Digitally signed by Jighili Tatiana
Date: 2022.09.15 11:00:14 EEST
Reason: MoldSign Signature
Location: Moldova

BERYLAS

User Manual

VERSION: A0

Table of contents

1. Introduction

Thank you for choosing the BERYLAS laser.

The BERYLAS medicial diode laser system is a surgical and therapeutic device which can can realize wonderful vaporization, incision and coagulation of the tissues with high power beam laser from fiber, designed for a wide variety of dental and surgical procedures, as well as for use in providing temporary relief of minor pain.

The BERYLAS utilizes a solid state diode as a semiconductor source for invisible infrared radiation. The energy is delivered to the treatment site via flexible fiber connected the laser source and the Handpiece. Various types of handpieces, disposable parameter are designed and optimized for different applications. The device is activated by means of a footswitch.

The BERYLAS is restricted to sale on the order of a licensed doctor and its use requires proper clinical and technical training. The manual provides instructions for those professionals who have completed the appropriate training.

When used and maintained properly, the BERYLAS will prove a valuable addition to your practice. Please contact Wuhan Dimed Laser Technology Co., Ltd Customer Service at +86 27 59706608 in China if you need any service.

1.1 System Part List

BERYLAS series have 10 versions: BERYLAS-15FJ、BERYLAS-15FI、BERYLAS-15F、BERYLAS-15I、BERYLAS-15J、BERYLAS-10FJ、BERYLAS-10FI、BERYLAS-10F、BERYLAS-10I、BERYLAS-10J (F=810nm, I=940nm , J=980nm). The BERYLAS medicial laser system includes the following:

1) Laser Console
2) Fiber
3) Screen Cover
4) Fiber Optic Cleaner
5) Fiber Stripper
6) User Manual
7) Warranty Card
8) Footswitch
9) Safety Goggles（for operator and assistant）
10) Safety Goggles（for patient）
11) Fiber Cutter
12) DC Power Supply
13) Safety Interlock
14) Power Cord
15) Qualified Certificate

NOTE:
Use proper care when transporting the unit. Refer to Section 8 in this User Manual for instructions.

WARNING: **No modification of this equipment is allowed.**

1.2 Facility Requirements

Electrical Supply(100-240V ~):	50/60Hz,120VA(single wavelength), 160VA(double wavelength)
Storage Temperature:	-20-70ºC
Storage Humidity:	10-90%, Non-condensing
Operation Temperature:	5-35ºC
Operation Humidity:	10- 90%, Non-condensing
Atmospheric Pressure (kPa) :	80kPa – 106kPa

2. Equipment Description

2.1 Base Console

The console has a display panel (Touch Screen and Emergency Stop Button) in front. It can be powered by an external mains power supply.

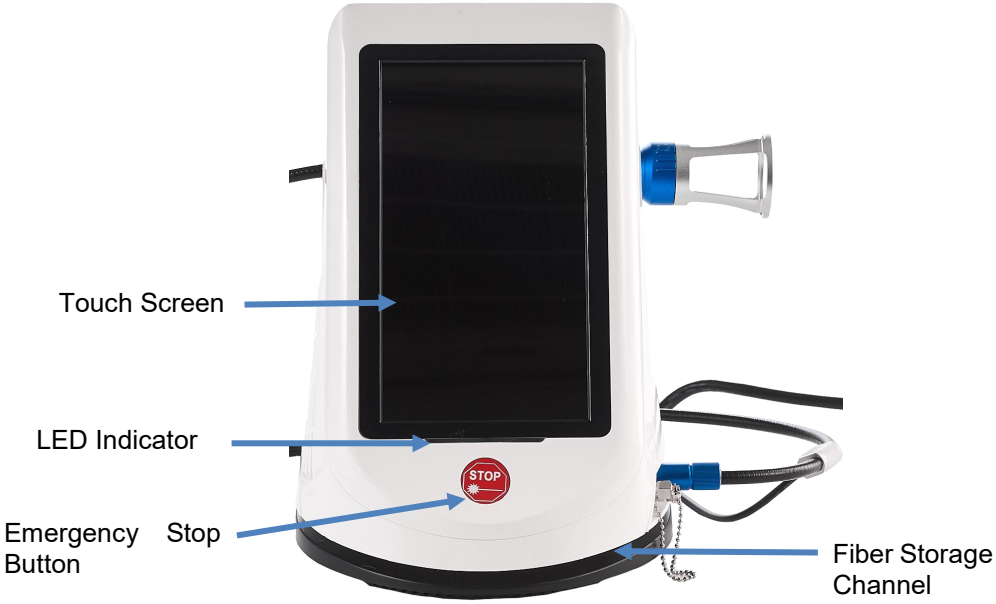


Figure 2.1 Front of the system

Figure 2.2 Back of the systerm

Figure 2.3 Optical Access Port

NOTE:
Indicator light,Blue means normal operation,red means warning,For example, the pedal is not Connected, orange means laser emission.

NOTE:
The APP card slot is used by developers to burn programs,Do not use this screen for non professionals. By Professional operators, insert the SD card into the socket, the machine will read the program to burn into the program, as well as the picture.

2.2 Power Cord

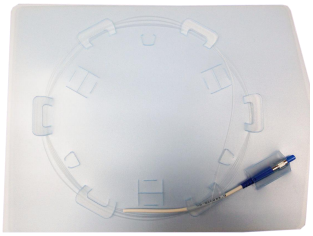
Figure 2.4 Power Supply Module with cord

2.3 Footswitch

Figure 2.5 Footswitch

2.4 Transmission System

BERYLAS transmission system includes:

Sterilized Fibers Of 400μm/600μm With SMA905 Connector	 *Figure 2.6*
Surgical Handpiece	 *Figure 2.7*

2.5 BEAM DELIVERY SYSTEM

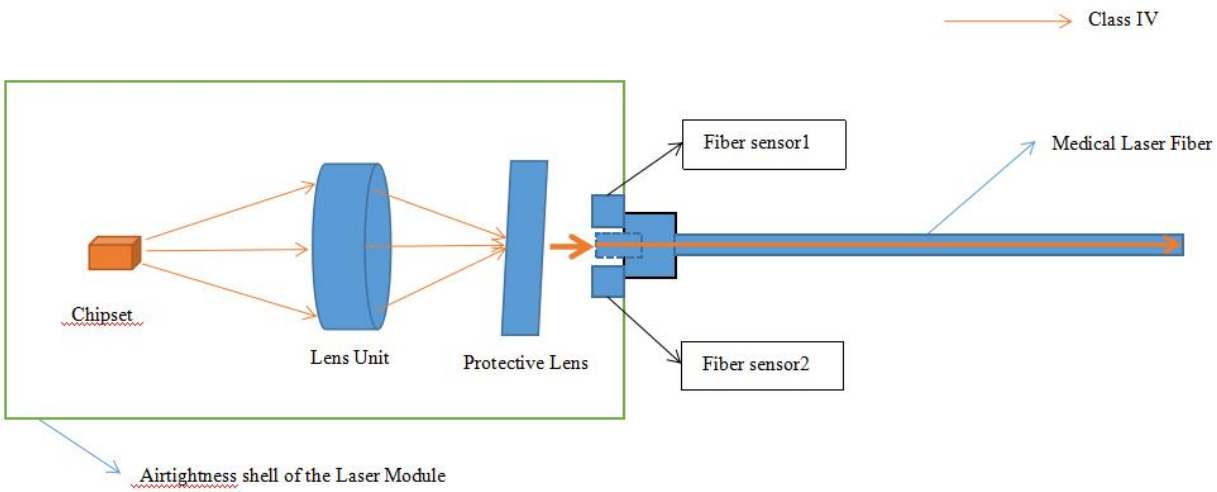


Figure 2.8 Diagrammatic sketch for Laser Radiation Fields and Paths

As the above diagrammatic sketch shows, the Laser Module is composed with Chipset, Lens Unit, Protective Lens, Fiber Sensors and Airtightness shell, which is assembled inside the laser product. The Chipset is used to control semiconductor material to emit laser. The defocusing laser beam is focused on the Protective Lens through the focusing function of lens Unit. Because there is a Airtightness shell, the laser can only emitted out by the Laser Aperture of the Laser Module. The Fiber sensors are used to monitor fiber connection status. When the Laser Module is connected with a Medical Laser Fiber, the laser will be coupled into the fiber and the laser will emitted out through the end of the Medical Laser Fiber. The level of laser radiation is Class IV.

3.Safety

NOTE:
This device is protected by a password, unauthorized persons should not use this device without authorization.

3.1 Precautions

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

3.2 Safety Instructions

Follow these safety instructions before and during treatments:

Do not operate in the presence of explosive or flammable materials. Flammable anesthetics or oxidizing gases such as nitrous oxide (N2O) and oxygen should be avoided. Solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before laser is used. Attention should also be drawn to the danger of ignition of endogenous gases.

NOTE:
Do not maintain the device when using it.

NOTE:
All persons present in the operatory must wear laser safety goggles. Safety goggles are suitable for laser wavelength.

CAUTION:
Periodically inspect safety goggles for pitting and cracking.

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

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

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

CAUTION:
This unit has been designed and tested to meet the requirements of electromagnetic, electrostatic, and radio frequency interference standards. However, the possibility of electromagnetic or other interference may still exist. Relocating the device may help to eliminate the interference.

CAUTION:
Always ensure that the proper laser parameters are set before the BERYLAS laser is used in a clinical setting.

CAUTION:
When using the device, the operator should not touch other ports and the patient at the same time.

LASER WARG:
Do not look directly into the beam or at specular reflections.
Never direct or point the beam at a person's eyes.


LASER WARNING:
Don't exchange the Handpieces or disposable tips when the device is in Ready mode, switch the power off or place the system into Standby mode before exchanging.
Toggle the ON/OFF switch (located on the rear of the console) to the OFF (O) position before leaving unit unattended.


LASER WARNING:
Do not open unit housing at any time. Danger from optical radiation may exist.


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

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

3.3 Safety Features

1) System Monitor

The system monitors the emergency stop switch, interlock, footswitch connection, and output power. An error in any one of these will stop the system. The text display will indicate the type of error. Operation will not resume until the error is cleared.

2) Power Switch

The laser console can be switched ON (I) or OFF (O) using the Power Switch on the back of the console (see Figure 2.2)

CAUTION:
Use only the Power Supply Module supplied with the BERYLAS laser system.

3) Access Key Code

The Access Key Code prevents unauthorized use of the system. It is activated every time system is turned on with the Power Switch (refer to Section 4 for code).

4) Footswitch

The BERYLAS will not emit laser energy until the user presses down on the footswitch and release it, while the laser is in READY mode.

Figure 3.1 Footswitch

5) Interlock

This feature prevents the laser to emit laser light when it is not connected.

Figure 3.2 Safety Interlock Connector

6) Emergency Stop

Press the red Emergency Stop Button (see Figure 2.1) to instantly turn off the laser console. The error screen will display an “Emergency Switch Error” message and the LED turns to red. To clear the error, switch off the power switch on the back then restart the device.

7) Functional Display

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

3.4 Safety Classification

The following safety classifications are applicable to the device:

- ✧ Laser Radiation – Class 4
- ✧ Aiming Beam – Class 1
- ✧ Type of protections against electrical shock – Class Ⅰ
- ✧ Degree of protection against electrical shock – Type B Applied Part
- ✧ Not protected against water ingress – Ordinary Equipment
- ✧ Not suitable for use in presence of flammable anesthetic mixture
- ✧ Operation Mode – Continuous Wave and Pulse Mode
- ✧ Footswitch – IPx8

4. Operation Instructions

4.1 System Setup

(1) Place the unit in a clean, dry, and well-ventilated area.

(2) Set warning sign on the operatory entrances.

(3) Make sure all persons present in the operatory wear laser safety goggles.

(4) Verify that the power switch is in the OFF (O) position.

(5) Connect the power cord of the power supply to the laser console and plug into a wall outlet. BERYLAS will work using DC power.

(6) Connect the Interlock to the laser console.

(7) Connect the footswitch to the console by inserting the connector of the footswitch to the back of the console (Figure 2.2).

(8) Connect the fiber to the laser console, the fiber is fixed to the console by the nut on the fiber.

Figure 4.1 Connect the fiber to the console

CAUTION:
Do not connect or disconnect the fiber while the laser console is turned on. Only connect or disconnect the fiber when the laser console is turned off.

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

CAUTION:
Do not bend the fiber optic at a sharp angle, as it can be broken, the bend radius must more than 15cm. Make sure it is not caught or pinched between the housing and the fiber optic access plug.

CAUTION:
Check the integrity of the beam transmission system before using the equipment.

The aperture protective hat acts as the protection for the laser aperture (see Figure 2.3). When the fiber is removed, please cover up the laser aperture with aperture protective hat immediately to prevent the aperture from being contaminated.

CAUTION:
Do prevent the laser aperture from the contamination of dust, liquid, oil or any other material. Otherwise, the output power of the laser will decrease or even the inner laser system will be damaged. Clean the aperture protective hat with alcohol before using it. But do care not to leave cotton yarn or other funicle inside the hat during the cleaning.

Remove protective cap from the end of the fiber shaft.Carefully connect the handpiece to the fiber optic assembly.Insert the selected tip and tighten it clockwise until snug.Wind any excess fiber optic cable onto the fiber spool counterclockwise around the base of the console.

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

LASER WARNING:
Never point the laser at a person's eyes.

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

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

4.2 Operation- Turn ON the BERYLAS

Ensure that the power supply cord to the power connector on the laser console and plug the cord into a wall outlet.

Turn the Power Switch at the rear of the console to the ON (I) position. The welcome screen will appear (Figure 4.2).

Figure 4.2

After three (3) seconds the BERYLAS “LOGIN” screen will be displayed (Figure 4.3).

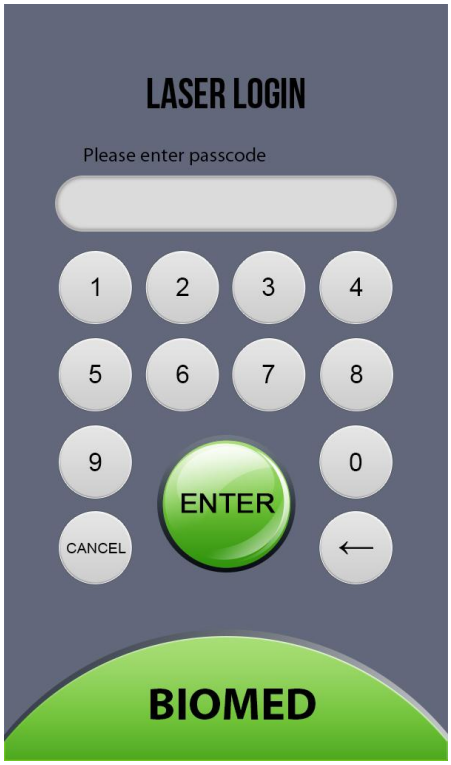


Figure 4.3

Enter the four digit access code using the touch screen. The Access Key Code is 1234, press the enter button, the system will go to the home screen. If the incorrect code is entered, the system can’t go to the home screen, re-enter the correct code.

4.3 Setting Screen

After typing the correct passcode, the system will go to the home screen, now the system is at the Standby mode (Figure 4.4, A is Single wavelength model; B is double wavelength model), users will set the parameters on this screen.

1）Status Bar

Verify that the footswitch, safety interlock and fiber are paired correctly, check the status bar on the top screen,  this indicator shows the pairing is established, if pairing is not confirmed, an “  ” will appear instead of the  like  .

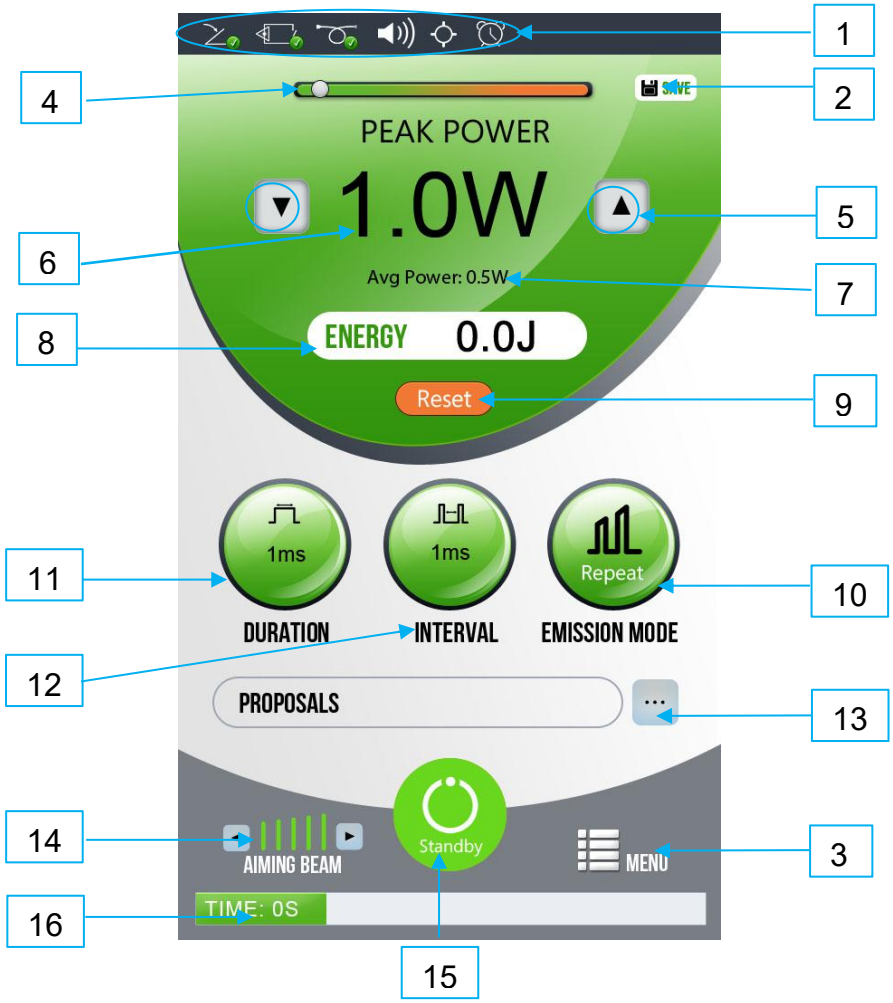


Figure 4.4: Home screen A（single wavelength model）

2) Save Button 

After setting the parameters, press the SAVE button to save the proposals.

3) Menu Button 

Pressing the MENU button on the home screen accesses the setting screen (Figure 4.5); this screen allows the user to make changes to several system settings:

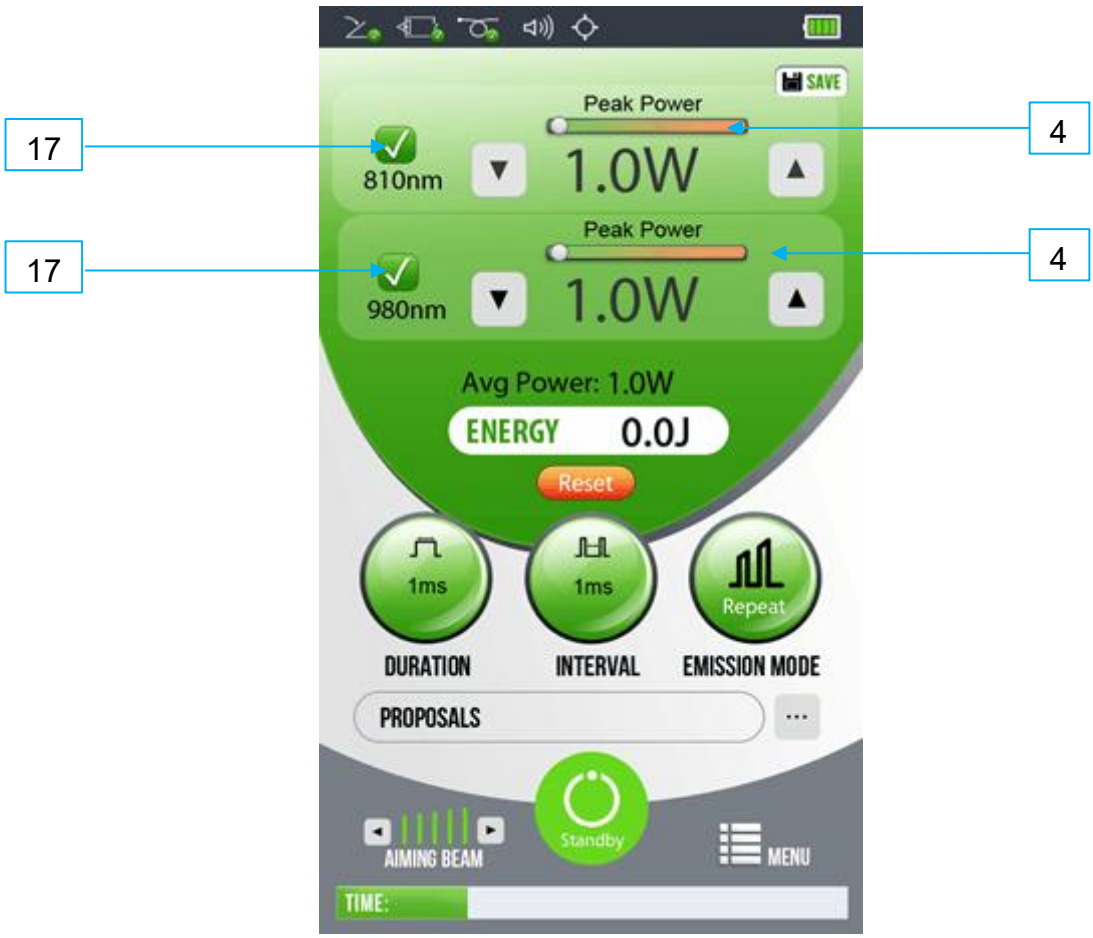


Figure 4.4 Home screen B（double wavelength model）

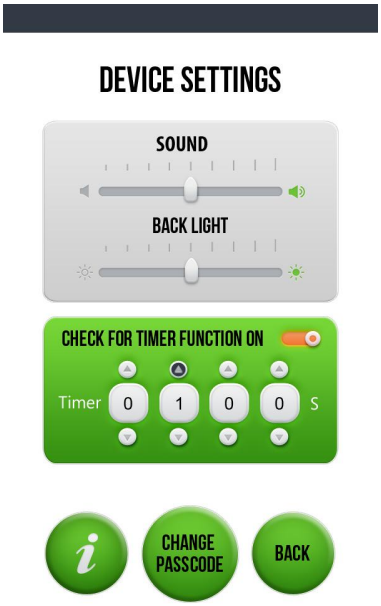


Figure 4.5

When the sound is mute, the symbol  will appear on the status bar.(Figure 4.4)

The back light setting bar allows the user to adjust the back light.

When the time setting button is on, users can click the arrows  to set the time. The clock  will appear on the status bar, if the time setting button is off,  this symbol will disappear.

Press the button  to change the login password.

Click the infor button  to check the device information.

6) Peak Power display 

This value shows the peak power output.

7) Average Power display 

The system calculates the average power and display it automatically.

8) Energy display 

The system calculates the total emitting power and display it automatically.

9) Power Reset button 

Click this button the user can reset the power output.

10) Emission Mode button

Press the EMISSION MODE button, the user can choose the pulse mode (Figure 4.6).

In Continuous Mode (CW), laser power is constantly delivered when the laser console is in Ready Mode and the footswitch is activated.

In Single Pulse Mode, laser power is delivered in a single time when the laser console is in Ready Mode and the footswitch is activated.

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

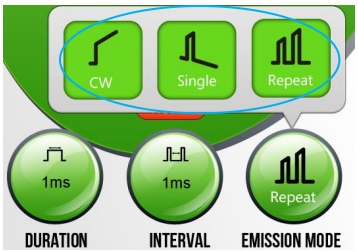


Figure 4.6

11) Duration time setting

After choose the repeat mode, press the DURATION button, the keyboard will occour to set the duration time (Figure 4.7).

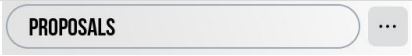
12) Interval time setting

After choose the repeat mode, press the INTERVAL button, the keyboard will occour to set the duration or interval time (Figure 4.7).

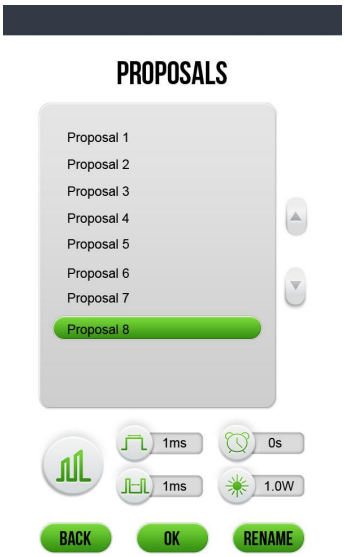
Figure 4.7

NOTE:
Only the emmision mode is in repeat pulse mode, user can set both the duration and the interval time, when in single pulse mode, user can set the duration time, when in CW mode, this two buttons  **are grey, user can't set the time.**

NOTE:
When the system is in pulse mode, the Duty Cycle should ⩾1%. When the Duty Cycle＜1% or the interval time＞3s, the error message will occur :DURATION TIME OR INTERVAL TIME SETTING ERROR. PLEASE RE-ENTER THE PULSE TIME.

13) Proposal 

Pressing the button to choose the proposals preseted in the system, the chosen proposal name will displayed in the left box, the parameters and name of the proposals can be changed (Figure 4.8).



The BERYLAS preseted proposals can be customized.

Choose one proposal and click button  can change the name the of the proposal (Figure 4.8 left).

Choose one proposal and click OK button, the system goes to the setting screen, users can reset the parameters and save it.

After setting the parameters, press the SAVE button  to save the proposal.

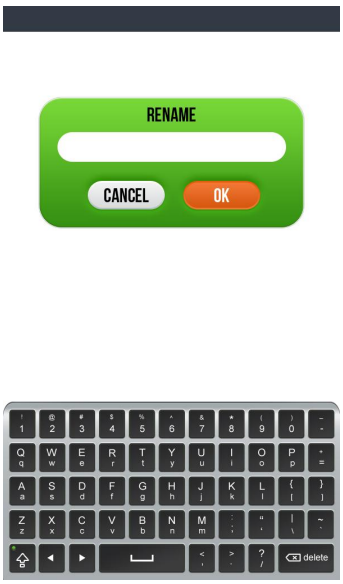


Figure 4.8

14) Aiming Beam setting 

Click the left arrow to dim the aiming beam and click the right arrow to lighten the aiming beam. When the aiming beam is on, the symbol  will appear on the status bar.

15) Change Mode

Click this button can switch the mode Standby and Ready.

16) Setting Time display 

When the time setting button is on, the system will calculate and display the working time here.

17) Wavelength display

The users should adjust the power according to the wavelength mark properly when they ues double wavelength model device.

4.4 READY Mode

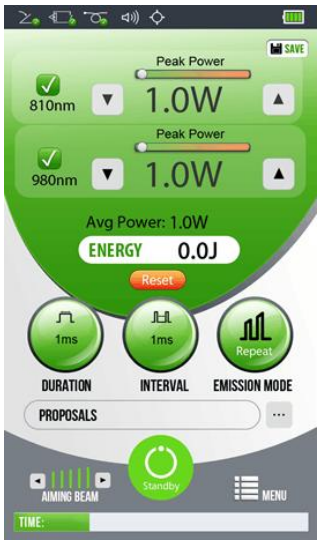


Figure 4.9 Home screen B（double wavelength model）

After the parameters setting, press the Standby mode to Ready mode, the laser console fan will turn on. Pressing the footswitch will activate laser radiation (Figure 4.9).

There is a 2seconds delay between switching to Ready mode and the ability of the laser console to emit a laser beam.

The system will show the Average power and total Energy on the screen automatically.

4.5 Error

When the device is in Ready mode, press and release the footswitch, the device will emit laser light, if the footswitch/ safety interlock / fiber is not connected, the error message bellow (Figure 4.10 left) will appear. When the footswitch is pressed but not released, the error message bellow (Figure 4.10 right) will appear. Other errors (Figure 11.1) may also happen when the BERYLAS is in use, please refer to the troubleshooting instructions to solve the problems.

While in Ready or Standy mode, mode setting and/ or power setting values may be changed only when the laser is not firing. If the laser is firing (i.e., the footswitch is engaged), the ability to change the settings is blocked.

Figure 4.10

4.6 Emergency stop

When the device needs to stop emergently, the user can press the Emergency stop button on the front of the laser console (Figure 4.11). Switch the power off first and restart the system, the system can get recovery.

Emergency Stop Button

Figure 4.11

4.7 Using the BERYLAS Touch Screen Display

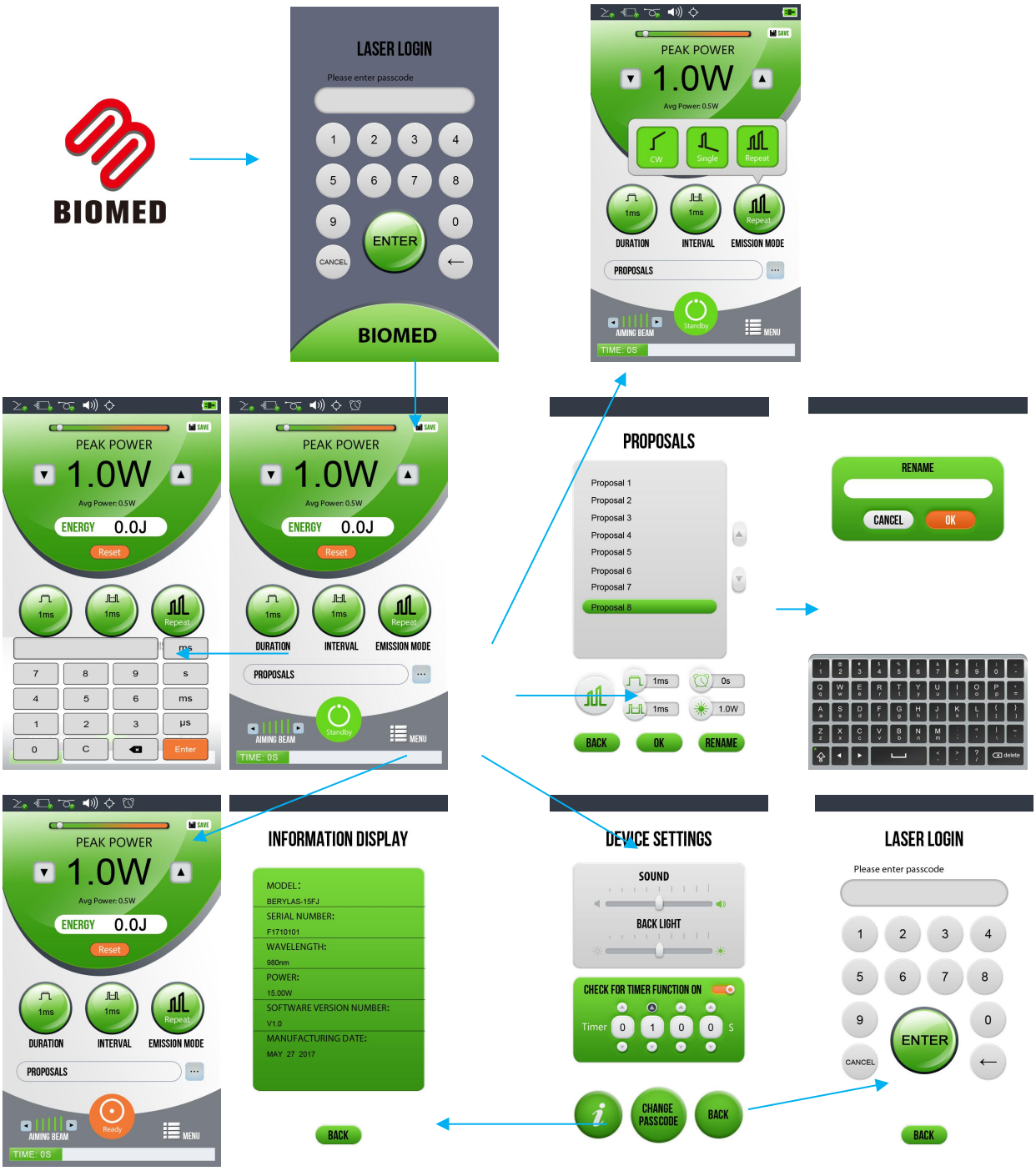


Figure 4.12

4.8 Turn the Laser Console Off

After the device stops to emit laser light, wind the fiber cable onto the fiber spool counterclockwise around the base of the console.

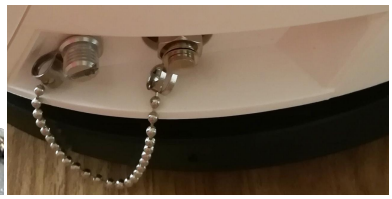
Place the handpiece onto the handpiece holder.  .

CAUTION:
Verify that the fiber optic tubing assembly is not twisted once the handpiece is returned to the holder.The fiber may break if it is twisted.

Press the Power Switch at the rear of the laser console to the OFF (O) position if the laser system will not be used for a long period of time.

Put the protective hat on the fiber and the optical access port to prevent the laser aperture from the contamination of dust, liquid, oil or any other material.





CAUTION:
Do prevent the laser aperture and the fiber connector from the contamination of dust, liquid, oil or any other material. Otherwise, the output power of the laser will decrease or even the inner laser system will be damaged.

5. Specifications

Electrical

Operating Voltage	100V - 240V ~ ; 120VA(Single), 160VA(Double)
Frequency	50/ 60Hz
Main Control	Power Switch
Disable Control	Emergency Stop Button
DC Power Supply Module	12V DC, 8.5A/11.5A

Laser

Laser Type	GaAlAs Diode Laser
Wavelength	810nm/ 940nm/ 980nm
Maximum Power	10W/ 15W/15+15W
Operation Mode	CW, Single Or Repeat Pulse
Pulse Duration	10μs- 3s
Repetition Rate	0.2Hz- 50KHz
Pilot Beam	Red Diode Laser Of 650nm, Power<5mW
Control Mode	True Color Touch Screen
Transmission System	Fibers Of 200 μm,400μm,600μm With SMA905 Connector
Dimensions	160(W)*180(L)*235(H) mm
Weight	2.1Kg
Power Accuracy	±20%
NOHD	8.7m
Beam Divergence	314mrad- 443mrad
Maximum permissible exposure	Class 4

6. Contraindications, Warnings & Precautions

6.1 Contraindications

All clinical procedures performed with BERYLAS must be subjected to the same clinical judgment and care used with traditional techniques. Patient risk must always be considered and fully understood before clinical treatment. The clinician must completely understand the patient’ s medical history prior to treatment. Exercise caution for general medical conditions that might contraindicate a local procedure. Such conditions may include allergy to local or topical anesthetics, heart disease, lung disease, bleeding disorders, or an immune system deficiency, or any medical conditions or medications that may contraindicate use of certain light/ laser type sources associated with this device.

WARNING:

These people are not suitable for the therapy of laser:

- **Patients with infectious disease.**
- **Patients who are immune compromised.**
- **Patients who are pregnant.**
- **Patients with a medical condition that may affect wound healing.**

6.2 Warnings and Precautions

1) Safety Goggles

All personnel inside the operatory must wear appropriate laser safety goggles for the diode laser wavelength of 810nm/ 940nm/ 980nm.

Item	Wavelength	VLT%	Protection grade	Recommend Manufacturer
Safety goggle	800-1100nm	40%	OD6+	Shenzhen Keyuan CO., LTD
Safety goggle	800-1700nm	40%	OD4+	Shenzhen Keyuan CO., LTD

2) Anesthesia

In soft tissue cases anesthesia may not be required, but patients should be closely monitored for signs of pain or discomfort at all times by touching the treatment area. If such signs are present, adjust settings, apply anesthesia or cease treatment if required.

3) Adjacent Structures

BERYLAS is designed to remove soft tissues. Therefore, always be aware of adjacent structures and substructures during use. Be extremely careful not to inadvertently penetrate or ablate underlying or adjacent

tissues. Do not direct energy toward hard tissue such as tooth or bone. Do not direct energy towards amalgam, gold or other metallic surfaces. Do not direct energy towards cements or other filling materials. Exercise extreme caution when using this device in areas such as pockets, cavities or channels such as third molar sockets, where critical structures (i.e. nerves, vessels) could be damaged. Do not proceed with using the laser if visibility is limited in these areas.

4) Suction

Use high-speed suction as required to maintain a clear field of vision during treatment. Do not use the BERYLAS if you cannot clearly see the treatment site.

5) Clinical Use

Use your clinical judgment to determine all aspects of treatment including, but not limited to, the laser treatment protocol, technique, power settings, pulse duration and interval settings, mode of operation as well as the accessories (e.g., tip type) and other procedural requirements.

Closely observe and monitor clinical effects and use your judgment to determine clinical parameters and approach for the treatment. Make appropriate power, pulse length, and interval adjustments to compensate for varying tissue compositions, density, and thickness. Always start treatment at the lowest power setting for that specific indication and increase as required.

Dimed assumes no responsibility for parameters, techniques, methods or results.

6) Training

Only licensed professionals who have reviewed and understood this User Manual should use this device. Dimed assumes no responsibility for parameters, techniques, methods, or results. Physicians must use their own clinical judgment and professionalism in determining all aspects of treatment, technique, proper power settings, interval, duration, etc.


LASER WARNING:

Never point the laser at a person's eyes. All persons present in the operatory must wear safety goggleswhen the laser is in operation

7. Clinical Applications

7.1 Introduction

To efficiently remove the disease it is imperative to understand the nature of the BERYLAS device. Please review this section carefully, practice on model tissues, and attend a diode laser training session before using this device in a clinical situation.

7.2 Indications for Use

BERYLAS has many advantages like effective treatment, fast healing time and less side effects, it is widely used in surgery, dentistry and therapy. Like in dentistry, BERYLAS device may be appropriate for incision, excision, vaporization, ablation and coagulation of oral soft tissues including marginal and inter-dental gingival and epithelial lining of free gingiva.

7.3 Surgery

To cut, excise, vaporize, and coagulate tissues in various surgical applications such as general surgery, lipolysis, percutaneous laser disc decompression (PLDD), benign prostatic hyperplasia (BPH) therapy.
The device is intended to be used in hospital, clinic , hospital operation room and ambulance.

7.4 Pre-programmed Settings for Proposals

To access the pre-programmed procedure values, press the up and down arrows to scroll for additional proposals (Figure4.8).

CAUTION:
Always use clinical judgment when selecting power, pulse, length, and pulse interval parameters to ensure optimal clinical results.

NOTE:
The Proposals Presets installed at the factory are based on clinical recommendations and feedback from experienced doctors.
Always use your clinical judgment when selecting power, pulse length, and pulse interval parameters to ensure optimal clinical results. At all times observe the clinical effects on the treatment area and adjust parameters accordingly.

8. Maintenance

WARNING: This product is a Class 4 laser product. During use and maintenance, do not look into the laser or direct beam to avoid irreversible damage to the eyes. It is strongly recommended that users carefully read the instructions to avoid injury to the patient and damage to the device caused by possible harmful laser radiation.

CAUTION:
The aiming beam pass through the same delivery system (optical fiber) of the laser beam, so it is strongly suggested to verify periodically the integrity of the fiber, included handpiece and tip If the aiming beam is not visible or its intensity is reduced, this could be a possible sign of failure (handpiece, fiber or laser source). If a relevant power decrease is detected, do not proceed to use the laser device and immediately contact the Service dept. of your DEALER.

8.1 PERIODICAL MAINTENANCE

All the maintenance operations below mentioned must be carried out by a specialised technician authorised by the manufacturer.

It is strongly recommended a periodical maintenance and power calibration of the device every two years to guarantee the correct operation.
The power measure must be performed with a suitable power meter and the deviation between the power set the one measured must be lower than 20% in continuous emission mode (CW).

It is also required to subject the device to a periodical electric safety check,for example,NC and SFC earth leakage current acc. to IEC 60601;NC and SFC housing leakage current acc. to IEC 60601 ;NC and SFC patient leakage current acc. to IEC 60601.

8.2 GENERAL CLEANING

All cleaning operations must only be conducted with the machine switched off and disconnected from power.

If the fiber is disconnected from the device, never leave the fiber connector and the laser aperture without protective cap.
The optical parts of these components are very delicate and may be damaged by the penetration of fluids, smoke, steam or dust.

The equipment does not require particular cleaning operation but it is advisable that the following general rules be followed:
a. Keep the working area clean by using vacuum cleaners to remove dirt and dust.
b. Handpiece and tip must be cleaned as described at the related chapter.
c. Use a soft cloth to clean the metal or plastic surface of the machine.
Take care not to damage the safety labels.

d. Do not use sharp instruments for the areas difficult to clean.

e. Do not use aggressive detergents.

f. Clean and disinfect the glasses only with soapy water. Do not use alcoholic solution to avoid any damage to the lenses. For more information refer to the leaflet inside glasses bag.

g. Do not clean and insert fingers or any other object inside the optical cavity of the diode.

8.3 Transportation

The BERYLAS is susceptible to damage if not handled properly. The unit should always be handled carefully and never banged, jarred, jolted, dropped or knocked.

Do not transport the unit unless it is completely packaged inside its shipping box. If you have any questions regarding transportation please call Dimed Service at +86 27 59706608.

8.4 Storage

The BERYLASshould be stored in a cool, dry place when not in use. Storage temperature -20° C-70° C, relative humidity 10%- 90%,non-condensing. Cover the unit when not in use for extended periods of time. Store the system in a place where it will not be accidentally bumped or banged.

CAUTION:
Make sure the distal end of the handpiece shaft is protected from dirt with the protective tip plug and handpiece.

The BERYLAS is shipped inside a custom shipping box. Please save and store the box in a cool, dry place for use when transporting the laser, or for long-term storage.

8.5 CHECK AND CLEANING OF TIP AND HANDEPIECE

In general, damaged or dirty tip can due to severe failure of handpiece, optical fiber and laser source. Verify the tip before each use.

Step 1 View the SMA905 connector ports.

Use end inspection instrument,There are three scenarios.

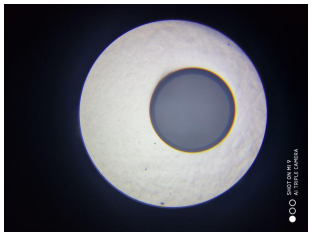


Figure 8.1 (Clean)

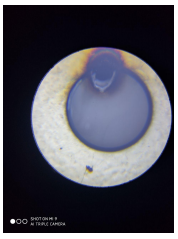


Figure 8.2(Burned)

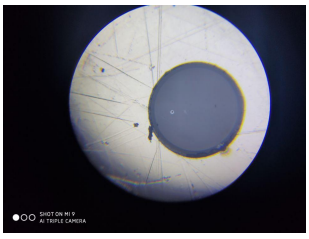


Figure 8.3(Dirty)

1.SMA905 interface, without cleaning, can be directly used see figure8.1.

2.SMA905 port is burned out and cannot be used see figure 8.2.

3.SMA905 port, dirty things appear, need to cleaner see figure 8.3

Step 2 optical connector cleaner

Figure 8.4

1:Press the yellow switch with your thumb to open the cleaning belt, release the yellow switch, and close the cleaning belt.

2:Use the SMA905 port to rub gently back and forth on the clean belt.

3:Finally, use the end detector to check.

Step 3 Verify the shape and intensiti of aiming beam

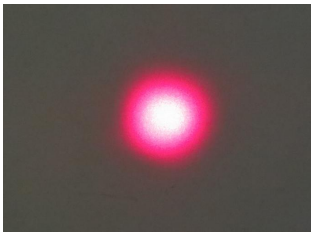


Figure 8.5(Excellent)

Figure 8.6 (Medium)

Figure 8.7 (Bad)

1.When the light spot appears in Figure 8.5, it is very good and can be used directly.

2.When the spot appears in Figure 8.6, it is medium and can be used directly.

3.When the light spot appears in Figure 8.7,it is very bad,You can't use it directly, you need to use a Peel off Device and a cutter.

Step 4 Use Peel off Device and a cutter

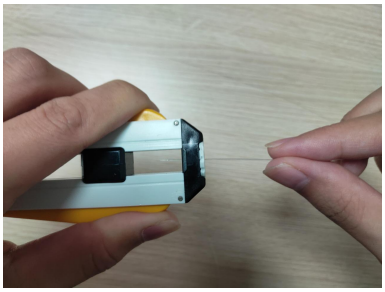


Figure 8.8(Peel off Device)

The use of fiber stripper, the black movable square in the middle, can adjust the length of stripped fiber. Insert the optical fiber through the white small hole on the left, hold the yellow at both ends with one hand, and pull the optical fiber out with the other hand.Use a fiber stripper to remove the coating of the surface layer, reserve about

30-40mm, wrap the fiber with absorbent cotton dipped in alcohol, and then wipe the fiber clean. Put it under the pen tip and cut the optical fiber.Note that the fiber section after cutting should be very careful not to touch any objects, otherwise it will affect the cutting effect.

Figure 8.9(cutter)

After the fiber is stripped, use a cleaver. Note that the cleaver needs to be cut at 90 degrees vertically, otherwise the shape of the cut spot is not good.Use the cutter carefully.

9. Calibration

Calibration procedure is recommended to be performed every twenty-four (24) months in order to maintain the required accuracy of output power versus displayed power. Bi-annual calibrations can be performed at a certified depot repair facility. Call Dimed Service at +86 27 59706608 or your Authorized Service Representative to schedule an appointment.

10. Software Specification

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

This product contains proprietary, copyrighted software developed by Dimed, Inc. all rights reserved in China and other countries.

11. Troubleshooting

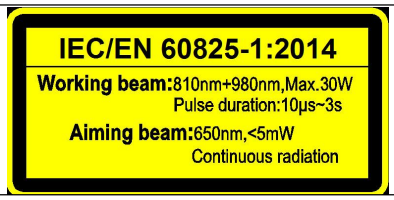
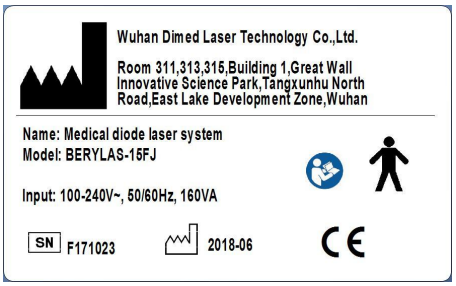
Should any of the on-screen messages listed in Figure 11.1 appear, follow the troubleshooting instructions for the specific message as noted below.

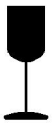
NOTE:
For any on-screen message not listed in Figure 11.1, re-power the laser console; if the message does not clear, call Dimed Service at +86 27 59706608 or your authorized Service Representative.

Title	Message !	Reason ?	Fix ✓
Error 1 	Laser Temperature too High	System too hot	Allow 5-10 mins for laser to cool down
Error 2 	Laser Temperature too Low	Environment temperature too low	Raise the environment temperature
Error 3 	Laser Temperature Sensor open circuit	Laser Temperature Sensor open circuit	Call Dimed Service
Error 4 	Laser Temperature Sensor short circuit	Laser Temperature Sensor short circuit	Call Dimed Service
Error 5 	Controller Overheat	System too hot	Allow 5-10 mins for laser to cool down
Error 6 	Controller Temperature Sensor open circuit	Controller Temperature Sensor open circuit	Call Dimed Service
Error 7 	Controller Temperature Sensor short circuit	Controller Temperature Sensor short circuit	Call Dimed Service
Error 8 	Fiber not connected	Fiber not inserted	Connect the Fiber
Error 9 	Footswitch not connected	Footswitch not connected	Connect the footswitch
Error 10 	Laser light Emergency stop	Laser light Emergency stop	Switch off the power and restart the system
Error 11 	Power Error	Power Error	Restart the device, call Dimed Service if error not cleared
Error 12 	Foot switch not released	Foot switch not released	Release the footswitch
Error 13 	Safety Interlock not connected	Safety interlock open	Check Remote Interlock closed
Error 14 	Duration time or Interval time setting error.	Duty Cycle〈1% or the interval time〉3s	Duty Cycle should ≥1%; Re-enter the pulse time
		Other unknown error	Call Dimed Service

Figure 11.1

APPENDIX A – Labeling

Symbols	Description
	Dangerous laser radiation Avoid exposure of the eye or skin to direct or scattered radiation Class 4 laser products Bottom of laser console
	Warns of potential laser radiation hazards when opening the laser unit. Avoid exposure of the eye or skin to direct or diffuse radiation Class 4 laser product Bottom of laser console
	Class 4 laser products Specification of laser output power and wavelength of diode and aiming beam.
	Warning for visible and invisible laser radiation Avoid exposure to laser aperture
	Laser warning: Indicate the system contains a laser.
	Product ID Label Location Bottom of laser console
	Manufacturer
	Date of Manufacture
	Product Serial Number
	Refer to User Manual

	**Type B Applied Part:** **The applied part is not conductive to the patient.**
	**Emergency Laser Stop Switch:** **The switch used in emergencies to stop laser output.** **Location: Right side of Laser Console**
	**DC Power, USB, Remote Interlock Label:** **Identifies input ports**
	**Power Input Rating:** **12VoltsDirectCurrent,8.5/11.5amps**
	**Interlock:** **Input for Safety Interlock Connector**
	**Fragile:** **Handle with care**
	**Keep Dry**
	**Humidity Limitations**
	**Temperature Limitations**
	**Atmospheric Pressure (kPa)Limitations**
	**This way up**

APPENDIX B – Spare Parts & Accessories

Dimed offers below spare parts or optional accessories for BERYLAS, users can order them according to different use.

	Description
1	Surgical Handpiece
2	Therapy Handpiece
3	Safety Goggles（for patient）
4	Safety Goggles（for operator and assistant）
5	Interlock
6	Power Cord with Power Supply
7	Disposable Tip
8	Disposable Massage Tip
9	Cannulas
10	Fiber
11	Fiber Cutter
12	Fiber Stripper

APPENDIX C – Electromagnetic compatibility

CAUTION:
Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the following tables.
Portable and mobile Radio Frequency (RF) communications equipment can affect medical electrical equipment

Accessories: Medical grade power cord, maximum length 2meters
Footswitch: Wired

WARNING:
No modification of the accessories and foot switch is allowed. As replacement parts for internal or external components, may result in increased EMMISSIONS or decreased IMMUNITY of the BERYLASdiode laser system.

Guidance and manufacture's declaration----electromagnetic emissions		
The BERYLASdiode laser is intended for use in the electromagnetic environment specified below. The customer or the user of the BERYLASdiode laser should assure it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The BERYLASdiode laser 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 emissions CISPR 11	Class A	TheBERYLASdiode laser is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Class A	

Guidance and manufacture's declaration----electromagnetic immunity			
The BERYLASdiode laser is intended for use in the electromagnetic environment specified below. The customer or the user of the BERYLASdiode laser should assure 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	±8kV contact ±15Kv air	±8kV contact ±15Kv 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	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines N/A	Main power quality should be that of atypical commercial or hospital environment. N/A
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV 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	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for5 seconds	<5% U_T (>95% dip in U_T)for 0.5 cycle 40% Ur (60% dip in U_T) for5 cycles 70% Ur (30% dip in U_T) for25 cycles <5% U_T (>95% dip in Ur) for5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of themodelBERYLASdiode laser requires continued operation during power mains interruptions, it is recommended that the model BERYLASdiode laser be powered from an uninterrupted power supply.
Power frequency (50-60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of atypical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. main voltage prior to application of the test level			
Conducted RF IEC 61000-4-6 Radiated RF IEC61000-4-3	3 Vrms 150 kHz to 80 GHz 3V/m 80 MHz to 2.5 GHz	3 V 3Vm	Portable and mobile RF communications equipment should be used no closer to any part of the model BERYLASdiode laser, including cables, than there commended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.2 √ P d = 1.2 √ P 80 MHz to 800 MHz d = 2.3 √ P 800MHz to 2.5GHZ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d 8s there commended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 - At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 – These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephone and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BERYLASdiode laser is used exceeds the applicable RF compliance level above, the BERYLASdiode laser should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Epic diode laser.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Recommended separation distances between for table and mobile RF communications equipment and the BERYLASdiode laser

The BERYLASdiode laser is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of theBERYLASdiode laser can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BERYLASdiode laser 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 D – Clean and disinfection procedures for headpieces

There are two headpieces for the BERYLAS series: Surgical Handpiece and Therapy Handpiece.

NOTE:
The Handpiece is a Re-usable accessory and will require cleaning and disinfection prior to each patient treatment. Tips are intended for single-use only and must be disposed of after each patient use. Proper tip disposal in a biohazard medical waste Sharps container is required. Tips must be steam disinfected prior to use.

Surgical Handpiece 

The contamination control method would be suggested the steam sterilization method for the BERYLAS Series system’s Surgical Handpiece.

CAUTION:
Handpiece and tips must be disinfected prior to initial use.
Tips are single-use only to avoid cross-contamination and are designed to withstand a single sterilization cycle; they must be disposed of after use in a biohazard medical waste Sharps container. Handpieces are reusable and must be cleaned and disinfected between patients to avoid cross-contamination.

Cleaning and Disinfecting Instructions for the Handpiece.

The cleaning process is intended to remove blood, protein and other potential contaminants from the surfaces and crevices of reusable accessories. This process may also reduce the quantity of particles, microorganisms and pathogens present. Cleaning should be performed prior to sterilization and must be conducted only by qualified office personnel trained to perform the procedure and handle the BERYLAS Series fiber optic delivery system.

Wear protective latex gloves when handling the contaminated delivery system.

Cleaning must be performed within a maximum of 1 hour after the procedure and always prior to sterilization.

- After use, carefully remove the tip from the handpiece and dispose of in a biohazard medical waste Sharps container.
- Carefully remove the handpiece from the fiber optic cable.
- Prepare any commercially available surgical instrument detergent/enzymatic cleaning solution with a pH of 7.0, such as Enzol ® or similar enzymatic presoak and cleaner, per the manufacturer’s instructions.
- Rinse the Handpiece under running lukewarm tap water (22 – 43° C) for a minimum of 10 seconds to remove gross soil.
- Wrap the handpiece in a piece of gauze that has been soaked in the cleaning solution; leave it wrapped in the gauze for a minimum of 10 minutes.
- Unwrap the handpiece from the gauze and use a soft-bristled brush dipped in the cleaning solution to gently scrub it for at least 15 seconds.

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

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

NOTE:
Always perform the procedure immediately after cleaning and prior to use and only use FDA-cleared (USA) or CE-marked (Europe) sterilization accessories, i.e., sterilization pouch and autoclave tray.

- Place the handpiece and fiber tips in separate single-wrap, self-seal autoclave pouches.
- Place on an autoclave tray; do not stack other instruments on top of the pouches.
- Place the tray inside the autoclave chamber and set the appropriate cycle asrecommended in Figure D.1.

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

Figure D.1

- Place the handpiece and fiber tips in separate single-wrap, self-seal autoclave pouches.
- Once the cycle is completed, remove the tray and let each sterilized item cool and dry. The handpiece and tips must remain in the sterilization pouches until used in order to maintain sterility.

Notice :

TO ALL OPERATORS “In keeping with the 2014/35EU, 2014/30EU, EN 50419:2006 Directive, with respect to the reduction and disposal of dangerous substances used in electronic andelectric devices.” The sign of the barred trash bin displayed on equipment or packaging there of indicates that upon completion of its life cycle, it should be disposed of separately from other waste.The separate disposal of dead equipment is the producer’s responsibility. Therefore, the usermust contact the producer and follow their established procedure for its disposal.The proper disposal of this equipment will automatically provide for the recycling and proper processing and disposal of the same which helps to prevent possible negative effects on our environment and health, and encourages the recycling of its parts. The improper or illegal disposalby the user will entail the application of administrative sanctions according to the laws and egulations in force.

Wuhan Dimed Laser Technology Co., Ltd
Tel.: +86 027 59706606/ 08
Email: sales@dimedlaser.com
Address: Room 311, 313, 315, Building 1, Great Wall Innovative Science Park, Tangxunhu North Road, East Lake Development Zone, Wuhan, China 430223
Website: www.dimedlaser.com