experienced dental hygienists who use the laser for the procedures listed.

	Preset Name	Mode	Peak Power	Avg. Power	Duty Cycle	Tip	Initiated Tip	Indications for Use
1	Pocket Therapy	CP10	0.5W	5W	10%	E4	No	Reduction of bacterial level (decontamination) and inflammation.
2	Perio Debridement	CP50	0.8W	1.6W	50%	E4*/PI4	Yes	Sulcular debridement. Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium.
3	Curettage	CP50	0.8W	1.6W	50%	E4*/PI4	Yes	Laser soft tissue curettage. Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket.
4	Aphthous Ulcers	CW	0.7W	0.7W	N/A	E4	No	Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa.
5	Herpetic Lesions	CW	0.7W	0.7W	N/A	E4	No	
6	Hemostatis	CW	0.5W	0.5W	N/A	E4	No	Hemostasis and coagulation.

* E4 tips may be initiated if preferred. PI4 tips may be labeled Pre-Initiated 400µm.

Figure 8.1

Any pre-set values used for a procedure other than the one listed may then be saved as a custom setting by following the steps outlined in Section 7.15.

9 Maintenance

NOTE: This device contains no user-serviceable parts and therefore no servicing instructions are available other than the regular maintenance procedures described in this manual. Any attempt to modify or repair the laser by anyone other than an authorized BIOLASE technician may lead to exposure to laser radiation and collateral radiation.

9.1 DAILY MAINTENANCE

Disposable screen protectors are supplied with the Epic Hygiene laser system. Apply these peel-off clear covers to the console screen to protect it from water and debris, and discard after use. Use disinfectant to wipe down the front panel and Handpiece Holder of the Epic Hygiene system after each procedure. **Do not use bleach or abrasive cleansers.**

9.2 CLEANING AND STERILIZATION PROCEDURES

The contamination control suggested for the Epic Hygiene Handpiece and Tips is the steam sterilization method. However, before sterilization, the Handpiece should be MANUALLY cleaned per the procedure noted below.



CAUTION: Handpieces and laser Tips are not sterile when sold and must be sterilized prior to initial use, and Handpieces must be cleaned and sterilized between patients. Tips are single-use only and must be discarded after single use in a biohazard medical waste sharps container. Cleaning must be performed within a maximum of 1 hour after the procedure and prior to sterilization.

CAUTION: The Fiber Optic Cable must be disinfected between patients by following the procedure outlined in Step 3 of this section.

STEP 1 - CLEANING PROCESS – HANDPIECE

The cleaning process is intended to remove blood, protein and other potential contaminants, as well as to reduce the quantity of particles, microorganisms and pathogens present from the Handpiece surface and crevices. Cleaning should be performed prior to sterilization and must be conducted only by qualified personnel trained in the process who know how to handle the laser Handpiece.

Wear protective latex gloves when handling the contaminated delivery system.

1. After use, carefully remove the Tip from the Handpiece and discard in a biohazard medical waste sharps container.
2. Carefully remove the Handpiece from the Fiber Optic Cable.
3. Prepare any commercially available surgical instrument detergent/enzymatic cleaning solution with a pH of 7.0, such as Enzol® or similar enzymatic presoak and cleaner, per the manufacturer's instructions. (Follow the manufacturer's instructions for disposal of used solution.)
4. Rinse the Handpiece under running lukewarm tap water (22 – 43°C) for a minimum of 10 seconds to remove gross soil.
5. Wrap the Handpiece in a piece of gauze that has been soaked in the cleaning solution; leave it wrapped in the gauze for a minimum of 10 minutes.
6. Unwrap the Handpiece from the gauze and use a soft-bristled brush dipped in the cleaning solution to gently scrub it for at least 15 seconds.

9 Maintenance

7. Rinse the Handpiece under running lukewarm tap water (22-43°C) for a minimum of 10 seconds and then dry with a lint-free cloth.
8. Visually inspect the Handpiece for any residual soil. If necessary, repeat steps 5 - 7 until all residual soil is removed.

STEP 2 - STERILIZATION PROCESS – HANDPIECE AND TIPS

The steam sterilization process is intended to destroy infectious microorganisms and pathogens.

NOTE: Always perform the procedure immediately after cleaning and prior to use; only use FDA-cleared (USA) or CE-marked (Europe) sterilization accessories, i.e., sterilization pouch and autoclave tray. The product packaging is NOT suitable for steam sterilization.

1. Place the Handpiece and fiber Tips in separate single-wrap, self-seal autoclave pouches.
2. Place on an autoclave tray; do not stack other instruments on top of the pouches.
3. Place the tray inside the autoclave chamber and set the appropriate cycle as recommended in Figure 9.1.

Type of Sterilizer	Temperature	Minimum Time	Drying Time
Gravity Displacement	121°C (250°F)	30 minutes	15 – 30 minutes
	132°C (270°F)	15 minutes	
Dynamic-Air-Removal (Pre-Vacuum)	132°C (270°F)	4 minutes	20 – 30 minutes
	134°C (273°F)	3 minutes	20 minutes

Figure 9.1

Once the cycle is completed, remove the tray and let each sterilized item cool and dry. The Handpiece and Tips must remain in the sterilization pouches until used in order to maintain sterility.

To re-connect the Handpiece to the Fiber Optic Cable, push the Handpiece onto the fiber shaft without twisting until it clicks into place and is secured, as described in Section 7.3.

STEP 3 – 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.

9 Maintenance

9.3 FIBER OPTIC CABLE LENS INSPECTION AND CLEANING

LENS INSPECTION PROCEDURE

The lens is at the distal end of the Fiber Optic Cable (Figure 9.2); this is where debris may accumulate over time with use. To inspect the lens, take the following steps:

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 9.3).
3. Inspect the lens.



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.

CAUTION: Never reuse single-use Tips as this will damage the Fiber Optic Cable.



Figure 9.2

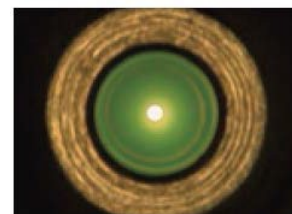


Figure 9.3

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, lint free cotton or foam swab to clean the lens (Figure 9.4).
2. Dip the lint free swab in isopropyl alcohol.
3. Gently rub the lens surface to remove debris or dark spots (Figure 9.5).
4. Repeat as needed using a new lint free swab each time until no residue appears on the swab.



CAUTION: If blemishes appear below or inside the lens, contact BIOLASE or your authorized service representative.



Figure 9.4



Figure 9.5

9 Maintenance

9.4 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.
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.
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 the Phillips screwdriver provided.
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 three 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. Dispose of the used Lithium Ion battery as regulated. Do not discard in a trash bin.

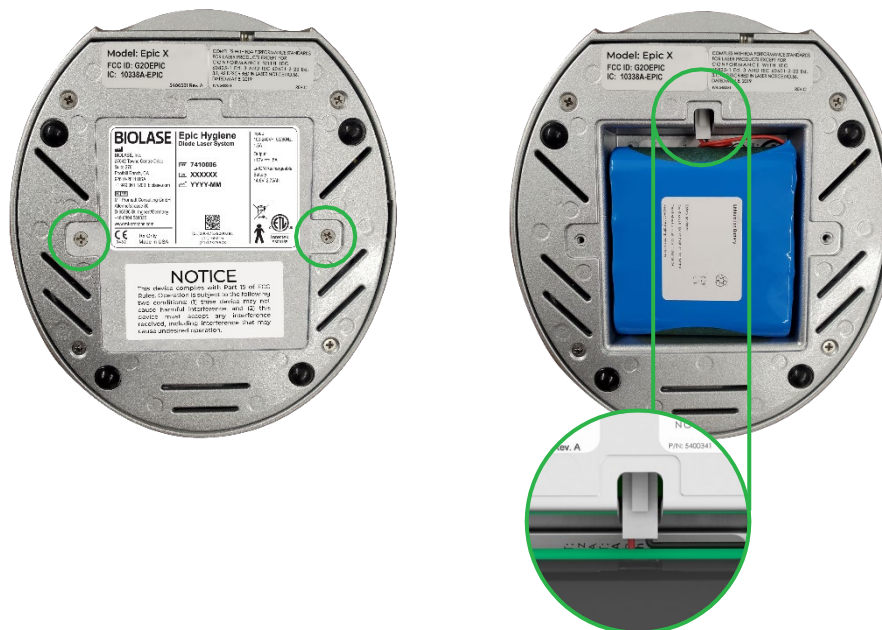


Figure 9.6

NOTE: Only use the battery pack supplied by BIOLASE. The battery pack is a separate accessory (BIOLASE P/N 4400268).

9 Maintenance

9.5 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 display screen 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.

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 communication has been interrupted, reestablish pairing by following the instructions provided in Section 7.



Figure 9.7 Battery cover screws.

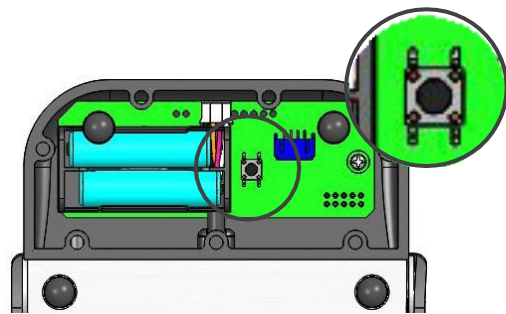


Figure 9.8 Pairing button (internal view).

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 Maintenance

9.6 TRANSPORTATION

The Epic Hygiene 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**.

9.7 STORAGE

The Epic Hygiene 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 Hygiene 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.



CAUTION: Make sure the distal end of the fiber shaft is protected from dirt by removing the Handpiece and installing the red protective cap over the end of the fiber. Remove the batteries from the Footswitch if the Epic Hygiene is not likely to be used for some time.

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

10 Calibration

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

11 Software Specification

BIOLASE respects the intellectual property of others, and we ask our users to do the same. Epic Hygiene software is protected by copyright and other intellectual property laws. This product contains proprietary, copyrighted software developed by BIOLASE. All rights reserved in the USA and other countries.

12 Troubleshooting

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 below.

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	Wireless not paired	No wireless connection	Re-establish pairing (see sec 4)
Alert 2	System must be in Ready mode to lase	System is not in Ready mode	Press the control button in any procedure screen

Figure 12.1

12 Troubleshooting




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 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 Tip Guide

NOTE: All BIOLASE tips for diode lasers are sold non-sterile and are for single-use only. See Section 9 in this User Manual for cleaning and sterilization instructions.

NON-INITIATED

Tip	Name	Diameter	Length (mm)	Part Number
	E4-4	400µm	4	7400016
	E4-7	400µm	7	7410003/ 7400019
	E4-9	400µm	9	7400019

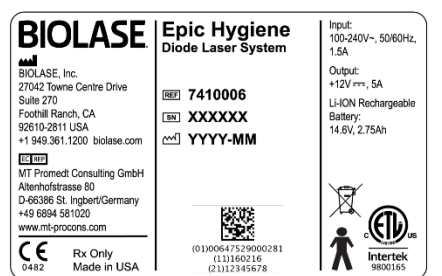








PRE-INITIATED

Tip	Name	Diameter	Length (mm)	Part Number
	PI4-4	400µm	4	7400067
	PI4-7	400µm	7	7400068
	PI4-9	400µm	9	7400069

Appendix B Accessories

PART NO.	DESCRIPTION
7420004	Handpiece (2-pack)
7420006	Handpiece (1-pack)
2400277	Laser Safety Glasses
6400058	Remote Interlock Plug
2400075	DC Power Supply
2400043	Power Cord (US)
2400055	Power Cord (International)
6400573	Wireless Footswitch
6400107	Tip Initiation Kit
6400465	Peel-off Clear Screen Covers (qty. 30)
4400268	Lithium-Ion Battery Pack for Console
6400463	Battery Pack (2 x AAA)
5400229	Laser Warning Sign

Appendix C Labeling

<p>PRODUCT IDENTIFICATION LABEL:</p> <p>LOCATIONS: Bottom of laser console. Outer carton (shipping box)</p>	 <p>The label contains the following information: BIOLASE BIOLASE, Inc. 27042 Towne Centre Drive Suite 270 Foothill Ranch, CA 92610-2811 USA +1 949.361.1200 biolase.com MT Promed Consulting GmbH Altenhofstrasse 80 D-66386 St. Ingbert/Germany +49 6694 581020 www.mt-grocons.com Epic Hygiene Diode Laser System REF 7410006 SN XXXXXX YYYY-MM Input: 100-240V~, 50/60Hz, 1.5A Output: +12V=, 5A Li-ION Rechargeable Battery: 14.6V, 2.75Ah CE, Rx Only, Made in USA (01)00647529000281 (11)160216 (21)12345678 Intertek 9800165</p>
<p>MANUFACTURER</p>	
<p>CATALOG/PART NUMBER</p>	
<p>PRODUCT SERIAL NUMBER</p>	
<p>DATE OF MANUFACTURE</p>	
<p>LASER WARNING: Symbol warns of laser beam hazard. Always wear appropriate eye protection.</p> <p>LOCATION: Back of Laser Console.</p>	
<p>TYPE BF APPLIED PART: The applied part is not conductive to the patient.</p>	
<p>EMERGENCY LASER STOP SWITCH: The switch used in emergencies to stop laser output.</p> <p>LOCATION: Right side of laser console.</p>	
<p>LASER APERTURE WARNING: Indicates visible and/or invisible laser radiation is emitted from this aperture.</p> <p>LOCATION: Back of laser console.</p>	

Appendix C Labeling

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 X
FCC ID: G2OEPIC
IC: 10338A-EPIC

5400581 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:


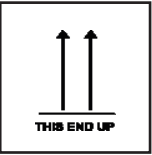


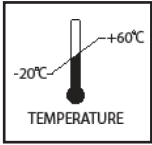
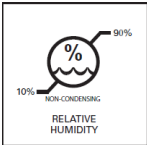
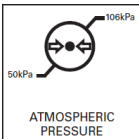
The Footswitch is water-resistant, protected from splashes of water

IPX6

SINGLE USE ONLY – DO NOT REUSE



Appendix C Labeling

<p>WEEE (WASTE ELECTRICAL AND ELECTRONIC): Recycle lithium ion battery as regulated. Do not throw in trash bin.</p>	
<p>THIS END UP</p> <p>LOCATION: Outer carton (shipping box)</p>	
<p>FRAGILE: HANDLE WITH CARE</p> <p>LOCATION: Outer carton (shipping box)</p>	
<p>KEEP DRY</p> <p>LOCATION: Outer carton (shipping box)</p>	
<p>TRANSPORTATION TEMPERATURE LIMITATIONS</p> <p>LOCATION: Outer carton (shipping box)</p>	
<p>HUMIDITY LIMITATIONS</p> <p>LOCATION: Outer carton (shipping box)</p>	
<p>ATMOSPHERIC PRESSURE LIMITATIONS</p> <p>LOCATION: Outer carton (shipping box)</p>	

Appendix C Labeling

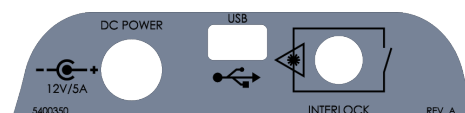
LASER WARNING SIGN

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 D Safety - Lithium-Ion Battery Packs

WHEN USING THE BATTERY:



WARNING:

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



CAUTION:

1. If the device is to be used by small children, the caregiver should explain the contents of the user's manual to the children. The caregiver should provide adequate supervision to ensure that the device is being used as explained in the user's manual.
2. When the battery is worn out, insulate the terminals with adhesive tape or similar materials before disposal.
3. Immediately discontinue use of the battery if, while using, charging, or storing the battery, the battery emits an unusual smell, feels hot, changes color, changes shape, or appears abnormal in any other way. Contact your sales location or BIOLASE if any of these problems are observed.
4. Do not place the batteries in microwave ovens, high-pressure containers, or on induction cookware.
5. In the event that the battery leaks and the fluid gets into one's eye(s), do not rub the eye(s). Rinse well with water and immediately seek medical care. If left untreated, the battery fluid could cause damage to the eye.

Appendix D Safety - Lithium-Ion Battery Packs

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 E Electromagnetic Compatibility



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 6400573




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 Hygiene diode laser system.

GUIDANCE AND MANUFACTURER'S DECLARATION — ELECTROMAGNETIC EMISSIONS		
The Epic Hygiene is intended for use in the electromagnetic environment specified below. The customer or the user of the Epic Hygiene 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 Hygiene 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. The Epic Hygiene 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.
RF conducted emissions CISPR 11	Group 1, Class A/B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Class A	

Appendix E Electromagnetic Compatibility

GUIDANCE AND MANUFACTURER'S DECLARATION — ELECTROMAGNETIC IMMUNITY			
The Epic Hygiene is intended for use in the electromagnetic environment specified below. The customer or the user of the Epic Hygiene 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 Hz 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 Hygiene requires continued operation during power mains interruptions, it is recommended that the model EPIC Hygiene 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 E Electromagnetic Compatibility

GUIDANCE AND MANUFACTURER'S DECLARATION — ELECTROMAGNETIC IMMUNITY (<i>Continued</i>)			
The Epic Hygiene is intended for use in the electromagnetic environment specified below. The customer or the user of the Epic Hygiene 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	3 Vrms 150 kHz to 80 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the model Epic Hygiene, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC61000-4-3	6Vrms At the standard specified ISM band 9 V/m to 28 Vm 385 to 5785 MHz	6Vrms At the standard specified ISM band	<p>Recommended separation distance</p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.3\sqrt{P} \text{ 800MHz to 2.5GHz}$ <p>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).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
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.			
<p>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 Hygiene is used exceeds the applicable RF compliance level above, the Epic Hygiene should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Epic Hygiene.</p> <p>b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.</p>			

Appendix E Electromagnetic Compatibility

RECOMMENDED SEPARATION DISTANCE BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE EPIC HYGIENE

The Epic Hygiene is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Epic Hygiene can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Epic Hygiene 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 = 1.2VP	80 MHz to 800 MHz d = 1.2VP	800 MHz to 2.5 GHz d = 2.3VP
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 F Wireless Equipment Statement

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

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

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



Intertek
9800165

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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