Waterlase
express™

BIOLASE

User Manual

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Waterlase Express is indicated for professional use on dental patients. Procedures must be performed only by licensed dental practitioners in a dental facility. Use of this device requires clinical and technical training, and this manual provides instructions for use.

The Waterlase Express tablet contains video animations which demonstrate specific clinical applications available with the device. All statements of individual claims presented are based on references which can be viewed withing the White Paper section of the Learning Center on the Waterlase Express tablet.

CAUTION: From time to time you may see software related updates from Samsung, please **do not accept or execute** software related updates without further instruction from BIOLASE to ensure that updates will not adversely impact the use of your Waterlase Express.

WARNING: No modification of this equipment is allowed.

Introduction

Congratulations on the addition of the Waterlase Express™ all-tissue laser to your practice! Waterlase patented technology provides a minimally invasive, highly precise, and exceptionally gentle dental experience for your patients, as well as unmatched results in treatment outcomes.

This User Manual is designed to help you become familiar with the operation and functions of the laser system. Read it carefully before using the laser clinically, follow all safety instructions and cautions, and always have it accessible as a reference.

We appreciate your commitment to better care and know your investment in this technology is a sound foundation for the successful growth of your practice.

BIOLASE Team

1 Overview

The Waterlase Express™ all-tissue laser is a unique Er,Cr:YSGG* solid state tissue-cutting system manufactured by BIOLASE for use in oral hard- and soft-tissue dental applications. It sets a new standard of affordability, accessibility, and ease of use for all-tissue lasers.

Waterlase Express utilizes advanced laser and water atomization tehcnologies to safely and effectively cut, shave, contour, roughen, etch, and resect oral hard-tissues, and direct laser energy to perform oral soft-tissue removal, incision, excision, ablation and coagulation. Waterlase Express may also be used for specific endodontic and periodontal applications.

When used for oral hard tissue procedures, the Waterlase Express laser provides optical energy to a user-controlled distribution of atomized water droplets and hydrated surface layer of hard tissue. The water present in the target tissue absorbs laser radiation, resulting in explosive molecular expansion and ablation of hard tissue. The water in the spray provides cooling and hydration for the target tissue.

For oral soft tissue procedures, the Waterlase Express laser applies optical energy to the soft tissue for tissue removal, incision, excision, ablation and coagulation, using direct laser energy. These procedures can be done in conjunction with water, for cooling and hydration, or without water for coagulation.

A flexible Fiber Optic Cable connects at one end to the laser and at the other to a Handpiece that delivers laser energy to the target tissue through a fiber Tip. A visible light emitted from the Handpiece head illuminates the area of treatment. Certain laser parameters may be adjusted by the user for both soft and hard tissue applications. The laser is activated using a Footswitch.

A removable Tablet serves as the user interface. Through the Tablet, the user may select laser procedures, access information on the system's clinical performance, and view educational and reference materials. The user may also utilize the Tablet to communicate directly with BIOLASE customer care, educators, and peer professionals. Additional service needs are also provided through the Tablet, but no patient data of any kind is stored on the Tablet itself or the laser system.

Waterlase Express is indicated for professional use on dental patients. Procedures must be performed only by licensed dental practitioners in a dental facility. Use of this device requires clinical and technical training, and this manual provides instructions for use.

If used and maintained properly, Waterlase Express will prove a valuable addition to a practice. Please contact BIOLASE customer service at **1-800-321-6717** in the U.S. and Canada for any service needs; if you are located outside North America, please contact your BIOLASE-authorized representative.

In Canada, this device must be installed, operated, and maintained according to the current revision of the guidelines specified in the Canadian standard CAN/CSA-Z386-2014, *Safe use of lasers in health care.*

* Erbium,Chromium:Yttrium-Scandium-Gallium-Garnet

2 Indications for Use

The Waterlase Express may be used for the following indications:

GENERAL HARD-TISSUE INDICATIONS*

- Class I, II, III, IV and V cavity preparation

- Caries removal

- Hard-tissue surface roughening or etching

- Enameloplasty, excavation of pits and fissures for placement of sealants

    *For use on adult and pediatric patients

CROWN AND VENEER REMOVAL

- Waterlase laser removal of porcelain and ceramic crowns and veneers

ROOT CANAL HARD-TISSUE INDICATIONS

- Tooth preparation to obtain access to root canal

- Root canal preparation including enlargement

- Root canal debridement and cleaning

ROOT CANAL DISINFECTION

- Laser root canal disinfection after endodontic treatment

ENDODONTIC SURGERY (ROOT AMPUTATION) INDICATIONS

- Flap preparation – incision of soft-tissue to prepare a flap and expose the bone

- Cutting bone to prepare a window access to the apex (apices) of the root(s)

- Apicoectomy – amputation of the root end

- Root end preparation for retrofill amalgam or composite

> **NOTE:** Any tissue growth (i.e., cyst, neoplasm or other lesions) must be submitted to a qualified laboratory for histopathological evaluation.

- Removal of pathological tissues (i.e., cysts, neoplasm or abscess) and hyperplastic tissues (i.e., granulation tissue) from around the apex

BONE SURGICAL INDICATIONS

- Cutting, shaving, contouring and resection of oral osseous tissues (bone)

- Osteotomy

SOFT-TISSUE INDICATIONS INCLUDING PULPAL TISSUES*

Incision, excision, vaporization, ablation and coagulation of oral soft-tissues, including:

- Excisional and incisional biopsies

- Exposure of unerupted teeth

SOFT-TISSUE INDICATIONS INCLUDING PULPAL TISSUES* (CONTINUED)

- Fibroma removal

- Flap preparation - incision of soft-tissue to prepare a flap and expose the bone

- Flap preparation - incision of soft-tissue to prepare a flap and expose unerupted teeth (hard and soft-tissue impactions)

- Frenectomy and frenotomy

- Gingival troughing for crown impressions

- Gingivectomy

- Gingivoplasty

- Gingival incision and excision

- Hemostasis

- Implant recovery

- Incision and drainage of abscesses

- Laser soft-tissue curettage of the post-extraction tooth sockets and periapical area during apical surgery

- Leukoplakia

- Operculectomy

- Oral papillectomies

- Pulpotomy

- Pulp extirpation

- Pulpotomy as an adjunct to root canal therapy

- Root canal debridement and cleaning

- Reduction of gingival hypertrophy

- Removal of pathological tissues (i.e., cysts, neoplasm or abscess) and hyperplastic tissues (i.e., granulation tissue) from around the apex

> **NOTE:** Any tissue growth (i.e., cyst, neoplasm or other lesions) must be submitted to a qualified laboratory for histopathological evaluation.

- Soft-tissue crown lengthening

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

- Vestibuloplasty

*For use on adult and pediatric patients

2 Indications for Use

LASER PERIODONTAL PROCEDURES

• Full thickness flap

• Partial thickness flap

• Split thickness flap

• Laser soft tissue curettage

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

• Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining junctional epithelium

• Removal of granulation tissue from bony defects

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

• Osteoplasty and osseous recontouring (removal of bone to correct osseous defects and create physiologic osseous contours)

• Ostectomy (resection of bone to restore bony architecture, resection of bone for grafting, etc.)

• Osseous crown lengthening

• Removal of subgingival calculi in periodontal pockets with periodontitis by closed or open curettage

• Waterlase Er,Cr:YSGG-assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium)

3 Contraindications, Warnings, and Precautions

3.1 CONTRAINDICATIONS

All clinical procedures performed with the Waterlase Express must be subjected to the same clinical judgment and care as with standard 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 which might contraindicate a local procedure. Such conditions may include, but are not limited to, allergy to local or topical anesthetics, heart disease (e.g., pacemakers, implantable defibrillators, lung disease, bleeding disorders, or an immune system deficiency. 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 and have received proper training on how to correctly operate the system should use this device. Procedures related to soft tissue, osseous, endodontic, or periodontal surgery should only be performed by clinicians who have training and experience in Oral Maxillofacial, Periodontal, or Endodontic surgery.

EYEWEAR
Doctor, patient, assistant, and all others inside or entering the operatory must wear appropriate laser protection eyewear for the 2780 nm wavelength OD4 (DI LB3) or greater whenever the laser is in use. Prior to use, inspect eyewear for pitting and cracking. Replace if damaged; do not use.

> ⚠️ **CAUTION:** The specifications for the protective eyewear provided with the Waterlase Express system are marked on the frame of the glasses. **Always check the eyewear specifications inscribed 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.

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

TREATMENT, TECHNIQUE, AND SETTINGS
Always start treatment at the factory-installed default settings for the chosen application and adjust as required. Closely observe clinical effects and use your judgment to determine the aspects of the treatment (e.g., technique, proper power, pulse mode, air and water settings, tip type, and duration of operation) and make appropriate adjustments to compensate for varying tissue composition, density, and thickness.

3 Contraindications, Warnings, and Precautions

CLINICAL ENVIRONMENT

Only use this device in clinical environments that observe proper standard aseptic techniques with all oral procedures.

HARD-TISSUE PROCEDURES

All hard-tissue (enamel, dentin, cementum and bone) procedures must be performed using air and water spray at appropriate settings. **Failure to use the spray will result in tissue thermal damage.**

SOFT-TISSUE PROCEDURES

Soft-tissue procedures can be performed using two pulse duration settings, H-Mode and S-Mode, either with water for cooling and hydration, or without water for coagulation

The S-Mode (long pulse) settings are indicated for soft-tissue applications only. **Do not use S-Mode to perform hard-tissue procedures.**

FLUID ENTRAPMENT AND AIR EMBOLISM

Do not direct air of spray toward tissues that may trap air or water. For example, when performing surgical procedures the clinician should be aware of adjacent soft-tissue pockets, cavities, or channels that may collect or entrap air. Always use high-speed suction to remove any excess fluid and avoid directing the spray into deep pockets. Do not use the Waterlase Express if it is not possible to access the treatment site without directing air into an area that may collect or entrap air. In general, the same care and precautions should be taken when using the Waterlase Express as are taken when using any air and water emitting cutting device.

ROOT CANAL PROCEDURES

The Waterlase Express is better suited for straight and slightly curved canals. Great care should be taken during instrumentation of curved canals as the endodontic Fiber Tip may break or perforate through the wall of these types of canals. If during insertion the Fiber tip does not advance easily into the canal, do not force it. If necessary, pull the Fiber Tip out and use an endodontic hand file or a broach to open the path. Do not force the Tip and/or activate the laser while moving the Tip inside a narrow or curved canal, or through the apex. Place the end of the Tip ~2mm from the apex or from being in contact with the wall of a curved canal. Activate the laser and spray only during the outward strok when the Fiber tip is pulled towards the coronal portion of the canal.

ROOT CANAL DISINFECTION PROCEDURES

The same precautions and warnings stated above are applicable to root canal disinfection procedures. The Fiber Tips designed for this indication are the radial emitting RFT2 and RFT3, which have a 200 μm and a 300 μm diameter, respectively, and come in various lengths to accommodate different root canal lengths. Effective laser root canal disinfection is performed with air and no water spray. Do not exceed the maximum air setting (10%) for this procedure.

ADJACENT STRUCTURES

Always be aware of adjacent structures and substructures during treatment. Be extremely careful not to inadvertently penetrate or ablate through underlying/adjacent tissues and be aware and use extreme caution when working on tissue adjacent to major anatomical structures, such as nerves or vessels. Exercise extreme care when using is device in areas such as pockets, where critical structures such as nerves or vessels could be damaged. Do not proceed with using the laser if visibility in these areas is limited.

TISSUE EVALUATION

Any tissue growth (i.e., cyst, neoplasm and other lesions), either removed with Waterlase Express or conventionally, must be submitted to a qualified laboratory for histopathological assessment.

TISSUE CONTACT AND TIP BREAKAGE

Do not contact any hard surface with the Fiber Tip as it is very brittle and fragile and could break. If the Fiber Tip should break during a procedure, immediately and carefully suction the debris from the treatment site, rinse, and repeat.

FIBER TIP CHANGING

Failure to correctly replace the Fiber Tip could result in damage to the Fiber Tip and/or Handpiece, or affect the emission of laser energy around the Tip. A careful review of the instructions on how to replace the Fiber Tip is recommended (refer to Section 7.3.10).

WATER SPLASHING

Water from spray may splash during laser use. The use of a face shield as protection from spattering is recommended. Use high-speed suction as required to maintain a clear field of vision during a procedure. Do not use Waterlase Express if you cannot clearly see the treatment site.

PLUME REMOVAL

> ⚠️ **CAUTION:** Laser plume may contain viable tissue particulates.

Special care must be taken to prevent infection from the laser plume generated by the vaporization of virally or bacterially infected tissue during procedures utilizing the laser with minimal or no water spray. Ensure that all appropriate protective equipment (including high-speed suction to remove the plume, appropriate masks, and other protective equipment) is used at all times during procedures utilizing this laser device.

DENTAL MATERIALS

Do not direct laser energy towards amalgam, gold, or other metallic surfaces; doing so, may damage the Waterlase Express delivery system.

CROWN AND VENEER MATERIALS

Do not use on crowns that are made from porcelain fused to high noble metals (PFM), or made from gold or other metallic materials.

4 Specifications

4.1 DIMENSIONS

- Laser console (W x L x H)   9 x 18 x 12 in (23 x 46 x 30.5 cm)
- Tablet (W x H x D)   6.7 in x 9.3 in x 0.2 in (16.9 cm x 23.8 cm x 0.6 cm)
- Screen size   9.7 in (24.6 cm)
- Weight laser console (with water)   27.2 lbs (12.3 kg)
- Weight Tablet   0.9 lbs (390 g)

4.2 ELECTRICAL

Class I Medical Electrical (ME) Equipment

- Operating voltage   100 - 240 VAC
- Frequency   50 / 60 Hz
- Current rating   6A / 3A
- Main control   Main Power Switch
- On / Off control   Keyswitch
- Remote interruption   Remote interlock connector

4.3 AIR AND WATER SPRAY

- Water type   Distilled or De-Ionized only
- External air source   60-120 psi. (4.1 – 8.2 bar)
- Water   0 - 100%
- Air   0 - 100%
- Interaction zone   0.5 - 5.0 mm from Handpiece Tip to target

4.4 OPTICAL

- Laser classification   IV (4)
- Medium   Er,Cr:YSGG

                                            (Erbium, Chromium: Yttrium, Scandium, Gallium, Garnet)

- Wavelength   2.78 µm (2780nm)
- Mode   Multimode
- Frequency (Pulse Rate)   5 – 50 Hz
- Average power   0.1-4.0 W
- Power accuracy   ± 20%
- Pulse energy   10– 250 mJ
- Pulse duration for "H" mode (Short pulse) 60 µs
- Pulse duration "S" mode (Long pulse)   700 µs
- Handpiece head angles   70° contra-angle
- Fiber Tip diameter range (Spot size)   200 – 1200 µm
- Output divergence   ≥ 8° per side
- Aiming beam   625-670 nm (red) laser, 1mW max (Laser Class 1)
- Nominal ocular hazard distance (NOHD)   5cm
- Maximum permissible exposure (MPE) 3.46×10^5 W/m²

5 Equipment Description

5.1 SYSTEM COMPONENTS

The Waterlase Express laser system includes the following*:

- Laser Console
- Tablet and International AC Adapter (packed separately)
- Tablet Protective Covers
- Fiber Optic Cable
- Fiber Optic Cable Support Arm
- Fiber Optic Cable Retainer
- Yellow Air Tube
- Laser Protective Eyewear (3)
- Handpieces (2)
- Handpiece Holder
- Fiber Tip Starter Kit (Assorted Tips)
- Fiber Tip Holder
- Internal Reservoir Fill Kit

- Tip Cleaning and Inspection Kit
- Power Cord (1-US, 1-Int'l, 1-UK)
- Remote Interlock Plug
- Wired Footswitch (standard)
- Wireless Footswitch (optional; includes Footswitch batteries)
- Welcome Kit – Includes:
  - Welcome Letter
  - Waterlase Express User Manual
  - Waterlase Express Quick Start Guide
  - Laser Warning Sign
  - Product Registration Flyer
  - Limited Warranty Statement

Additional accessories, including extra Handpieces, Tips, and screen protectors may be ordered separately from the BIOLAS online store: https://store.biolase.com/

5.2 GENERAL

The Waterlase Express laser system consists of four primary components:

1. Laser Console
2. Tablet
3. Fiber Delivery System
4. Footswitch

5 Equipment Description

5.2.1 LASER CONSOLE

POWER CONNECTION/MAIN POWER SWITCH

The power cord attaches to the back panel of the laser console. The other end must be plugged into an electrical power source in order for the laser system to work. The main power switch serves as a line switch to separate the console from the main power supply (O = OFF, I = ON)
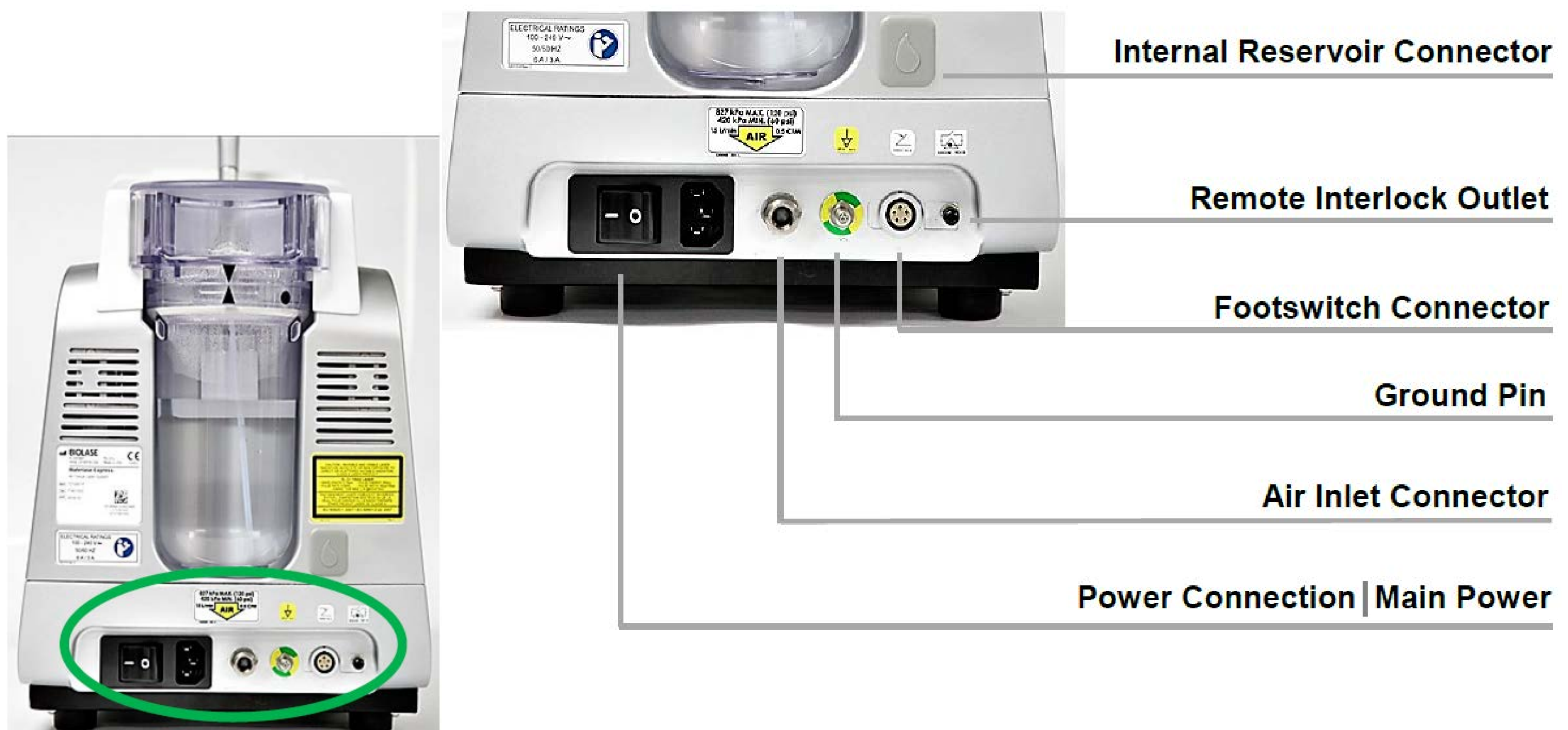

Figure 5.1

KEYSWITCH

Located on the right front panel of the laser console, the Keyswitch is used to turn the laser ON by turning the key clockwise to a horizontal position; always use only the key provided. The key cannot be removed while it is in the ON position. Always remove the key when the laser is left unattended.

EMERGENCY STOP

The emergency stop (red) button is located on the left front panel of the laser console. Pressing this button instantly stops the emission of laser energy; the button will glow red to indicate the emergency stop has been engaged and the screen will display the message "Emergency Stop Pressed."

5 Equipment Description

TABLET HOLDER

The Tablet Holder is the hinged panel located at the front of the console and includes the control panel and Tablet Latch. The Tablet is inserted into the control panel; once in place and connected to the micro USB inside the panel, it is locked into position by flipping the Latch over the top of the Tablet (a thumbscrew at the rear of the latch prevents removal of the tablet).

CONTROL PANEL

The Function Control button is located in the center of the control panel; it activates the controls and display and is used to place the system into **Ready** (green), **Standby** (amber), or **Sleep** mode. There are also two LED indicators on either side of the Function Control button; one indicates the Tablet is properly installed, and the other confirms the wireless connection with the Footswitch is active if a wireless Footswitch is used.

HANDPIECE HOLDER

The Handpiece Holder cradles the Handpiece when it is not in use. It can be attached to the Tablet Holder on the right or left, based on user preference.
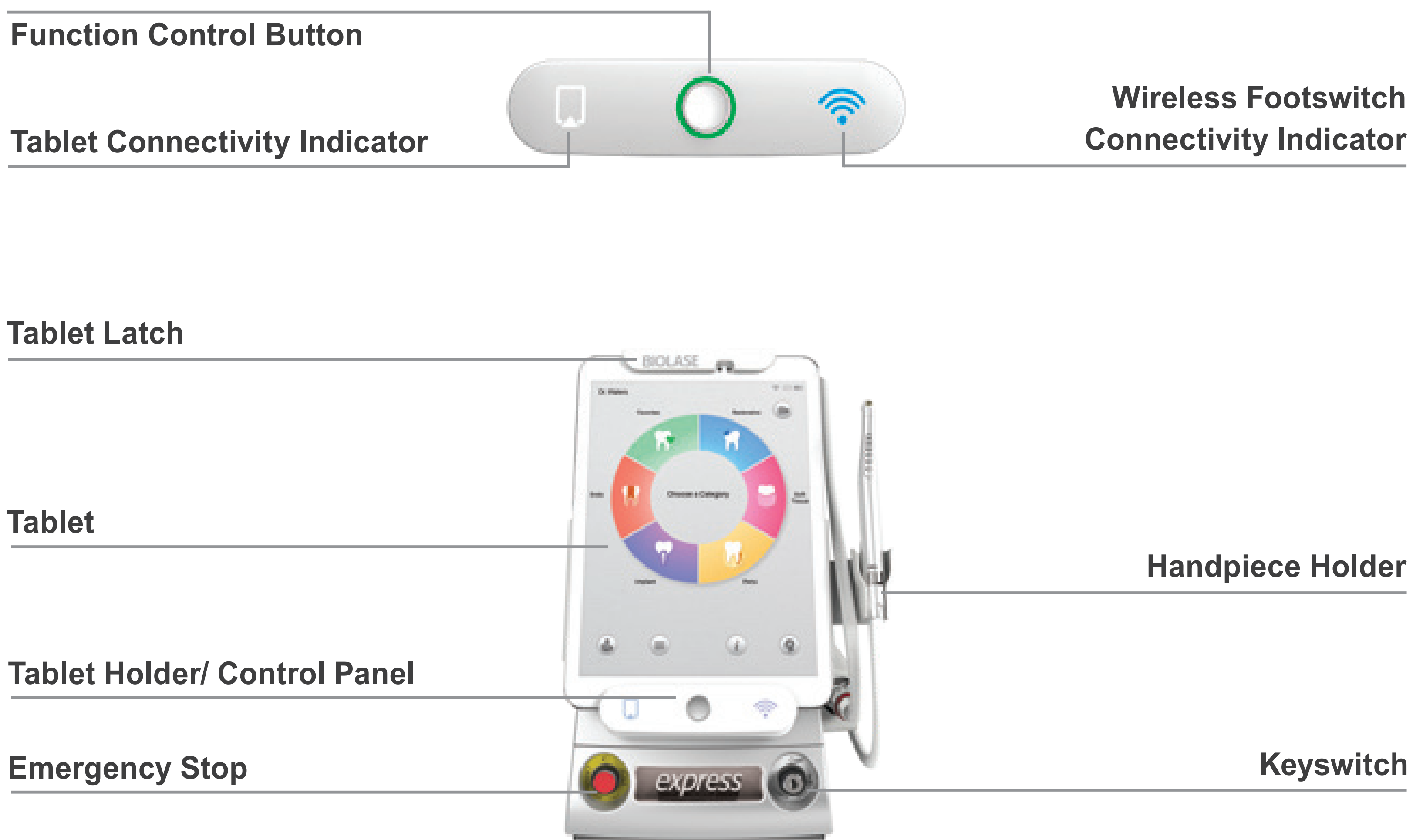
Function Control Button

Tablet Connectivity Indicator

Wireless Footswitch Connectivity Indicator

Tablet Latch

Tablet

Handpiece Holder

Tablet Holder/ Control Panel

Emergency Stop

Keyswitch

Figure 5.2

5 Equipment Description

PATIENT WATER BOTTLE

This detachable water bottle is located on the back of the console and is the water supply for the Handpiece atomization spray. A push-button release is located on the top of the self-contained patient water bottle that frees the bottle from the console for filling/refilling with distilled or de-ionized water.

VENTILATION CHANNELS

The slots on the sides and rear of the console provide an air flow path to cool the laser system. Do not cover or block these during use; leave a minimum of 4 inches between the laser console and any wall or partition.

AIR INLET CONNECTOR

This adaptor on the back of the console provides the connection to a compressed dry air outlet at 60-120 psi (4.1 - 8.2 bar) using the yellow tubing provided.
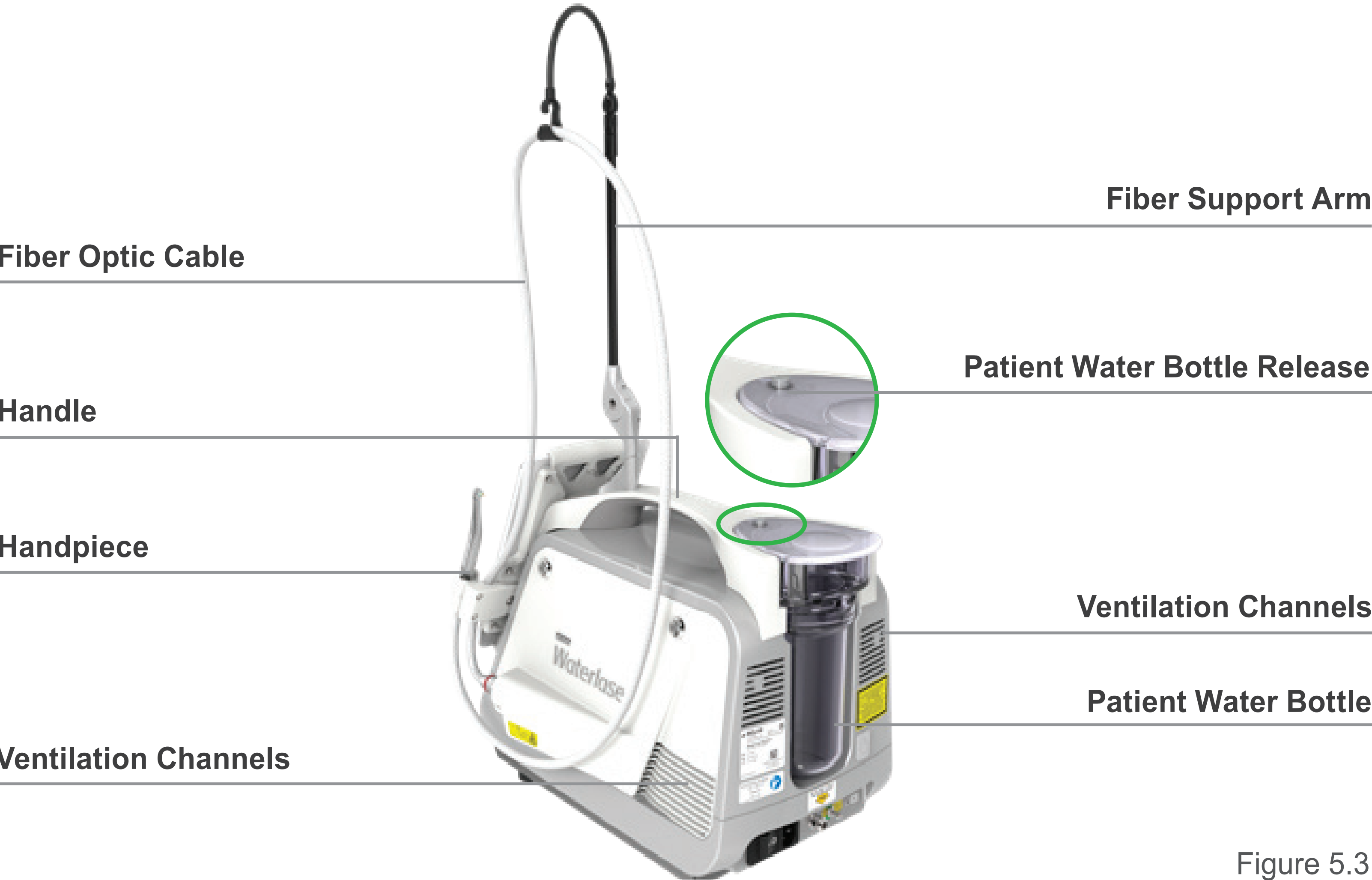

Fiber Support Arm

Fiber Optic Cable

Patient Water Bottle Release

Handle

Handpiece

Ventilation Channels

Patient Water Bottle

Ventilation Channels

Figure 5.3

> ⚠️ **CAUTION:** Moisture or oil in the air supply line will damage the laser system. Always provide an air dryer, mist separator, and proper filtration at the compressor output to eliminate all moisture or oil from the air source. Any damage from moisture or oil in the air line is not covered by the system warranty.

5 Equipment Description

REMOTE INTERLOCK PLUG

This plug connects the laser to a door switch (not included). It will stop the laser immediately if the operatory door is opened while the laser is in use. Although use of this feature is optional, the plug itself must be inserted in the Remote Interlock Outlet at the rear of the console for the laser system to operate.

> **NOTE:** To enable the interlock feature, call BIOLASE for instructions if necessary.

INTERNAL COOLING WATER RESERVOIR FILL CONNECTOR

The Waterlase Express laser system contains an internal cooling water reservoir which must be filled prior to initial use of the laser. A reservoir fill kit is included with the system and attaches to the connector on the rear of the console.

FIBER OPTIC CABLE SUPPORT ARM

This removable accessory supports the weight of the Fiber Optic Cable, keeping it from looping to the ground; its use is optional, based on user preference.

HANDLE

Use the handle at the top of the console to lift, carry, or reposition the laser on a stable, flat surface.

5.2.2 TABLET

The system is operated through a Tablet terminal display that has wireless remote access capability; when WI-FI connectivity is activated, the Tablet allows remote access by BIOLASE for diagnostics, software/firmware updates, and other system data requirements. No patient data is accessed. When installed in the Tablet Holder, the Tablet will charge only if the power to the laser system is ON.

5.2.3 FIBER DELIVERY SYSTEM

FIBER OPTIC CABLE

The Fiber Optic Cable contains the optical fiber together with the illumination waveguide, air tubing and water tubing. Laser radiation is delivered from the laser and through the Handpiece via the optical fiber.

FIBER OPTIC CABLE RETAINER

Please note that a Fiber Optic Retainer, as described in Section 7, is included with the Waterlase Express. This optional accessory is initially attached by the Waterlase Field Service Technician at the time the laser is installed. The Cable Retainer can only be installed if the Handpiece Holder is set up on the right side of the Tablet Holder. Its use is not recommended if the Handpiece Holder is placed on the left side of the Tablet Holder.

5 Equipment Description

A visible light emitted from the Handpiece head illuminates the area of treatment. The visible spot of the aiming beam should be clear, uniform, and well-defined. If the aiming beam is not present while in **Ready** mode or when the laser is firing, replace the Fiber Delivery System.

5.2.4 FOOTSWITCH

The Waterlase Express laser system standard configuration includes a wired Footswitch; however, a wireless option is available as a separate purchase. Whether wired or wireless, the laser will only emit laser energy when the user presses down on the Footswitch while the laser is in **Ready** mode.

To install the wired Footswitch, make sure the laser is either OFF or in **Standby** mode, then secure the Footswitch cable into the Footswitch connector on the back panel of the laser console (Figure 4.1). If an attempt is made to install or remove the Footswitch while the system is in **Ready** or **Firing** mode, an error message will appear on the display screen.

> ⚠️ **CAUTION:** To avoid tripping, make sure the power cord from the Footswitch to the laser console is visible and properly situated.

5.2.4.1 WIRELESS FOOTSWITCH (Optional)

The wireless Footswitch (Figure 5.4.) is designed to pair with the laser console using wireless technology and is powered by two (2) AAA batteries. (Refer to Section 12 for instructions on how to replace the Footswitch batteries included with the wireless Footswitch).
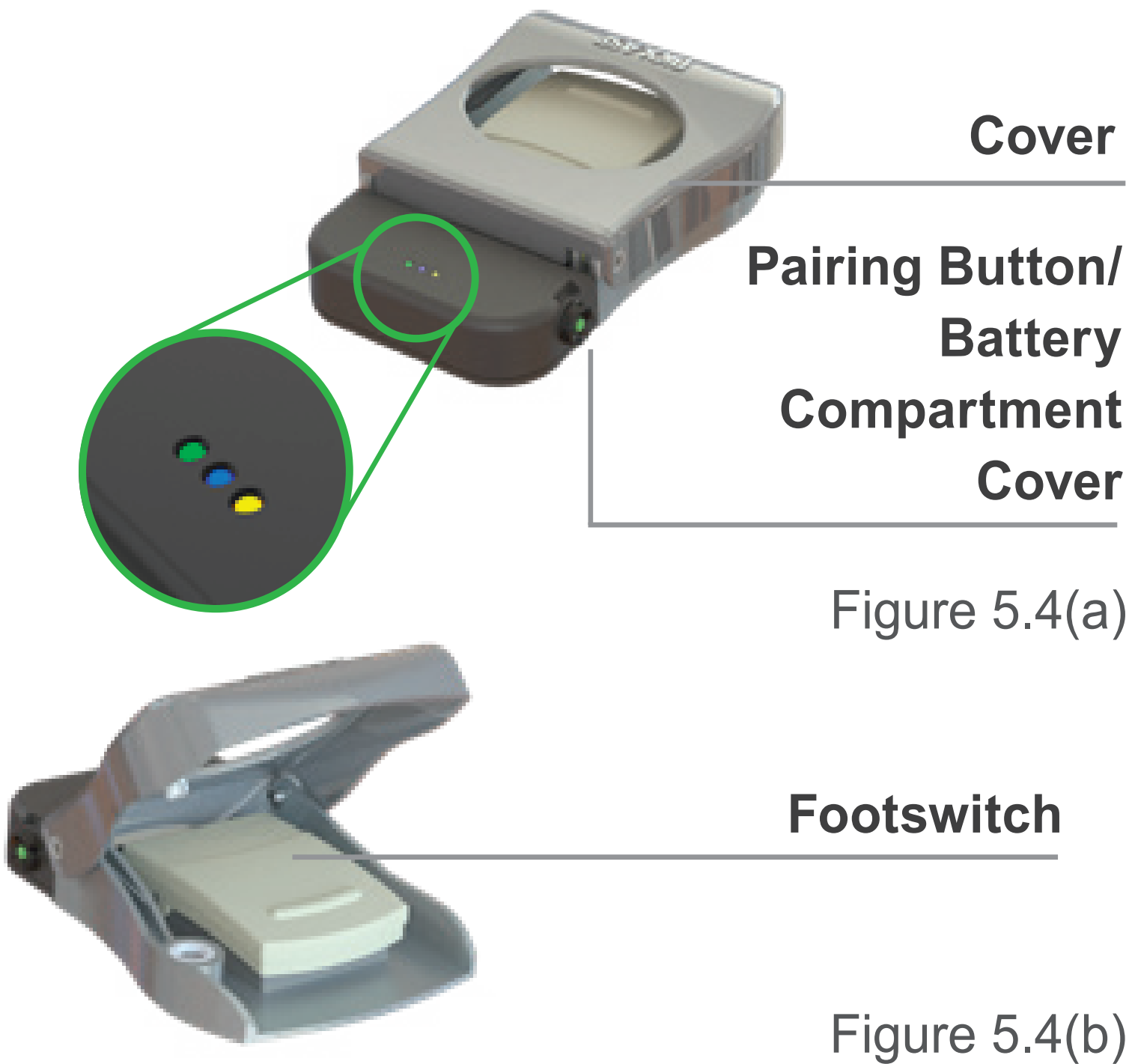
Three separate LED indicator lights are displayed on the top of the battery housing of the Footswitch (Figure 5.4(a)).

For instructions on how to pair the Footswitch and laser, see Section 12.

Both the wired and wireless Footswitch are protected by the Footswitch cover. To release the cover, press down on it; the cover will lift, allowing access to the Footswitch (Figure 5.4(b)).

Cover

Pairing Button/ Battery Compartment Cover

Figure 5.4(a)

Footswitch

Figure 5.4(b)

LED Indicator	Status	
Blue	Solid	The Footswitch is connecting to the laser, or has successfully paired with the laser.
Green	Solid	**ON:** The Footswitch is pressed while paired to the laser. **OFF:** The Footswitch is not pressed, or the system is in **Sleep** mode, or the batteries are dead.
Green	Blinking	The Footswitch batteries are low; replace the batteries.
Amber	Blinking or Solid	A critical error or short has occurred; the relevant error message will appear on the Tablet screen.

Figure 5.5

> ⚠️ **CAUTION:** Repeated rapid tapping of the Footswitch may cause a system error; release the Footswitch, wait 2 seconds, then press firmly down on the Footswitch to clear it. A system restart is not required.

6 Safety with The Waterlase Express

6.1 SAFETY MEASURES

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

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

⚠ **CAUTION:** Use of controls or adjustments, or carrying out procedures other than those specified in this User Manual, may result in hazardous radiation exposure.

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

⚠ **DANGER:** Invisible and/or visible laser radiation – avoid eye or skin exposure to direct or scattered radiation. Do not use this Laser System in any manner other than as described in this User Manual. Do not use the Laser System if you suspect it is not functioning properly; contact BIOLASE for assistance.

🗩 **NOTE:** For Canada, this device must be installed, operated, and maintained according to the current revision of the guidelines specified in the Canadian standard CAN/CSA-Z386-2014, *Safe use of lasers in health care*.

6.2 SAFETY CLASSIFICATION

The following safety classifications are applicable to the device:

- Laser Radiation - Class 4

- Aiming Beam - Class 1

- Type of protection against electrical shock - Class 1

- Applied part, laser Handpiece – Type BF

- Not protected against water ingress - Ordinary Equipment

- Console - IPX0

- Wired Footswitch - IPX8

- Wireless Footswitch – IPX6

- Not suitable for use in the presence of flammable anesthetic

- Not suitable for use in oxygen-rich environments

- Operation Mode – Free-running pulsed

⚠️ **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 of adhesive and flammable solutions used to cleaning and disinfecting should be allowed to evaporate before the laser equipment is used.

6.3 SAFETY INSTRUCTIONS

Follow these safety instructions before and during treatments:

1. Remove or cover all highly reflective items in the treatment area, if possible.

2. **Do not** operate in the presence of explosive or flammable materials.

3. All persons present in the operatory, including patients, must wear protective eyewear suitable for blocking 2.78 μm (2780 nm) laser energy, OD4 (DI LB3) or greater.

⚠️ **CAUTION:** Prior to use, inspect eyewear for pitting and cracking; **do not use if damaged**. For replacements or additional protective eyewear, please contact BIOLASE Customer Service or your authorized local BIOLASE representative.

4. **Do not** look directly into the beam or at specular reflections.

5. Direct the cutting spray toward targeted tissues only.

6. Place the laser system in **Standby** mode by pressing the Function Control button on the Tablet Holder **before** changing the water in the patient water bottle, installing the Fiber Optic Cable, attaching the Handpiece, changing a Fiber Tip, and turning off the laser system.

⚠️ **CAUTION:** Only remove the Patient Water Bottle when the system is in **Standby** mode; the Patient Water Bottle is pressurized while the system is in **Ready** mode.

7. Switch the circuit breaker to the OFF (O) position and remove the key before leaving the laser unattended for long periods of time.

8. All operatory entrances must be marked with an approved warning sign (included with the laser system) indicating a laser is in use.

⚠️ **DANGER: DO NOT** open the side doors of the console as danger from radiation exposure and high voltage may exist. These are to be opened only by authorized BIOLASE service personnel.

9. Take special care to contain the laser plume, i.e., particles produced by the vaporization of virally or bacterially infected tissue, during procedures utilizing the laser **with minimal or no water spray**. Ensure that all appropriate protective equipment (including high-speed suction to remove the plume, appropriate masks, and other protective equipment) is used at all times during procedures.

📝 **NOTE:** Please direct any safety questions to your authorized BIOLASE representative; US and Canada, call BIOLASE at **(888) 424-6527**, or BIOLASE Service at **(800) 321-6717**.

6.4 SAFETY FEATURES

ENERGY MONITOR

The energy monitor checks power output. Power deviations of more than ± 20% and ± 50% for power levels below 1 Watt from the selected value will cause the display to show the error message "Internal HV System Error", the laser will not operate until the error is resolved, at which time the laser will be in **Standby** mode; if the error message persists, please contact BIOLASE Service or your authorized BIOLASE representative.

SYSTEM MONITOR

Waterlase Express continually monitors all system functions, including the Fiber Optic Cable, water bottle status, air status, voltage, Tablet connection, and Footswitch connectivity. An error in any one of these areas will stop the system and the Tablet will display an error message. Operation cannot resume until the error is cleared. If the Tablet is not properly connected to the laser, the system will stay in **Standby** mode until the Tablet is installed and the error is cleared.

EMERGENCY STOP

The emergency stop (red) button is located on the front panel of the laser console. Pressing this button instantly stops the emission of laser energy; the button will glow red to indicate an emergency stop has taken place and the screen will display the message "Emergency Stop Pressed." To restart the laser system, press the button a second time (the system will be activated in **Standby** mode).

REMOTE INTERLOCK

When used, this feature enables a cable to connect the laser to a remote switch/sensor attached to a door. When the remote switch is activated, for example when the entrance door to the operatory is opened while the laser is firing, it will immediately turn the laser off, protecting anyone entering from inadvertent exposure to laser radiation.

> **NOTE:** The remote interlock plug must be installed in the console in order for the system to operate, even if the remote interlock function is not used.

FOOTSWITCH

Waterlase Express will only emit laser energy when the user presses down on the Footswitch while the laser is in **Ready** mode. The Footswitch Cover shields the Footswitch to prevent it from being pressed unintentionally. The protective cover can be opened or closed only by pressing down on it.

If the wired Footswitch is installed when the laser is in **Ready** or **Firing** mode, an error message will appear on the display screen, "Wired Footswitch Detected." Press "OK" at the bottom of the screen to clear the error; the system will revert to **Standby** mode. Switch to **Ready** mode to begin the procedure.

If the wired Footswitch is disconnected when the laser is in **Ready** or **Firing** mode, an error message will also appear on the display screen, "Footswitch Not Detected." Either re-connect the wired Footswitch, or install a wireless Footswitch.

> **NOTE:** Make sure the wired Footswitch is disconnected and turn the laser OFF, then ON, before installing the wireless Footswitch. If the wireless Footwitch was previously paired to the laser, simply press on the Footswitch to clear the error. However, if the wireless Footswitch is new, or has not been previously paired to the laser, proceed to pair the Footswitch and laser as outlined in Section 12.

CIRCUIT BREAKER

The circuit breaker serves as a line switch to separate the console from the main power supply (O = OFF, I = ON).The Waterlase Express laser system must be unpacked and installed by a qualified BIOLASE employee or agent. Please leave the shipping container unopened until your trained representative arrives.

7 Installation and Set-Up

7.1 FACILITY REQUIREMENTS

> **NOTE:** The main power supply of the Waterlase Express laser system has an isolation transformer that complies with a Transient Voltage of 4kV.

ELECTRICAL SUPPLY: 100VAC @ 6.0 Amps max to 240VAC @ 3.0 Amps, 50/60 Hz

COMPRESSED AIR SUPPLY: 60 -120 psi (4.1 – 8.2 bar)

> ⚠ **CAUTION:** Moisture in the air supply line may damage the laser system. Always provide an air dryer, mist separator, and proper filtration at the compressor output to eliminate all moisture from the air source. If water is introduced into the air supply line call your authorized BIOLASE service representative for assistance.

7.2 ENVIRONMENTAL REQUIREMENTS

TEMPERATURE: 15 – 30 °C

HUMIDITY: 20% - 80%, non-condensing

ATMOSPHERIC PRESSURE (altitude):

> **Functional:** 80KPa (2000 meters) to 102kPa (-56meters)

> **Storage:** 50KPa (4944 meters) to 102KPa (-56 meters)

AIR SUPPLY: Connections for an air supply must be available in each operatory. Attach an air hose with a ¼ inch outside diameter male quick connector on each end between the air inlet connector and the operatory air source.

> ⚠ **CAUTION:** Prior to connecting the yellow air hose, verify that the outlet is for the air, NOT the water supply. Connection to the water supply may cause damage to the Waterlase Express system. If the laser system is connected to the water supply, DO NOT turn the system on; contact your service representative. Any damage resulting from connecting the air line to the water supply is not covered by the system warranty.

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

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

7.3 SETUP REQUIREMENTS

The Waterlase Express is designed to be transporable between operatories either manually, using the console handle, or by wheeling it on the custom cart offered as a system option. In either case, prior to use the laser must be properly set up, as described in this user manual, to ensure safe and efficient functionality.

7.3.1 CONNECTING THE LASER SYSTEM

To ensure proper operation, always place the laser console upright on a flat, clean, dry surface a minimum of four (4) inches from any wall.

> ⚠️ **CAUTION:** Waterlase Express ships from the factory with the internal cooling water reservoir empty. Before first-time use, the reservoir must be filled with distilled or de-ionized water using the reservoir fill kit included with the laser system. For instructions on how to rill the reservoir, refer to Section 12.10. **DO NOT USE TAP WATER.**

1. Verify the main power switch is in the OFF position.

2. Verify the Keyswitch is in the OFF position.

3. Connect the power cord to the rear of the console.

4. Verify the minimum air pressure of 60 psi (4.1 bar) is emitted from the air supply (max 120 psi, 8.2 bar). Using air pressure greater than 120 psi may damage the internal components of the laser system.

5. Check the air supply for moisture.

6. Connect the air supply to the console's air inlet connector at the rear of the console with the yellow tubing provided.

> ⚠️ **CAUTION: DO NOT** connect the operatory air supply to the console if water or oil is present. The air compressor may need to be drained or cleaned. Install an air dryer, mist separator, and proper filtration. Wet air will damage the laser system. Check the air supply weekly to verify the absence of water and oil.

7.3.2 USING THE REMOTE INTERLOCK

The remote interlock is a safeguard designed to protect anyone who might enter the operatory while the laser is firing without wearing appropriate laser protection eyewear. To utilize this safety feature, the remote interlock plug **(a)** must be wired to a multi-conductor wire and inserted into the rear of the laser console. The other end of the wire **(b)** is attached to a door switch/sensor; if the door is opened, the connection to the switch is deactivated, immediately stopping the laser from firing. Contact BIOLASE or your authorized BIOLASE representative with any questions on how to install this feature.

> **NOTE:** The plug must be installed into the console in order for the laser to work, whether or not the remote interlock function is used (Figure 7.1). Cable is not included.

(a)

(a)

(b)

Figure 7.1

7.3.3 INSTALLING THE HANDPIECE HOLDER

The Handpiece Holder is packaged as a separate item in the system packaging. Attach it to the Tablet Holder utilizing the smaller of the two screws and Allen wrenches provided (Figure 7.2):

1. Grip the Handpiece Holder with the cradle facing the same direction as the Tablet Holder (Figure 7.3).

2. Slide the Handpiece Holder into the slot at the back of the Tablet Holder (Figure 7.4) until the holes in both pieces are aligned.

3. Insert the smaller of the two screws provided into the hole and tighten with the smaller Allen wrench.

> **NOTE:** The Handpiece Holder can be installed on the left side of the Tablet Holder, if preferred. To do so, the cradle must be rotated; remove the two screws holding the cradle to the flat surface of the Handpiece Holder, rotate it 180 degrees, then reattach it, again using the two screws.

Cradle

Figure 7.2

Figure 7.3

Figure 7.4

7.3.4 INSTALLING THE TABLET

The Tablet is attached to the console by a USB connector incorporated inside the bottom of the control panel. Holding it parallel to the Tablet Holder, slide the Tablet downward into the Holder/Control Panel so that it makes contact with the USB connector, and lock into place by slipping the upper Latch over the Tablet; tighten the thrumbscrew on the back of the Tablet Latch to prevent the Tablet's removal. Once the Tablet is properly connected and active, the LED indicator on the front of the Tablet Holder/ Control Panel will light up.

The Tablet batter is fully charged prior to shipment. However, if it does not turn on when the power button on the side of the Tablet is pressed, take the following steps:

1. Remove the Tablet from the Tablet Holder by either pulling up on the upper two corners or pushing up from the bottom two corners.

2. After connecting the USB cable to the charging adapter, insert it into the Tablet's USB/accessory port at the bottom of the Tablet and plug the charging adapter into a standard AC power outlet. It should take at least 15 minutes to charge the tablet for use on the console. The Tablet will continue to charge when the console is on. International power adapters are provided for the charging adapter

3. Remove the USB cable from the Tablet and replace the Tablet in the Tablet Holder.

Tablet Latch

Tablet Holder/ Control Panel

USB Connector (Inside Holder)

Power Button

Volume

USB/Accessory Port

Figure 7.5

NOTE: When installed, the Tablet will charge only when the system is plugged in and ON. If the system is OFF, the Tablet will not charge.

7.3.5 FILLING THE PATIENT WATER BOTTLE

The patient water bottle provides the water supply for the Handpiece spray. An error message will appear on the screen if the built-in sensor detects the water level is low, or the bottle empty; fill or replace the water in the patient water bottle following the steps outlined below:

1. Make sure the system is in **Standby** mode for at least five seconds; this allows the bottle to depressurize.

2. Push the bottle release button on top of the bottle holder and pull the bottle straight back.

3. Twist the bottle assembly so that the **arrow on the cap** aligns with the **circle on the base** (Figure 7.6); lift the cap off the base.

4. Fill the bottle only with distilled or de-ionized water. **DO NOT USE TAP OR FILTERED WATER.**

5. Replace the cap by matching the **arrow on the cap** to the **circle on the base** (Figure 7.6). Twist the cap clockwise until the arrow on the cap and the arrow on the base are aligned (Figure 7.7).

6. Attach the bottle back into its Holder; make sure the connector is fully engaged.

Figure 7.6

Figure 7.7

⚠ **WARNING:** Be careful when handling the patient water bottle; do not drop or knock it against a hard surface. Even a small crack may cause damage when the bottle is pressurized. **DO NOT USE IF DAMAGED.**

🗩 **NOTE:** BIOLASE recommends replacing the patient water bottle every five years. Refer to the expiration date noted on the bottle label.

7.3.6 INSTALLING THE FIBER OPTIC CABLE SUPPORT ARM

The Fiber Optic Cable support arm is packaged as a separate item in the system packaging. If used, attach it to the laser console using the larger of the two screws and Allen wrenches provided:

1. Remove the triangular plastic plug (Figure 7.8) located on the console handle behind the Tablet Holder (Figure 7.9).

2. Install the Fiber support base; make sure the hole in the base aligns with the hole in the console (Figure 7.10).

3. Place the larger of the two screws supplied, with the lock washer, into the hole and tighten with the Allen wrench.

4. Insert the fiber support arm into the fiber support base (Figure 7.11).

Figure 7.8

Figure 7.9

Figure 7.10

Figure 7.11

7.3.7 CONNECTING THE FIBER OPTIC CABLE

The Fiber Optic Cable dispenses an air/water spray, along with laser radiation, through the Handpiece to the target tissue.

> **NOTE:** It may help to drape the Fiber Optic Cable around your neck for ease of handling as you prepare it for installation.

> ⚠️ **WARNING:** Always hold the Fiber Optic Cable by the fixed collar connector (below the red line). Holding and/or twisting the Fiber Optic Cable, or bending it to a diameter less than 4.0 inches can damage it, making it inoperable.

1. Remove the Fiber Optic Cable from its packaging.

2. Remove the protective silver cap from the proximal end of the fiber; this is the connector that attaches to the Waterlase Express console.

3. Remove the protective cover of the fiber shaft at the distal end and hold the shaft towards any light source; look into the proximal end of the fiber; it should glow yellow, be flat, and clean. Replace the cover.

4. Remove the plastic cover from the laser aperture (do not lose; save for future use).

5. There is a red dot over the two gold pins on the barrel connector; keep these pins oriented to the top of the connector and slowly insert the long central pin into the laser aperture so that the red dot above the pins aligns with the red dot on the aperture (Figure 7.12). Push the connector in until it is fully engaged by holding it by the collar; do not twist or force it into place. Turn the locknut clockwise to fix the Fiber Optic Cable snugly in place (Figure 7.13).

6. Remove the protective cover from the distal end of the Fiber Optic Cable once more and confirm there is no debris on the window, it is clean and not damaged.

7. Carefully place the Fiber Optic Cable with its protective cover, or with the Handpiece connected, in the Handpiece Holder.

> ⚠️ **WARNING: DO NOT APPLY FORCE** when installing the Fiber Optic Cable. Applying force may damage the laser head components and Fiber Optic Cable.

Figure 7.12

Fiber Connector

Locknut

Collar
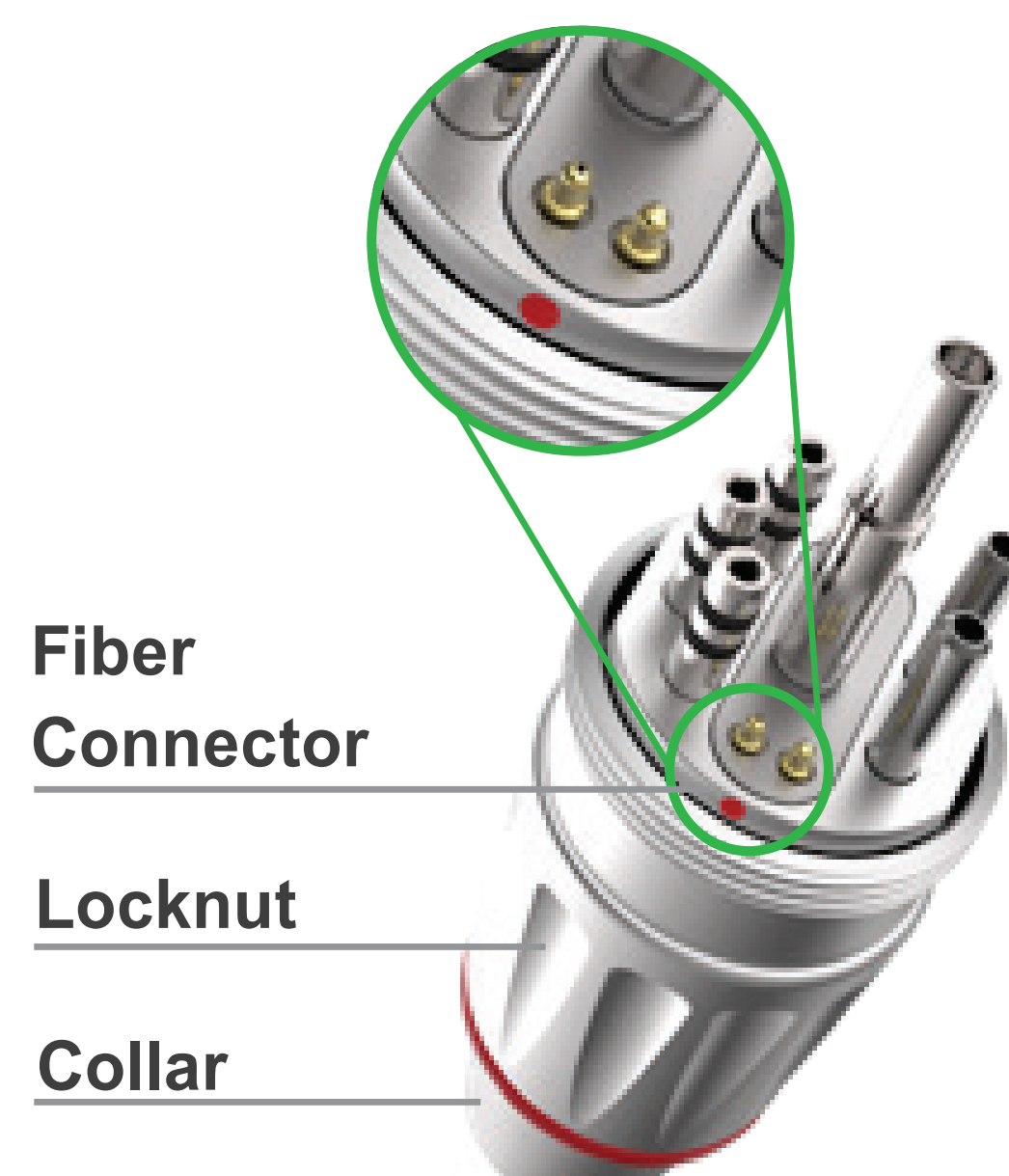
Figure 7.13

7.3.8 INSTALLING THE FIBER OPTIC CABLE RETAINER

The Fiber Optic Cable Retainer is designed to secure the excess length of the Fiber Optic Cable to keep it clear of the Tablet (Figure 7.14).

1. After connecting the Fiber Optic Cable to the laser console, hold the length of the Fiber straight out to remove any twisting, then loop it up towards the hook on the Fiber Support Arm; place the Handpiece into the Handpiece Holder and then insert the Fiber into the hook (keep the black O-ring on the proximal side of the hook.

2. Place the looped portion of the Fiber between the two long tabs of the Cable Retainer (Figure 7.15). Adjust the fiber by sliding it through the retainer to create a natural radius (>2.0 inches). Carefully slide the Cable Retainer onto the space between the Tablet Holder and the Handpiece Holder and snap it into place (Figure 7.16).

3. To remove, push the bottom ends of the tabs back to unsnap them from the Tablet Holder; pull up and over. If they do not move easily, press down on the top fo the Cable Retainer while pushing the tabs.
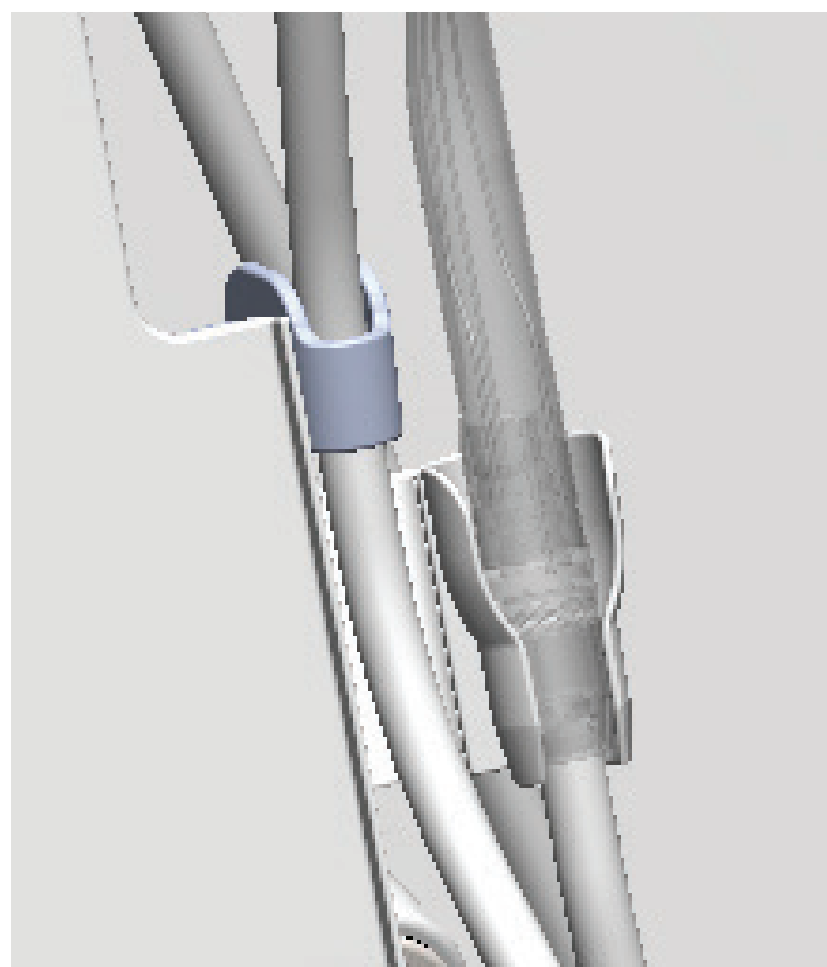
Figure 7.14
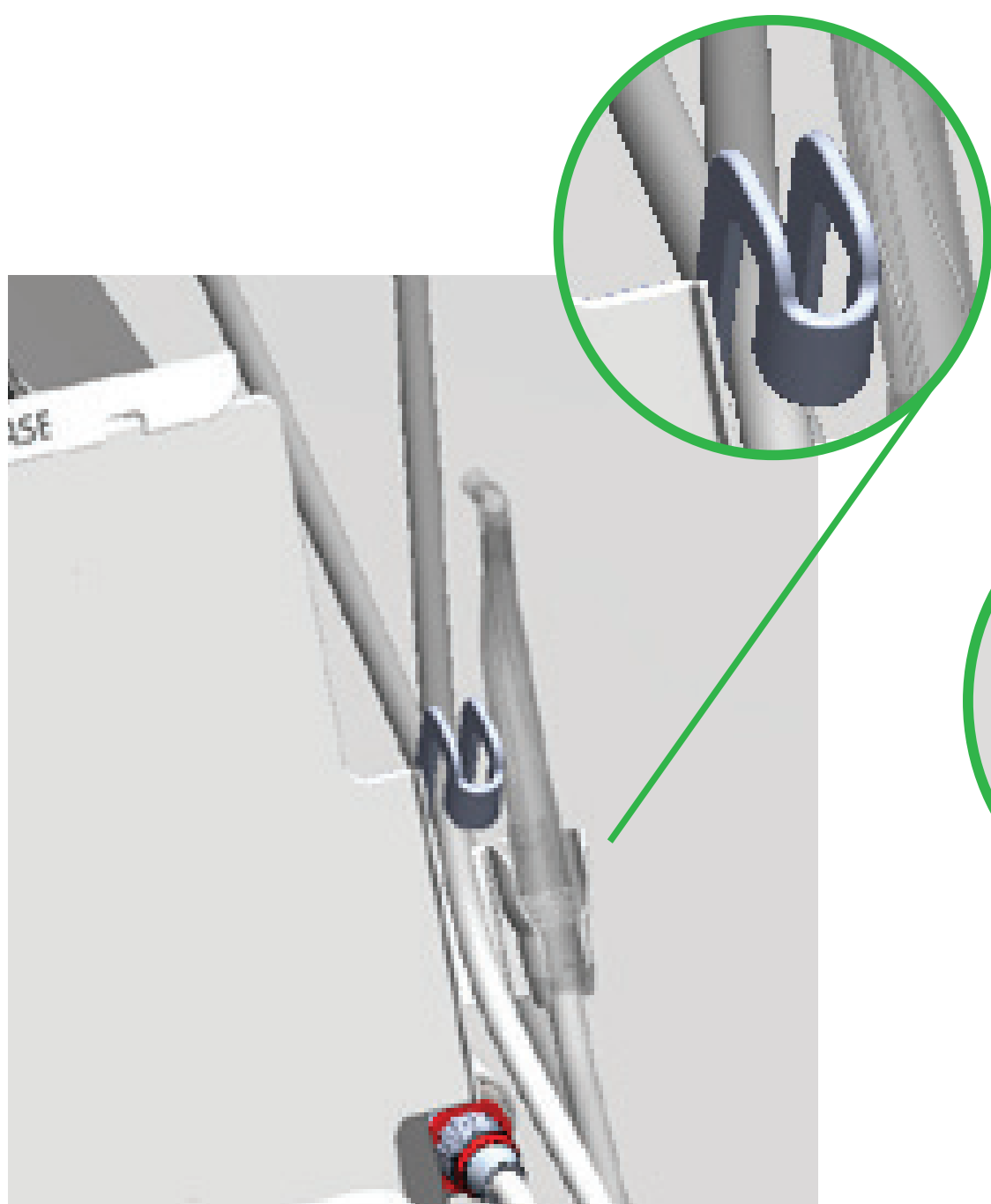
Figure 7.15
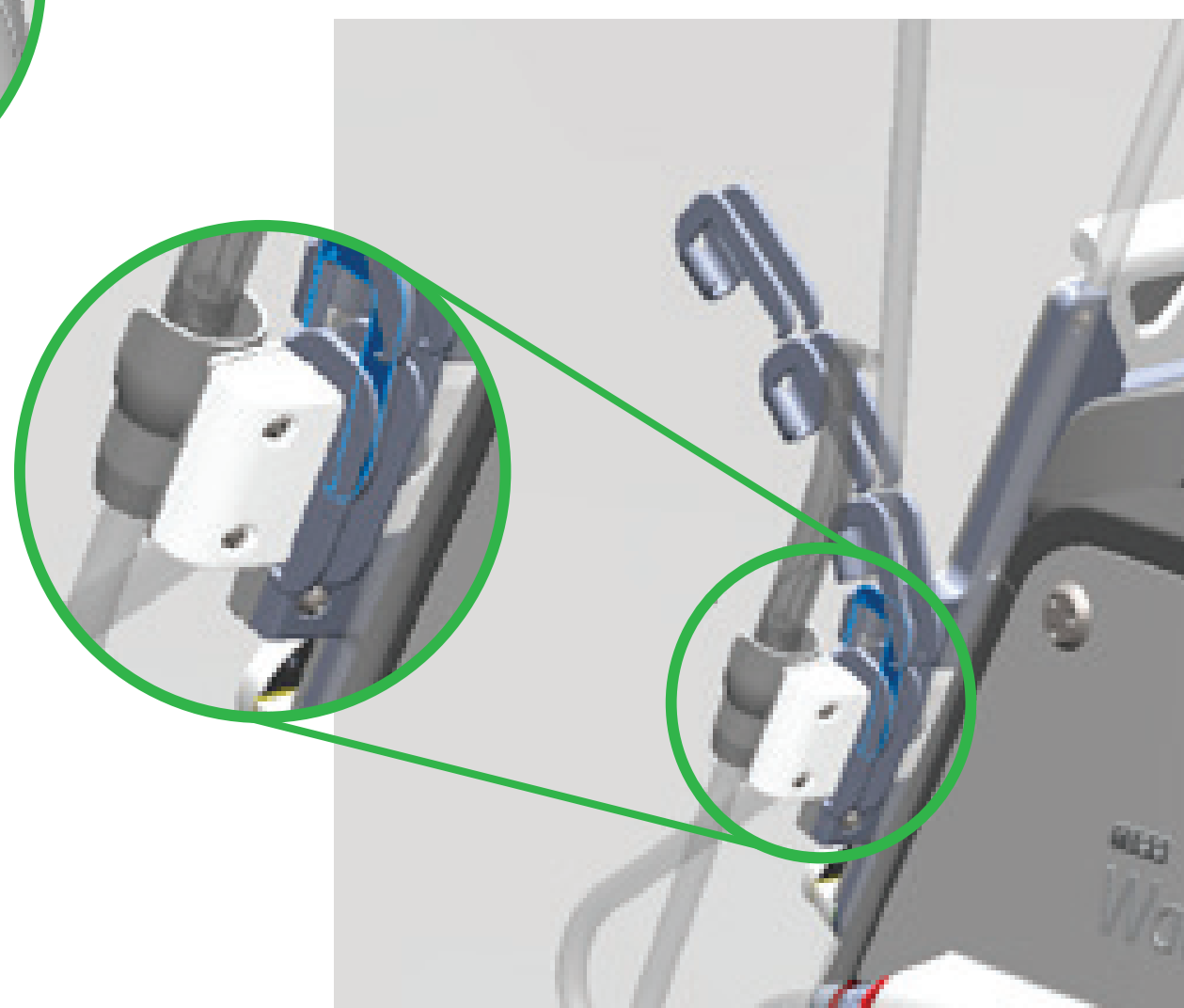
Figure 7.16

7.3.9 CONNECTING/DISCONNECTING THE HANDPIECE TO THE FIBER OPTIC CABLE

> ⚠️ **CAUTION:** Handpieces are not sterile when sold and MUST be sterilized **prior to initial use, and cleaned and sterilized between patients.** Refer to Section 11 for complete instructions on cleaning and sterilization.

1. Remove the rear plug and the Tip plug from the Handpiece. Be sure to save the plugs, as they will always be required when preparing the Handpiece for cleaning and sterilization

Tip Plug

Rear Plug
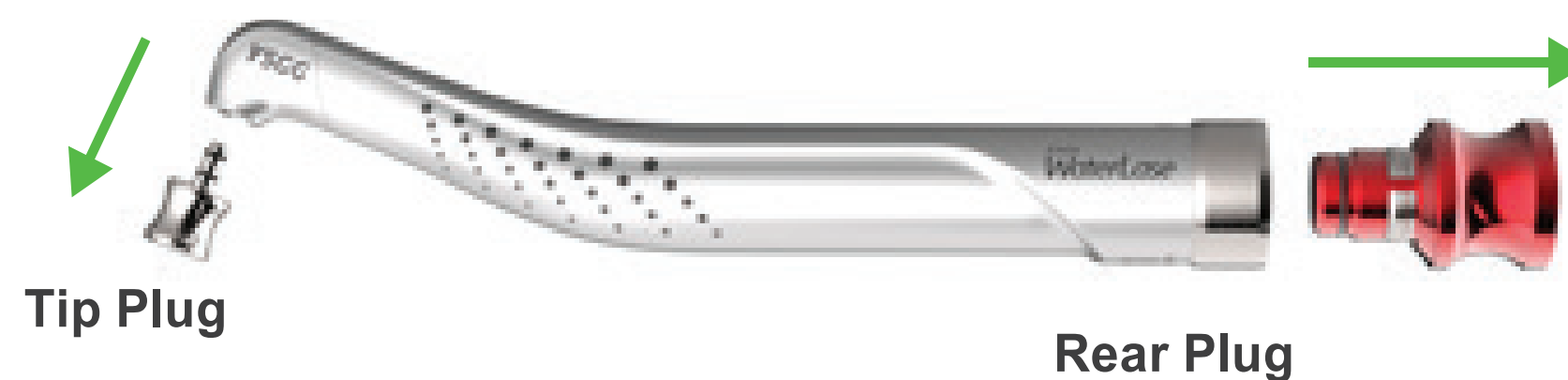
Figure 7.17

2. Hold the Fiber Optic Cable by the connector; remove the fiber protective cover from the fiber shaft gently, but firmly, pulling it; be sure to save the cover.

Fiber Optic Cable

Protective Cover
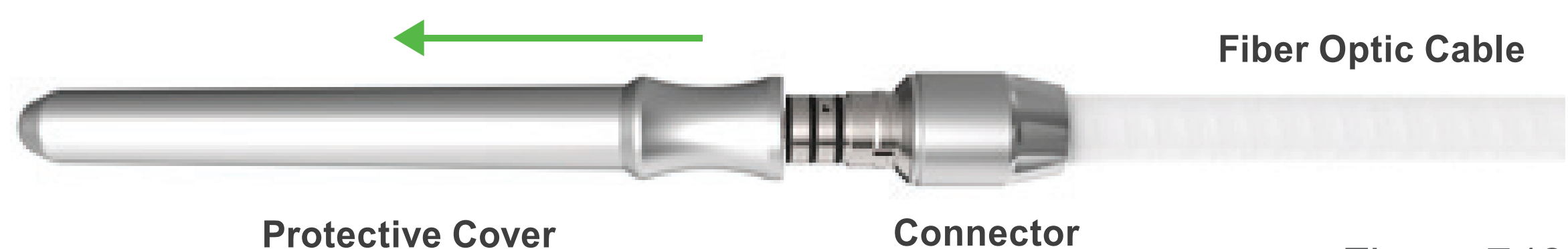
Connector

Figure 7.18

3. Check the fiber shaft for any moisture and wipe with a dry, lint-free tissue if any moisture is present.

Fiber Shaft
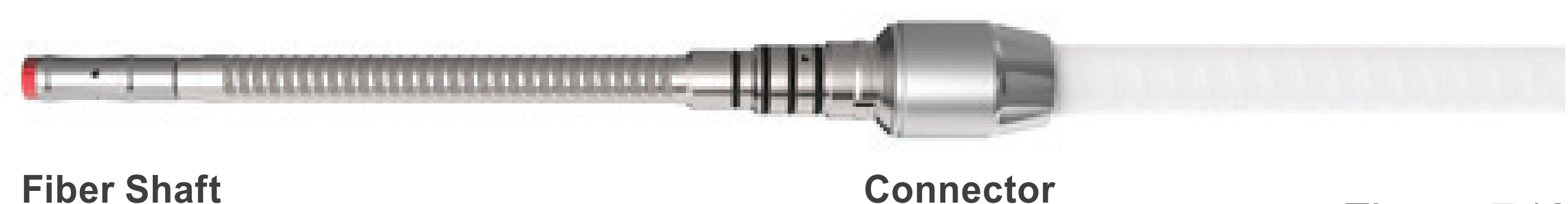
Connector

Figure 7.19

4. Carefully insert the Handpiece onto the fiber shaft until it sits firmly against the connector and clicks into place (do not twist).
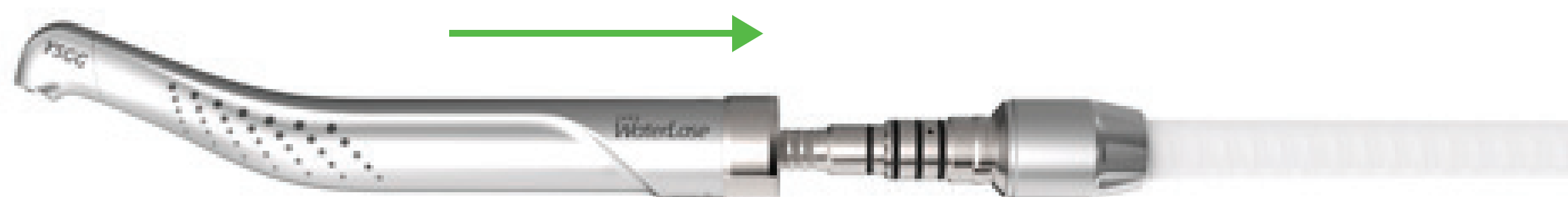
Figure 7.20

5. To disconnect the Handpiece, hold the Fiber Optic Cable by the connector and gently, but firmly, pull on the Handpiece until it comes completely off the fiber shaft. **DO NOT** apply excessive force.

Figure 7.21

7.3.10 INSTALLING AND CHANGING THE TIP IN THE HANDPIECE

A laser tip is installed in the Handpiece to direct the laser energy: based on its shape and length, a tip will focus that energy differently onto the target tissue.

Tips may be installed using the Revolving Tip Holder, which safely holds/stores up to 6 tips at one time (Figure 7.22), or the Tip Remover included with the Handpieces (Figures 7.23, 7.24, 7.25).

Always inspect the Tip prior to use as described in Section 12.

DO NOT use if damaged.

1. Place the system in **Standby** mode;

2. Remove the Tip Plug from the Handpiece head.

3. The tip must be sterilized before initial use and between patients as described in Section 11. If not sterilized in the Tip Holder, remove the Tip from its sterilization pouch and insert it into the Tip Holder or Revolving Tip Holder by aligning the first groove of the Tip ferrule against the receiving edges of the Holder, then sliding the Tip in; using tweezers facilitates this process.

4. Align the Tip orifice of the Handpiece over the input end of the Tip placed in the Tip Holder or Revolving Tip Holder (Figure 7.23).

5. Carefully lower the Handpiece and insert a clean/inpsected Tip all the way until the shoulder of the Tip ferrule sits against the Handpiece head (Figure 7.24).

6. Slide the Handpiece laterally through the slot, away from the Tip Holder or Revolving Tip Holder (Figure 7.25).

> ⚠️ **WARNING:** Never touch the proximal (input) or distal (output) end of the Tip. If the proximal surface is contaminated, it may damage the Tip, Handpiece, and Fiber Optic Cable. Hold the Tip only by the plastic ferrule.

> ⚠️ **WARNING:** Be careful not to hit the proximal (input) end of the Tip against the Handpiece head and not to break the remaining fingers of the plastic ferrule.

Figure 7.22
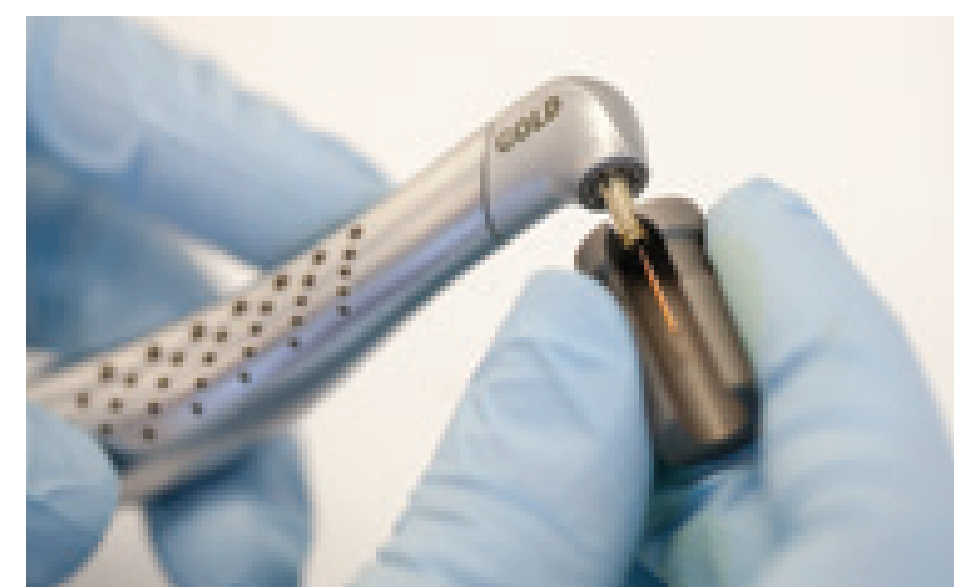
Figure 7.23

Figure 7.24

Figure 7.25

To remove the Tip, repeat this process in reverse order:

1. Slide the Handpiece laterally through the slot toward the Tip Holder or Revolving Tip Holder.

2. Place your thumb against the selected tip slot to prevent the laser Tip from falling out of the Tip Holder when disconnecting it from the Handpiece.

3. Carefully lift the Handpiece to disengage the tip ferrule from the Handpiece head.

4. Use tweezers to slide the Tip out from the Tip Holder or Revolving Tip Holder; discard the used Tip in a medical waste sharps container.

Figure 7.26

7.3.11 FIRST TIME START-UP

First time start-up of the Waterlase Express requires the user to follow a series of steps before initial use:

1. Insert the Tablet in the Tablet Holder; make sure it is turned ON.

2. Turn the power switch at the rear of the console and the Keyswitch at the front of the console to the ON (I) position; the BIOLASE logo screen will appear, and the system software will begin to load (approximately 30 seconds.

3. If no communication with the laser is detected by the Tablet, a screen will appear prompting the user to check that the console is plugged in, the Keyswitch is turned to the ON (I) position, the power switch is ON, and the Tablet is properly docked (Figure 7.26).

4. A "Welcome" screen will display a message encouraging the user to review the User Manual for detailed instructions on how to set up and start the laser. This screen will appear at first-time start-up as long as "Do not show this message again' is checked at this time. Press "Continue" to proceed to the next step.

5. Tap on the blank box; a keyboard will appear. Enter the sytem license code (issued at purchase), press "Continue" Figure 7.27).

6. Enter the doctor's first and last name, telephone number, email, and create a password, as prompted (Figure 7.28).

7. (Optional) Press the Set-Up Wi-Fi button, the system will begin to scan for Wi-Fi networks.

8. (Optional) Select a Wi-Fi network, enter the password for the network selected (Figure 7.29), then press OK (Figure7.30).

9. Initinal set-up is now complete; the system will proceed to the daily start-up menu prime screen (Figures 7.31, 7.32).
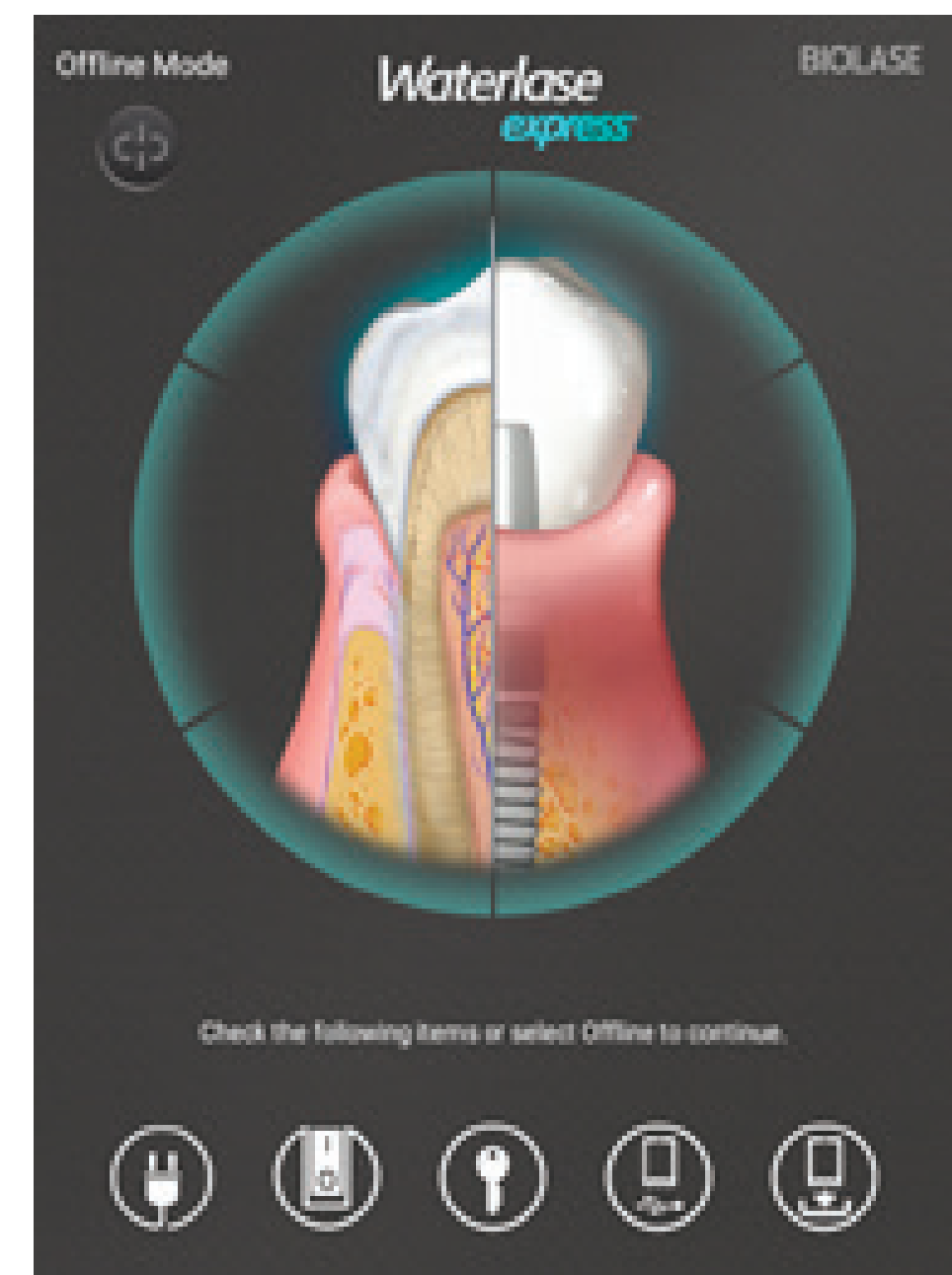
Figure 7.27
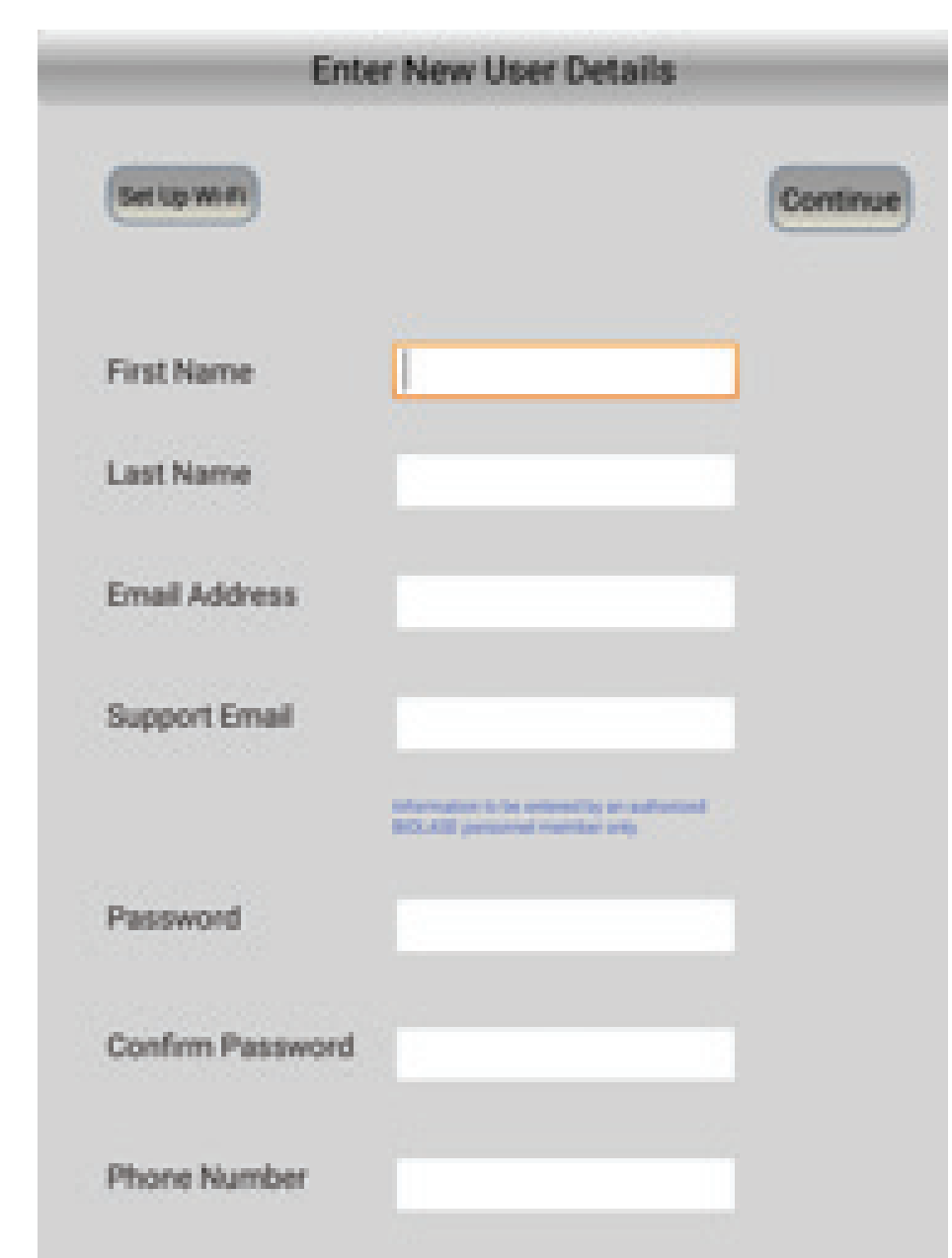
Figure 7.28
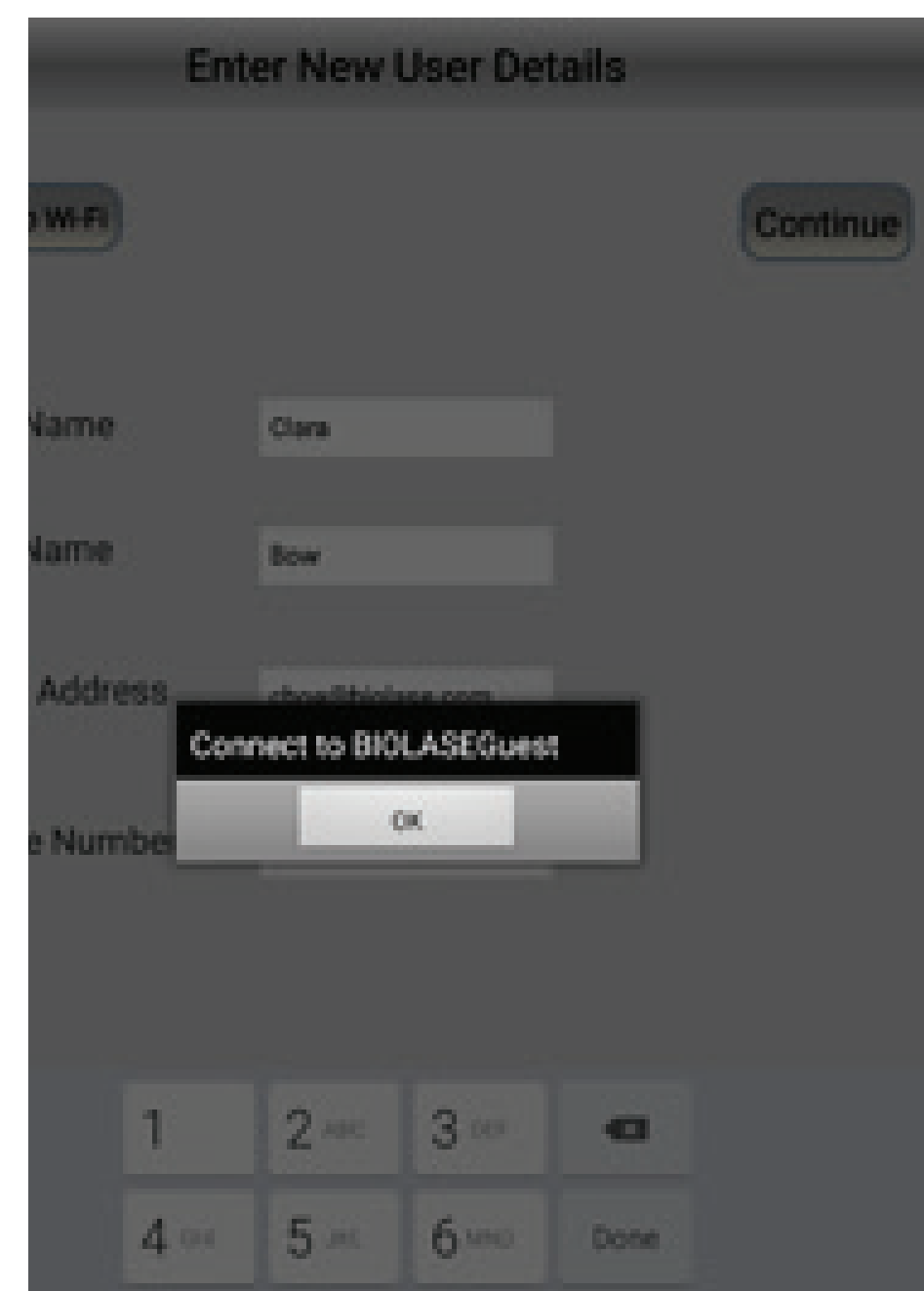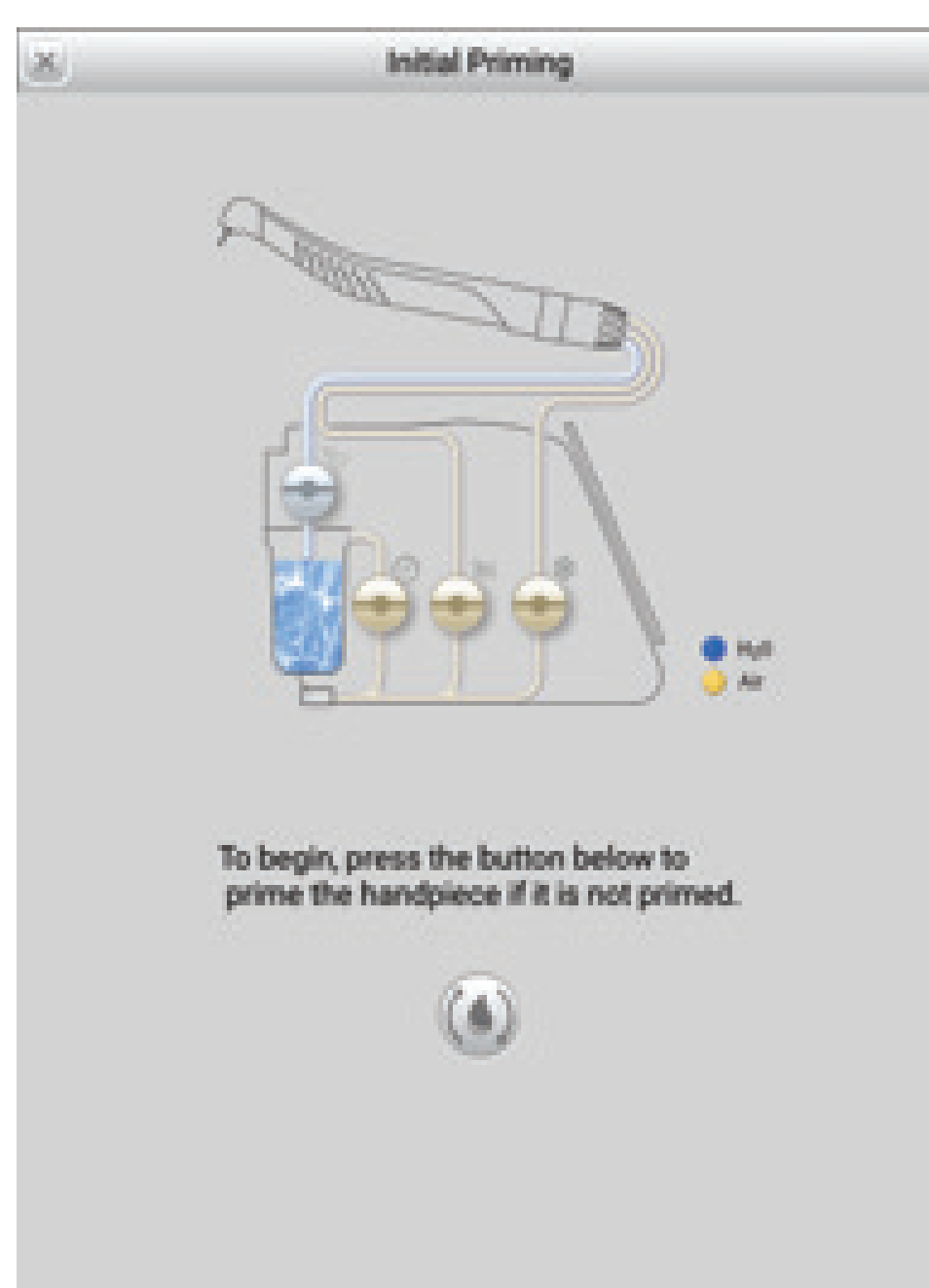
Figure 7.29

Figure 7.30

Figure 7.31
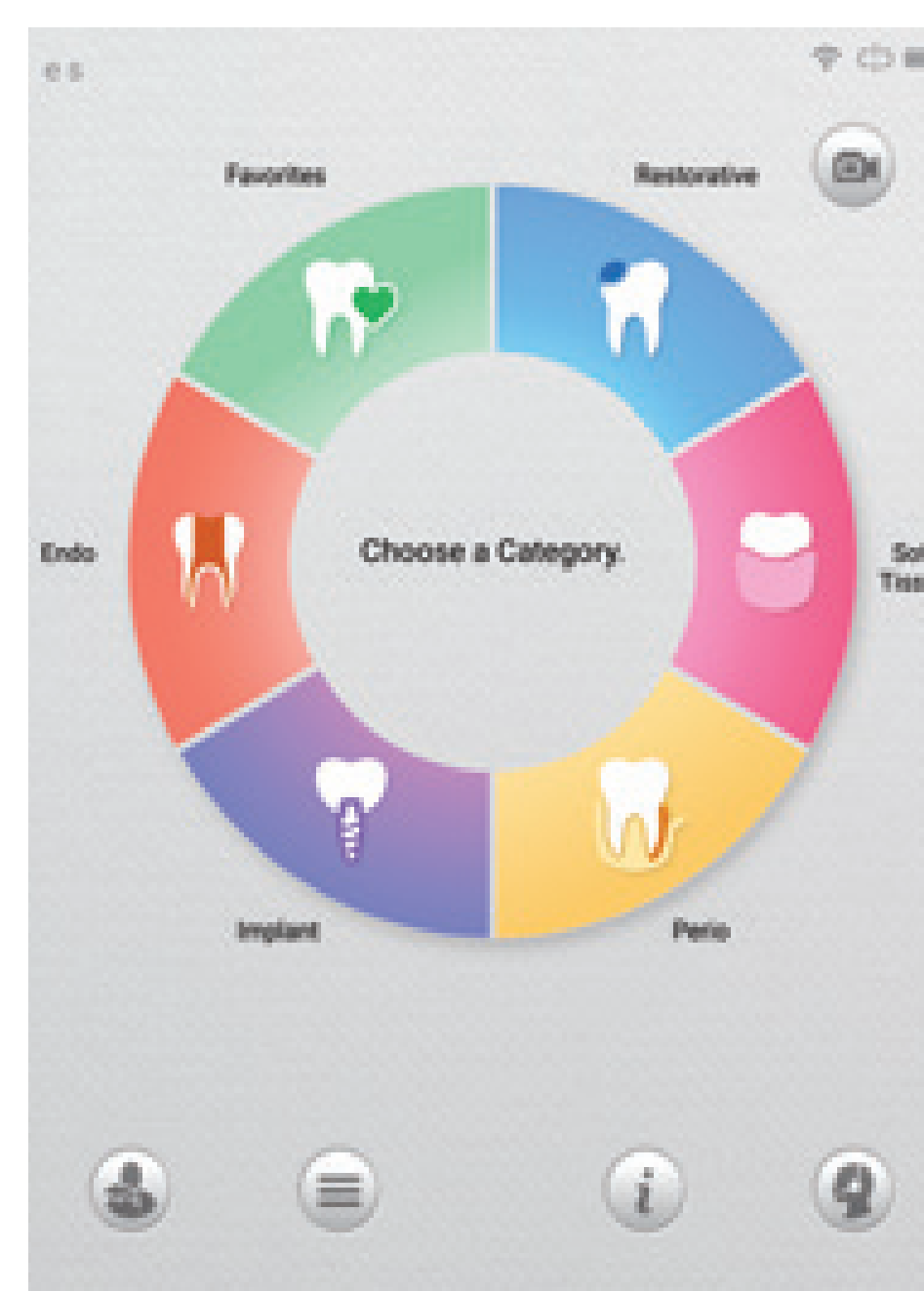
Figure 7.32

7.3.12 ENABLING BIOLASE CONNECT

> **NOTE:** An active wireless connection is necessary to implement this feature on the Waterlase Express. Wi-Fi may be enabled during first-time start-up, or at any later time by going to the main menu and selecting the Wi-Fi option. BIOLASE is not responsible for any internet connectivity issues; these must be reported to the local internet service provider or similar personnel for resolution.

Waterlase Express includes a set of features which allow the user to interact with BIOLASE utilizing Wi-Fi. These features provide direct contact with Customer Care for clinical and/or technical support, automated software and content updates, remote access for diagnostic purposes, access to training tools, courses and study reports, and participation in an Online Forum with other users. However, **no individually identifiable patient data of any kind is accessed or stored on the Tablet itself**.

BIOLASE Connect may be enabled during first-time set-up, or at any later time by going to the main menu and selecting the Wi-Fi option. An active wireless connection is necessary to implement this feature on the Waterlase Express.

> **NOTE:** To contact BIOLASE for technical or clinical assistance, simply press the Call Customer Care button located on the bottom right of most screens. This will automatically generate an email request to BIOLASE Customer Care; a representative will respond via phone as soon as possible (within business hours).

8 Operating Instructions

> ⚠️ **WARNING:** Post the laser warning sign provided with the laser system outside the operatory when the laser is in use. Anyone entering the room must put on appropriate laser protection eyewear before going in. Doctor, patient, assistant, and all others inside the operatory must wear appropriate laser protection eyewear for the 2780 nm wavelength at all times when the laser is active. Prior to use, always inspect eyewear for pitting and cracking. Replace if damaged.

> ⚠️ **WARNING:** Use of controls or adjustments, or performing procedures other than those specified in the User Manual, may result in hazardous radiation exposure.

8.1 OVERVIEW

Before using the Waterlase Express be sure the laser has been installed properly, as described in Section 7 of this user manual, to ensure safe and efficient functionality.

8.2 TABLET HOLDER - FUNCTION CONTROL BUTTON AND LED INDICATORS

The Function Control button, located in the center of the Tablet Holder, activates the controls and display, and is used to place the system into **Ready** (green), **Standby** (amber), or **Sleep** mode.

Status Indicator

Wireless Footswitch Connectivity Indicator

Tablet Connectivity Indicator

Function Control Button
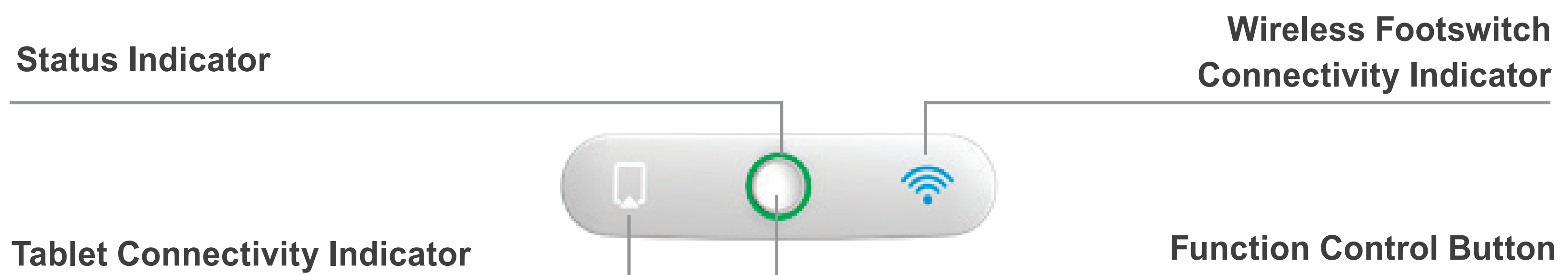
Figure 8.1

There are two LED indicators on either side of the Function Control Button to indicate the Tablet is connected to and to confirm the wireless connection to the Footswitch is active; the Footswitch Connectivity indicator will only light up when the Footswitch and Laser are actively communicating, i.e., the Footswitch is pressed.

> 💬 **NOTE: Ready (green) mode:** The laser is active and prepared to fire once the Footswitch is pressed. The laser will only fire while in **Ready** mode. Laser will revert to **Standby (amber)** mode after 10 minutes of inactivity. When the green LED is *flashing*, the laser is firing.
>
> **Standby mode:** The laser is powered but not operable. To operate (fire), the laser must be in **Ready** mode.
>
> **Sleep mode:** the laser will go to sleep after 10 minutes of inactivity while in **Standby** mode to conserve energy, or by pressing the Function Control button for 3 seconds before releasing; the light around the button will go off. To take the system from **Sleep** mode to **Standby** mode, press and hold the Function Control button again for 3 seconds.

8.3 DAILY START-UP

1. Power up the Tablet. Verify that all connections have been properly secured; turn the main power switch at the back of the console ON (I); insert the key into the Keyswitch and rotate it clockwise to the ON (I) positiion. The LED light on the Tablet Holder lights up when the Tablet is properly powered on and docked in the Tablet Holder, connected and active (if the power switch and Keyswitch are not both ON, the LEDs will not light up.

2. Make sure the air supply is connected and verify that the patient water bottle is no less than ⅓ full with distilled or de-ionized water. It is suggested to completely fill the patienter water bottle at the start of the day.

8.3.1 INITIATING THE LASER FROM OFF STATUS

- Turn the main power switch at the back of the console ON (I) (when the power switch is OFF, LEDs will not light up); insert the key into the Keyswitch and rotate it clockwise to the ON (I) position

- Press and hold the power switch on the right side of the Tablet to turn it on

- The startup screen will appear, and the sytsem software will begin to load (approximately 30 seconds

- Verify that the Footswitch and laser are paired (see Section 12.9)

- Attach the Handpiece to the Fiber Optic Cable (see Section 7.3.9)

- Ensure the Tablet is properly docked in the Tablet Holder and secured with the Tablet Latch; if the Tablet is not properly docked, the screen will stay fixed and the Tablet indicator light on the Control Panel will not light up. However, if the Tablet is docked correctly but cannot communicate with the laser, the error message "Tablet Communication Error" will appear on the Tablet screen; restart both the laser and the Tablet.

- All users configured to the system will be listed on the User selection screen (Figure 8.2); select the proper account. If the system is configured to only one user, this screen will not be displayed

- A screen will appear giving the user the option to prime the Handpiece or skip this step (if the Handpiece is already primed). If "prime" is selected, a message will appear confirming that priming is taking place (approximately 6 seconds) (Figure 8.3)
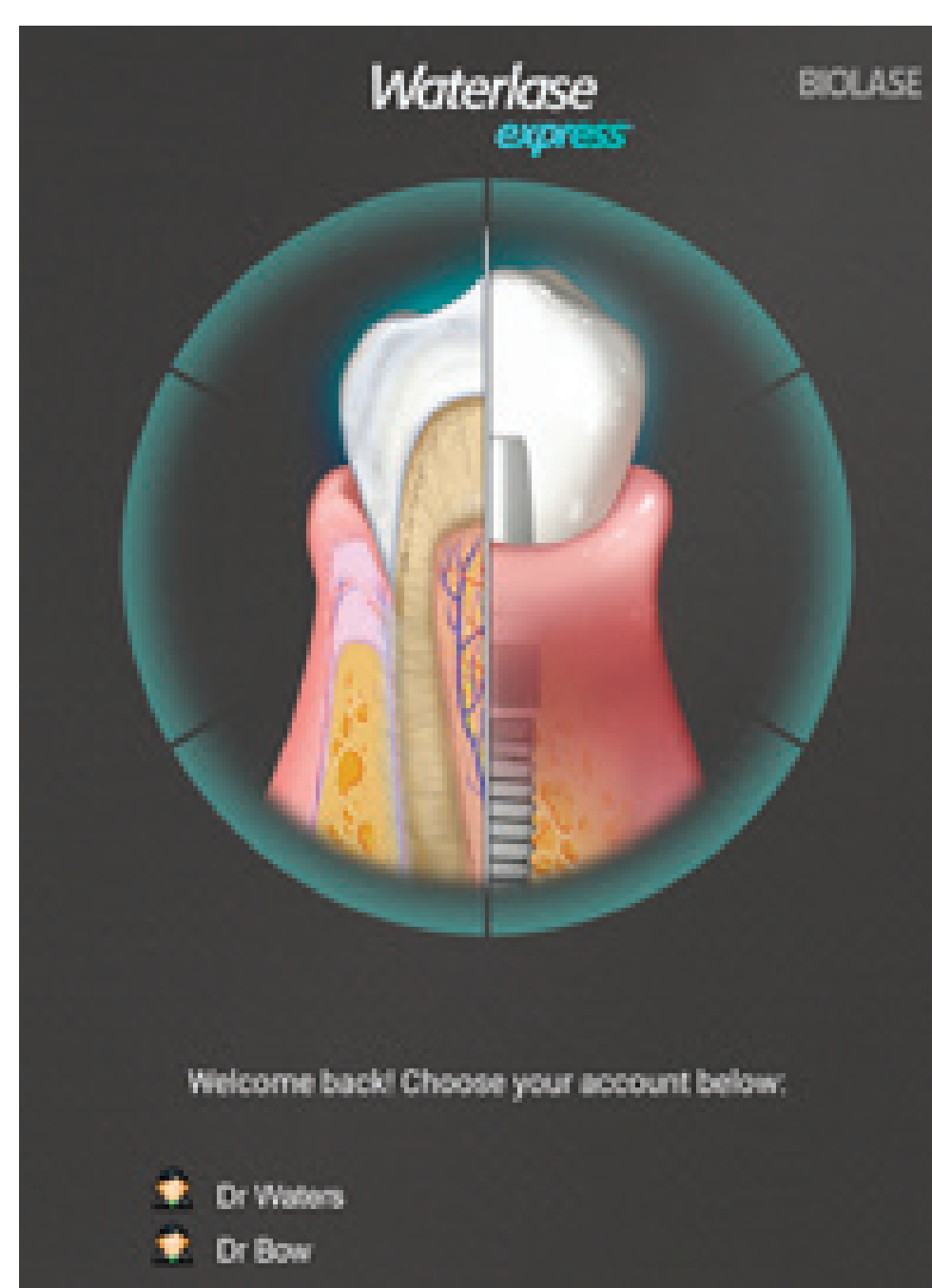
Figure 8.2
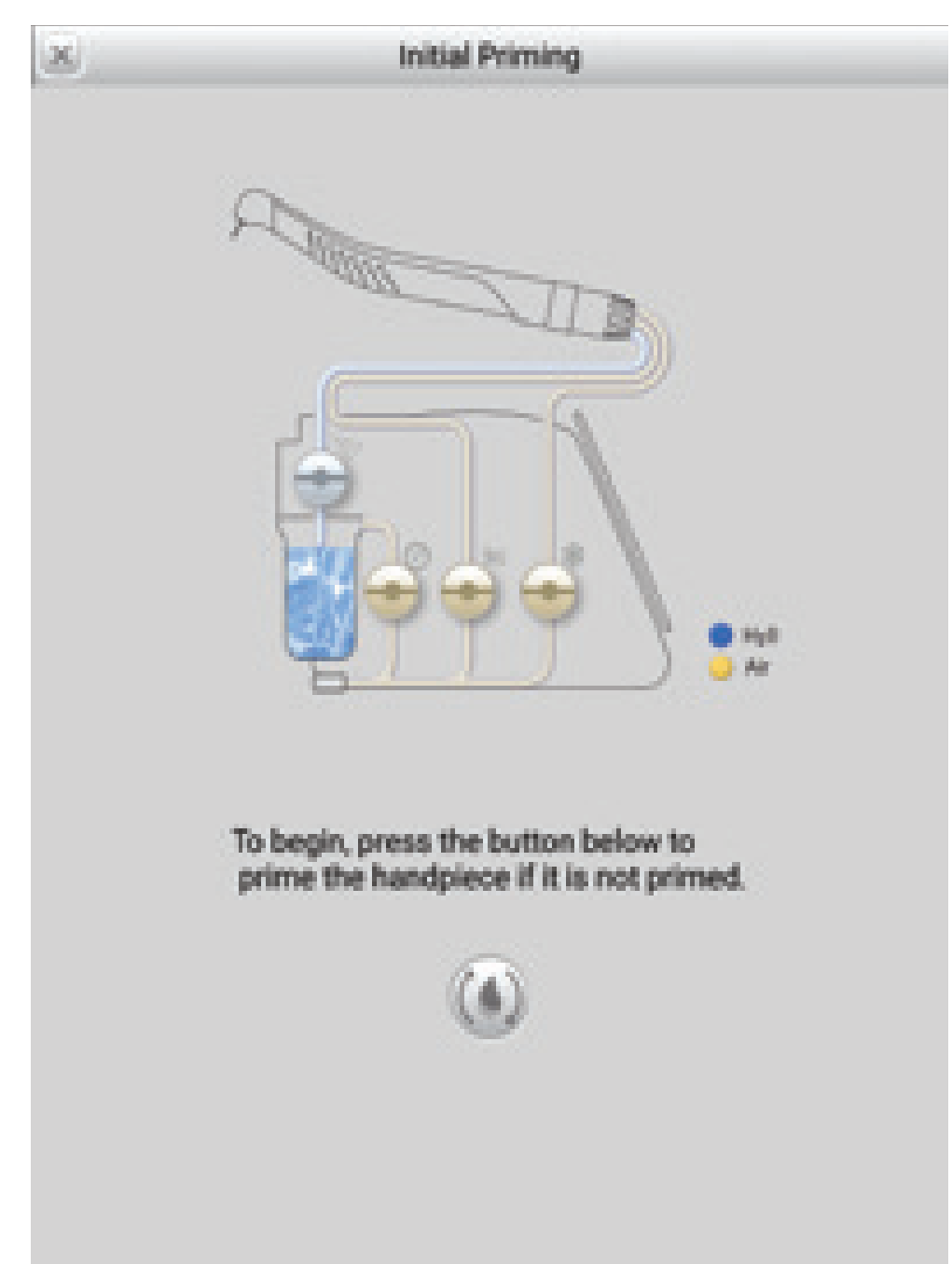
Figure 8.3

8 Operating Instructions

> **NOTE:** The Handpiece must be primed during setup; priming forces water from the patient water bottle to the Handpiece. If priming does not take place, no water will spray from the Handpiece during the procedure. Conversely, the Handpiece should be purged at the end of the day.
>
> To avoid damaging the laser console or Tablet, do not point the Handpiece towards either one during priming, as water will come out of the Handpiece head.

After priming, set-up is complete; the system will now transition to the home (Procedure) screen in **Standby** mode.

8.3.2 WAKING THE SYSTEM FROM SLEEP MODE

When the laser system is not shut OFF (O) at the power switch, the laser and Tablet will go into **Sleep** mode (Tablet will be blank) after 10 minutes of inactivity when in **Standby** mode. The system can also be placed into **Sleep** mode by pressing and holding the function control button for three seconds.

To "wake" the system:

- Press and hold the Function Control Button on the center of the control panel for three seconds

- Press the power button on the side of the Tablet

> **CAUTION:** Make sure the Handpiece is stored in the Handpiece Holder whenever the laser system is powering up or waking from **Sleep** state.

8.4 ACTIVATING THE WATERLASE EXPRESS

Place the system into **Ready** mode after selecting a procedure by pressing the Function Control Button on the Tablet Holder; wait approximately 2 seconds, then press down on the Footswitch when ready to fire the laser.

> **NOTE:** Approximately 2 seconds will elapse between the time the Footswitch is pressed and the laser actually fires. This delay is designed to help prevent the unintentional activation of the laser.

8.5 TURNING THE WATERLASE EXPRESS OFF

While it is not necessary to turn the laser OFF at the end of the day, it is best practice to do so. If the system is not turned OFF, the Tablet will go dark after a period of no activity.

1. Press the logout icon at the bottom of the home screen (Figure 8.4).

2. A screen will appear offering to Switch User or Turn Off/Purge; select "purge" and wait for the process to complete (Figure 8.5).

3. Disconnect the Handpiece and Tip. Dispose of the Tip in a medical waste sharps container.

4. Turn the key counterclockwise to the OFF (O) position.

5. Turn the power switch to the OFF (O) position.

6. Turn the Tablet off by pressing the power button on the side of the Tablet (optional).

> **NOTE:** When the system power is OFF, the Tablet battery will not charge; the Tablet battery charges only when the system is ON. Always turn the Tablet off at the end of the day to conserve its battery charge.

Figure 8.4
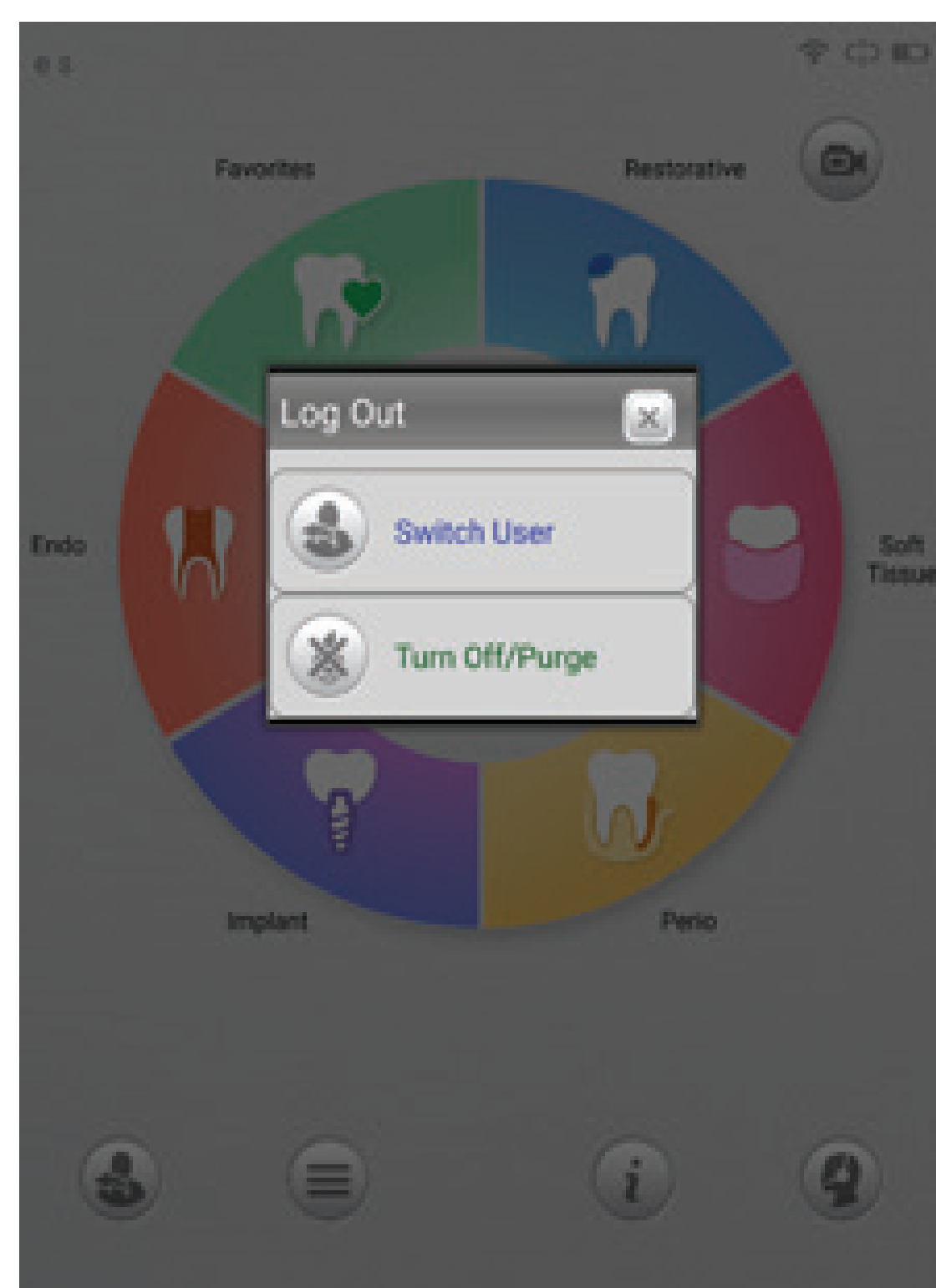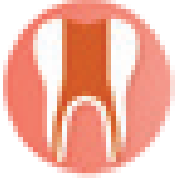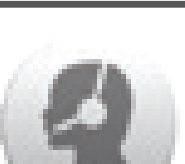
Figure 8.5
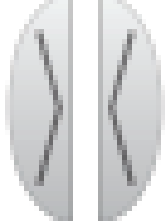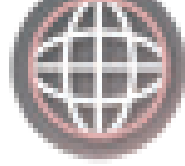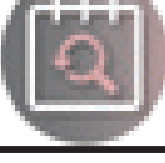
9 User Interface

The graphical user interface (GUI) is the main part of the system control. It communicates with the user through the interactive Tablet screen display and is designed to provide easy and intuitive interaction with the laser system while performing clinical procedures. Buttons on each screen allow easy navigation of the GUI.

9.1 ICONS-DEFINITION

	RESTORATIVE PROCEDURES		IMPLANT PROCEDURES
	SOFT-TISSUE PROCEDURES		ENDO PROCEDURES
	PERIO PROCEDURES		FAVORITES
	MENU System menu		AIMING BEAM (Red light)
	ILLUMINATION (White light)		WATER
	LASER ENERGY		AIR
	HOME Return to Procedures main menu		LEARN User Manual
	VIDEOS and ANIMATION Access animation of procedure/step		CALL CUSTOMER CARE Contact BIOLASE customer care
	TURN OFF/PURGE		PRIME/PURGE
	BACK Back to previous screen		FORWARD Advance to next screen
	STEP UP Increase settings for air/water/ illumination/aiming beam/laser power/pulse rate		STEP DOWN Decrease settings for air/water/ illumination/aiming beam/laser power/pulse rate
	FAVORITES Save procedure/settings to favorites		HANDPIECE Handpiece selection
	DOCTOR CREDENTIALS		TIP Tip selection
	DEFAULT SETTINGS		PULSE PER SECOND

9 User Interface

⚡	PULSE ENERGY	🔓	UNLOCKED Settings are modified but not saved
🔒	LOCKED Modified setting are saved	👤	LOGOUT OR CHANGE USER
⌄	PULL DOWN/UP When pressed, displays/hides additional controls	)(	TAB FORWARD OR BACK Allows going back one screen or forward one screen
⊕	CLINICAL CALL Identifies the CALL as clinical and directs it to BIOLASE customer care	🔧	TECHNICIAN CALL Identifies the CALL as technical and directs it to a BIOLASE service technician
📱	REMOTE ACCESS SUPPORT When pressed by the user, allows BIOLASE Tech support to access the laser system for problem diagnosis/resolution	💾	SAVE
⚙	SETTINGS	🦷	RETURN TO PROCEDURE
🔋	BATTERY STATUS LOW	🔋	BATTERY CHARGING
⊘	OFFLINE Tablet is not connected to the laser system	🔗	STATUS CONNECTION Tablet is connected to the laser system
🌐	WEB PORTAL	📖	LEARNING CENTER
⚙	SETTINGS	ℹ	SYSTEM INFORMATION
🔧	MAINTENANCE	📅	SESSION REVIEW
⌒	LASER STATUS INDICATOR Bottom of screen – Gray = Laser/Tablet not connected	⌒	LASER STATUS INDICATOR Bottom of screen – Green = Laser is **Ready**
⌒	LASER STATUS INDICATOR Bottom of screen – Amber = Laser in **Standby**	⌒	LASER STATUS INDICATOR Bottom of screen – Red = Laser is **Firing**
📱	Place the Tablet in the Tablet Holder	📱	Check Tablet is properly coupled to USB connector
🔑	Turn the Keyswitch to the ON position	🔌	Check the laser system is plugged in
⎉	Turn the power switch to the ON position (I)	📶	Wi-Fi connected. 📵 Wi-Fi not connected.

9.2 MAIN MENU

Press the MENU button at the bottom of any screen to access a number of key features included with the Waterlase Express (Figure 9.1). To return to the menu at any time from any procedure screen, press the MENU button.

9.2.1 LEARNING CENTER

Within this selection the user is offered six options (Figure 9.2):

- Best practices (grouped by procedure)

- News (current industry news, articles)

- Marketing help (current marketing articles and content)

- Training and education (opportunity for learning new procedures, online training, classroom training schedules, short biographies of BIOLASE educators, and upcoming events)

- White papers (grouped by procedure, research, and clinical)

- Videos and animation (grouped by procedure)

Return to Procedure

Main Menu Button

Go Back Button

Figure 9.1

Figure 9.2

9.2.2 SETTINGS

This category allows the user to personalize the laser system in the following areas (Figure 9.3):

- Initial Setup (first-time start-up)

- Modes (choice of Basic or Advanced*)

- User (rename user, add user, clear user, delete user, or restore user data)

- Language

- Wi-FI (enable Wi-Fi, change network, disable Wi-Fi)

- Footswitch Pairing

*Requires the completion of a BIOLASE-sponsored training course to access.

9.2.3 SYSTEM INFORMATION

System Information provides the user with the following data (Figure 9.4):

- Specifications (system specifications and icon glossary)

- Memory

- Software Versions

- Applications

- License Code

- Set Date and Time

Learn Button

Call Customer Care Button

Figure 9.3

Figure 9.4

9.2.4 MAINTENANCE

The Maintenance selection offers the user six options (Figure 9.5):

- Handpiece and Tips
- Purge/prime (starts the purge/prime process)
- Footswitch battery
- Daily
- Service
- System log

In addition, the Remote Access Button, when activated, allows BIOLASE Service to provide remote access support in real time.

9.2.5 SESSION REVIEW

Waterlase Express stores all session information (Figure 9.6), including procedure settings and duration, and allows the user to sort by:

- Date
- Procedure
- Doctor

Remote Access Button

Figure 9.5

Review Categories

Figure 9.6

9 User Interface

> **NOTE:** No patient information is stored in the laser software.

9.2.6 WEB PORTAL

This selection offers the user four choices (Figure 9.7), each accessible only if Wi-Fi is enabled:

- Breaking news (displays a list of latest news items to choose from)

- Discussion forum

- BIOLASE Home

- BIOLASE Store

**Return Home
(Procedures Main) Screen**

Figure 9.7

9.3 HOME (PROCEDURES MAIN) SCREEN

The Home screen displays 6 procedure categories (Figure 9.8):

- Restorative
- Perio
- Endo
- Soft-tissue
- Implant
- Favorites

- For each category, the screen will display a selection menu for that option, offering a choice of up to six procedures (Figure 9.9)

- Once a procedure is selected, the procedure step screen is displayed (Figure 9.10). Choose the desired step to begin the procedure

- A Tip Selection screen appears highlighting the Tip most appropriate for that step, as well as any acceptable alternatives, if there are any (Figure 9.11). After changing the Tip, confirm by pressing the image of the tip installed.

- If changing handpieces, press the Handpiece Selection icon at the bottom of the Tip Selection screen. An image of the recommended Handpiece will appear. Press the image of the Handpiece chosen; the system will purge. Change the Handpiece, then begin the priming process by pressing the prime icon. Once completed, the Handpiece will be ready to use.

> **NOTE:** The Tip selection screen may also be accessed by pressing the Tip selection icon on the lower left of the screen. To exit the screen, a Tip must be selected. If the procedure or step has been chosen in error, a tip **must** still be selected to exit the screen. After exiting, choose the procedure or step desired. The previous choice of Tip, if different, will automatically be superseded.

Figure 9.8
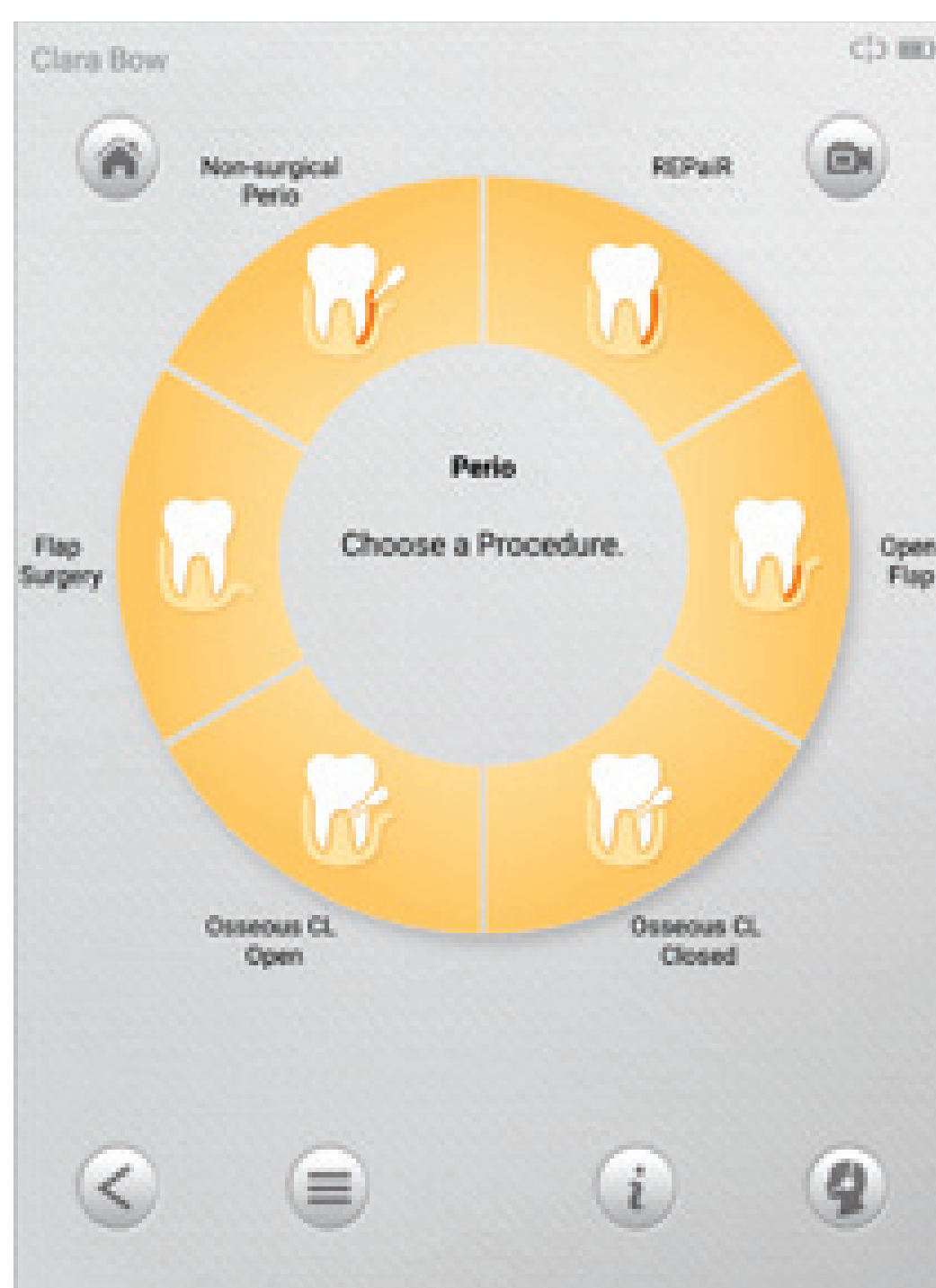
Figure 9.9

Figure 9.10

9 User Interface

- Settings have been pre-programmed at the factory for each step and are displayed in the center of the screen. The user may modify these settings within a set minimum and maximum range, as needed, by sliding the bar at the bottom of the page to the right or left (Figure 9.12)

> **NOTE:** The bar will only move within a prescribed range regulated by the number of settings pre-set for the procedure step. For example, if only one setting is designated for the step, the bar will not move; if two settings are designated, the bar will only move from one to the other, with no settings in-between the two.

- Pressing and holding a step allows the modified setting to be saved, cleared, or saved to favorites (Figure 9.13)
    - **Save** makes the modified setting the default for that step and displays a "lock" icon on the step (Figure 9.15), replacing the "star" icon (Figure 9.14)
    - **Save to Favorites** saves the "new" step values to the selected Favorites slot
    - **Clear** restores the factory default setting
- Press the control button on the Tablet control panel to transition from **Standby** to **Ready** mode, then press the Footswitch to fire the laser
- Continue through each step until the procedure is finished. Press the HOME icon to return to the Procedure screen to prepare for the next patient

> **NOTE:** The Standby/Ready/Firing indicator at the bottom of the Tablet screen is not a button. To change the status of the laser, use the control button on the control panel.
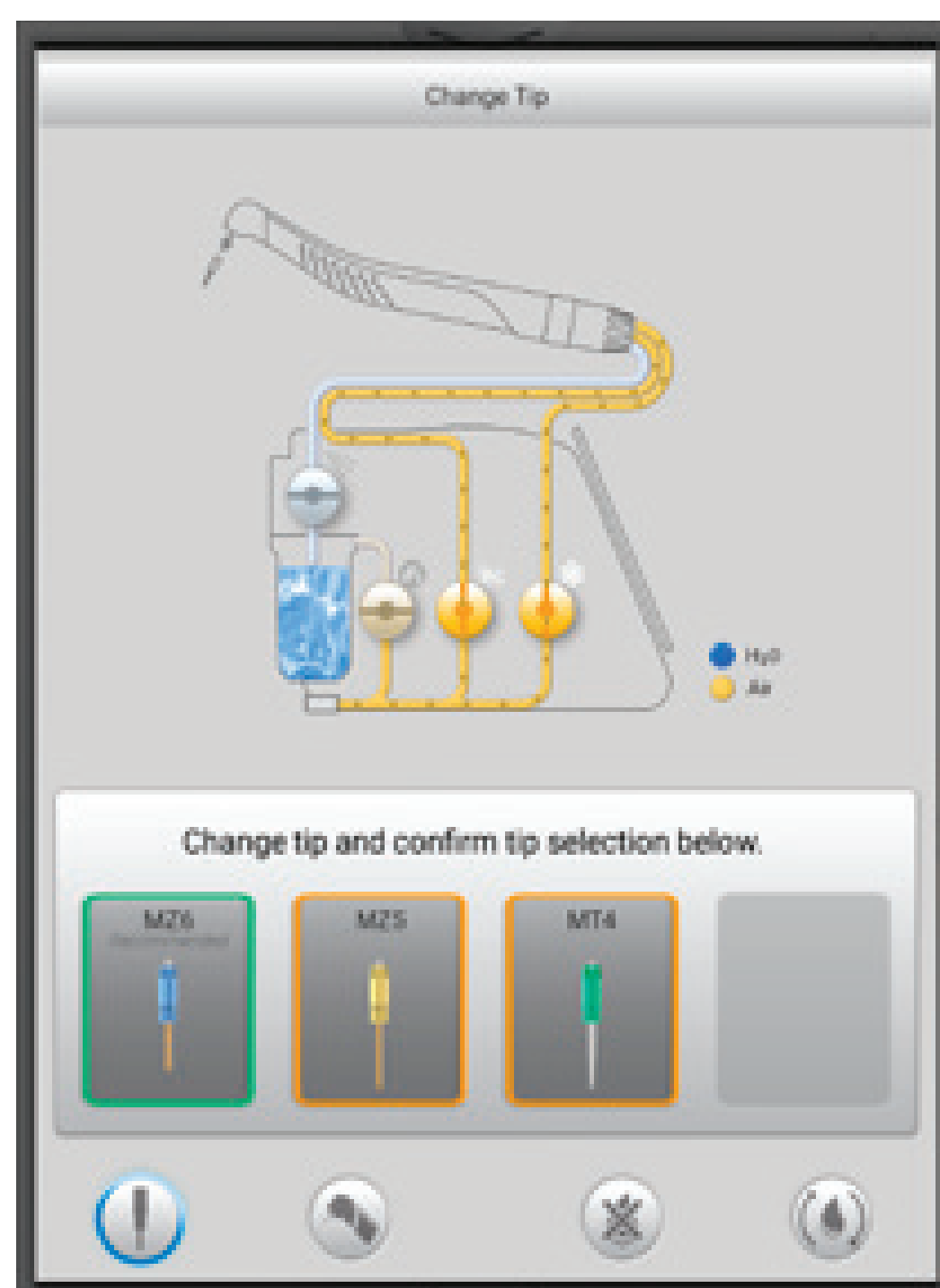
Figure 9.11
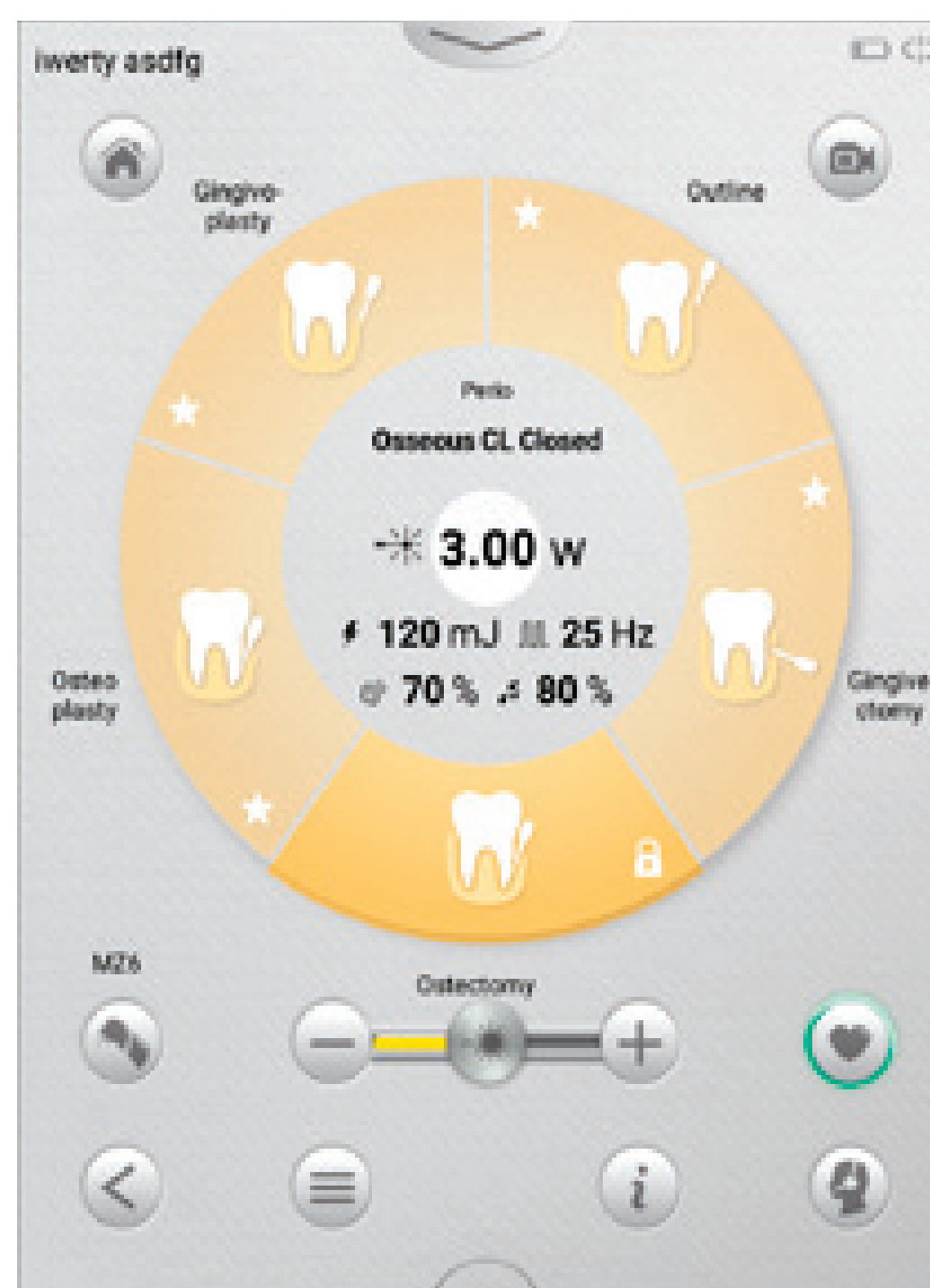
Figure 9.12
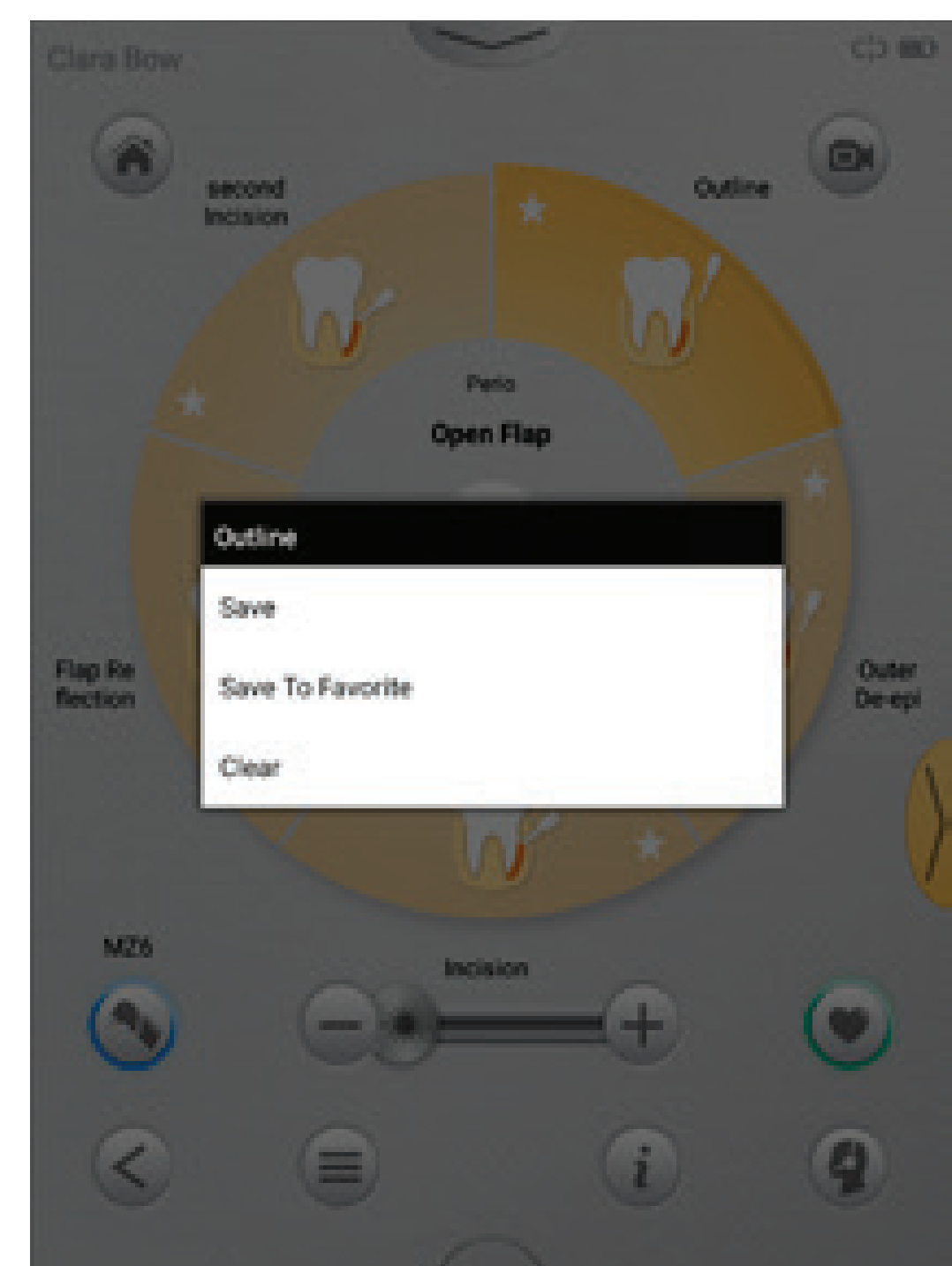
Figure 9.13

9 User Interface

9.4 FAVORITES

The Waterlase Express has the capacity to store up to 12 favorite procedure or step settings. To access settings stored as Favorites, choose the Favorites category on the Procedures Home screen.

9.4.1 CREATE A FAVORITE

Anytime a preset is modified, the star symbol that appears in the step selection segment changes to an unlocked lock. (Figure 9.14, 9.15)
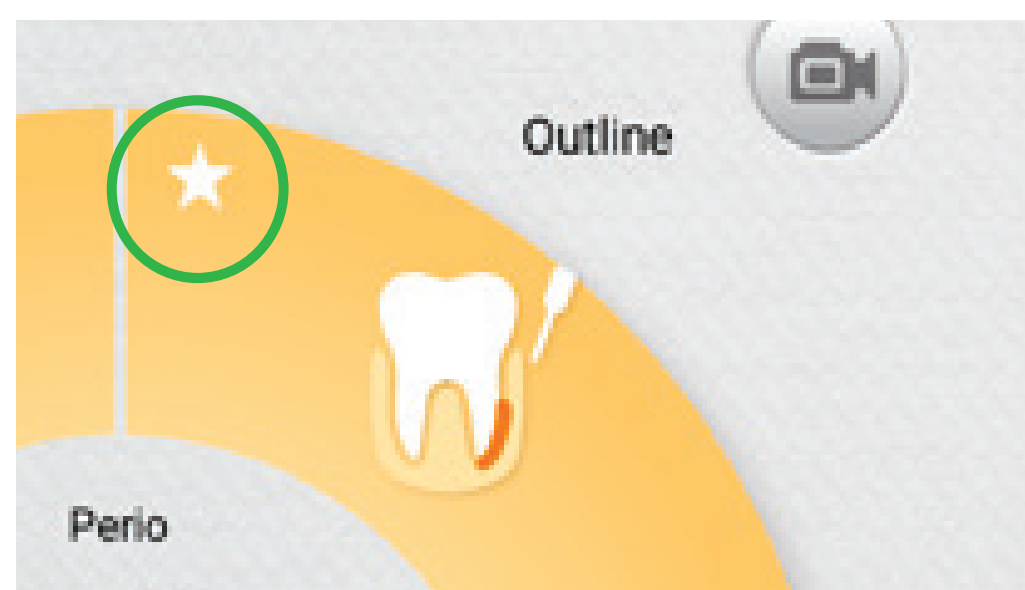
Figure 9.14
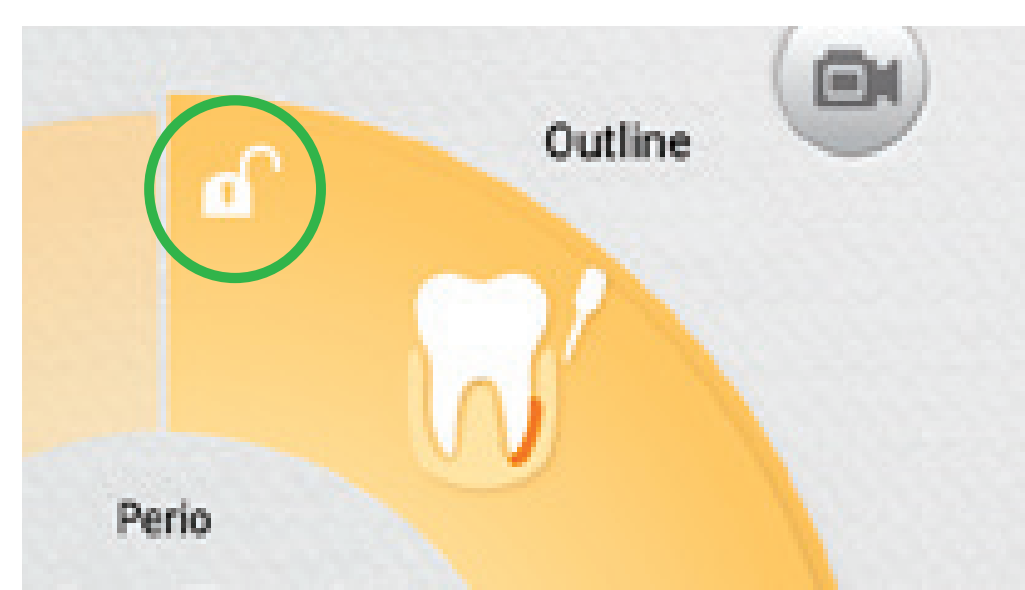
Figure 9.15

To save the changed settings as a Favorite, press the Favorites (heart) icon on the bottom right of the screen.

1. Choose any one of the slots available to save the modified settings as a Favorite (Figure 9.16)

2. Name the Favorite (Figure 9.17)

3. The name will appear in the chosen slot on the Favorites screen (Figure 9.18)
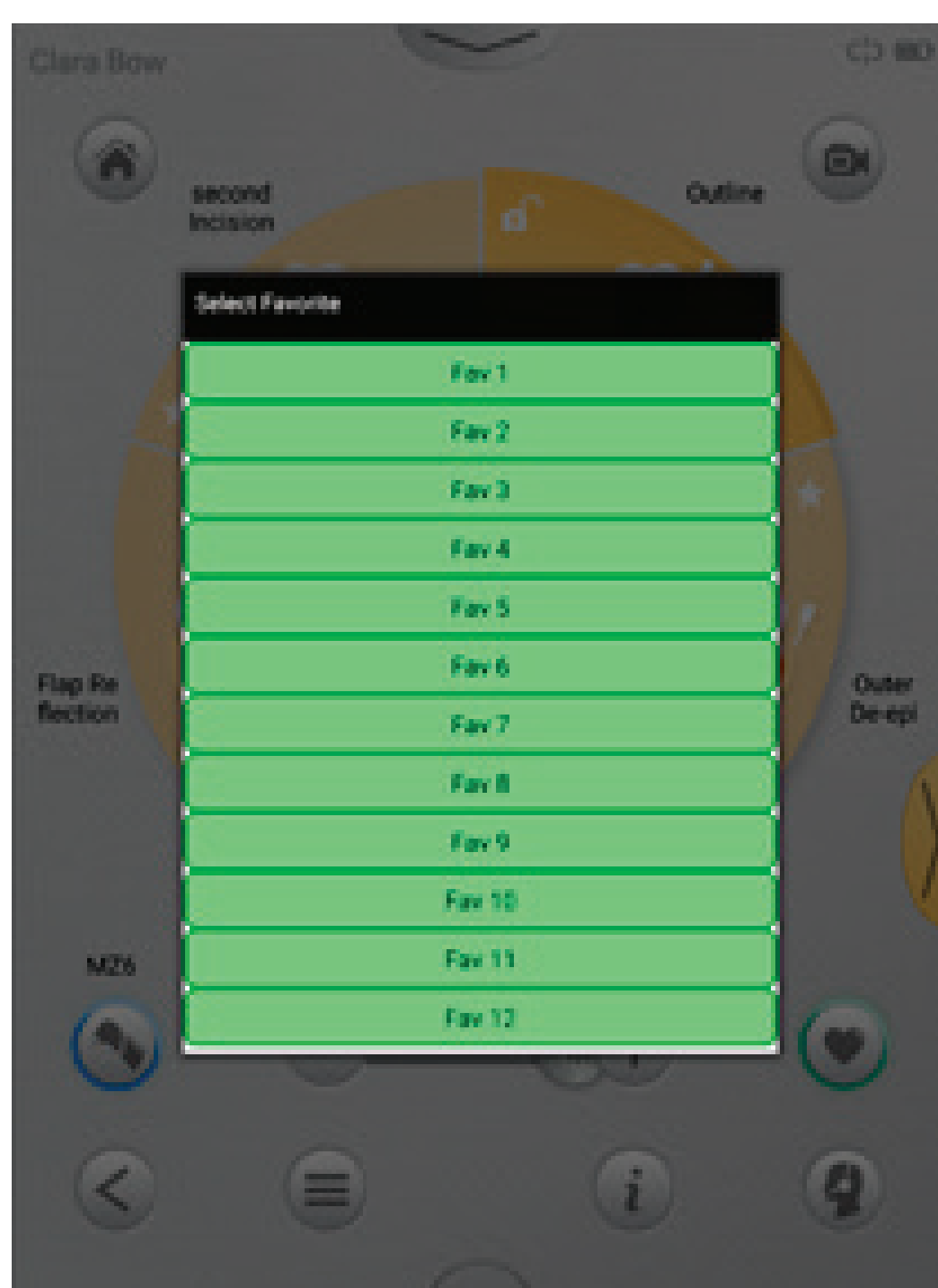
Figure 9.16
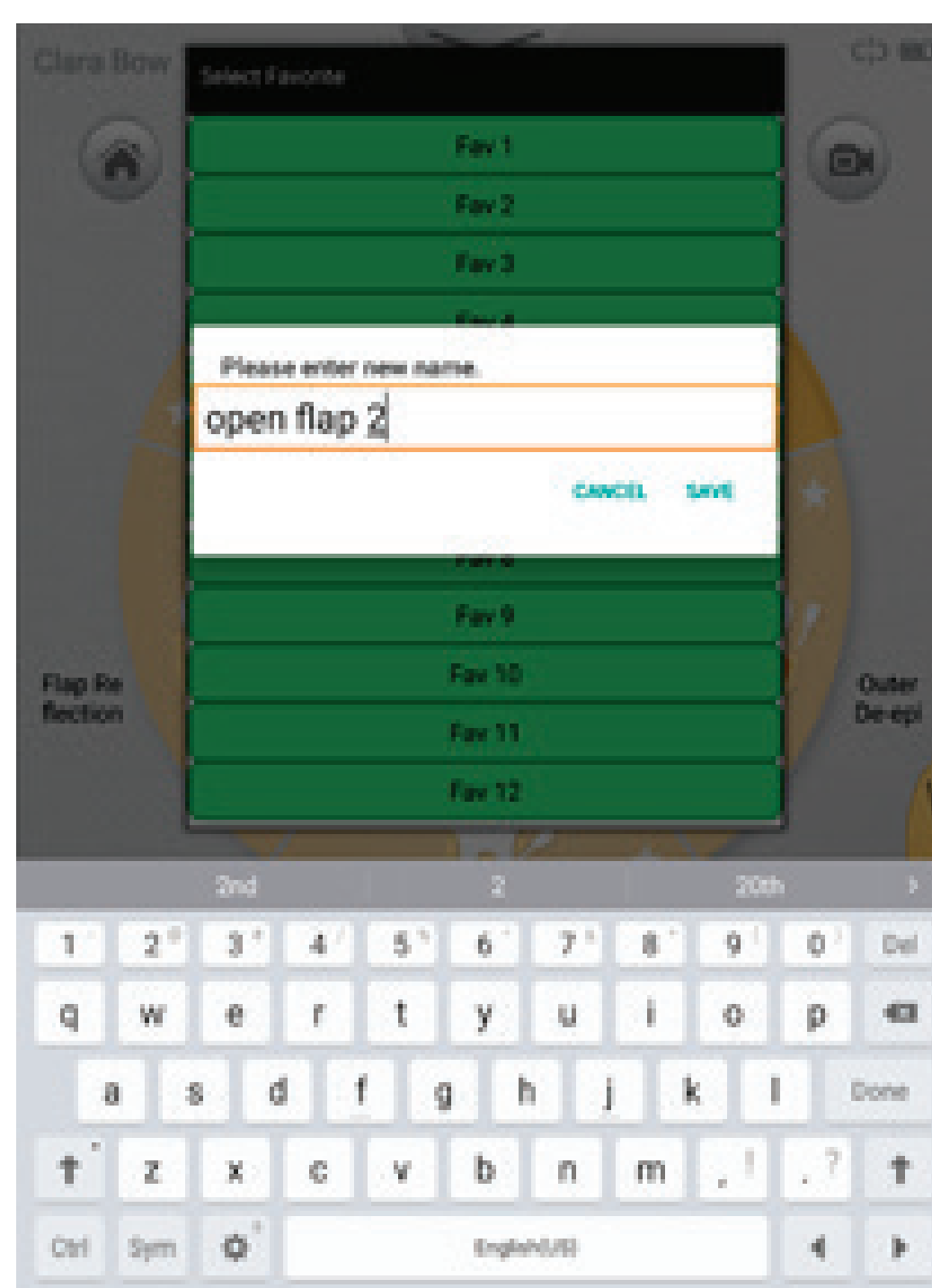
Figure 9.17
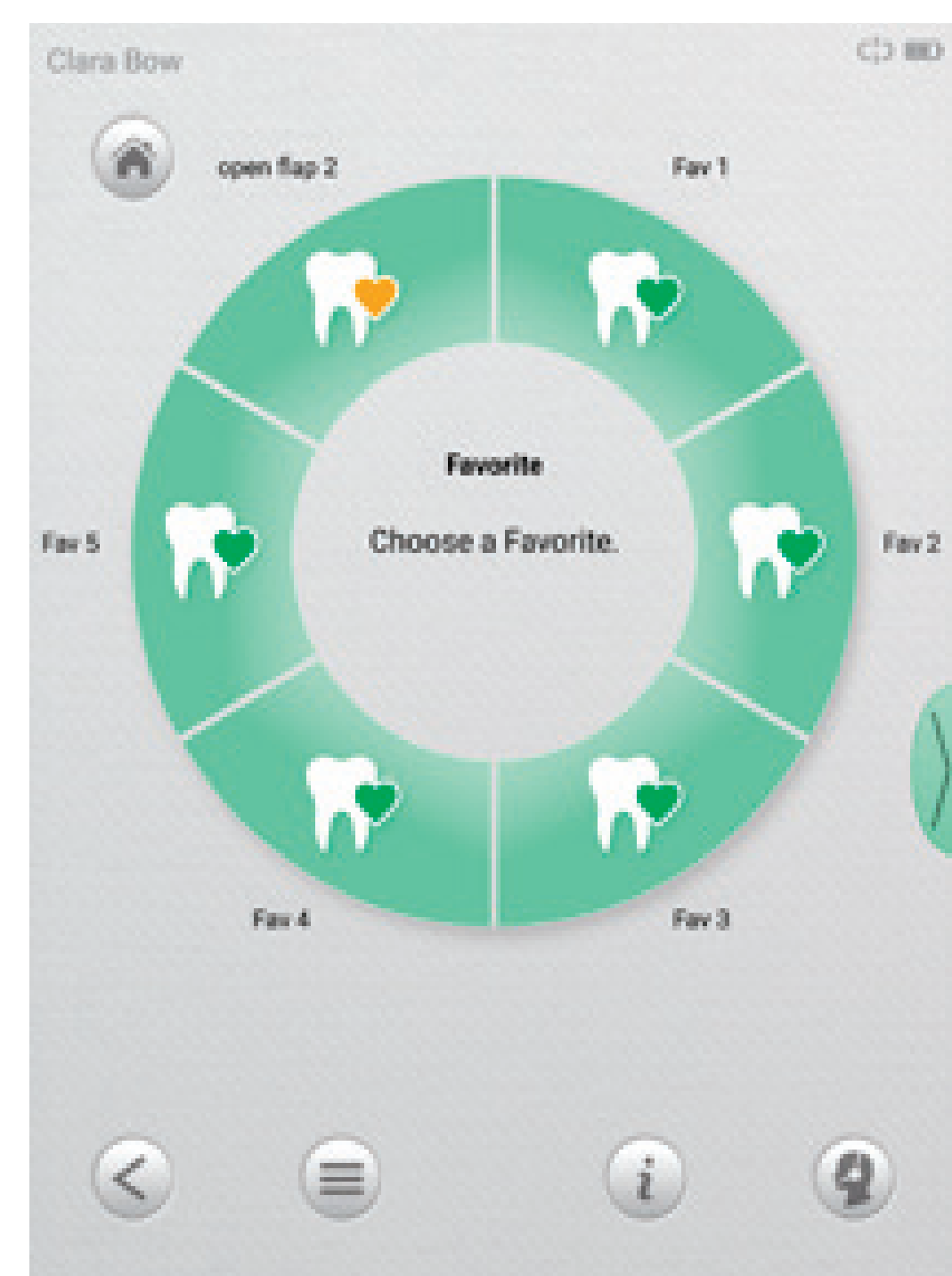
Figure 9.18

9.4.2 RENAME OR DELETE A FAVORITE

- Select "Favorites" on the Home screen to access personalized settings (Figure 9.18)

- Press and hold the favorite chosen for approximately 2 seconds (Figure 9.16)

- Options to either "Rename" or "Delete" the favorite will be displayed (Figure 9.17)

- If "Rename" is pressed, a screen with a keyboard will appear; type in the new name for the favorite, then press Enter

- The Favorites screen will reappear and the new name will be displayed

- If "Delete" is pressed, a message will appear confirming the selected favorite has been deleted

> **NOTE:** The user may also just "lock" in a setting for a step by pressing the open lock on the step selection segment (Figure 9.15) and then choosing Save (Figure 9.13); the open lock will change to a locked lock. This new setting will become the standard setting for this step unless/until the factory presets are re-established through the Factory Reset option in the Main Menu (Settings).

9.4.3 ADJUSTING THE HANDPIECE AIMING BEAM, AND ILLUMINATION

To change the brightness of the Handpiece illumination (white light) or aiming beam (red light):

- Touch the pull down icon at the top of the screen (Figure 9.19)

- Adjust each element to the desired level (Figure 9.20)

- Touch the pull up icon at the bottom of the screen to return to the Procedure screen (Figure 9.20)
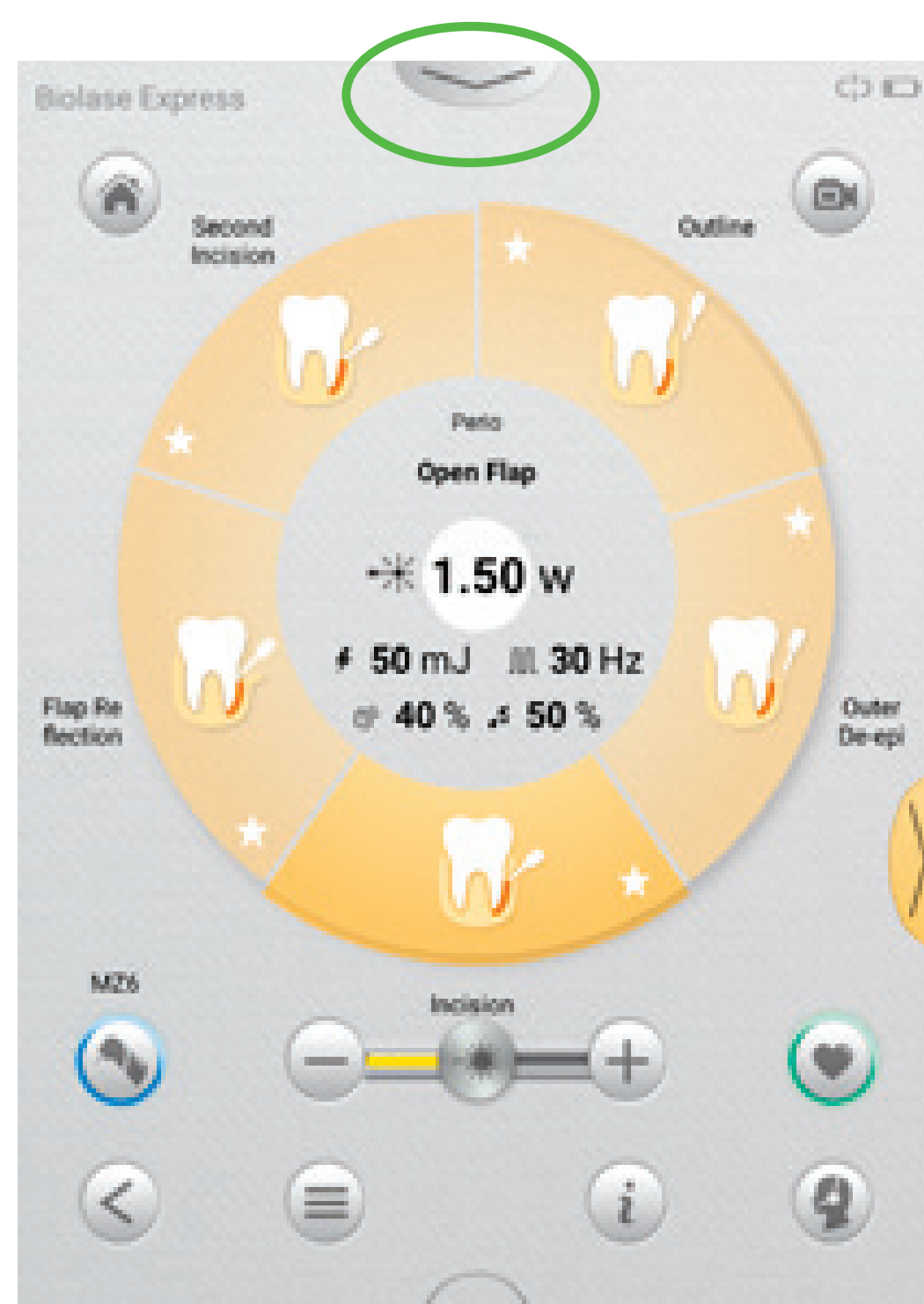
Figure 9.19
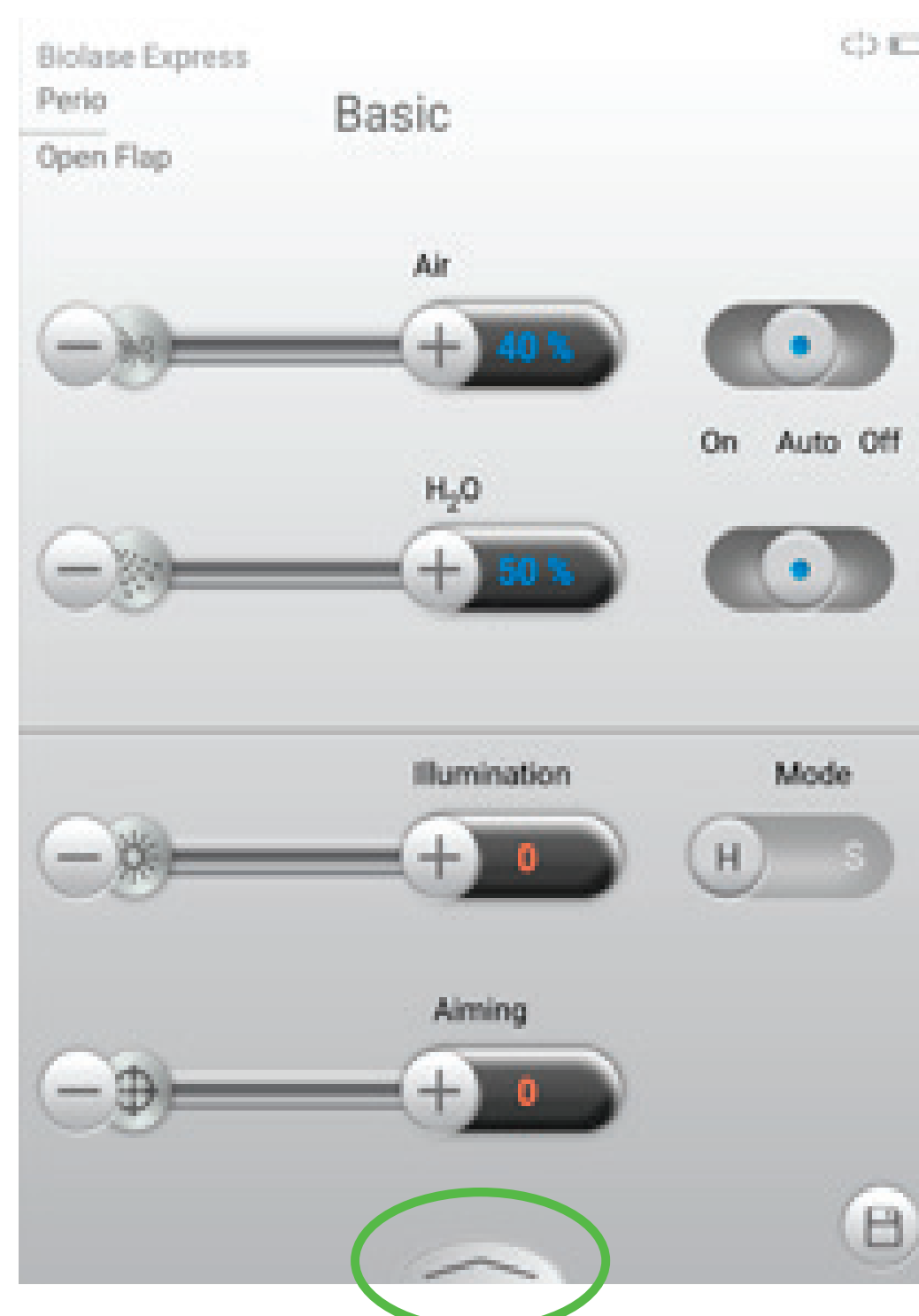
Figure 9.20

9 User Interface

9.5 PRESETS

The settings chosen for a procedure will contribute to its overall success. Waterlase Express uses a spray combining air and water to effectively cut tissue, in conjunction with pulse repetition rate and mode, and must be balanced appropriately in order to obtain optimal clinical outcomes and positive patient results.

As examples, a greater percentage of water is good for cooling targeted tissue, but too much water will reduce the power delivered because the laser radiation is absorbed by water; more air in the mix will generate a finer spray, making it easier for the water molecules to penetrate the tissue, facilitating cutting; a higher pulse repetition rate will allow faster, smoother cutting of hard tissue, but could result in a higher tissue temperature, possibly making the procedure more painful for the patient, while a longer pulse (S mode) works well for soft tissue because it increases tissue temperature, reducing bleeding.

If uncertain which parameters are best for a chosen procedure, pleaser refer to the suggested settings on the device or make the appropriate adjustments based on prior clinical experience. Attend training courses and experiment on model tissues before using the Waterlase Express on patients.

9.5.1 ADJUSTING ENERGY / WATER / AIR / PULSE / MODE

The recommended settings for each procedure/step have been pre-programmed into the Waterlase Express at the factory for ease of use. However, depending on the mode used (Basic or Advanced), these may be modified within a limited range by sliding the bar at the bottom of the screen to the right or left. **Always use clinical judgment when making adjustments to power, water, air, pulse repetition rate, and mode** as may be necessary to compensate for variations in tissue composition, density and/or thickness.

Note that some procedures do not have pre-programmed settings; recommended laser parameters for these can be found in Appendix A.

> **NOTE:** Any combination of customized values that prove particularly effective in a specific procedure may be saved to Favorites.

9.6 BASIC MODE

Basic is the default mode of the Waterlase Express. It provides access to most of the applications within the main categories and utilizes a pre-defined range of parameters for each. The energy (W) may only be adjusted within a set minimum and maximum range by slinding the bar at the bottom of the screen either right (**+**) or lef (**-**); millijoules (mJ) adjust automatically in relation to energy (W).

9.7 ADVANCED MODE

Advanced mode allows the user to modify each of the settings for a procedure, *i.e.*, energy, pulse per second, air, and water individually, but still only within established parameters (Figure 9.22). The code that "unlocks" this mode is only provided once the user has completed initial classroom and hands-on training. Contact BIOLASE Customer Care for the individualized code, which is unique to a specific system and will not work with any other Waterlase Express.

> **NOTE:** Some procedures require at least minimal air or water. In these cases, although the slider can be moved to lower the air or water settings to "0," thus effectively shutting off the air/water spray, the procedure settings will never stay at "0," but will always revert to the minimum air/water values appropriate for the procedure.

9.7.1 ACCESSING ADVANCED MODE

To enter Advanced mode:

1. Go to the main menu.

2. Select Settings, then Modes (Figure 9.21).

3. Press Advanced (Figure 9.2.1).

4. Enter the customized code issued by BIOLASE Customer Care and press continue.

5. Return to the Procedure Home screen by pressing the home button (Figure 9.21).

6. Choose the desired procedure category and proceed as outlined in Section 9.3.

7. A Tip Selection screen appears highlighting the tip most appropriate for that step, as well as any possible alternatives, if there are any (Figure 9.22). Confirm the tip selected before proceeding by pressing the tip image chosen. Purge/prime as needed.

8. On the procedure screen, touch the pull down icon at the top of the screen to open the advanced settings display (Figure 9.23).

9. Adjust the settings for the procedure as needed, then touch the pull up icon at the bottom of the screen to return to the procedure (Figure 9.24). The modified settings will appear in the center of the screen (Figure 9.25).

> **NOTE:** To contact BIOLASE for technical or clinical assistance, simply press the call customer care button located on the bottom right of most screens. This will automatically generate an email request to BIOLASE Customer Care; a representative will respond via phone as soon as possible (within business hours).

9 User Interface

The Main menu may be accessed at any time from a procedure screen by pressing the System Menu icon at the bottom left of the screen (Figure 9.25). To return to the procedure from the Main menu, simply press the icon at the upper right hand corner of the screen (Figure 9.21).
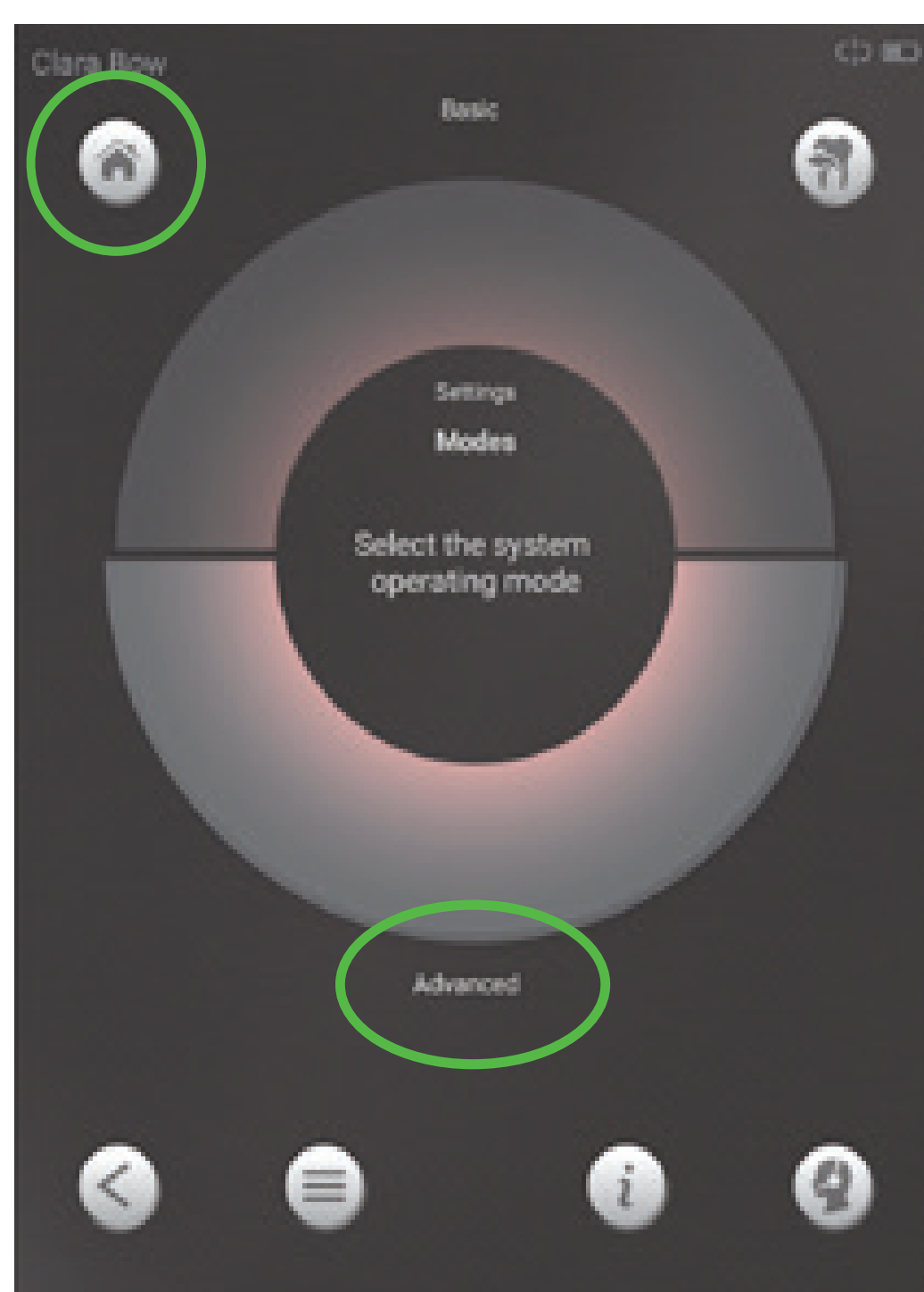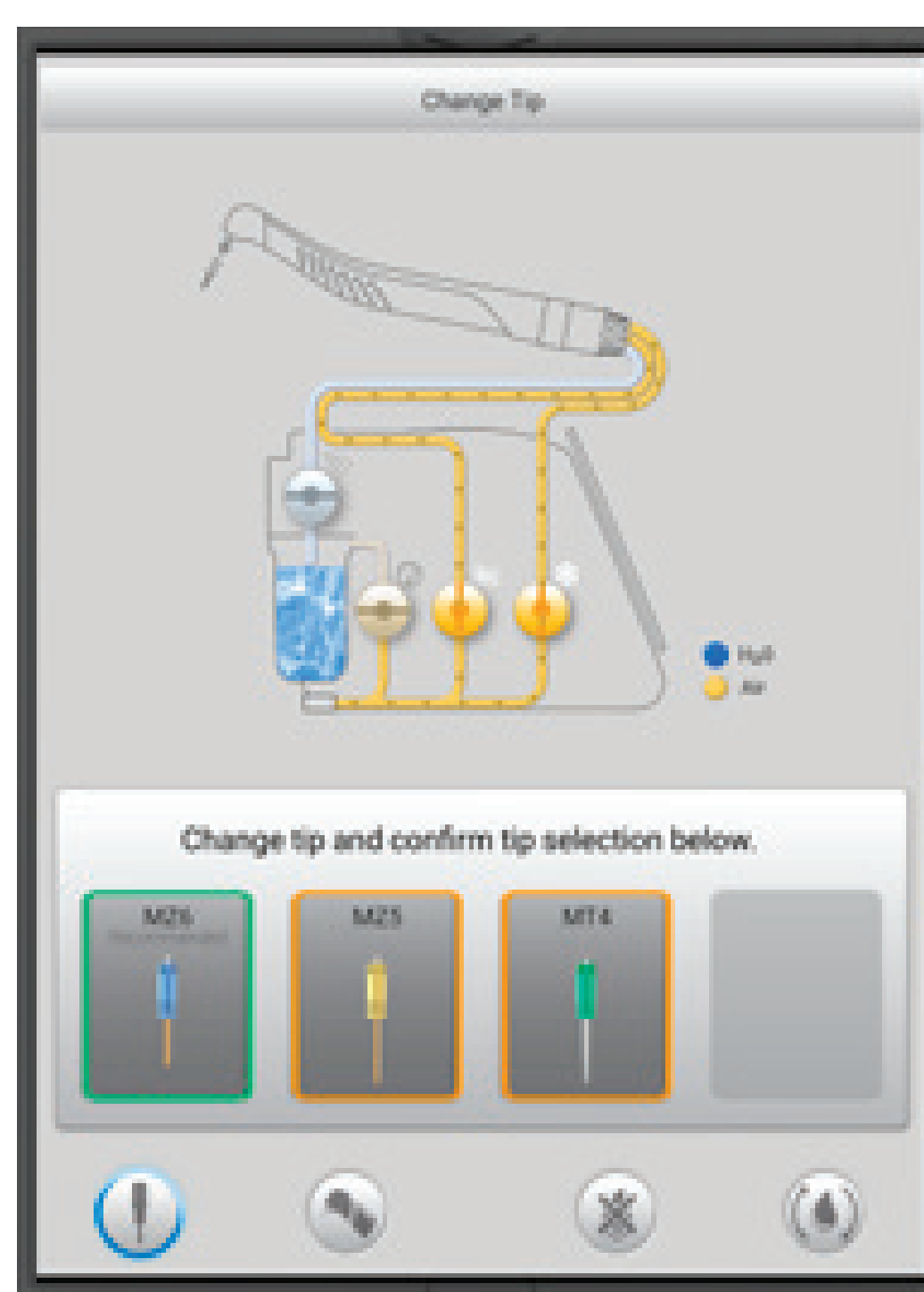
Pull Down Icon

Figure 9.21

Figure 9.22
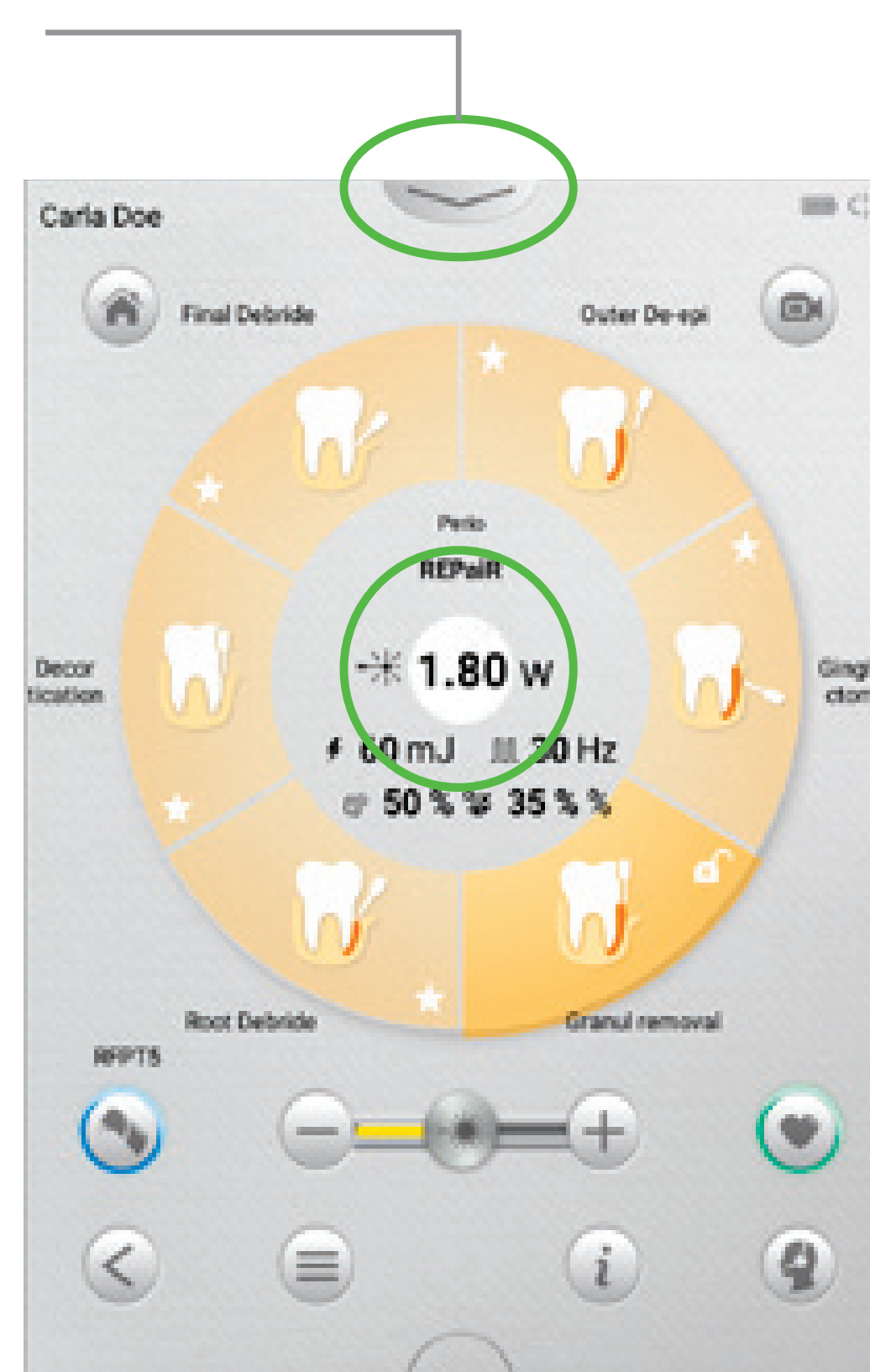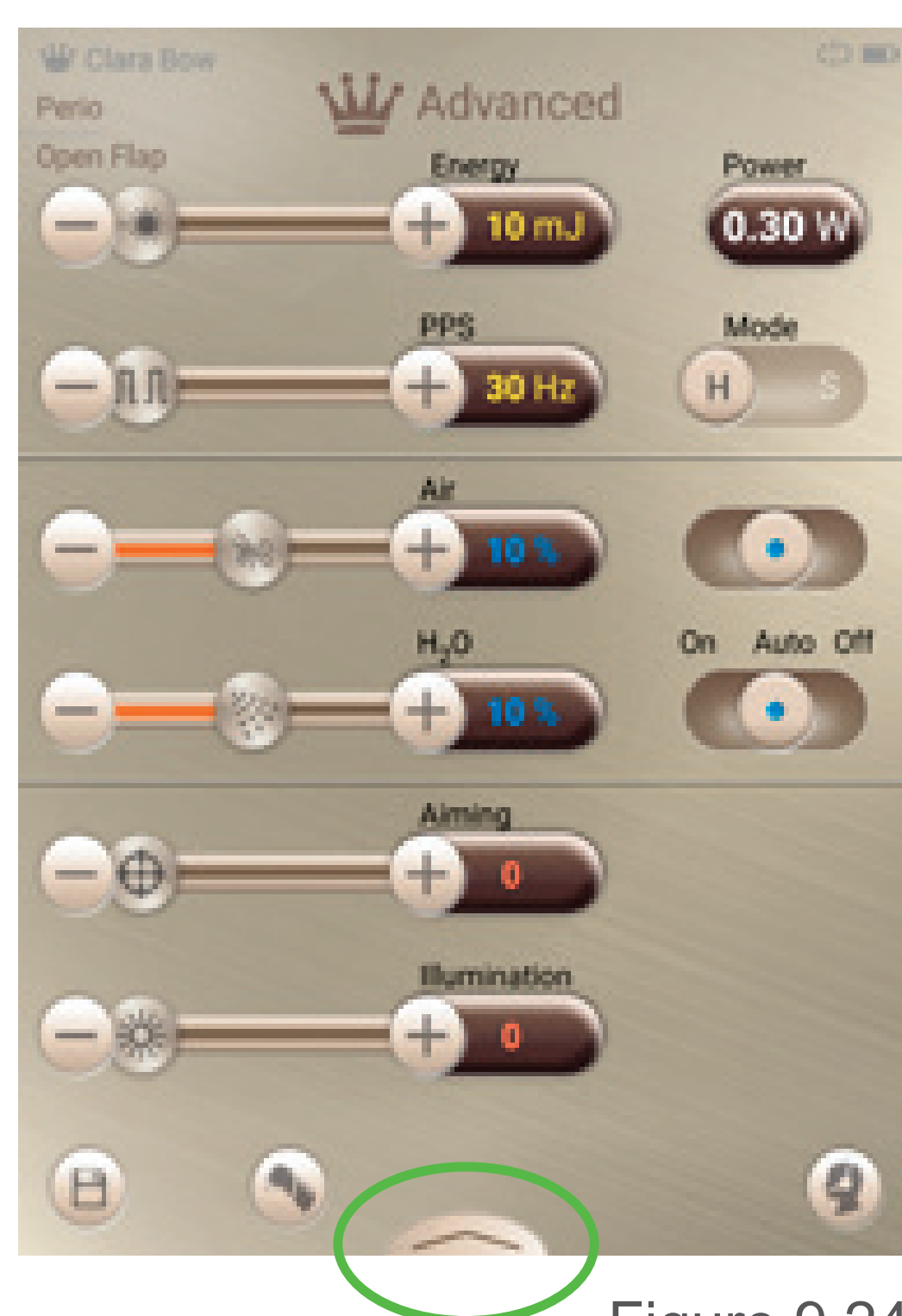
Figure 9.23

Figure 9.24

Figure 9.25

9.7.2 SOFTWARE/FIRMWARE/CONTENT UPDATES

From time to time BIOLASE will update the Waterlase Express system Software and/or Firmware, or refresh the content of the Learning Center, adding new videos, animations, white papers, etc.

All users will be notified of upcoming updates, along with a summary of the enhancements included with each update.

Users who are utilizing BIOLASE Connect will be able to execute updates through their Wi-Fi connection. The tablet screen will display easy-to-follow step-by-step instructions throughout the implementation process.

For systems that have not enabled the Wi-Fi feature, one or more SD cards will be provided via mail, along with detailed instructions.

NOTE: Software updates will take 30 seconds to one minute to upload, but Firmware will take approximately 20-25 minutes. Contact BIOLASE or your authorized BIOLASE representative directly for assistance, if needed.

9 User Interface

9.8 SYSTEM FLOW CHART

Main Menu

Learning Center
- Best Practices
- News
- Marketing Help
- Training and Education
- White Papers
- Video & Animation

Settings
- Initial Setup
- Modes
  - Basic
  - Advanced
- User
- Language
- Wi-Fi
- Footswitch Pairing

System Information
- Specifications
- Memory
- Software Versions
- Applications
- License Code
- Set Date and Time

Maintenance
- Purge/Prime
- Service
- Daily
- System Log
- Handpieces and Tips
- Footswitch Battery

Session Review
- Select Session

Web Portal
- Breaking News
- Discussion Forum
- BIOLASE Home
- BIOLASE Store

Figure 9.26

10 Clinical Application

The Waterlase Express laser is designed to cut and remove hard- and soft-tissues. Cutting is achieved in a contact or non-contact mode by application of direct laser energy either with water for cooling and hydration, or without water for coagulation. It helps to understand the unique nature of the Waterlase Express laser in order to efficiently remove tissues. Waterlase Express operates unlike traditional medical instruments or devices, and a proper technique must be practiced and perfected to ensure efficient operation.

BIOLASE recommends anyone using Waterlase Express study this section carefully, practice on tissue models, and attend a company-sponsored training seminar before using this laser in a clinical situation.

10.1 HARD-TISSUE CUTTING

Hard-tissue cutting is achieved through the removal of tissue with laser-energized water.

1. Select the desired procedure from the Home (Procedures Main) screen (Section 9).

2. Begin the procedure with Step 1; the optimum settings for each step of each procedure have been preset at the factory.

3. Point the Tip away from the patient and laser system, and step on the Footswitch. You will see water spray flow from the Handpiece and hear a gentle "popping" sound.

4. If the water flow and "popping" sound are both present, stop firing the laser and move the Handpiece Tip to the targeted tissue site. Press on the Footswitch to fire the laser and begin cutting tissue.

5. Use high-speed suction as necessary to keep the field clear. There is a pronounced difference in cutting techniques between a traditional dental drill and Waterlase Express; it is very important to have the exact treatment location visually identified before and during the procedure.

6. Maintain a distance of 0.1 to 1.5 mm between the Tip and the tissue being treated while moving the Handpiece over the tissue surface as required.

7. Cutting speed is determined primarily by parameter settings and distance from tissue, not by rapid hand movement as with the high-speed drill.

8. Gently and slowly move the Handpiece in a circular, brushing, or in-and-out motion, as required, to remove desired tissues or materials. Do not leave the Tip stationary over one spot as it may cause the patient pain or discomfort. Unlike with traditional dental instruments, with the Waterlase Express the slower you move the Handpiece Tip, the quicker you will remove tissue.

9. Once treatment is completed, release the Footswitch and remove the Handpiece from the patient's mouth. Be careful not to hit the Handpiece Tip against teeth or other instruments, as the Tip may break.

⚠️ **CAUTION:** If no water spray or distinct popping sound is present, stop the laser immediately and prime the Handpiece. If priming does not result in water spray, refer to the troubleshooting section of this manual for instructions, or call your authorized BIOLASE representative for assistance.

10. To remove the Tip from the Handpiece, use the Tip Holder; place a new Tip in the Handpiece as described in Section 7. If it's not immediately needed, use the Tip Plug to avoid contamination and damage to the Handpiece until it can be cleaned and sterilized for the next patient.

11. Clean, disinfect, and then sterilize the Handpiece, as outlined in Section 11.

12. Disposable, single-use tips, i.e., quartz (glass), must be disposed of in a biohazard medical waste sharps container. **Single-use Tips should not be reused.**

Cutting efficiency will vary depending upon the power setting, tip diameter, and spray configuration. If the system appears to be working slowly at the preset power setting, the air and water spray settings can be adjusted; tap the pull down arrow at the top of the screen and then use the sliders to increase or decrease the air and water values as needed. Note that clinical efficiency depends on power as well as spray; with experience, the user will be able to gauge spray and power efficiency from the sound of the popping water droplets. A sharper, more distinct popping sound represents a higher cutting rate. Use clinical judgment to adjust the air and water spray to compensate for variations in tissue composition, density and/or thickness.

10.2 SOFT-TISSUE CUTTING

Soft-tissue procedures are performed with direct laser energy, either with or without water spray.

A. Select the desired procedure from the Home (Procedures Main) screen.

B. Begin the procedure with Step 1; the optimum settings for each step of each procedure have been preset at the factory.

C. Carefully place the tip approximately 1-2 mm from the targeted tissue.

D. Step on the Footswitch and slowly move the tip along the tissue surface. The incision will be noticed immediately after laser activation.

> **NOTE:** Bleeding is controlled through a reduction in water. The most effective hemostasis is achieved when the water spray is eliminated completely.

10.3 REMOVAL OF PORCELAIN AND CERAMIC CROWNS AND VENEERS

The Er,Cr:YSGG laser wavelength has been shown to be effective in removing prosthetic materials that are at least partially transparent to the wavelength, including porcelain and ceramic restorations. Laser energy is transmitted through the crown or veneer, ablating the cement between the restoration and tooth, reducing the bond strength of the interface between the two.

10 Clinical Application

> **NOTE:** Laser energy may not be effective on some restoration materials; if the crown or veneer cannot be removed after the maximum recommended time, revert to conventional removal method.

> ⚠️ **CAUTION: NEVER** use on metal or metal-backed surfaces. Do not use on crowns that are made from porcelain fused to high noble metals (PFM).

The recommended settings noted in Figure 10.1 have been optimized for maximized results but are not pre-set in the laser system and have to be manually entered for this procedure. Once set up, they can be saved to Favorites for future use as outlined in Section 9. **Only use the tips noted in the table above; tips that are not listed are not effective for this procedure.**

1. Make sure you are in Advanced mode (see Section 9).

2. From the Procedures screen, select Restorative.

3. Select either Class 1 or Class 2 and then Comfort Prep.

4. The Tip Selection screen will appear; choose either of the tips presented.

5. Insert any one of the tips recommended for this procedure **as listed in Figure 10.1** into the Handpiece; **DO NOT** install the tip chosen from the Tip Selection screen;.

6. Touch the pull down icon at the top of the screen to open the advanced settings display (see Section 9).

7. Adjust the settings (Energy, PPS, Air, H_2O) for the procedure to those noted in Figure 10.1, then touch the pull up icon at the bottom of the screen to return to the procedure (see Section 9); the modified settings will appear in the center of the screen.

Application	Procedure (GUI)	Tip Types	Handpiece	Energy per Pulse	Hz	Power*	Mode	Water	Air
Veneer Removal	Restorative	MZ8 MZ10 MC12	Express	175mJ	20Hz	3.5W	H	50%	50%
Crown Removal	Class 1 or 2 Comfort Prep			250mJ	15Hz	3.75W			

*Adjusts automatically as the Energy per Pulse and Hz are increased or decreased.

Figure 10.1 Recommended Settings

Settings may be adjusted up or down based on clinician's judgement as per Figure 10.2.

Energy per Pulse	Hz	Power*	Mode	Water	Air
140 – 250mJ	15Hz	2.5 – 4W	H	50 – 100%	40 – 100%
	20Hz	3 – 4W			
	25Hz	3.5 – 4W			

*Adjusts automatically as the Energy per Pulse and Hz are increased or decreased.

Figure 10.2 Adjustments Range

- The maximum recommended treatment time to remove veneers is 1 minute.

- The maximum recommended **total** treatment time to remove crowns is 5 minutes.

⚠ **CAUTION: DO NOT** exceed the recommended total treatment time as this may cause the tooth pulp to overheat.

1. For both crowns and veneers, first treat the margins of the prosthetic surface (Figure 10.3), and then treat the center in a scanning motion (Figure 10.4).

2. For crowns, option to treat in 1 minute cycles; attempt to remove the restoration with a mechanical instrument after each cycle; if the crown is still bonded to the underlying tooth, repeat up to no more than a cumulative of 5 minutes.

Figure 10.3

Figure 10.4

11 Cleaning, Disinfection, and Sterilization

⚠️ **CAUTION:** Handpieces and laser tips are not sterile when sold and must be sterilized prior to initial use following the sterilization instructions noted below (see Step 2, Item 3), and **cleaned and sterilized between patients**. Cleaning must be performed within a maximum of 1 hour after the procedure and prior to sterilization.

Single-use tips, i.e., quartz (glass), as marked on the packaging, are intended for one-time use only and must be discarded after use in a biohazard medical waste sharps container.

Use only the MANUAL cleaning process described below. Other cleaning methods should be avoided since water may damage the fiber optics inside the Handpiece.

⚠️ **CAUTION:** The Fiber Optic Cable cannot be autoclaved; doing so will make it unusable. However, the Fiber Optic Cable must always be disinfected between patients by following the procedure outlined in Step 3 of this section.

STEP 1—CLEANING PROCESS (HANDPIECE, TIPS)

The cleaning process is intended to remove blood, protein and other potential contaminants, as as to reduce the quantity of particles, microorganisms and pathogens present from the Handpiece, laser Tip surfaces 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 gloves when handling the contaminated delivery system.

1. After each clinical procedure, detach the Handpiece from the fiber with the Tip still attached. Do not remove the Tip.

2. Insert the rear plug into the Handpiece; **during the cleaning procedure ensure the cleaning solution and rinse water does not enter the interior of the Handpiece.**

3. Rinse the Handpiece with the Tip still installed under lukewarm water (22 – 43°C) for 10 seconds to remove gross soil.

4. Prepare a cleaning solution per the manufacturer's instructions. Use a commercially available surgical instrument detergent/enzymatic cleaning solution with a pH of 7.0, such as Enzol® or similar enzymatic presoak and cleaner. Follow instructions for the disposal of used solution.

5. Soak a piece of gauze large enough to wrap the Handpiece in the cleaning solution. Squeeze out the excess liquid and wrap the Handpiece with the Tip still installed and leave wrapped for a minimum of 10 minutes.

6. Unwrap the Handpiece and Tip. Using a soft-bristled brush dipped in the cleaning solution, gently brush around the Tip ferrule, crevices, and other hard-to-clean areas for 15 seconds. The brush should be wet, but not dripping.

7. Rinse the Handpiece under lukewarm running tap water (22-43°C) for 10 seconds.

8. Dry the Handpiece with a lint-free cloth.

9. Visually inspect the Handpiece for any residual soil. If any is still present, repeat steps 5 through 8 until any residual soil is removed.

11 Cleaning, Disinfection, and Sterilization

10. Using the Tip Holder or Revolving Tip Holder, remove the Tip from the Handpiece:

    A. Slide the Handpiece laterally toward the Tip Holder or Revolving Tip Holder (Figure 11.1).

    B. Place your thumb against the selected Tip slot to prevent laser Tip from falling out of the Tip Holder when disconnecting it from the Handpiece.

    C. Carefully lift the Handpiece to disengage the Tip ferrule from the Handpiece head (Figure 11.2).

    D. Use tweezers to slide the Tip out from the Tip Holder or Revolving Tip Holder; dispose of the used Tip in a medical waste sharps container.

Figure 11.1

11. Gently wipe the orifice of the Handpiece head with a dry, lint-free cloth, making sure to remove any soil/debris that may have accumulated in the crevice between the laser Tip and the Handpiece.

12. Once removed from the Handpiece, single-use Tips must be disposed of in a biohazard medical waste sharps container; if the Tip is meant to be reusable, rinse with distilled or sterile water for 10 seconds and then dry with a lint-free cloth. Sterilize per the procedure outlined below.

Figure 11.2

13. Visually inspect the Tip for any residual soil; if any is present, repeat step12 until all residual soil is removed.

STEP 2—STERILIZATION PROCESS
The steam sterilization process is intended to destroy infectious microorganisms and pathogens.

> **NOTE:** Always perform this 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. Prior to sterilization, remove the Rear and Tip Plugs, if installed. It is also recommended to remove the mirror from the Handpiece before proceeding (see Section 12.6.1).

2. Place the Handpiece inside a single-wrap, self-sealed pouch.

3. Tips may be autoclaved in the Tip Holder or Revolving Tip Holder. Place the individual Tips, or the Tip Holder or Revolving Tip Holder loaded with Tips, inside a separate single-wrap self-sealed pouch.

4. Place the pouches on an autoclave tray. Take care when handling the Handpiece and Tip(s).

5. Do not stack other instruments on top of the pouches.

6. Place the tray into the autoclave chamber and set appropriate cycle, as noted in (Figure 11.3).

7. Upon completion of the cycle, the Handpiece and tips must remain in the sterilization pouches until used to ensure sterility.

8. To reassemble the Handpiece, insert the shaft of the fiber into the Handpiece until it "clicks' into place and is secure. to insert a Tip, remove the Tip from the sterilization pouch with tweezers and place it into the Tip Holder or Revolving Tip Holder (if not already in the Tip Holder), then follow the instructions outlined in Section 7.

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

Figure 11.3

STEP 3—DISINFECTING THE FIBER

Always disinfect the Fiber Optic Cable between patients by wiping it completely with an appropriate disinfecting solution such as Cavicide™ or a similar quaternary ammonium compound product (containing 20% alcohol or less), and follow the manufacturer's instructions. **DO NOT AUTOCLAVE.**

CAUTION: Use of damaged or worn Tips may cause damage to the delivery system and will compromise the clinical performance of the Waterlase Express Laser System. The Tips must be inspected prior to each use for damage or wear as described in Section 12.

Repeated processing of the Handpiece and reusable Tips may reduce the useful life of these devices. Check the Handpiece for damage or wear prior to each use. The Handpiece should be free of nicks, distortion, corrosion or other signs of mechanical degradation. If damage or wear is observed, discard the Handpiece as required by local Wast Electrical and Electronic Equipment (WEEE) laws. Used or damaged Tips must be disposed of in a biohazard medical waste Sharps container.

12 Maintenance

12.1 DAILY CARE OF THE TABLET AND CONSOLE

Use the adhesive-backed Tablet protective covers provided (p/n 7250003) to protect the Tablet. Be sure to cover the Tablet, wrap the top of the protective cover around the Tablet Latch and drape the bottom over the control panel. If necessary, use a lightly pre-moistened lens cleaning wipe or equivalent to clean any residue or dirt from the Tablet. **DO NOT use soap, water, chemicals containing ammonia, bleach, alcohol, or abrasive cleaners.**

A standard disinfectant, such as Cavicide, can be used to wipe down the laser console; however, **DO NOT use bleach or abrasive cleaners.**

12.2 ANNUAL MAINTENANCE

The Waterlase Express should be serviced annually only by a qualified, trained, and certified BIOLASE technician to keep the product in compliance with its specifications. Any attempt to perform maintenance by anyone other than an authorized BIOLASE technician may lead to exposure to laser radiation and collateral radiation. During the service visit the field service engineer will fully inspect the system and all relevant electronic circuits will be calibrated, and filters and cooling fluid will be changed. Please contact your local representative to discuss extended service contracts and annual maintenance options.

12.3 SERVICE AND CALIBRATION

Calibration requires specialized equipment, and is to be performed only by a BIOLASE-trained technician who is provided with the proper training, calibration procedure, and necessary circuit diagrams, component parts list, descriptions, etc.

Power calibration is to be performed annually. A calibration log is maintained within the laser system software, and may be accessed through the maintenance segment of the system menu.

12.4 TIP INSPECTION

> ⚠️ **CAUTION:** Use of damaged or contaminated tips may damage the Fiber Optic Cable and will compromise clinical performance of the laser. Tips can be inspected using magnifying lenses, a microscope, the laser aiming beam, or the Tip inspection kit included with the Waterlase Express Laser System.
>
> Prior to each use always check both ends of the Tip for damage or contamination before inserting it into the Handpiece.

Check that both ends of the Tip appear flat and present a mirror-like reflection of any light source. Look for chips or nicks along the edges of the Tip (Figure 12.6).

12 Maintenance

12.4.1 TIP INSPECTION INSTRUCTIONS (USING THE TIP CLEANING AND INSPECTION KIT)

1. Remove the Tip from the Handpiece or its packaging and insert it into the correct side of the Tip test holder using the Tip Holder (Figure 12.1).

2. Insert the Tip test holder into the test adapter with the distal (laser-emitting) end of the Tip toward the microscope (Figure 12.2).

3. Slide the adapter over the microscope to move the Tip surface toward the focal point of the microscope. The focal point lies in the plane at the end of the clear end tube of the microscope (Figure 12.3).

4. Turn on the microscope's built-in light by gently pulling apart the upper and lower tubes, or hold it up to another light source, and bring the surface of the Tip into focus using the thumb wheel. Examine the Tip surface carefully for damage or contamination (Figure 12.3).

5. To examine the proximal (Fiber) end of the Tip, remove the adapter from the microscope and gently fit the other side of the test holder into the clear end tube of the microscope (Figure 12.4). Refocus the microscope.

Tip Holder With Tip Inside

Figure 12.1

Figure 12.2

Focal Point

Thumb Wheel
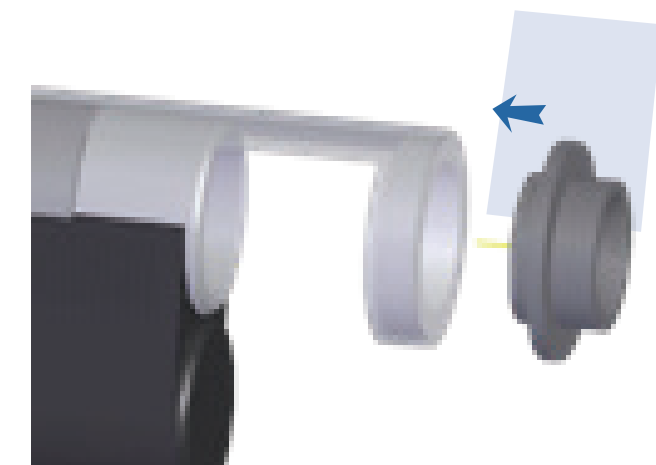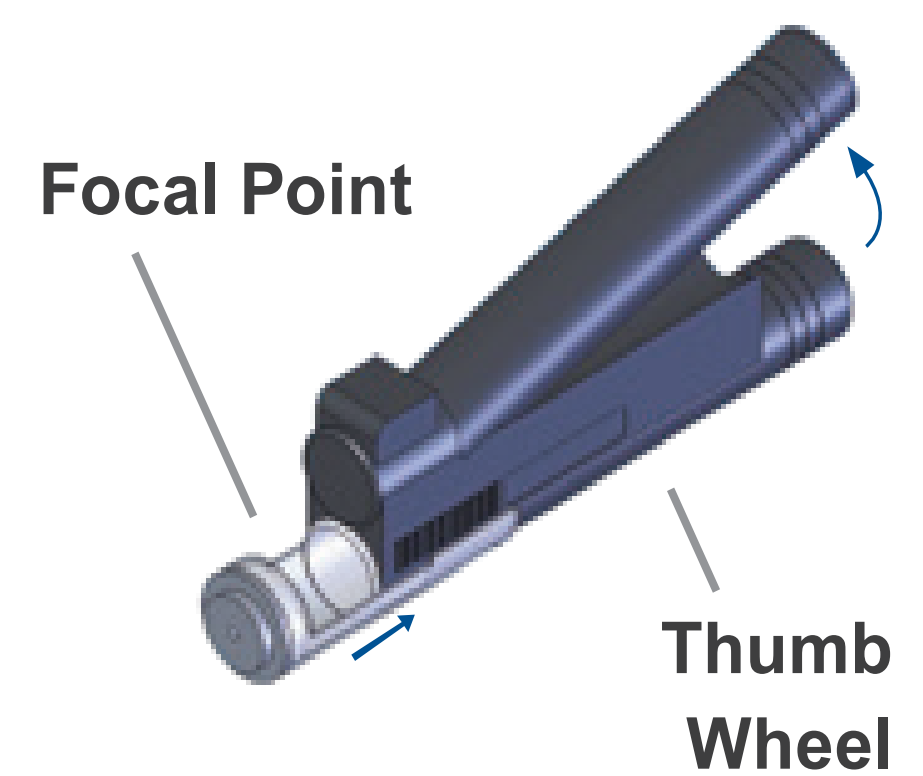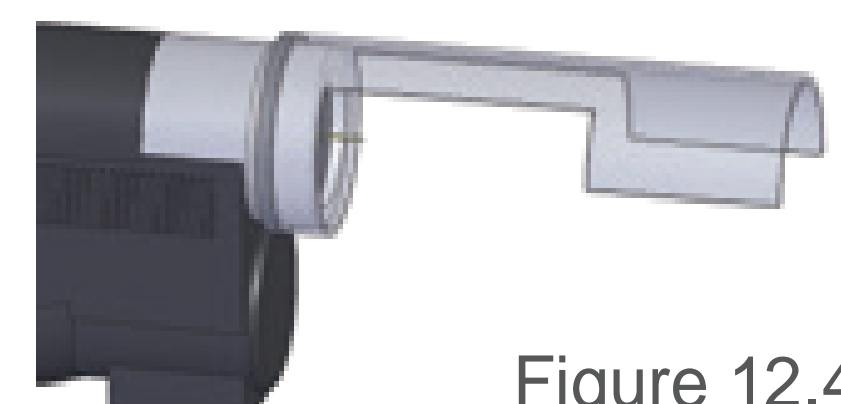
Figure 12.3

Figure 12.4
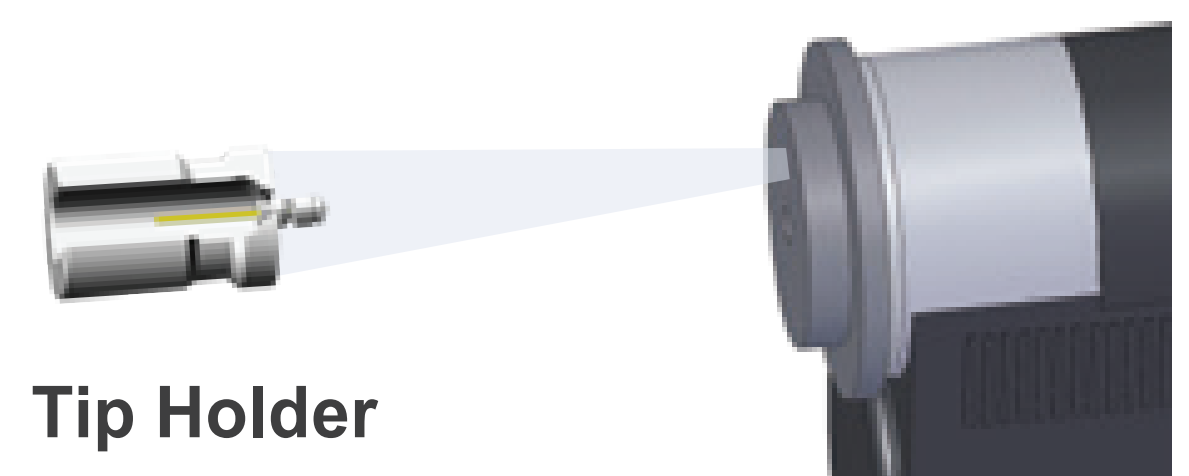
Tip Holder With Tip Inside

Figure 12.5

6. Remove the tip from the test holder using the Tip Holder. If the tip is contaminated at either end, try cleaning it as shown in Section 12.5. A damaged tip will continue to degrade and will increase procedure time, as the laser will not cut efficiently, and may cause patient discomfort.

Good **Burnt** **Broken** **Contaminated**
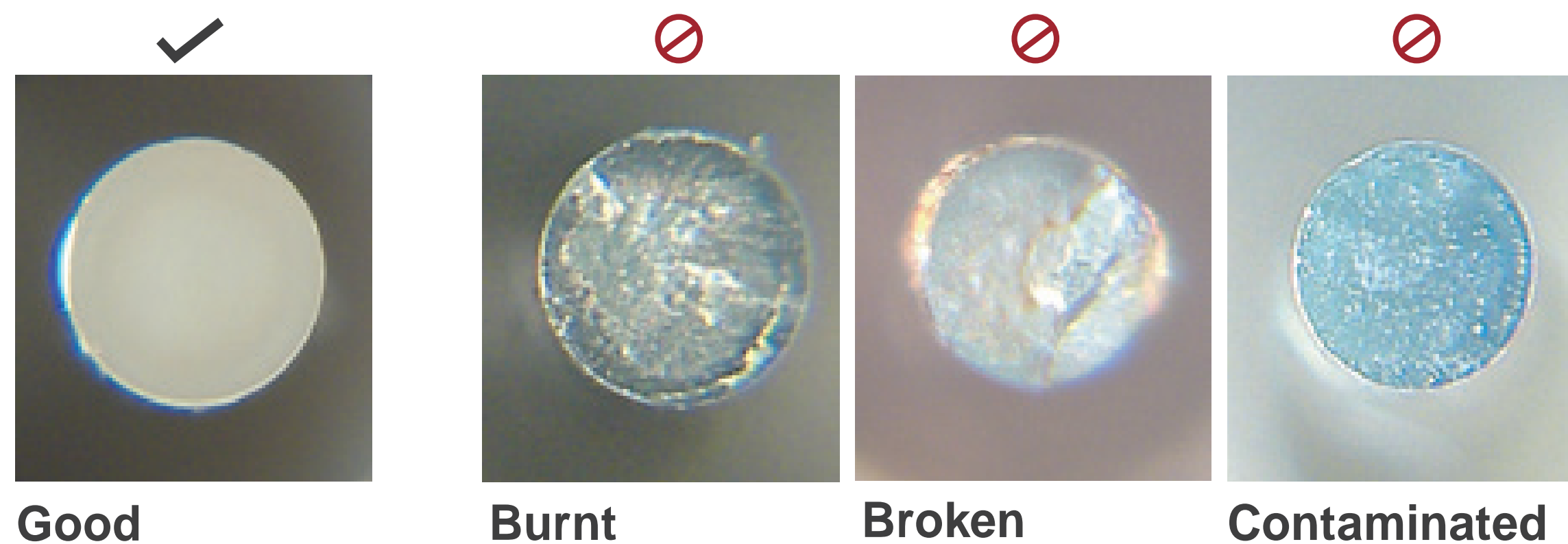
Figure 12.6

> **NOTE:** To replace the batteries for the built-in microscope light, gently pull apart the upper and lower tubes of the microscope. Locate the battery cover marked "OPEN," slide the cover in the direction of the arrow, remove the old batteries and replace them with two AA 1.5V (Europe size M) batteries.

12.4.2 INSPECTING THE PLASTIC FERRULE

Check the plastic ferrule to ensure it's clean (Figure 12.7), isn't broken (Figure 12.8), and/or that no burn marks are visible (Figure 12.9). If the ferrule is damaged, place the tip in a medical waste sharps container and replace it in the Handpiece.

Figure 12.7

12.5 TIP CLEANING

1. Hold the tip by the ferrule with tweezers (Figure 12.7).

2. Moisten a cotton swab with isopropyl alcohol drops.

3. Push the fiber (distal/output) end into the cotton swab.

4. Twirl the cotton swab while maintaining pressure on the tip.

5. Repeat on the ferrule (proximal/input) end of the tip.

Figure 12.8

Figure 12.9

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> ⚠️ **WARNING:** Check the Handpiece for damage or wear prior to each use. It should be free of nicks, distortion, corrosion, or other signs of mechanical degradation. If damage or wear is observed, discard the Handpiece as required by local recycle/waste disposal regulations.

12.6 HANDPIECE MIRROR INSPECTION

A damaged or contaminated mirror will damage the Fiber Optic Cable. If the plastic ferrule on the Tip is repeatedly damaged at the input end, check the alignment of the mirror in the Handpiece and clean or replace it as needed.

Point the Handpiece towards a white surface. The visible spot of the aiming beam should be clear, uniform, and well-defined (Figure 12.10). If dark areas and irregularities are present, inspect the mirror.

12.6.1 REMOVING THE HANDPIECE MIRROR

1. Insert the 3-pin side of the Handpiece mirror tool included in the Waterlase Express Accessory Box into the 3 holes of the cap at the Handpiece head. Make sure all the pins fit snugly (Figure 12.11).

2. Turn counterclockwise approximately 3 turns to unscrew the cap; remove the cap and store it in a safe place.

3. Before removing the mirror, note the orientation of the two dots visible on its surface; when re-installing the mirror, these two dots must be placed in their original position (Figure 12.12)

4. Insert the opposite side of the tool inside the opening perpendicular to the plane of the backside of the mirror (Figure 12.13).

5. Screw the threaded side of the tool into the mirror by turning it 2 to 2½ full turns. Do not thread all the way into the mirror; it will make it easier to release later.

6. Pull the mirror straight out from the opening (Figure 12.14). Wear gloves to avoid damaging the mirror.

7. Unscrew the mirror from the tool with gloved hands or tweezers. If there is any contact with the mirror surface, gently clear it with a cotton swab moistened with alcohol.

8. The mirror is oval symmetrical; ensure it is properly oriented when inserting it back into the opening of the Handpiece head.
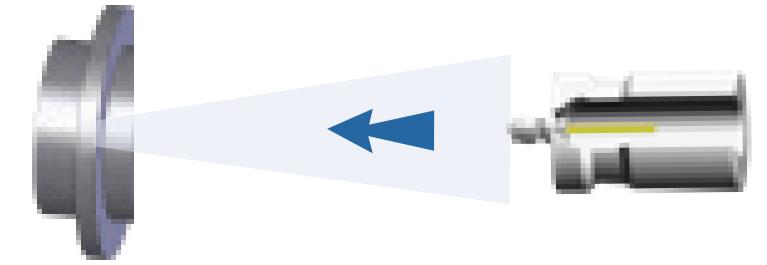

Figure 12.10

Figure 12.11

Figure 12.12

Figure 12.13

Figure 12.14

> ⚠️ **CAUTION:** If the mirror has burn marks, clean the **internal** surfaces of the Handpiece head using a long, moistened cotton swab. Use only **isopropyl alcohol** to moisten the swab.

12.6.2 CHANGING THE HANDPIECE MIRROR

A mirror that is contaminated (Figure 12.15) can be cleaned using a cotton swab moistened with optical grade acetone or alcohol.

1. Place the wet swab over the mirror surface (Figure 12.16); wait for approximately 5 seconds for the solvent to soften the contaminating material.

2. Wipe off the contaminant by a quick turn and removal of the swab (Figure 12.16).

3. Repeat until the contaminant is removed.

4. Re-install the cleaned mirror and check for proper alignment.

If the mirror is damaged, i.e., it has burn marks or scratches (Figure 12.15), it should be replaced. Install a new mirror and check for proper alignment.

Figure 12.15

Figure 12.16

12.6.3 MIRROR ALIGNMENT CHECK

1. Point the Handpiece towards a white surface. The visible spot of the aiming beam should be clear, uniform, and well-defined (Figure 12.10). If dark areas and irregularities are present, inspect the mirror.

2. If the spot is uneven on one side (Figure 12.17), the mirror may not be aligned correctly.

3. To improve the alignment, remove the mirror, turn it 180°, and re-install it.

4. If this does not correct the problem, replace the Handpiece; if the visible spot is still uneven after replacing the Handpiece, replace the Fiber Optic Cable.
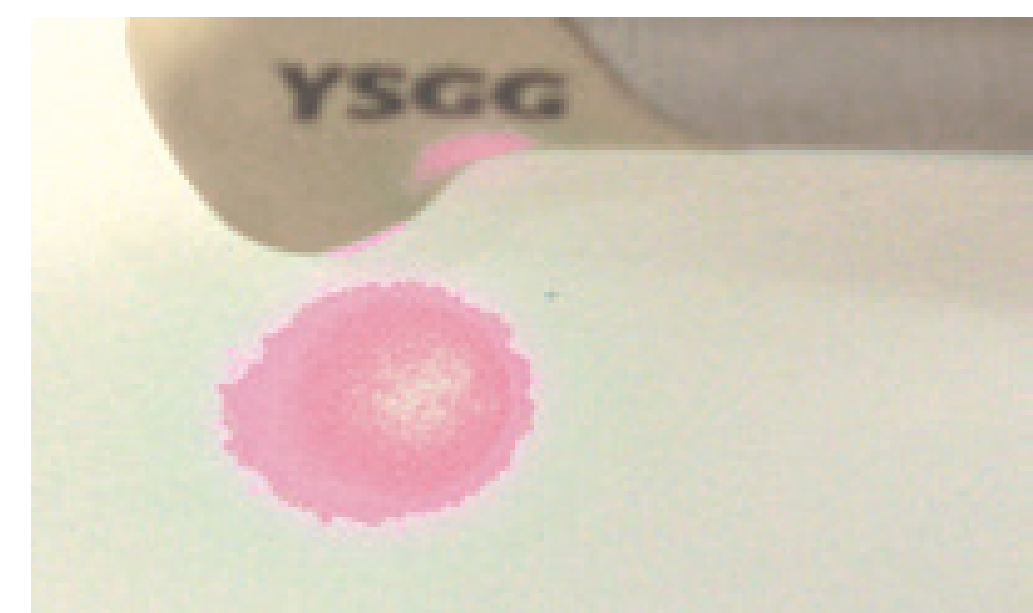
Figure 12.17

12.7 FIBER OPTIC CABLE CHECK

Regularly inspect the end of the Fiber Optic Cable shaft; always inspect and clean the protective window at the end of the Fiber Optic Cable shaft after the input end of the Tip or Handpiece is damaged.

> ⚠ **DANGER:** Invisible and/or visible laser radiation-avoid eye or skin exposure to direct or scattered radiation.

> ⚠ **CAUTION:** Using a contaminated or damaged protective window will damage the Fiber Optic Cable.

1. Make sure the laser is in **Standby** mode (no laser emission is possible).

2. Purge the Handpiece and Fiber Optic Cable of any residual water.

3. Disconnect the Handpiece.

4. Check the surface of the window inside the red ring holder at the distal end of the Fiber Optic Cable shaft (Figure 12.18).

5. If the surface is contaminated, clean the window with a cotton swab dipped in isopropyl alcohol.

6. If a crater is visible in the middle of the window, it is damaged and must be replaced.
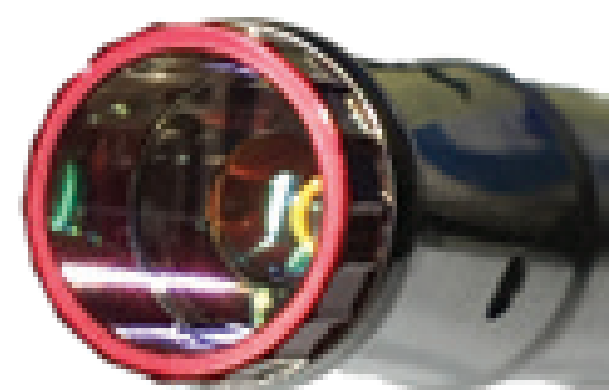
Good / Standby Mode

Good / Ready Mode

Figure 12.18

12 Maintenance

12.7.1 REPLACING THE PROTECTIVE WINDOW

A protective window is used in conjunction with the Waterlase Express Fiber Optic Cable. A Fiber Optic Cable ships with a preinstalled Protective Window. The Protective Window may become burned or damaged during use, please follow the steps outlined below, should your Protective Window need to be replaced.

PRELIMINARY STEPS:

1. Before replacing the Waterlase Express Fiber Optic Cable protective window, purge the Handpiece and Fiber Optice Cable of any residual water.

2. Power off the laser system.

3. Remove the Handpiece from the Fiber Optic Cable. **Never remove the Handpiece from the Fiber Optic Cable without purging properly first.**

4. Locate the distal end of the Fiber Optic Cable.

PROTECTIVE WINDOW REPLACEMENT STEPS:

1. To remove the protective window from the Waterlase Express Fiber Optic Cable, gently pull the protective window, while unscrewing the protective window counter-clockwise until it is removed (Figure 12.19).

2. Gently insert the replacement protective window by aligning it to the circular opening and carefully screwing the replacement protective window clockwise (Figure 12.20).

3. Discard the burned/damaged protective window into a normal waste disposal bin.

4. Re-attach the Handpiece and prime before using the laser.
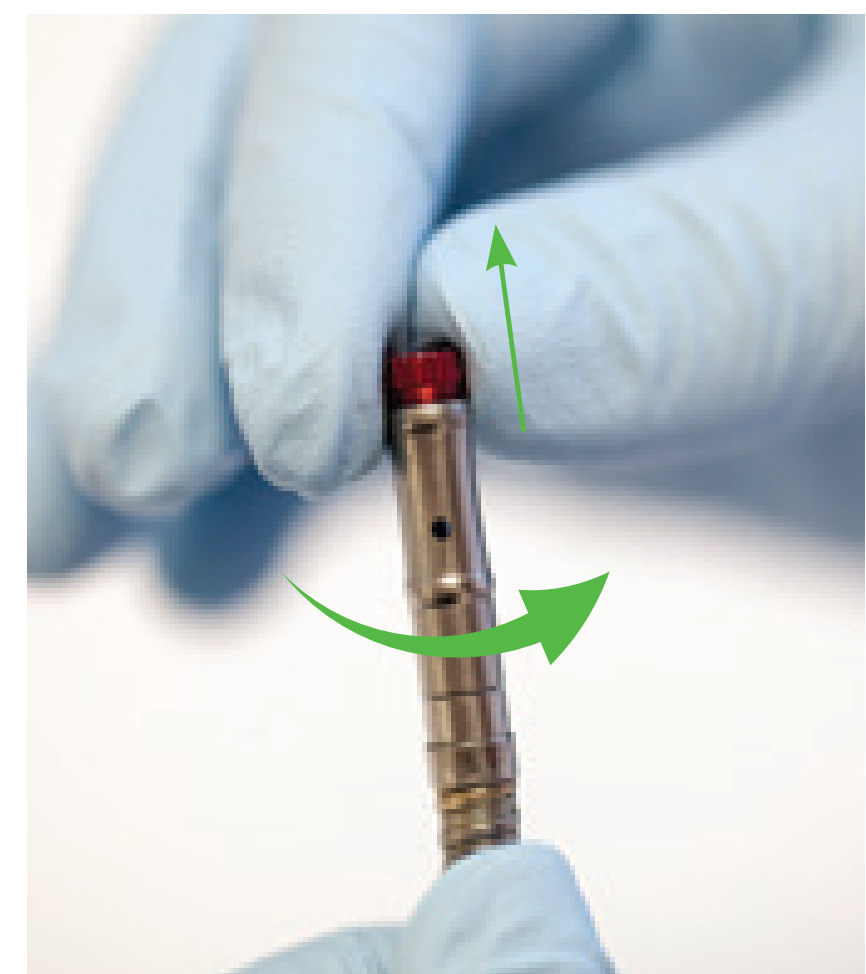
Figure 12.19
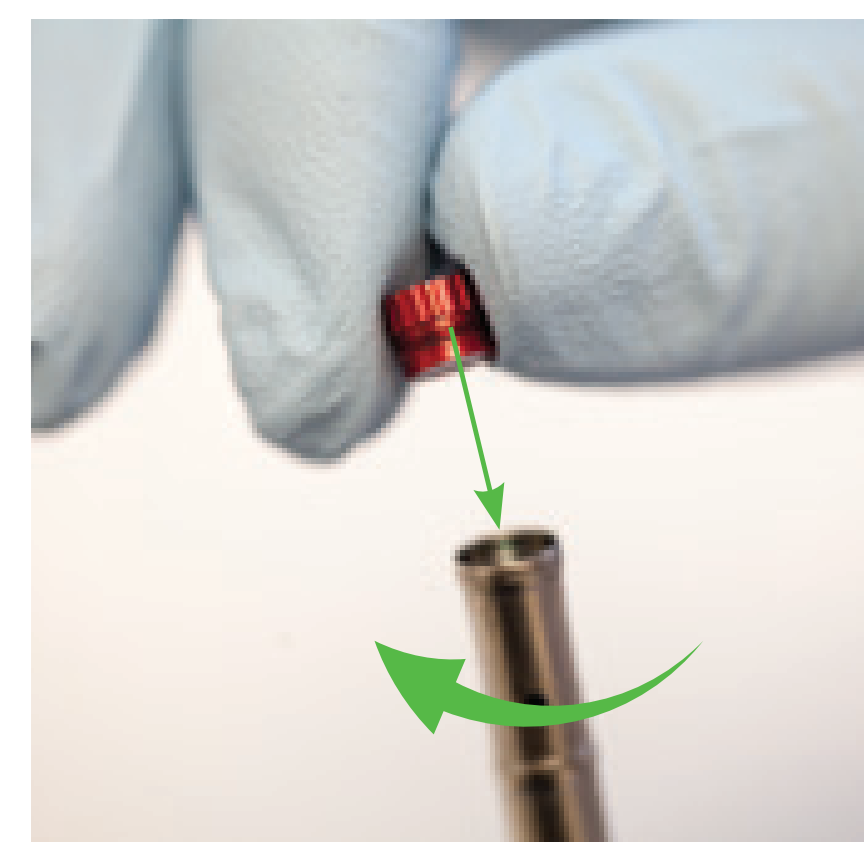
NOTE: The protective window will continue to rotate after fully installed. There should be minimal to no gap between the end of the Fiber Optic Cable and protective window. The protective window kit is available for re-order (p/n 7240002).

Figure 12.20

12 Maintenance

12.8 INSTALLING/REPLACING THE WIRELESS FOOTSWITCH BATTERIES

The Wireless Footswitch is powered by two AAA batteries that are not rechargeable. When the batteries are low, the green LED on the Footswitch will blink rapidly and a warning message will appear on the Tablet screen indicating that the batteries need to be replaced.

Figure 12.21

To replace the batteries:

1. Close the Footswitch cover (Figure 12.21).

2. The Footswitch battery compartment cover will be either a flat cap or a round button on the side of the Footswitch; remove by turning it counter-clockwise (Figure 12.22).

Figure 12.22

3. Remove the depleted batteries from the compartment and insert two new batteries (Figure 12.23).

4. Replace the battery compartment cover; turn clockwise to secure.

In most cases, replacing the batteries will not disrupt the pairing of the laser console and Footswitch.

Figure 12.23

⚠️ **CAUTION:** Do not press down on the Footswitch while installing the batteries; keep the Footswitch cover closed throughout the battery replacement process to avoid disrupting the pairing of the Footswitch to the laser console.

📝 **NOTE:** Replace both batteries at the same time; do not mix old and new batteries. Dispose of old batteries as regulated; do not throw them in a trash bin.

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

12.9 PAIRING THE FOOTSWITCH AND LASER

📝 **NOTE:** Make sure 2 new AAA batteries are installed in the Footswitch. If replacing the existing Footswitch, first insert 2 new AAA batteries in the battery compartment, then follow the instructions listed below.

> **NOTE:** The Footswitch will go to sleep if not activated for some time. To wake the Footswitch, press it briefly. To confirm it is paired to the laser console, place the laser in **Standby** mode and then press the Footswitch. If pairing is active, a message will appear on the Tablet screen indicating "Footswitch pressed in **Standby** mode." If this message does not appear, pairing may have failed and will need to be re-established following the procedure outlined below.

12.9.1 PAIRING THE FOOTSWITCH AND LASER

Waterlase Express ships with a wired Footswitch. However, the laser system will work with a wireless Footswitch, which may be purchased separately. The wireless Footswitch must be paired to the laser prior to use. To pair the Footswitch and laser, follow the steps outlined below:

1. Make sure the wired Footswitch has been unplugged from the laser console; reboot the laser.

2. Go to the System Menu by pressing the Menu button on the bottom left of the screen.

3. Select "Settings." (Figure 12.24)

4. Select "Footswitch Pairing." (Figure 12.25)

5. Select "Pair Footswitch." (Figure 12.26)

6. Follow the step-by-step instructions illustrated on the screens that follow.

> **NOTE:** Make sure the blue and green LEDs are on; if the LED lights are not on, the Footswitch has gone to sleep. Press on the Footswitch before selecting the "Pair" command; the blue and green LED lights will appear, indicating the Footswitch is "awake" and ready to pair.

If pairing is successful, the message "Pairing Success - Your laser device is ready for use" will appear. on the tablet and the blue LED will stay on the Footswitch and the green LED will turn off.

If pairing is not successful, the message "Pairing Failed" will appear on the screen and both the green and blue LEDs will stay on. Press the "Retry" icon to repeat the pairing process. If pairing has been unsuccessful after two attempts, turn OFF and then restart both the laser and the Tablet, then repeat steps 1-6 above.

Figure 12.24   Figure 12.25   Figure 12.26

12.9.2 SELECTING THE FOOTSWITCH CHANNEL

It is possible that the wireless Footswitch could be subject to interference from other wireless electronic devices if all are set on the same Wi-Fi channel. The default Footswitch channel has been chosen at the factory to minimize the possibility of interference, however the Waterlase Express allows the user to choose from a list of available alternate channels in the event that interference is present on the default channel.

1. Go to System Menu by pressing the Menu button on the bottom left of the Tablet screen.

   a. Select "**Settings.**"

   b. Select "**Footswitch Pairing.**"

   c. Select "**Select Footswitch Channel.**"

   d. A screen will appear listing the Wi-Fi channels available to your location (Figure 12.28). Select a new channel, then press "**Set Channel.**"

2. Follow the directions that appear on the screen to lock the Footswitch into the new channel (Figure 12.29), then press "OK".

3. Press the Home button to return to the Procedure menu.
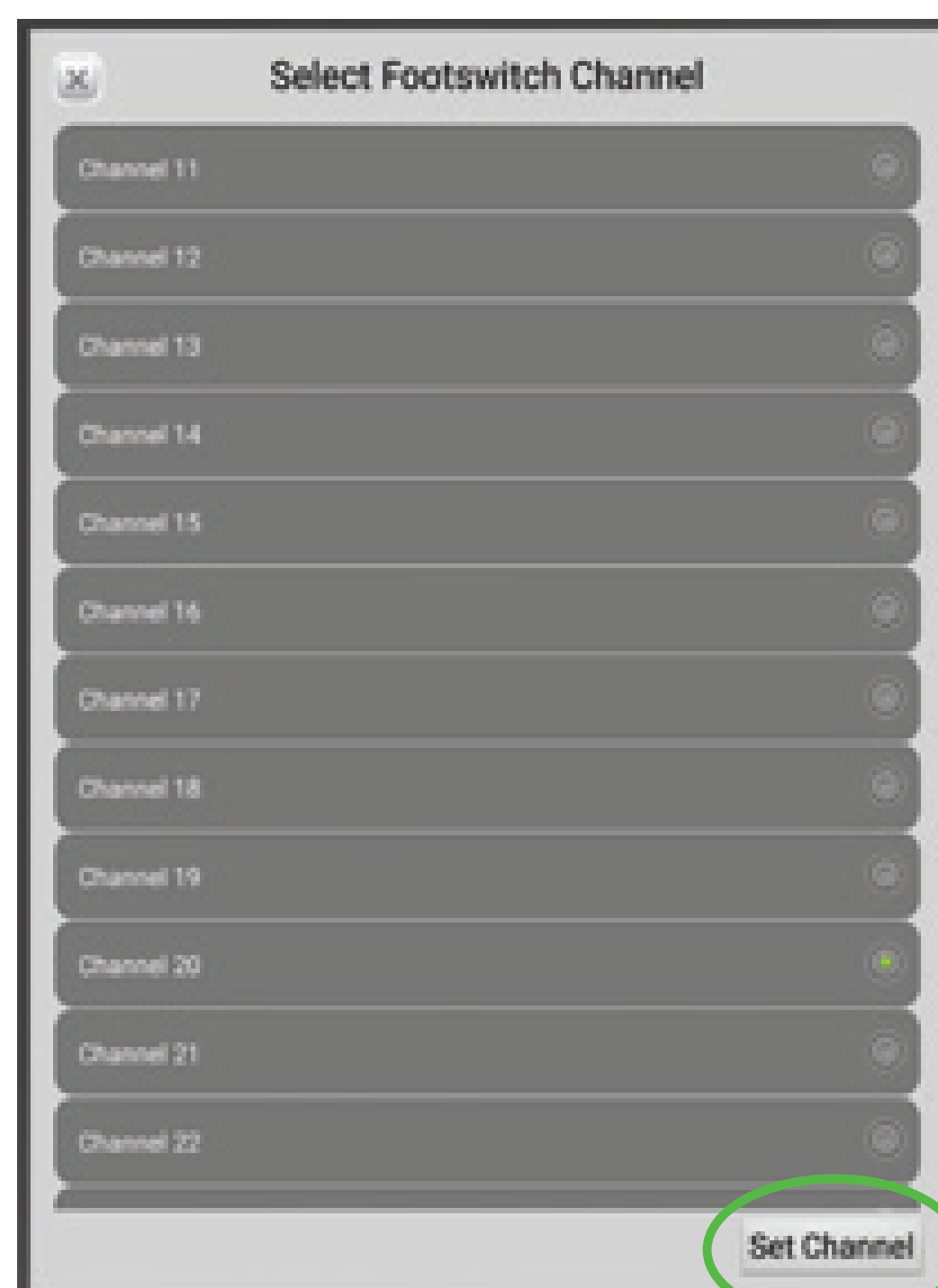
Figure 12.27   Figure 12.28   Figure 12.29

12.10 INTERNAL COOLING WATER RESERVOIR

12.10.1 FILLING THE INTERNAL COOLING WATER RESERVOIR

The Waterlase Express ships with the internal cooling water reservoir empty. Before first-time use, fill the reservoir with **distilled or de-ionized water** using the reservoir fill kit included with the laser system. **DO NOT USE TAP OR FILTERED WATER.**

Normally, the reservoir will be filled at the time the system is installed by an authorized BIOLASE representative; however, it may need to be replenished after the laser has been in use for an extended period. The water level is visible through a small window on the side of the laser (Figure 12.30). A yellow floating ring makes it easy to determine the water level.

To fill the internal cooling water reservoir, the laser system must be turned ON and the user logged in.

Figure 12.30

1. Go to System Menu. Go by pressing the Menu button on the bottom left of the Tablet screen and select "Maintenance."

2. Select "Service"

3. Select "Fill Cooling Water Reservoir." The water level in the reservoir is visible through the viewing port on the side of the console.

A series of prompts will appear on the screen; after following each instruction, press "Continue".

4. Fill the cooling water syringe provided in the Reservoir Fill Kit with distilled or de-ionized water.

5. Open the plug at the back of the console and attach one end of the tubing **(a)** to the internal reservoir connector **(b)** at the back of the laser console (Figure 12.31) by inserting and then twisting until it clicks into place (about a ¼ turn), and the other to the Tip of the **full** syringe. Gently tug on the tubing to verify it is properly connected.

6. Push the plunger while viewing the water level on the side of the laser console until the water level gauge indicates the reservoir is full. This step may require filling the syringe more than once.

7. Detach the tubing from the laser console.

8. Press the "OK".

(a)

(b)
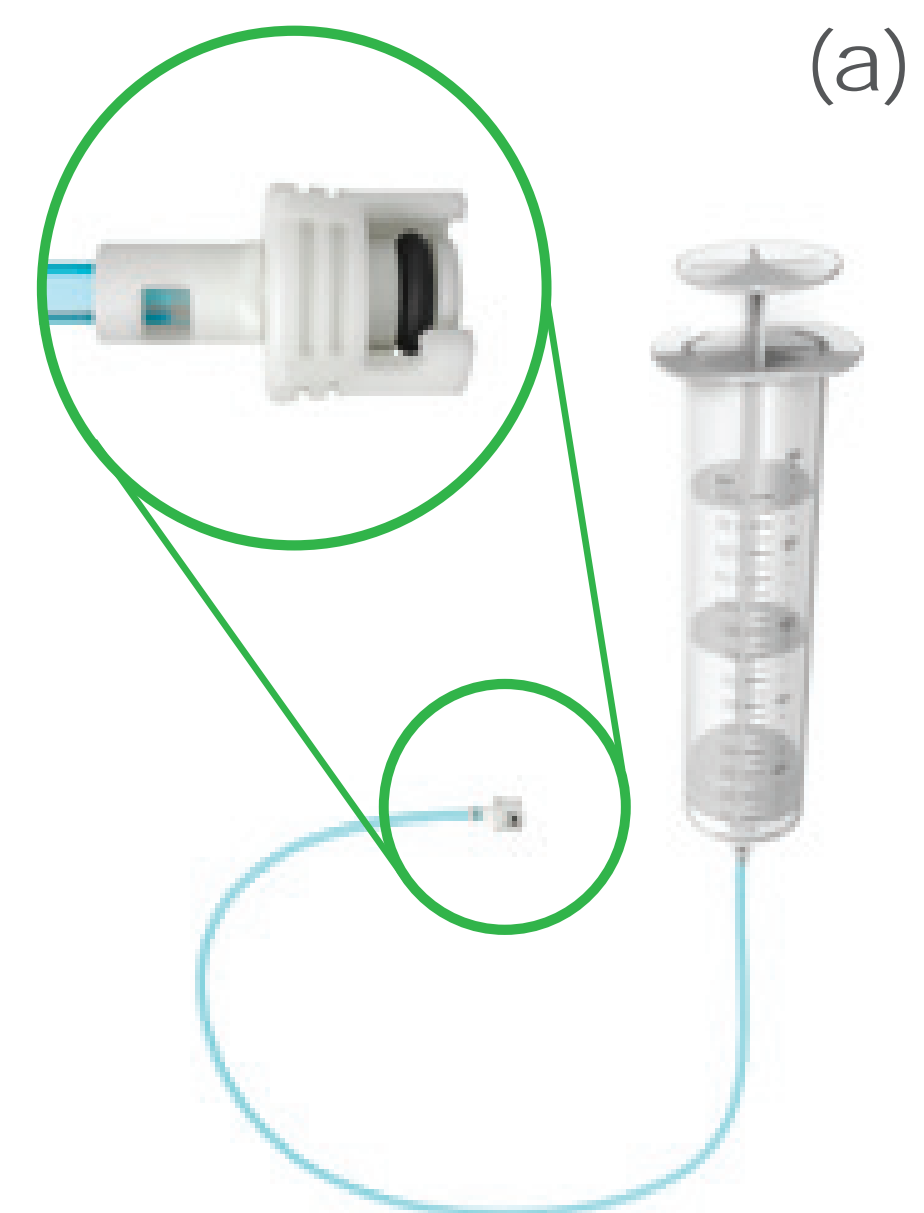
Figure 12.31

9. The pump will turn on for approximately 10 seconds; once it stops, view the water level. If the reservoir is still low, reattach the fill kit and repeat step 5-8.

10. Place the system into Ready mode; allow the water pump to run for approximately 10 minutes; if air bubbles are present in the reservoir, the laser console will emit a spluttering sound. Tilt the console 45 degrees to the water level window side until the sound stops.

If the internal cooling reservoir level falls to below acceptable level while the laser system is in operation, the error message "**INTERNAL COOLING RESERVOIR WATER LEVEL LOW**" will appear on the screen and the laser will stop. Fill the reservoir following the instructions noted above.

⚠️ CAUTION: **DO NOT OVERFILL**; excess water will drain out of the bottom of the console.

12.10.2 DRAINING THE INTERNAL COOLING WATER RESERVOIR

If the laser needs to be returned to BIOLASE for maintenance or repair, the water in the internal cooling water reservoir should be drained prior to shipping. Although draining the reservoir can be done by the user, it would be preferable to have an authorized field service technician prepare the unit for shipment.

To drain the internal cooling water reservoir, the laser system must be turned OFF and the electrical cable, and air tubing disconnected from the back of the console.

1. Remove the patient water bottle from the laser console.

2. Carefully place the rear portion of the laser console over the edge of a counter or sink; make sure to support the laser console to prevent it from falling off the edge.

3. Rotate the drain connector on the bottom of the laser console and remove the plug by pushing in the outer ring while pulling the plug out. Note that water may drain out immediately once the plug is removed; if the laser console has been placed on a counter, make sure a suitable receptacle is placed on the floor beneath it to contain the water pouring out.

4. Remove the rectangular plastic plug at the back of the console and attach one end of the tubing (a)(Figure 12.26) to the internal reservoir connector at the back of the laser console, and the other to the tip of the empty syringe without the plunger installed.

5. Insert the plunger into the syringe and push all the way in to force the water out of the reservoir; repeat 5-10 times, then leave the tubing attached to the console without the syringe attached. Allow the water in the console to drain, approximately 10-15 minutes.

6. Replace the green drain plug on the bottom of the laser console and rotate it back into place.

12 Maintenance

12.11 TRANSPORTATION

The Waterlase Express is susceptible to misalignment if not handled properly. The system and accessories are shipped inside custom shipping boxes; please save and store the boxes in a cool, dry place until needed.

The laser system should **ALWAYS** be packed inside its shipping box when transported from one facility to another. Although the laser system is portable and may be carried or rolled on a cart from one operatory to another inside the same facility, care should be taken when pushing the laser system on   a cart over doorway thresholds and other bumps or objects on the ground.

> **NOTE:** The packaging materials used for Waterlase Express include paper products, polypropelene, polystyrene, low density polyethylene, and polyethylene foam. Paper products are recyclable. Dispose of all other materials in accordance with local waste regulations.

12.12 STORAGE

The Waterlase Express and accessories should be stored in a cool, dry place when not in use. Storage temperature should be 5° to 45°C (41°F to 113°F), relative humidity 10% to 90%, non-condensing. Cover the system when not in use for extended periods of time and store in a place where it will not be accidentally bumped or banged.

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

13 Troubleshooting

The Waterlase Express constantly monitors its own performance and calibration and will alert the user of a performance error.

13.1.1 ERROR MESSAGES

If a performance error occurs, the system will automatically go into **Standby** and the screen will display a message indicating the cause of the error and the recommended action for resolution (Figures 13.1, 13.2).

If after following the directions on the screen the error or warning does not clear, please call your local BIOLASE service representative for assistance.

Error / Warning		Cause	Action
01	Footswitch Not Detected	Wired footswitch disconnected, or wireless footswitch batteries low, or the wireless footswitch may be out of range or not paired.	Check the wired footswitch connection or press the wireless footswitch. Also check wireless footswitch battery and ensure the footswitch is within range, re-pair the wireless footswitch with you laser system if necessary.
02	Internal HV System Error*	Power accuracy above / below acceptable levels.	Restart the system; contact your authorized BIOLASE service provider for further assistance if the problem persists.
03	Tablet Communication Error	The system has detected a communication error.	Restart the system and the Tablet; contact your authorized BIOLASE service provider for further assistance if the problem persists.
04	Data Integrity Error	The system has detected a data integrity error.	Restart the system and the Tablet; contact your authorized BIOLASE service provider for further assistance if the problem persists.
06	Emergency Stop Pressed	The Emergency Stop button was pressed.	Check and release by pressing the Emergency Stop button again. If the Emergency Stop button was not pressed and this message appears, contact your authorized BIOLASE service provider for further assistance.
07	Fiber Not Detected	The laser Fiber was not detected.	Fiber is not installed or not installed correctly. Remove and reinstall the Fiber. Contact your authorized BIOLASE service provider for further assistance if the problem persists.

* L = Low, H = High, C = Calibration data corrupt

13 Troubleshooting

Error / Warning		Cause	Action
08	Cooling Water Flow Error	No cooling water flow was detected.	Re-press control button to set system to **Ready** mode again. Contact your authorized BIOLASE service provider for further assistance if the problem persists.
09	Patient Water Bottle Sensor Error	The patient water bottle sensor may be defective.	Restart the system; contact your authorized Biolase service provider for further assistance if the problem persists.
10	Internal HV System Temperature Error	Temperature levels above / below acceptable levels.	Leave the system on for a few minutes then restart the system; contact your authorized Biolase service provider for further assistance if the problem persists.
11	Air Pressure Error	No or low air pressure was detected.	Verify that airline has sufficient pressure. Release the air from the system and then re-attach airline quick connector. Contact your authorized BIOLASE service provider for further assistance if the problem persists
12	Remote Interlock Not Detected	The Remote Interlock is open.	Check the Remote Interlock connector on the back panel; contact your authorized BIOLASE service provider if the problem persists.
13	Internal Shutter Error	The system has detected an internal shutter error.	Restart the system; contact your authorized BIOLASE service provider if the problem persists.
14	Internal Cooling Water Temperature Error	The internal water reservoir temperature exceeds operating limits.	Allow the system to cool off by placing the laser in **Standby** mode for at least 10 minutes before using the laser; contact your authorized BIOLASE service provider if the problem persists.
15	Control Button Error	The system has detected a problem with the front control button.	Press and release the Control Button, then restart the system; contact your authorized BIOLASE service provider if the problem persists.
16	Patient Water Bottle Empty or Missing	The Patient Water Bottle is empty or missing.	Insert, check and/or refill the patient water bottle. If the bottle is full, do not use the laser and contact your authorized BIOLASE service provider for assistance.
17	Fiber Not Recognized	The system does not recognize the fiber that is installed.	Turn off the laser, disconnect and reconnect the fiber and turn the laser on. Contact your authorized BIOLASE service provider for assistance if the error persists.

13 Troubleshooting

Error / Warning		Cause	Action
20	Unauthorized Tablet Connected	The tablet is not authorized for this laser.	Use the correct Tablet for the laser system. If you are using the correct Tablet, contact your authorized BIOLASE service provider for assistance.
21	Unrecognized Command	The system received an unexpected command from the Tablet.	Restart the tablet and the laser; contact your authorized BIOLASE service provider for further assistance if the problem persists.
22	Invalid Parameter	The system received invalid data.	Restart the Tablet and the laser; contact your authorized BIOLASE service provider for further assistance if the problem persists.
23	Incompatible Software Version	The system detected incompatible software.	Contact your authorized BIOLASE service provider for assistance.
24	Internal Simmer Supply Error	An internal simmer supply or flash lamp error has been detected.	Restart the system; contact your authorized BIOLASE service provider for further assistance if the problem persists.
25	Footswitch Error	A Footswitch error has been detected.	Press and release the Footswitch 4-5 times; if,this does not resolve the issue, remove* the batteries and install fresh batteries. Contact your authorized BIOLASE service provider for further assistance if the problem persists. *only applies to wireless Footswitch
26	Thermistor Error	A thermistor problem has been detected.	Restart the system; contact your authorized BIOLASE service provider for further assistance if the problem persists.
28	Internal Cooling Reservoir Water Level Low	The internal cooling reservoir water level is low.	Refill the cooling water reservoir; contact your authorized Biolase service provider for further assistance if the problem persists.
29	System Water Spray Error	The system has detected an error in the spray system.	Restart the system; contact your authorized BIOLASE service provider for further assistance if the problem persists
30	Internal LV System Error	Internal system error.	Restart the system; contact your authorized BIOLASE service provider for further assistance if the problem persists.

13 Troubleshooting

31	No Footswitch Available	No wired footswitch is connected and no wireless footswitch has been paired with the system.	Connect a wired footswitch or pair a wireless footswitch to the Express system.
32	Wired Footswitch Detected	A wired footswitch was inserted while the system was in Ready or Firing mode.	To continue using the wired footswitch, dismiss this error, or to use the wireless footswitch, disconnect the wired footswitch.

Figure 13.1

13 Troubleshooting

13.1.2 PROBLEM/WARNING MESSAGES

Problem / warning	Reason(s)	Fix
100 Patient Water Bottle Level Low.	Approximately 5 minutes of water remain in the Patient Water Bottle.	Add distilled or de-ionized water to the Patient Water Bottle.
101 Internal Cooling Temperature Warning	The Internal water reservoir temperature is elevated.	Allow the laser to cool down by placing the system in **Standby** mode for at least 5 minutes.
103 Update Failed Warning	Software update has failed to complete.	Press OK to return to the BIOLASE software application; contact your authorized BIOLASE service provider for assistance if the problem persists.
104 Data Download Failed Warning	The system was unable to download data and learning center updates.	Check network connection and contact your authorized BIOLASE service provider for assistance if the problem persists.
105 Low Memory or Resources	The system is low on free memory or other resources.	Restart the tablet and the laser; if the problem persists contact your authorized BIOLASE service provider for assistance.
106 Footswitch Battery Low	The Footswitch battery is low.	Replace the Footswitch battery.
107 Footswitch Pressed in Standby.	The Footswitch was pressed while in **Standby** mode.	Release the Footswitch and place the laser in **Ready** mode before pressing the Footswitch again.

Figure 13.2

⚠ **CAUTION: There is one additional error that applies specifically to the Tablet:** "The BIOLASE warning system has detected a condition which requires a Tablet reset." This can be accomplished by pressing the OK button. The Tablet will restart automatically. If the warning persists, please contact your authorized BIOLASE service provider for assistance.

Appendix A Labels

PRODUCT IDENTIFICATION LABEL: Identifies product part number, serial number, manufacturer, manufacturing date **LOCATION:** Rear of console	**BIOLASE** 4 Cromwell Rx Only Irvine, CA 92618 USA Made in USA 0482 **C E** **Waterlase Express** All-Tissue Laser System REF 7210001 SN XXXXXXXX YYYY-MM (01)00647529002339 (11) YYYY-MM (21)XXXXXXXX
MANUFACTURER	
CATALOG/PART NUMBER	**REF**
PRODUCT SERIAL NUMBER	**SN**
DATE OF MANUFACTURE	
LASER HAZARD SYMBOL: Indicates the system contains a laser **LOCATION:** Laser aperture and internally on the laser head	
TYPE BF APPLIED PART: Side panel of laser console **LOCATION:** Adjacent to the Laser Cable Assembly	5201523 Rev. A
HIGH VOLTAGE HAZARD SYMBOL: Warning – Dangerous voltage **LOCATION:** Inside console (only visible during service)	
LASER APERTURE: Indicates laser energy is emitted from the Fiber Optic Cable end **LOCATION:** Side of console, near laser output	LASER APERTURE AT FIBER END 5201573 REV. A

Appendix A Labels

CERTIFICATION:
This device complies with FDA laser standards

LOCATION:
Bottom of 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

LASER EXPLANATORY LABEL:
Lists laser specifications

LOCATION:
Rear panel of console

SYSTEM GROUND CONNECTION

LOCATION:
Inside laser console (only visible during service)
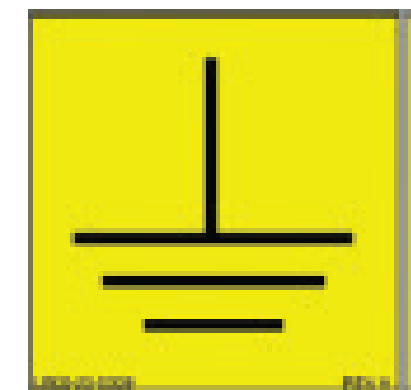
ELECTRICAL SHOCK RATINGS, READ USER MANUAL

LOCATION:
Rear panel of console

ELECTRICAL RATINGS
100 - 230 V∼
50/60 HZ
6 A / 3 A
5201516 Rev. A
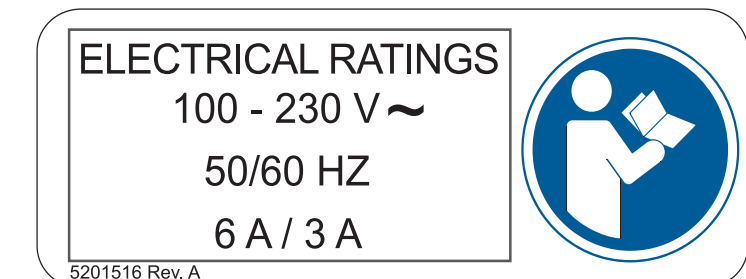
REFER TO USER MANUAL

AIR LABEL (INDICATES MINIMUM AND MAXIMUM AIR PRESSURE)

LOCATION:
Rear panel of console

827 kPa MAX. (120 psi)
420 kPa MIN. (60 psi)
15 L/min   0.5 CFM
AIR
5200008   REV. A
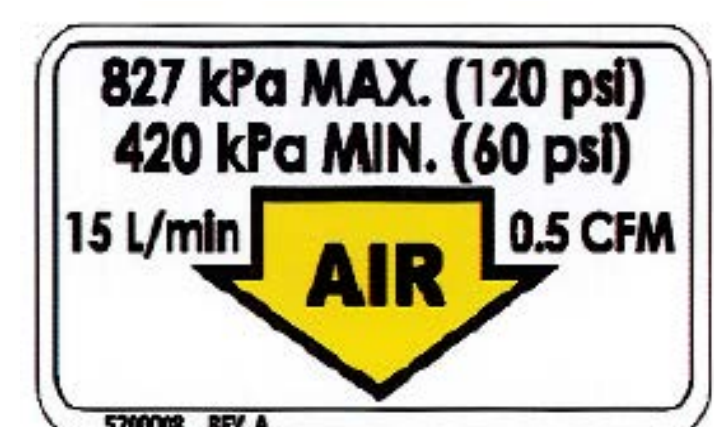
EMERGENCY STOP BUTTON

LOCATION:
Front panel, below Tablet Holder

PROTECTIVE EARTH GROUND

LOCATION:
Inside laser console (only visible during service)

Appendix A Labels

ATTENTION/GENERAL WARNING

LOCATION: Inside laser console (only visible during service)

KEY SWITCH:

Insert key to turn laser ON and OFF

LOCATION:

Front panel, below Tablet Holder
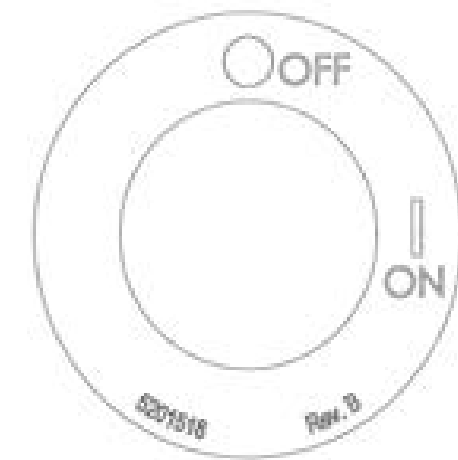
POTENTIAL EQUALIZATION TERMINAL (PEQ):

Potential equalization conductor used to connect the GND

LOCATION:

Rear panel

ETL LABEL: Conforms to ETL standards

LOCATION: Bottom of console

ETL CLASSIFIED
CONFORMS TO AAMI STD ES60601-1
IEC STDS 60601-2-22, 80601-2-60, 60825-1
CERTIFIED TO CSA STD C22.2 No. 60601-1
Intertek
9800165
5201626 Rev. A
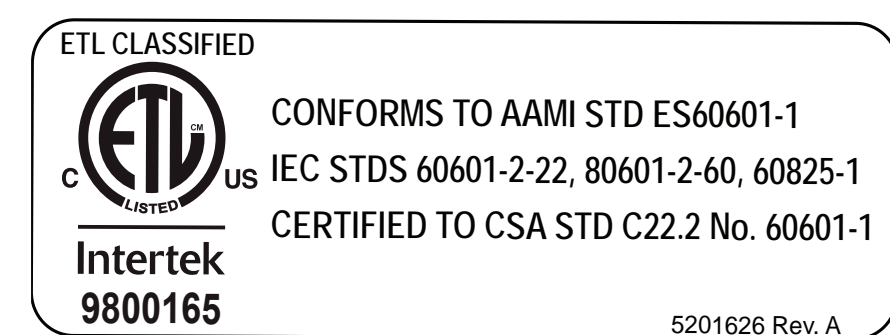
FCC COMPLIANCE NOTICE: The wireless Footswitch and laser console comply with Part 15 of FCC rules regarding licensed transmissions.

LOCATION:

Bottom of console, bottom of wireless 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.

FCC AND IC LABEL:

Lists Federal Communications Commission and industry Canada registration numbers.

LOCATION:

Bottom of console and of wireless Footswitch

Contains:
FCC ID: OA3MRF24J40MA
IC ID: 7693A-24J40MA
5201522 Rev. B
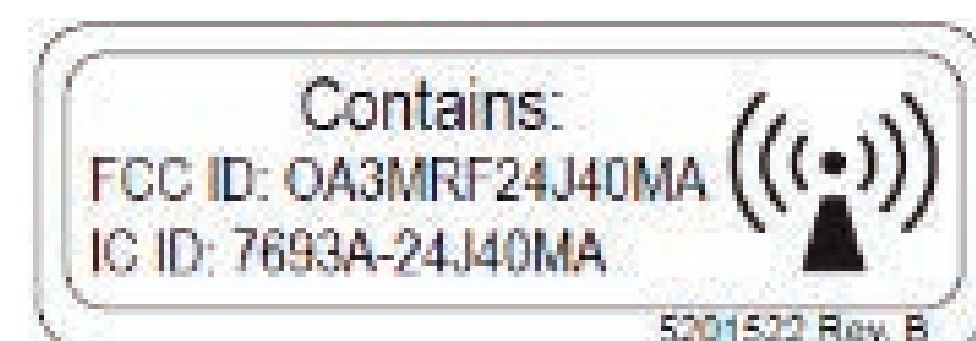
NON-IONIZING RADIATION:

Device includes an intentional radiator (Bluetooth)

CONNECTION TO WIRED FOOTSWITCH:

LOCATION:

Rear of laser console

5200051 REV.B

Appendix A Labels

TABLET ID LABEL

LOCATION: Back of Tablet
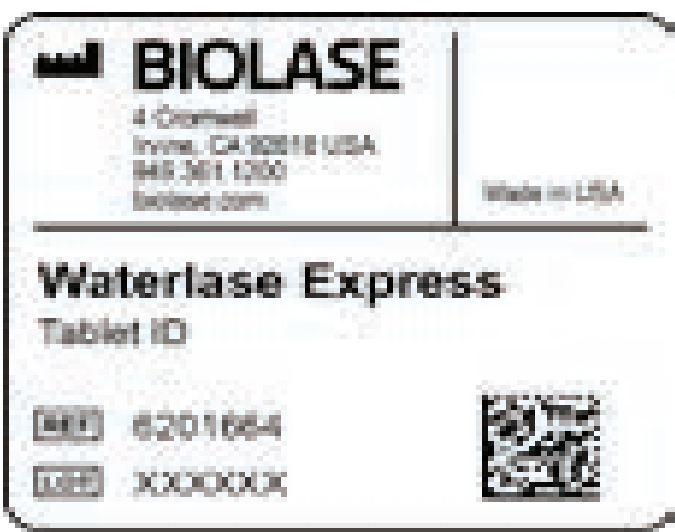
DO NOT USE TAP WATER, REFER TO USER MANUAL

LOCATION: Patient water bottle cap

SINGLE USE ONLY – DO NOT REUSE

LOCATION:
Tips packaging

REMOTE INTERLOCK

LOCATION: Rear of console
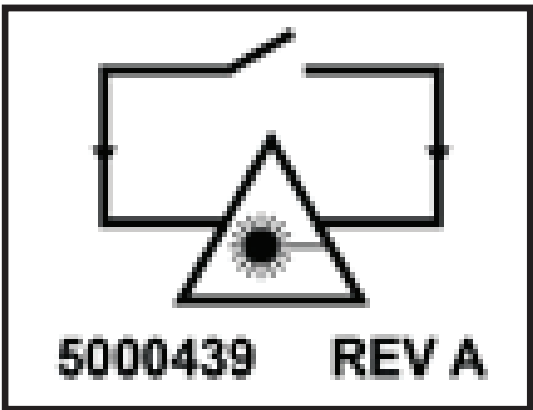
SHIPPING LABEL – LASER SYSTEM

LOCATION: Outer carton (shipping box)
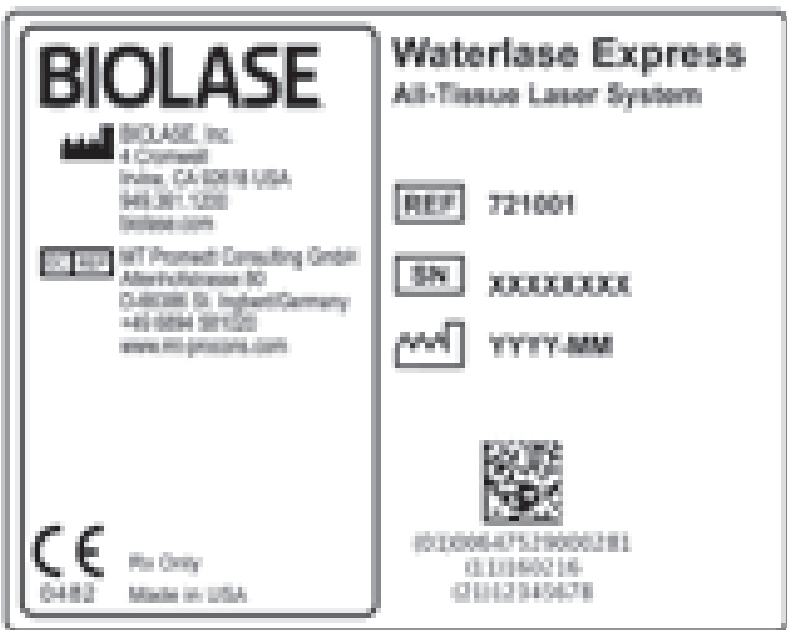
EUROPEAN REPRESENTATIVE

LASER WARNING SIGN
Included in the welcome kit; must be placed outside of the operatory whenever the laser system is in use.
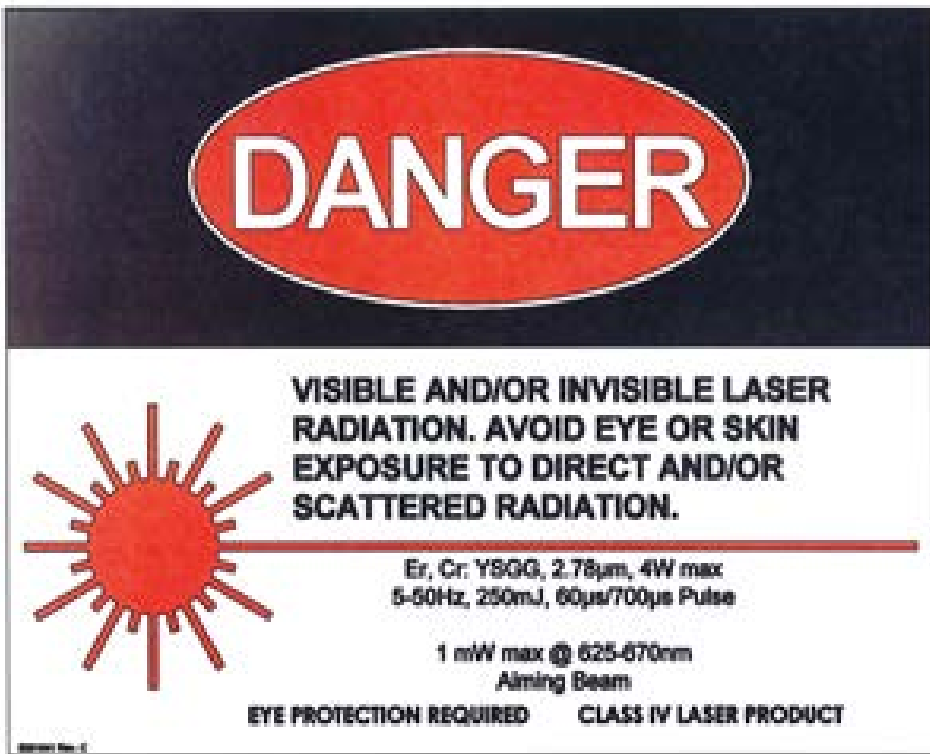
Appendix A Labels

WEEE (WASTE ELECTRICAL AND ELECTRONIC:
Do not throw in trash bin. Dispose of as regulated.)

LOCATION: Bottom of console

THIS END UP

LOCATION: Outer carton (shipping box)
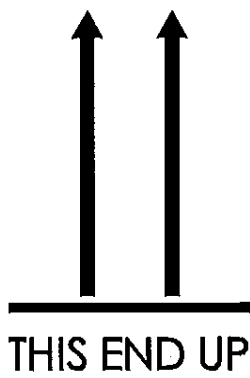
FRAGILE: HANDLE WITH CARE

LOCATION: Outer carton (shipping box)
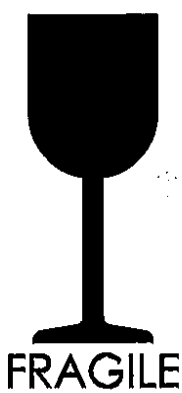
KEEP DRY

LOCATION: Outer carton (shipping box)

TRANSPORTATION TEMPERATURE LIMITATIONS

LOCATION: Outer carton (shipping box)
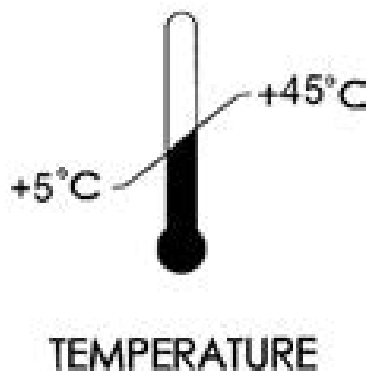
HUMIDITY LIMITATIONS

LOCATION: Outer carton (shipping box)
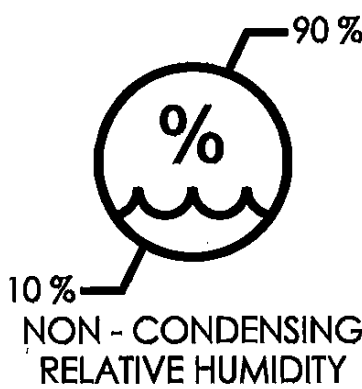
ATMOSPHERIC PRESSURE LIMITATIONS

LOCATION: Outer carton (shipping box)
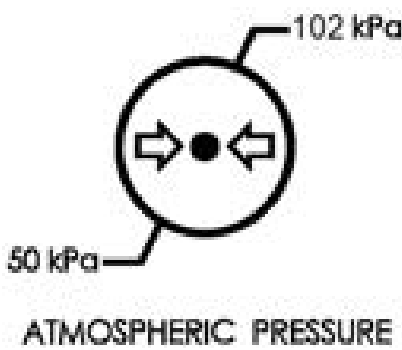
Appendix B Accessories / Spare parts

BIOLASE P/N	DESCRIPTION
7220001	Handpiece
3200105	Mirror Removal Tool
7240001	Fiber Optic Cable
2201222	Protective eyewear
6200150	(Wired) Footswitch
6201880	(Wireless) Footswitch
6400463	AAA Footswitch batteries (2-pack)
6201664	Tablet
2000605	Keys
6201812	Remote interlock plug
2201078	Power cord 120 VAC, 50/60 Hz (USA)
2200892	Power cord 220-230 VAC, 50/60 Hz (International)
2200893	Power cord 240 VAC, 50/60 Hz (UK)
6001029	Yellow air tube
7250002	Internal reservoir fill kit
7250003	Tablet protective covers (20/Pack)
7000414	Tip Holder/remover
7230001	Tip starter kit
7200104	Tip cleaning and inspection kit
5201541	Laser warning sign
7250001	Waterlase Express Premium Cart
7250004	Waterlase Express Economy Cart
6201658	Fiber Optical Cable support arm
6201102	Mirror Refill Kit, 1 pc
6201037	Mirror Refill Kit, 3 pcs
7240002	Fiber Optic Cable protective window refill

TIP TYPES FOLLOWING DENTAL STANDARD ISO SERIES DIAMETER/COLOR CODES

Zip Tips

MZ5
RFPT5
500μm*

MZ6
600μm*

MZ8
800μm*

MZ10
1000μm*

RFT2
200μm*

MZ3
RFT3
320μm*

20	25	30	35	40	45	50	55	60	70	80	90	100	120

MC3
300μm

MT4
400μm

MGG6
600μm

MC6
600μm

MS75
750μm

SFT8
800μm

MC12
1200μm
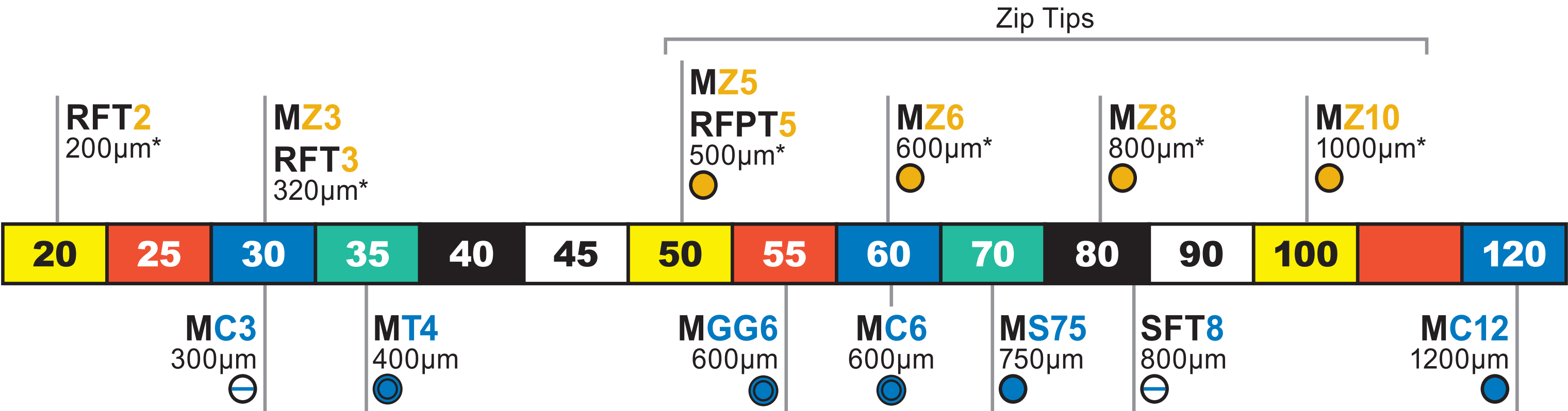
TIP IDENTIFIERS	TIP TYPES		
	Glass Tips: **Z, RFT, RFPT**		
M Z 6	Sapphire Tips: **C, G, GG, S, T**		
Product Type — M (MD, iPlus, Express) / Tip Type — Z (Glass), T (Sapphire) / Tip Diameter (x 100μm)	Cylindrical	Tapered	Chisel

*Fiber Core Diameter

TIP SETTINGS, WATERLASE EXPRESS HANDPIECE

SINGLE-USE TIPS (GLASS)

Tip Type	Ferrule Color/ Diameter (μm)	Lengths (μm)	Handpiece		Tissue Types
			Calibration Factor*	Maximum Power (W)	
RFT2	200	21, 25	0.55	4.0	Root Canal
MZ3	320	9, 14, 20, 25, 28	0.85	4.0	Root Canal, Soft-tissue
RFT3		17, 21			Root Canal
MZ5	500	3, 6, 9, 14	.95	4.0	All Types
RFPT5		10, 14		6.0	Bone, Soft-tissue
MZ6	600	3, 6, 9, 14	1.00	No Limit	Enamel, Bone, Dentin, Soft-tissue
MZ8	800	3, 6, 9	1.00	No Limit	Enamel, Bone, Dentin, Soft-tissue
MZ10	1000	3, 6, 9	1.00	No Limit	Enamel, Bone, Dentin, Soft-tissue

Appendix C Tips

RE-USABLE TIPS (SAPPHIRE)

Tip Type	Ferrule Color/ Diameter (μm)	Lengths (μm)	Handpiece		Tissue Types
			Calibration Factor*	Maximum Power (W)	
MT4	400	6	1.00	2.5	Enamel, Dentin, Soft-tissue
MS75	750	6	1.00	No Limit	Enamel, Bone, Dentin, Soft-tissue
MC3	300 x 1200	9	1.00	No Limit	Enamel, Bone, Dentin, Soft-tissue
MC6	600	9	1.00	No Limit	Enamel, Bone, Dentin, Soft-tissue
MGG6	600	4, 6, 9	1.00	No Limit	Enamel, Bone, Dentin, Soft-tissue
SFT8	800	18	0.95	2.4	Bone, Soft-tissue
MC12	1200	9	1.00	No Limit	Bone, Dentin, Soft-tissue

⚠️ **CAUTION:** Tips are shipped non-sterile and require sterilization before use. If a reduction in cutting efficiency is observed, replace the Tip. Failure to replace the Tip correctly could result in damage of the Tip or the Handpiece mirror. The Tips have a limited lifetime therefore damage of the cable attributed to overuse of the Single-Use Tip may not be covered by warranty.

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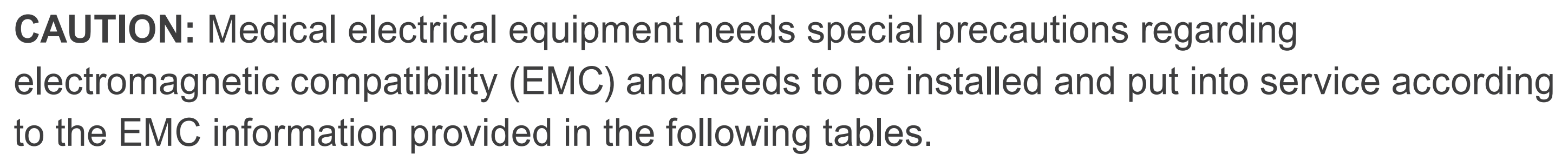
Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment.

⚠️ **WARNING:** The use of accessories, other than those specified, except those supplied or sold by BIOLASE as replacement parts for internal or external components, may result in increased EMISSIONS or decreased IMMUNITY of the Waterlase Express.

Accessories:

- Medical grade power cord, maximum length 10 feet (2.44 meters); refer to Appendix B for applicable part number.
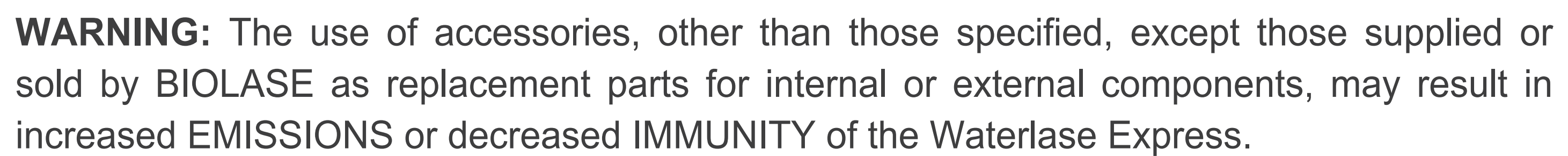
- Footswitch: Wireless, BIOLASE p/n 6201880.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS		
The Waterlase Express is intended for use in the electromagnetic environment specified below. The customer or the user of the Waterlase Express 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 Waterlase Express uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF conducted emissions CISPR 11	**Group 1, Class A/B**	
Harmonic emissions IEC 61000-3-2	**Class A**	The Waterlase Express 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.
Voltage fluctuations/flicker emissions IEC 61000-3-3	**Class A**	

Appendix D Electromagnetic Compatibility

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

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY *(Continued)*			
The Waterlase Express is intended for use in the electromagnetic environment specified below. The customer or the user of the Waterlase Express should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Continuous level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 GHz 6Vrms At the standard specified ISM band	3 Vrms 150 kHz to 80 GHz 6Vrms At the standard specified ISM band	Portable and mobile RF communications equipment should be used no closer to any part of the model Waterlase Express, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHZ Where **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and **d** is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC61000-4-3	9 V/m to 28 V/m 385 to 5785 MHz		
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.			

Appendix D Electromagnetic Compatibility

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

Appendix E Wireless Equipment Compliance

FEDERAL COMMUNICATIONS COMMISSION (FCC) COMPLIANCE STATEMENT

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

INDUSTRY CANADA (IC) COMPLIANCE STATEMENT

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

INDUSTRIE CANADA (IC) DÉCLARATION DE CONFORMITÉ

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes: (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

> ⚠️ **CAUTION:** Changes or modi cations not expressly approved by the manufacturer responsible for compliance could void the user's authority to operate the equipment.

To satisfy RF exposure requirements, this device and its antenna must operate with a separation distance of at least 20 centimeters from all persons and must not be collocated or operating in conjunction with any other antenna or transmitter.

BIOLASE

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Waterlase *express*™

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