

# BWF-5-810 Dental Laser User Manual



# TABLE OF CONTENT

<b>1</b>	<b>WARNING AND SAFETY INFORMATION .....</b>	<b>4</b>
1.1	HIGHLIGHTING OF WARNING AND SAFETY INFORMATION.....	4
1.2	INTENDED USE.....	4
1.3	WIRELESS PHONE INTERFERENCE .....	5
1.4	DISPOSAL .....	5
1.5	SALE .....	5
<b>2</b>	<b>GLOSSARY, SYMBOLS AND ABBREVIATIONS .....</b>	<b>6</b>
2.1	SYMBOLS AND LABELS ON THE BWF-5-810-5 .....	6
2.2	GLOSSARY .....	8
2.3	ABBREVIATIONS.....	8
<b>3</b>	<b>INTRODUCTION .....</b>	<b>9</b>
3.1	CLASSIFICATION.....	9
3.2	SAFETY PRECAUTIONS.....	9
3.3	TRANSPORT AND STORAGE.....	12
3.4	PRECAUTIONS.....	12
<b>4</b>	<b>SYSTEM SET-UP.....</b>	<b>15</b>
	SPARE PARTS .....	15
4.1	LASER UNIT SET-UP.....	15
4.2	FIBER INSTALLATION .....	18
4.3	CONNECTION OF THE FOOT CONTROL .....	18
4.4	SWITCHING THE LASER UNIT ON AND OFF.....	18
4.5	OPTICAL FIBER PREPARING.....	19
<b>5</b>	<b>OPERATING INSTRUCTIONS.....</b>	<b>21</b>
5.1	POWER ON DISPLAY .....	21
5.2	STANDBY AND READY DISPLAY .....	22
5.3	LASER POWER SETTING.....	23
5.4	CW MODE.....	23
5.5	SINGLE PULSE MODE.....	23
5.6	REPEAT PULSE MODE.....	23
5.7	LASER EMISSION ENERGY RESET .....	24
5.8	SETUP MODE.....	24
5.9	PRESET PROGRAMMING.....	25
5.10	EMISSION MODE .....	25
5.11	STOP EMISSION .....	25
5.12	PRESET MODE .....	25
5.13	ERROR MESSAGE .....	26
<b>6</b>	<b>CLEANING AND STERILIZATION .....</b>	<b>28</b>
6.1	CLEANING .....	28
6.2	DISINFECTION .....	29
6.3	STERILIZATION.....	29
6.4	CLEANING OF THE LASER UNIT .....	30
<b>7</b>	<b>MAINTENANCE AND SERVICE .....</b>	<b>31</b>
7.1	SAFETY CHECKS .....	31
7.2	MAINTENANCE.....	31
7.3	BASIC TROUBLESHOOTING .....	32



7.4	TECHNICAL SUPPORT.....	32
<b>8</b>	<b>TECHNICAL DATA.....</b>	<b>33</b>
<b>9</b>	<b>WARRANTY INFORMATION.....</b>	<b>34</b>
	TERMS AND CONDITIONS .....	34

# 1 Warning and Safety Information

## 1.1 *Highlighting of warning and safety information*

To prevent any personal injury or material damage, please observe the warning and safety information provided in the present operating instructions. All such information is highlighted as follows:



### **NOTICE**

For additional information



### **CAUTION**

If there is any risk of damage to the laser unit



### **WARNING**

If there is any hazard to the life or health of persons



This symbol indicates that you have to take action



This symbol indicates that a certain result will occur

## 1.2 *Intended use*



### **NOTICE**

The user should read and be thoroughly familiar with this manual before operating the instrument. The equipment should be routinely inspected and maintained in accordance with the instructions given in the maintenance section of this manual. Accidental irradiation to other than the target tissue may result in laser burn. Surrounding the target area with moist drapes or saline-soaked gauze pads and keeping them moist will greatly reduce these hazards. Be sure the draping is appropriate for laser surgery. It is recommended that a smoke evacuator or in-line filter be used to capture the plume whenever possible. The plume should be regarded as source of active biological material by the operating room personnel; it may contain viable tissue particulates.



### **NOTICE**

Nominal Ocular Hazards Distance (NOHD) is 1.5 m from the distal end of the fiber



### **NOTICE**

For the installation and use of the BWF-5-810-5, Velopex requires:

- Compliance with IEC 60825-1 and its amendments
- Compliance with any additional national laws and ordinances

**NOTICE**

BWF-5-810-5 laser is intended for surgery and coagulation of soft tissues. This laser unit must only be used by trained personnel in compliance with the applicable occupational safety regulations and accident prevention measures as well as the present operating instructions.

**NOTICE**

The user is obliged to use only faultless materials, to observe the correct application as well as to protect himself or herself, the patient and other persons against hazards.

**WARNING**

This laser unit is not intended for operation in areas subject to explosion hazards or in the vicinity of flammable materials or substances.

**WARNING**

Public legal provisions may include special safety regulations for the protection of persons against laser radiation. These regulations must be complied with.

**WARNING**

Using controls or settings or performing procedures other than those specified in this manual may result in hazardous radiation exposure.

### 1.3 *Wireless phone interference*

**CAUTION**

To ensure the operational safety of electro -medical equipment, the use of mobile wireless phones in practice or hospital environments must be prohibited.

### 1.4 *Disposal*



If you plan to discontinue the use of your BWF-5-810-5 and intend to dispose of the unit, observe all applicable legal provisions. Please contact Velopex for the disposal of the BWF-5-810-5.

### 1.5 *Sale*

**CAUTION**

Federal Law (USA) restricts sales of this device to or on the order of a physician, dentist, or licensed practitioner.

## 2 Glossary, Symbols and Abbreviations

### 2.1 Symbols and labels on the BWF-5-810-5



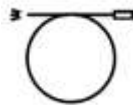
**Manufacturer’s General Identification Label** (See Figure) Located on the side of the device. The label displays the manufacturer, model number, serial number, date of manufacture of the unit. This label also presents various regulatory compliance declarations.



**General Safety Declaration Label** (See Figure) Located on the side of the device, this label indicates the laser classification. It warns of the radiation exposure hazard potential to eyes and skin.



**Laser Radiation warning Label** (See Figure) Located at the top center of the front faceplate.



**Laser Emission (Aperture)** Located on the front of the device, the laser emission (Aperture) label indicates that the laser energy emission occurs at the distal end of a properly connected optical fiber.



**Warranty Seal Label** (See Figure) These labels are positioned on the underside of the laser device in such a way that any attempt to open the panels of this device will break this seal.



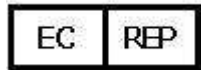
**Emergency Stop switch**



CE mark in accordance with Council Directive 93/42/EEC, stating the manufacturer's Notified body



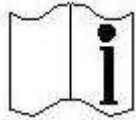
Type BF device



EU representative



Manufacture



Read instruction



Please refer to the user manual



The symbol indicating separate collection for electrical and electronic equipment

SN

Product Series Number



Foot Switch



Interlock

## 2.2 *Glossary*

CONTINUOUS EMISSION	Continuous laser emission
PULSED EMISSION	Pulsed laser emission (chopped mode)
FREQUENCY	Number of laser pulses per second
HERTZ	Measuring unit for frequency
INTERLOCK	Safety device that stops laser radiation when the door of the treatment room is opened
JOULE	Unit of measure for emitted energy
WATT	Unit of measure for laser power
STOP	End of treatment or treatment break
TIME	Treatment time setting mode

## 2.3 *Abbreviations*

cm <sup>2</sup>	Square centimeter
Hz	Hertz
S	Second
W	Watt
mW	Milliwatt (one thousandth of a Watt)
J	Joule
nm	Nanometer
V	Volt
IR	Infrared diode
NOHD	Nominal Ocular Hazard Distance according to EN 60825-1: 2003

## 3 Introduction

### 3.1 Classification

According to the applicable standards, the BWF-5-810-5 laser is classified as follows:

- Class I Type B device according to EN IEC 60601-1:1990 + A1:1993 + A2:1 1995 plus amendments
- Class IIb according to Council Directive 93/42/EEC
- Class IV laser product according to IEC 60825-1 plus amendments
- Degree of protection according to EN IEC 60601-1:1990 + A1:1993 + A2:1 1995 plus amendments: medical unit: IP 20 (enclosure not waterproof); foot control: IPX7



#### **CAUTION**

The laser unit itself cannot be sterilized. However, some accessories must be sterilized when used for contact applications.



#### **WARNING**

The laser unit is not suitable for use in the presence of anesthetics that are flammable when in contact with air, oxygen or nitrogen monoxide.

### 3.2 Safety precautions

BWF-5-810-5 laser is manufactured in compliance with the provisions of Council Directive 93/42/EEC concerning medical devices (MDD).

Always observe the following precautions:



#### **WARNING**

Always cover the optical fiber connection with the special protection caps provided, if the fiber is disconnected from the laser.



#### **CAUTION**

Use of the operating controls or adjustment options in a way other than described herein can lead to dangerous radiation.



#### **CAUTION**

Never insert your fingers or any objects into the exit ports. This is important in order to avoid damage to the optical system.

**CAUTION**

In case of an emergency, switch the laser unit OFF immediately. To do this, press the “LASER STOP” button on the top of the unit.



Figure 1: “LASER EMERGENCY STOP” button

*Observe all labels on the laser unit*

**WARNING**

Operation of this laser unit by unauthorized persons must be prohibited in order to prevent incorrect or improper use.

**WARNING**

Never direct the laser beam or the aiming beam towards the eyes or the thyroid gland of a person. All persons present in the room (patient, doctor and assistant) must always wear the laser protective goggles delivered along with the laser unit.

**WARNING**

Never use optical instruments such as microscopes, eye loupes or magnifiers together with the original protective goggles. Adequate eye protection is no longer ensured in this case.



**CAUTION**

Always cover the optical fiber connection with the special protection caps provided.

**WARNING**

The unit is not suitable for use in the presence of anesthetics that are flammable when in contact with air, oxygen or nitrous oxide.

**WARNING**

Oxygen-saturated materials such as cotton wool can catch fire due to the high temperature that the unit reaches during operation. Label removers and flammable solutions used for cleaning and disinfecting the laser unit should be allowed to evaporate before using the device. Be aware of the fire risk caused by flammable gases.

**WARNING**

Never direct the laser beam toward paper, plastics or dark surfaces. They may catch fire or be damaged due to the high temperatures produced by the laser beam.

**WARNING**

Laser plume must contain tissue particles. There is a risk of contamination! Always wear a face mask.

Observe the following in addition:

**NOTICE**

The unit must only be operated in rooms that comply with requirements of Council Directive 89/336/EEC. The applicable national or local legal regulations must be complied with.

**CAUTION**

Avoid interference of the laser emission with optical sensors of devices operated in the vicinity of the BWF-5-810-5 laser.

### 3.3 *Transport and storage*

#### 3.3.1 **Transport and storage**

The BWF-5-810-5 laser is supplied in a case that ensures proper and easy transport. However, please observe the following:

Do not leave the laser unit in a car parked in the sun. The temperature inside the car can reach levels that may damage its components.

To ensure appropriate storage, the laser unit must always be kept in the case supplied.

When stored in the case provided by Velopex, the BWF-5-810-5 laser withstands the following environmental conditions:

- Temperatures from -20°C (-4°F) to +70°C (+158°F)
- Relative humidity from 10% to 90%

When stored in its original transport packing, the BWF-5-810-5 laser withstands the following environmental conditions:

- Temperatures from -20°C (-4°F) to +70°C (+158°F)
- Relative humidity from 10% to 95%

#### 3.3.2 **Operating conditions**

The BWF-5-810-5 laser may be operated in the following environmental conditions:

- Temperatures from +10°C (+50°F) to +35°C (+95°F)
- Relative humidity from 10% to 95%



#### **CAUTION**

Following transport and storage, allow the laser unit to acclimate for about hour in order to reduce the risk of malfunction due to condensation.

### 3.4 *Precautions*

Using controls or settings or performing functional tests other than those specified in this manual may result in hazardous radiation exposure.

Velopex can not be held liable for any damage caused by improper use or non-compliance with the instructions and information provided in this manual.

Please remember the following:



#### **CAUTION**

BWF-5-810-5 laser may only be operated by trained and qualified personnel.



### **CAUTION**

Laser equipment not in use must be protected against unauthorized access. This can be achieved by switching off the laser unit after use, so that the electronic access key must be entered prior to further operation.

Set up the BWF-5-810-5 laser unit properly and completely before putting it into operation (See Chapter 4)

Make sure that the electrical system is equipped with the required devices for protection against direct and indirect contact (thermo magnetic switches, residual current circuit-breaker) and has been set up by a qualified electrician in compliance with the applicable IEC standards.

National regulations concerning electrical installations shall be obeyed.

Verify that the line voltage corresponds to the voltage indicated on the rating plate of the switching power supply or in the technical specifications.



#### **WARNING**

Do not use the laser unit if a visual inspection reveals damage.



#### **WARNING**

Do not use the laser unit in the presence of flammable materials.

If you accidentally spill liquid on the unit, immediately stop treatment, disconnect the power supply cable and contact your local distributor or authorized service center for assistance.



#### **CAUTION**

Never attempt to disassemble the laser unit. This is limited exclusively to the manufacturer.

Do not place the laser unit near heat sources.

Do not cover the convection openings for air cooling on the back of the unit.



#### **CAUTION**

Always protect the optical fiber socket as well as the optical fiber itself with the special protection caps. Do not allow dust, dirt or other foreign bodies to enter the optical fiber socket. Always make sure that the optical system is clean before connecting the optical fiber.



***WARNING***

Prior to each treatment, the hand pieces must be sterilized and the optical fibers must be steam sterilized.

## 4 System Set-up

If national or local legal regulations require that the installation of the BWF-5-810-5 laser be performed by specialized personnel, these regulations must be complied with.

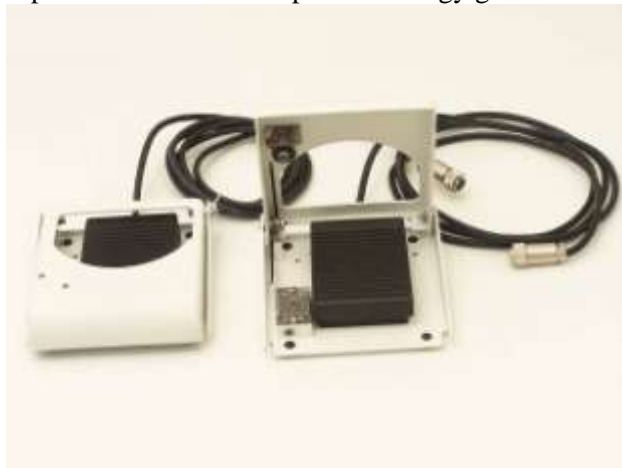


### **WARNING**

The optical fibers and hand piece are supplied non-sterile, you must clean, disinfect and sterilize these products prior to first use and prior to each subsequent use.

### *Spare parts*

A single intensity footswitch comes with this laser device. The laser device treats the footswitch as a simple on/off device. Pressing down on the footswitch produces 100% of the laser energy set by the operator. Fully releasing the pressed footswitch stops laser energy generation.



### **NOTICE**

When closed, the cover of the foot switch is designed to prevent inadvertent foot pedal control. When the laser is properly configured and all safety features have been complied with, open the footswitch cover by pressing it fully down then releasing. Disable laser emission and/or turn power off to further prevent inadvertent laser activation due to unattended foot switch depression.

### 4.1 **Laser unit Set-up**

Setup Location



### **NOTICE**

Ensure that the surface will properly support the entire system.

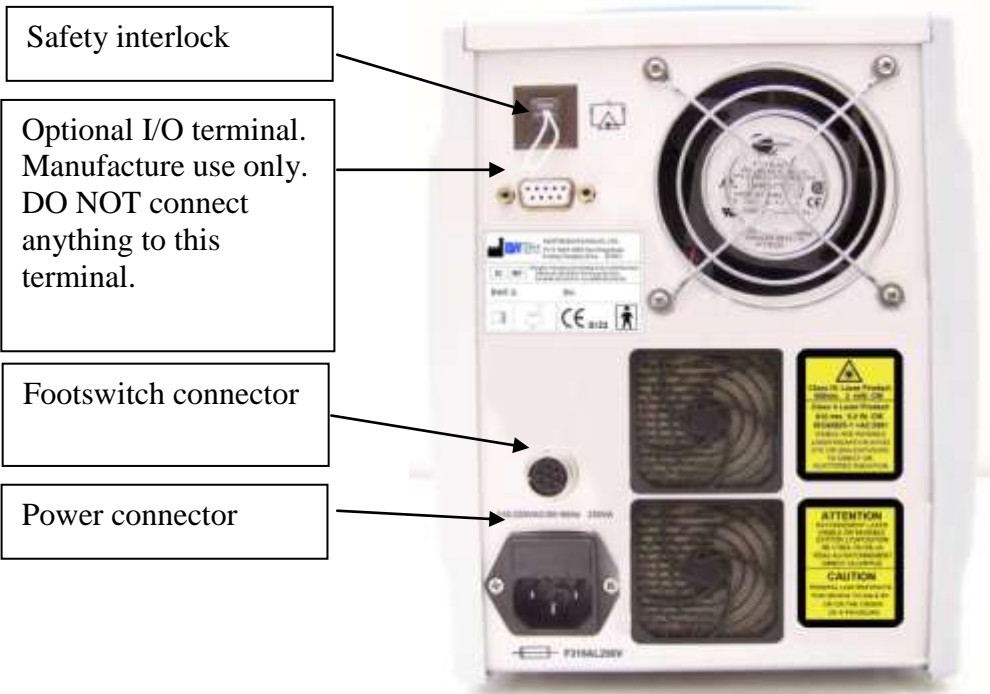
***NOTICE***

Place within 6 feet of an available 110~240V electrical outlet

***NOTICE***

Ensure adequate airflow around the system

- Open the box.
- Remove the protective packaging cover.
- Locate and keep this manual in a secure location.
- Remove any intermediate protective packaging material.
- Remove the power supply and power cord.
- Remove the laser system.
- Select a flat surface (not a surface that will inhibit airflow through the base of the system)
- There must be a minimum 4" (10 cm) clearance around the rear of the system



**WARNING**

The optional I/O terminal is only for manufacture use only. DON'T connect anything to this terminal

## 4.2 *Fiber Installation*

**WARNING**

Please follow the recommend sterilization condition to sterilize the optical fiber before laser surgery. Use of a non-sterilized optical fiber to perform surgery may cause serious infection.

Only standard SMA-905 connector can be used with the BWF-5-810-5 laser in the spectral range of 810nm+/-10nm.

If the optical fibers from other manufacturers are used, physical properties, such as tensile and transmission behavior, may vary. For this reason, Velopex assumes no liability in such cases.

**WARNING**

400um (or larger) core size with 0.37NA silicon core silicon cladding optical fiber with Use Velopex or CE marked Medical Grade optical fiber only.

## 4.3 *Connection of the foot control*

Uncoil the footswitch. Connect the footswitch to the laser unit on the rear.

## 4.4 *Switching the laser unit on and off*



Locate and uncoil the AC power cord.



Plug the power cord into the AC input on the rear of the laser system.



Plug the male end of the AC power cord into an available electrical outlet.



Insert the safety interlock into position.



Insert one of the keys into the key-lock switch located the front of the system.

Turn the key clockwise to the right one-quarter turn.

**WARNING**

The key can only be inserted into and removed from the key switch when it is in the vertical (standby) position.



The fan will start.



There will be an audible beep and the LCD panel will illuminate displaying the initial start-up splash screen.



Refer to the Operation Section to configure and operate the system.

## 4.5 *Optical fiber preparing*

**WARNING**

Always avoid pointing the aiming beam at of anyone's eyes. It is an intense light source even at lower power levels! Wear laser protective goggles!

Check whether the aiming beam signal is an evenly illuminated, round-shaped pattern. To do this, aim the tip of the probe vertically at a white background located approx 15cm away. If there is no beam pattern at all or the beam pattern of the laser probe is unevenly illuminated, the fiber may be damaged or broken. In this case, send the laser fiber in to your distributor for exchange under warranty. Do not use damaged optical fibers.

If the aiming beam signal produces a non-evenly illuminated beam pattern, cut the fiber off with the fiber cleaver until an evenly illuminated round pattern has been obtained.

**CAUTION**

If you switch on the laser unit and the signal of the red aiming laser is not visible or you cannot see the aiming beam during the treatment, proceed as follows:

Turn off the laser and check the optical fiber as well as the fiber connection for mechanical damage.

If the optical fiber is damaged, replace it with a new one.

Check the setting to make sure the aiming is not set at OFF selection.

If you cannot detect any damage on the optical fiber and the aiming setting is not at OFF but the signal of the aiming laser is not visible with the new optical fiber either, turn off the laser and contact BWTEK, your local distributor or your authorized service center.

***CAUTION***

The optical fiber must be sterilized prior to the first treatment.

## 5 Operating Instructions

### 5.1 Power ON Display



The presentation of the revision display screen signals the initiation of the power ON sequence and shall be accompanied by an audible alert.



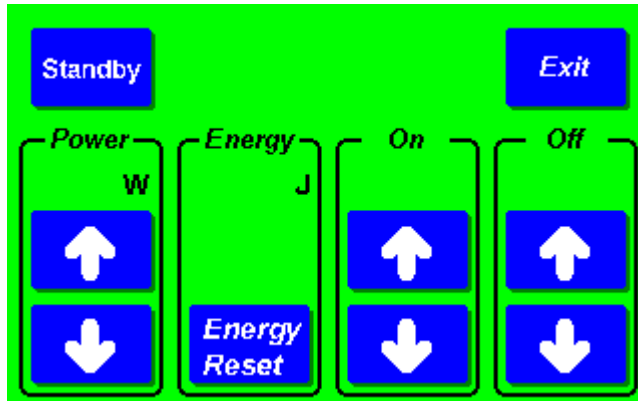
The initialization process shall not exceed 5 seconds and then change to main menu as following.



## 5.2 Standby and Ready Display

➔ Press **Run** button to enter **Standby** mode.

➔ **Standby** screen presentation.



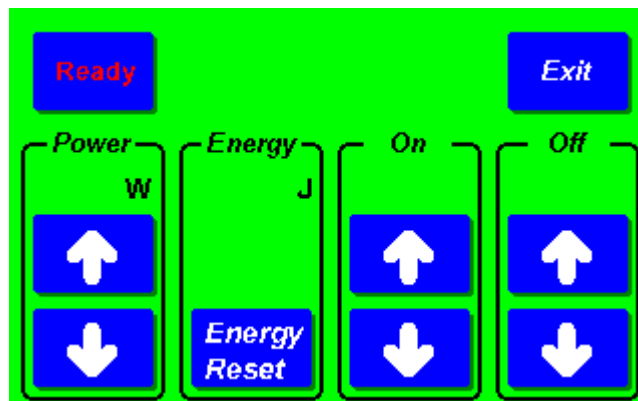
### 5.2.1 Standby to Ready Mode

➔ Press **Standby** button to enter **Ready** mode. A six-second laser emission enabling audible alert notification sequence occurs.

➔ The **Standby** button shall change to **Ready** button.

➔ The laser will be enabled upon the completion of the laser-emission alert sequence and occur when the footswitch is pressed.

➔ **Ready** screen presentation.





**WARNING**

The device shall not leave **Standby** mode if any of the following conditions occur. If the device is already in **Ready** mode, the device shall go back to **Standby** mode if any of the following conditions happen.

- Optical fiber is not properly inserted
- Safety interlock is not properly installed
- Footswitch is depressed

**5.2.2 Ready to Standby Mode**



Press **Ready** button to return to **Standby** mode.



The **Ready** button shall change to **Standby** button.

**5.3 Laser Power Setting**



Pressing the Up-arrow shall increase the power setting until the maximum power is reached. Pressing the Down-arrow shall decrease the power setting until the minimum power is reached.



Set laser power will be displayed as mean power for **CW** mode and peak power for **Pulse** mode and **Repeat Pulse** mode.

**5.4 CW Mode**



Set **Off** duration to CW by pressing Down-arrow under the *Off* icon. The word **CW** will appear on the mid-top of the screen.



In **CW** mode, the **On** duration is not allowed to be set.

**5.5 Single Pulse Mode**



Set **Off** duration by pressing Up-arrow or Down-arrow under the **Off** icon. The word **PULSE** will appear on the mid-top of the screen.



In **Single Pulse** mode, the **On** duration can be set within 0.1S – 120.0S.

**5.6 Repeat Pulse Mode**



Set **Off** duration between 0.1S and 120.0S by pressing Up-arrow or Down-arrow under the *Off* icon. The word **REPEAT** will appear on the mid-top of the screen.



In Repeat Pulse mode, the **On** duration can be set within 0.1S – 120.0S.

## 5.7 Laser Emission Energy Reset

The laser emission energy could be automatically accumulated and monitored during laser emission. Press **Energy Reset** button under the **Energy** icon to reset accumulated energy to 0.0J. The laser emission energy can be reset only in **Standby** mode or **Ready** mode.

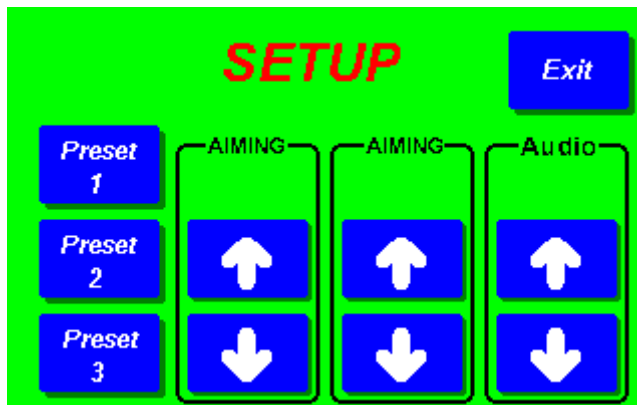
## 5.8 SETUP Mode

Aiming beam status, audible warning tone and preset could be set in **Setup** mode.

- ⇒ Turn on the main power the **Main Menu** screen will display.
- ⇒ Or press **Exit** button at **Standby** mode or **Ready** mode to enter **Main Menu** screen.
- ↶ The **SETUP** screen shall display by pressing **Setup** button in **Main Menu** screen.

The **SETUP** screen presents four columns buttons and an **Exit** button on the right-top of the screen. Press the **Exit** button to enter the **Main Menu** screen.

The sequential sequencing of the Audible Tone, Aiming Beam Frequency, and Aiming Beam Intensity settings shall occur as follows:



### Audible Tone Volume Level

Valid upward selection sequence: Low, Medium, High; Low, Medium, High; etc...

Valid downward selection sequence: High, Medium, Low; High, Medium, Low; etc...

### Aiming Beam Intensity

Valid upward selection sequence: Low, Medium, High; Low, Medium, High; etc...

Valid downward selection sequence: High, Medium, Low; High, Medium, Low; etc...

### Aiming Beam Flash Frequency

Valid upward selection sequence: CW, Slow, Fast; CW, Slow, Fast; etc...

Valid downward selection sequence: Fast, Slow, CW; Fast, Slow, CW; etc...

The system shall remember and restore the settings of the Audible Tone, Aiming Beam Flash Frequency and Aiming Beam Intensity last used across a POWER OFF/POWER ON cycle.

## 5.9 Preset Programming

The **Preset** buttons on the **Setup** screen shall enable programming of three treatment preset configurations.

The programming sequence shall be as follows:

1. On the **Main Menu** screen press **Run** button.
2. While in **Standby** mode, set the power and On/Off durations as desired.
3. Press **Exit** button to return to the **Main Menu** screen.
4. Press **Setup** button.
5. Set the parameters of Audible Tone Volume, Aiming Beam Flash Frequency, and Aiming Beam Intensity as desired.
6. Press one of; **Preset 1**, **Preset 2**, and **Preset 3** buttons where you wish to assign above set parameters.
7. Press **Exit** button.
8. **Preset** programming is complete.

To confirm a successful **Preset** programming, the operator shall press one of **Preset** buttons on **Main Menu** screen to enter **Standby** mode and observe to confirm the previously programmed parameters of power and On/Off durations are presented in **Standby** mode. If desired, the operator shall press **Exit** button to go back to **Main Menu** screen, then press **Setup** button enter **Setup** screen to observe and confirm the previously programmed parameters of Audible Tone Volume, Aiming Beam Flash Frequency, and Aiming Beam Intensity are presented.

## 5.10 Emission Mode

- ➡ In **Ready Mode**, the device shall produce laser energy when the foot-switch is depressed. The device shall present a flashing **EMISSION** message on the screen during emission. No button is selectable or changeable during laser emission.

## 5.11 Stop Emission

- ➡ When the laser is in **EMISSION** mode, release footswitch to stop the emission and get the laser back to **Ready** mode.

## 5.12 Preset Mode

- ➡ Press Preset 1, 2 or 3 on Main Menu.

- ↶ Enter Preset Mode

**Preset 1 (Perio)**

Power Variable or set at 1.6W in repeat mode  
On time 50m sec & Off time 120m sec

**Preset 2 (Endo)**

Power variable or set at 1.8W in repeat mode  
On time 60m sec & Off time 130m sec

**Preset 3 (Toughing)**

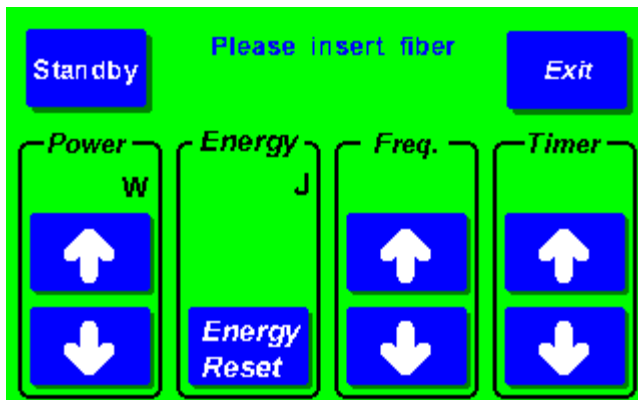
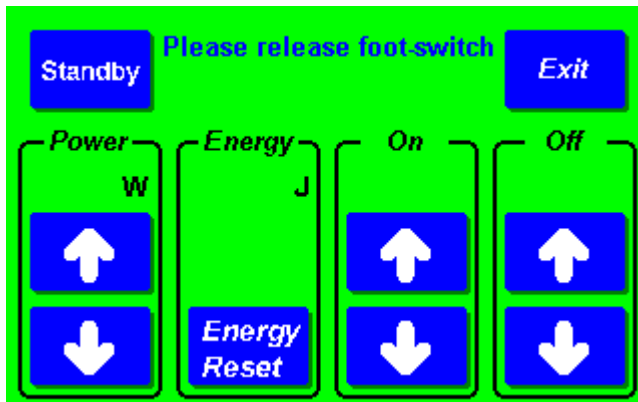
Power variable or set at 1.0W in repeat mode  
On time 100m sec & Off time 100m sec

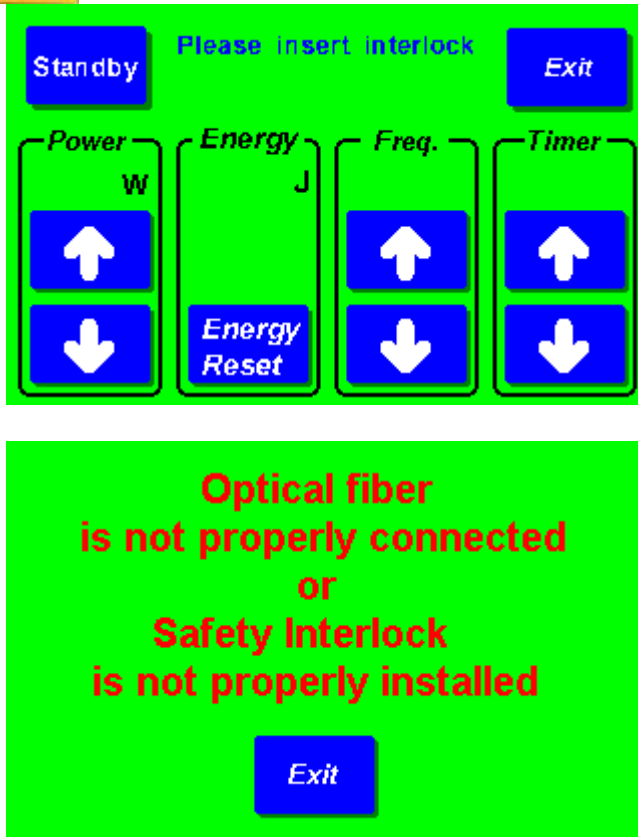
**5.13 Error Message**



**NOTICE**

In the event there is an error or a non-standard operating condition exists, the screen will clear and an explanation of the error condition will appear. The error messages are listed as follows.





Please follow the message to correct the non-standard operating condition.

⇒ Press the **Exit** button to return to **Standby** mode.



**WARNING**

If the error message still comes up after the corrective action, contact Velopex for assistance.

## 6 Cleaning and Sterilization

After finishing treatment, switch off the laser and disconnect the power cord from the power supply.



### **WARNING**

The fibers, hand pieces are both provided sterile – please check that pack seals are Not broken. The tips are supplied non-sterile, you must sterilise (cold sterilant) these products prior to use. Please note these should be disposed of as Clinical waste after each use.

### 6.1 *Cleaning*



#### **NOTICE**










Manual cleaning must always be combined with disinfection.



#### **NOTICE**

Before you remove the optical fiber from the hand piece, please be sure to clean any tissue residue from the optical fiber. This prevents contamination of the inside of the tip.

After treatment end:

-  Remove the optical fiber from the hand piece.
-  Cut off approx. 4 cm from the distal end of the optical fiber. Make sure to cut perpendicular to the fiber axis.
-  Remove approx. 4 cm of the sheath if necessary.
-  Remove the tip from the hand piece.
-  Disassemble the hand piece by unscrewing the two threaded joints.
-  Clean the hand piece and the tip by brushing them off under running water. Clean the distal end of the optical fiber using a soft, damp cloth.
-  Disinfect the distal end of the optical fiber by spray or wipe disinfection.
-  Disinfect the finger switch by spray or wipe disinfection.
-  Disinfect the LCD touch screen by spray or wipe disinfection.

## 6.2 *Disinfection*

⇒ Disinfect the distal end of the optical fiber by spray or wipe disinfection.



### **NOTICE**

Use only disinfectants that have been tested and approved by the competent national bodies, or have been proven to have bactericidal, fungicidal and virucidal properties.

You can use: MinutenSpray classic from Alpro; MinutenWipes from Alpro. In the USA: cavicide® and caviwipes™

Observe the instructions provided by the manufacturers of these disinfectants.



### **CAUTION**

Strong bending or improper routing of the optical fiber inside the hand piece may damage the optical fiber, thus creating a health hazard for patients, doctors and assistants. The minimum bending radius for the fiber is 9 cm (diameter 10 cm). Take care that the fiber will not be squeezed or cracked during the handling procedure.

## 6.3 *Sterilization*



### **NOTICE**

Manual cleaning and disinfection must always be combined with sterilization.



### **NOTICE**

Remove any residual water from the hand piece and the tips



The disassembled hand piece, the tips and the fiber must be sterilized only in autoclaves with saturated water vapor at 121.1~122.3°C (250~252.1 °F), 30 min. A 10<sup>-6</sup> SAL would be obtained.



### **WARNING**

You must sterilize the hand piece, the tips and the fiber prior to first use and prior to each subsequent use.



### **CAUTION**

Strong bending or improper routing of the optical fiber inside the hand piece may damage the optical fiber, thus creating a health hazard for patients, dentists and assistants. The minimum

bending radius for the fiber is 9 cm (diameter 10 cm). Take care that the fiber will not be squeezed or cracked during the handling procedure.

**CAUTION**

Please always cover the proximal end of the fiber with the special protection cap for sterilization. Use only this special protection cap for sterilization!

Approved for sterilization are steam sterilizers that fulfill the requirements of prEN 13060 or at least use fractionated vacuum and are suitable for the sterilization of hand pieces.

## 6.4 *Cleaning of the laser unit*



Use a dry, soft cloth to remove dust from the BWF-5-810-5 laser. More stubborn spots can be removed with a damp cloth.

For disinfection, you can treat the BWF-5-810-5 laser with all products commonly used for medical electrical equipment, such as MinutenSpray classic, cavicide® and caviwipes™

Observe the instructions provided by the manufactures of these disinfectants.

You can use: MinutenSpray classic from Alpro; MinutenWipes from Alpro. In the USA: cavicide® and caviwipes™

Observe the instructions provided by the manufacturers of these disinfectants.

**CAUTION**

Take care that the fiber will not be damaged in case of disconnecting the finger switch.

**WARNING**

The BWF-5-810-5 laser unit cannot be sterilized.

**CAUTION**

The hand pieces and tips must be sterilized after each treatment!

## 7 Maintenance and Service

### 7.1 Safety checks

The following safety checks must be performed every 24 months by a qualified service engineer:

- Visual inspection of the unit and its accessories for mechanical damage that might impair operation
- General function check
- Check of the audible and visual indicators
- Earth leakage current NC and SFC accd. To IEC 601
- Housing leakage current NC and SFC accd. To IEC 601
- Patient leakage current NC and SFC accd. To IEC 601
- Laser power measurement with calibrated measuring equipment in the range between 1.0 W and 5.0 W

### 7.2 Maintenance

The BWF-5-810-5 laser does not require special maintenance. In case of malfunctioning, see chapter Technical support.



#### **NOTICE**

If national or local legal regulations require additional safety checks for your laser unit, these regulations must be complied with and the corresponding checks must be performed.

The manufacturer accepts responsibility for the safety of the laser unit only if the following prerequisites are fulfilled:

- Modifications of the laser unit or repair work must be performed by authorized personnel.
- The electrical system at the premises where the BWF-5-810-5 laser is installed must comply with the applicable legal requirements for electrical installations.
- The laser unit must be used in compliance with the instructions provided in this manual.

### 7.3 *Basic troubleshooting*

In case of malfunctions, check the following first:

- Check the connection of the power cord.
- Check the connection of the Safety Interlock connector.
- Check the connection of the optical fiber.
- Be sure that all operational steps have been executed correctly.
- Check the connection of the foot control.

### 7.4 *Technical support*

Technical information concerning parts to be repaired may be supplied by Velopex only to authorized agents and after providing a training course to the technical personnel. Please contact your local distributor or authorized service center for technical support.

Please always use the **original packaging** when shipping the laser unit. Please disinfect and sterilize the laser unit according to the relevant Operating Instructions before shipping it.

## 8 Technical Data

<b>Model</b>	BWF-5-810-5
Laser Type	Solid State laser (Class IV)
Wavelength	810nm
Output power	Max. 5.0W @ output port
Output Port	SMA 905
Fiber	400um, 0.37NA
Operating modes	Continuous Wave (CW) Pulsed
Duty ratio	On/Off duration adjustable
Cooling	Thermal Electrically Cooled with Forced Air
Weight	4.5 kg
Dimensions	170mm x 235mm x 320mm (WxHxL)
Power requirement	100-220VAC/50-60Hz 250VA
Operation Temperature	10 °C to 35 °C
Storage Temperature	-20 °C to 70 °C

## 9 **Warranty Information**

### *Terms and Conditions*

The lasers and power supplies are warranted to be free from defects in materials and workmanship for a period of 12 months, starting from the date of initial shipment. This warranty does not extend to incidental or consequential damages and to damage caused by negligent or improper handling in use, storage, nor to products from which the original identification markings or labels have been defaced, altered or removed nor any damage caused in shipping where this has been organized by the buyer.

Special contracts or contracts for non-standard products may have modified terms of warranty and, in such cases, the terms as stated in the individual contract and will supersede the standard terms.

The supplier reserves the rights of determining cause or existence of defect and the options to repair the products, which prove to be defective during the warranty period. Products replaced under warranty will be warranted only for the balance of the warranty period starting from the date of the first shipment.

This warranty extends only to the original purchaser of the equipment from the supplier. The purchaser must notify the supplier within 15 days of first detecting the defect and promptly return the defective product before expiration of the warranty period.

Products claimed by purchaser to be defective shall be returned to the supplier with transportation and insurance (if necessary) prepaid by purchaser. The supplier will return repaired or replaced products to purchaser with FOB city destination. Transportation fees insurance (if necessary) beyond this limit will be charged to purchaser.