Elli 810/980

Medical Diode Laser Systems

Operating Manual

(Version:2019/07)

Lysistech AG
Lettenstrasse 39, 9491 Ruggell, Liechtenstein
Phone: +423 230 20 22
kontakt@lysistech.li
www.lysistech.com

1.Model	ELLI 810: 810nm, 30W ELLI 980: 980nm, 30W
2.Serial number	
3.Software version	
4.Date of sale	
5.Manufacturer	Lysistech AG Lettenstrasse 39, 9491 Ruggell, Liechtenstein +423 230 20 22

6. European Representative	Lysistech GmbH Freihamer Str. 2 82166 Gräfelfing Deutschland Tel.: +49 89 89 89 92 90 Fax: +49 89 89 89 92 91 Kontakt@lysistech.com

CE **0483**

Medical Device: ELLI 810/980, 810nm/980nm+-10nm/ 30W, 400µm

We herewith declare that the above mentioned product meet the essential requirements of the Annex II of the **Directive 93/42/EEC** and is classified subject to **Annex IX rule 9** as a medical device of Class **IIb**.

The product is designed in conjunction with the following safety standards:

EN 60825-1:2007 Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility- Requirements and tests.

EN 60601-1:2006 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance.

EN 60601-1-2:2007 Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility- Requirements and tests.

EN 60601-1-6: 2010 Medical electrical equipment-Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability

EN 60601-2-22:1996 Medical electrical equipment. Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.

This declaration is based upon a Quality System meeting the requirements of EN ISO 13485:2012, EN ISO 13485:2012/AC: 2012.

Our expected sales countries are the European Union. This manual is only for EU-English speaking countries. We will prepare the local language for the non-English speaking countries.

Content

1 Introduction

Thank you for using the ELLI 810/980 Medical Diode Laser Systems.

“ELLI 810/980” is class 4 laser. Care is required to avoid hazards or injures. Please read the operation manual carefully before operating. If you have further questions which are not answered by this manual regarding safety, application or operating of the device please get in touch with LYSISTECH AG (See sales and service information, paragraph 13) or your local distributor.

The intended use of the “ELLI 810/980” is: General surgery and ear/nose/throat (ENT) interventions.

1.1 Copyright

The appearance, the fiber-coupled technology, control software and other related parts are parts of the Lysistech AG copyright with all rights reserved. Any person or company will bear legal liability for counterfeit.

Under the copyright laws, this manual cannot be copied in whole or in part without the express written permission of LYSISTECH AG. Permitted copies must carry the same proprietary and copyright notices as were affixed to the original.

The manual will be updated with the continuous modifications and upgrade for the device.

1.2 Warnings and safety precautions

Visible and Invisible Laser Radiation
Avoid Eye or Skin Exposure to
Direct or Scattered Radiaton
CLASS 4 LASER PRODUCT

DIODE LASER 810 or 980 +/-10nm cw 30W

DIODE LASER 635 +/-10nm PWM 5mw (max)

EN 60825-1:2007 EN 60601-2-22:1996

WARNING: Always wear protective eyewear when using this unit.

The optical power output from this system can cause severe eye damage or other injuries. Always wear protective eyewear when using this unit. Exercise extreme caution to prevent injury.

This equipment is intended for use by trained physicians or scientists only, and should only be operated by qualified personnel who have familiarized

themselves with the operating parameters of this product prior to use.

The “ELLI 810/980” is a class 4 laser according to Directives EN 60825:2007.

A class 4 laser is hazardous to the eye from both direct beam and diffuse reflection of the beam. It also represents significant skin and fire hazards.

Danger!

Do not use the unit near flammable anesthetics or other flammable substances.

Avoid eye or skin exposure to direct or scattered radiation. Take all necessary precautions in areas in which the laser is being used.

Near infrared light (810nm/980nm) from the “ELLI 810/980” passes through the transparent components of the eye and is focused on the retina at the back of the eye. This can cause an accidental retinal burn.

Only protective glasses designed for protection from cw-diode laser radiation at a wavelength of 810nm/980nm +/-10nm with an optical density of **OD≥ 4** should be used. Glasses not designed to this specification are not suitable for eye protection. Suitable glasses are available from your *Lysistech AG Laser* representative

Nominal Ocular Hazard Distance (NOHD) is 10.5m from the distal end of the fiber.

Attention!

Do not stare into the aiming beam or view the aiming beam directly through optical instruments. Avoid direct exposure to the aiming beam.

Avoid placing reflective material, such as metal and glass, into the beam.

Attention!

Accidental irradiation to other than the target tissue may result in laser burn.

Attention!

The “ELLI 810/980” is only to be used in combination with a footswitch and specified application and light delivery systems appendant to the device.

Attention!

Please avoid touching the patient and the foot switch / door contact /service connector socket simultaneously.

NOTE:

A minimum distance of 25 cm should be maintained between the ventilation slots and the walls.

To prevent the risk of electrical shock, do not remove the cover. All servicing should be done by *Lysistech AG Laser* or by qualified personnel authorized by *Lysistech AG Laser*. After the end of guarantee period servicing can also be done by sufficiently qualified persons.

The equipment should be routinely inspected and maintained in accordance with the instructions given in the maintenance section of this manual.

Separate the unit from power supply before cleaning and disinfecting.

Caution!

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

NOTE!

Laser equipment not in use should be protected against unqualified use by removing the key from the key switch.

1.3 Vigilance

Lysistech AG Laser maintains a procedure to review the experience gained from devices in the post-production phase and to implement any necessary corrective action. This medical device vigilance system is designed to improve the protection of the health and safety of patients, users, and others by reducing the likelihood of the same type of adverse incident recurring. This will be achieved by the evaluation of reported incidents, and where appropriate, the dissemination of information to prevent repetitions, and/or alleviate the consequences.

Organizations and individuals involved in the purchasing of medical devices and

in the provision of health-care should be aware that their co-operation is vital in providing the first link in the Vigilance chain. This includes organizations and individuals responsible for providing calibration and maintenance of medical devices.

The following incidents should be reported to *Lysistech AG Laser* immediately upon them becoming known:

Any malfunction or deterioration in the characteristics and/or performance of a device, or inadequacy in the labeling or instructions for use, which led to or might have led to:

- Death of a patient or user
- Serious deterioration in the state of health of a patient or user

Reports should be made to the following:

Lysistech AG

Add.: Lettenstrasse 39, 9491 Ruggell, Liechtenstein

Tel.: +423 230 20 22

Mail: kontakt@lysistech.li

2 Theory and technical information

Diode laser is a kind of laser with semiconductor as working material. It consists of working material, cavity resonator and power source.

The diode laser for this unit is GaAlAs diode bar, and the wavelength is 810/980nm. It features impact structure, high efficiency and long lifetime. Generally the beam shall be emitted as the big beam divergence of the laser from the diode. With the LYSISTECH AG unique fiber-coupling technology, the laser beam can be coupled efficiently into the fiber.

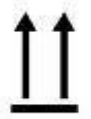
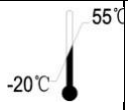
3 Transportation and Storage

3.1 Information on the packaging

NOTE:

Please keep the packaging in case you need to return the product for servicing or repair.

The symbols printed on the outside are for transportation and storage, and have the following meaning:

	This end up.
	Keep away from moisture.
	Don’t turn over.
	Temperature extremes.
	Fragile – handle with care.
	Not to be stowed under other cargo.

The “ELLI 810/980” should only be transported and stored in its original container to prevent damage. The drastic shaking during the transportation should be prohibited. Also please don’t throw or beat the device.

The device should avoid any contamination of acid, alkali or caustic material. Protect it from direct exposure under the sun or the rain.

3.2 Transportation and storage conditions

The ambient air has to be dry (no more than 80%) and clean. The temperature ranges from -20℃ to 55℃, and the atmospheric pressure ranges from 500hPa to 1060hPa.

4 Installation

4.1 Unpacking and installation

In most of the cases the device should be unpacked and installed by LYSISTECH AG or one of the representatives who is responsible for the tests and inspections on the spot.

The product is well packed before transportation. Please do check carefully whether there's any damage to the package after you receive it.

When unpacking, please check whether all the items are inside according to the packing list and save them with care, for them will be in demand when you return the product to LYSISTECH AG. If you have any questions, please contact LYSISTECH AG or authorized distributor immediately.

4.2 Requirements to the Room

The use of a medical Class 4 laser requires warning logos on the unit itself and clear markings at the entrances to the room. Please refer to the information below for further instruction.

4.2.1 Labelling of the Entrance

Each entrance door has to be marked clearly so that from the outside the laser room can be recognized immediately.

➢ A laser warning logo with laser wavelength information must be put up on all entrance doors.

➢ Each entrance door has to be equipped with a warning light. Every time the laser is switched on the warning light has to come on and be illuminated to the outside.

➢ Entering the room is strictly prohibited while the laser is in use.

4.2.2 Laser protection at windows

During surgery, it is important that no laser light can escape from the room. All openings to the exterior of the laser room including windows must be properly secured to prohibit the escape of laser beams. If you need information or help in designing the room please get in touch with LYSISTECH AG or your local distributor.

4.2.3 Protection against high reflective Surface

To avoid any direct or indirect scattered radiation from the laser beam, no highly

reflective material should be found in the surgery room. This includes mirrors, picture frames, polished chromium surfaces and windows. All such surfaces have to be removed or protected by non-reflective material.

4.3 Safety indicators

Safety indicators must be affixed to all entrances, exits and places, including windows, from where the laser or laser radiation could escape.

5 Safety Tips and Technical Acceptance

5.1 General

The “ELLI 810/980” is a precise medical laser device and can only be used for medical application. The system has been thoroughly developed and will be thoroughly tested before shipment. To enjoy your product through the lifetime and to protect you and your personal from laser radiation we recommend reading this chapter very carefully. In addition, the person to operate the unit should get relative professional training before using.

The “ELLI 810/980” is classified as class 4.

Class 4 describes only high energy lasers and therefore needs certain precautions before switching on the system to allow a safe and troublefree operation. Additional we high recommend not using any flammable close to the laser.

⚠ Caution!

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

5.2 Eye Protections

⚠ Attention!

Do not look into the laser beam or reflected or scattered light of the laser beam. Never look directly into the output of the fiber optic or the output of the laser handpiece. Otherwise damages of the retina could occur.

To avoid any eye injuries, in the treat room where safety goggles placed has to be clearly marked. All the people including patients have to wear safety goggles as soon as the laser is turned on.

Item	Type	Manufacturer
Safety goggle	IRD5	NoIR Laser Co., LLC.

Different safety goggles for corresponding wavelengths are available to protect the eyes. If you have further questions about safety goggles please get in contact with LYSISTECH AG or your local distributor.

The “ELLI 810/980” offers external interlock connector which directly connects

the door's switch of the room. The unit will be shut off quickly once the door is opened. We recommend that the door should be closed entirely and can't be opened from outside when the unit is in use, or it'll terminate the therapy at once.

5.3 Electrical Protection

- Opening the device to repair or maintain should only be carried out by certified person from LYSISTECH AG or the distributors. LYSISTECH AG will not take any responsibility if any other person opens the device without the approval of LYSISTECH AG or the distributors.
- "ELLI 810/980" mini surgery diode laser system has already been set limitation of current before shipment so as to prevent the dangerous output in a non-normal condition.
- Please make sure that the device is firmly grounded when it is in operation.
- The room where the device is installed should be clean and dry. Please make sure that there is no water drop or water vapor when the device is turned on.

Warnings!

To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.
No modification of this equipment is allowed

Attention!

Do never attempt to work with the laser when a failure code is displayed and please get in contact with LYSISTECH AG or the distributors.

5.4 Fire Hazards

Danger!

Do not work with the device and the laser beam close to flammable, anesthetic or any other solvents which are easily flammable. Remove the paper and plastics from the laser working area. Within a certain distance, these materials absorb considerable energy can be ignited.

When the laser is not in use or patients are changed or a break in the treatment occurs please turn the device into "stand-by" status. At this mode the laser cannot be activated by the foot switch.

5.5 Protection against Scattered Light

To prevent any triggering of the laser during connecting handpieces or fiber optics, please follow the connection sequence described below:

(1) Install the fiber optic

(2) Connect the laser handpiece

(3) Switch the laser on

As mentioned above, don't focus the laser beam onto flammable materials.

The foot switch must be replaced in the doctor's working area and can only be controlled by the doctor who is responsible for the treatment. Never trigger the laser via a third person.

5.6 Main Switch and Key Switch

The main switch of the unit is a power switch at the back of the device and the key switch is at the front panel. The device is equipped with two keys and can't be operated without a key. The key should only be carried or be available by the physician who operates the device.

Turning the main switch to "|" position and turn the key switch into "|" position, the system will boot. Then the system will perform a self-check. After inputting the password, you can enter into the main operate interface.

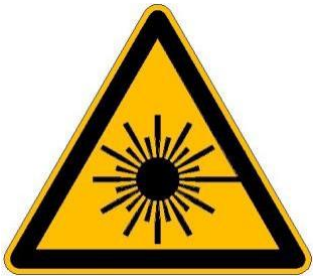
5.7 Manual Reset

Any improper function of the system will immediately cut the voltage supply to the laser and the complete unit is switched off. To restart the unit the main switch has to be turned into "O" and then "I" position. If the failure shows up repeatedly, please contact LYSISTECH AG or the distributor at once.

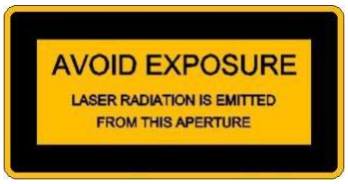
5.8 External interlock connector

There's an external interlock connector at the back panel of the unit, which connect the door's interlock of the room through cable. The unit will be shut off as soon as the door is opened. By default, the external interlock connector is disconnected.

5.9 Safety Signs

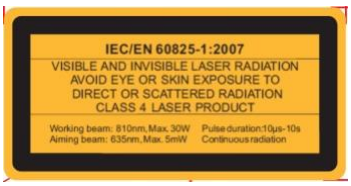


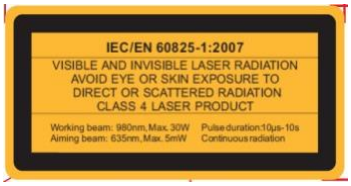
Danger for laser



Laser output window

Pay attention to the fiber connector

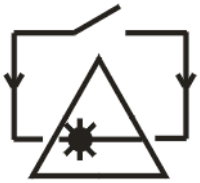




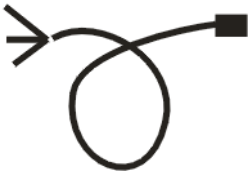
Model: ELLI 810 Model: ELLI 980

Laser Product Information

Emergency Laser Stop



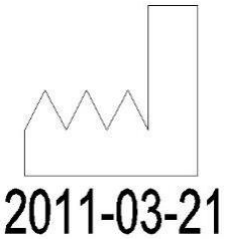
Interlock



Fiber

Type B Equipment

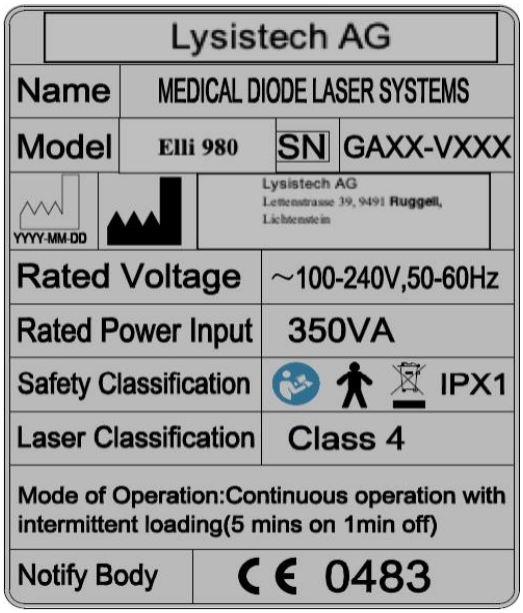
Refer to operate manual



Production date

Manufacturer

Safety mark



Model: ELLI 980

Product nameplate

6 Environmental protection

Fiber is single use and should be abandoned in accordance with the disposal of medical waste which contact with the human body.

Warnings!

It is prohibited to reuse the disposable sterile medical fiber. It may become the important means of disease transmission.

"ELLI 810/980" will not generate any wastes during the normal use. When scrapped, the host can be disposed as the conventional electric products.

7 Clinic indications

Main clinic applications are: General surgery and ear/nose/throat (ENT) interventions

The physician should be aware of the clinical applications for the laser when the exact therapy of the diode laser in each clinical case cannot be known clearly.

Prohibited to be applied in :

The patients who have heart trouble, psychosis, hypertensive diseases or any patient who has been proved are not suitable for the therapy of laser.

7.1 ENT Department

Staphylectomy/ Cavernous hemangioma/ Apostaxis/ Coryza (chronic, hypertrophic, allergic)/ Rhinopolypus cutting, conchotomy/ Tonsillectomy/ Neoplasm cutting

8 Product description

8.1 General Overview

The “ELLI 810/980” consists of five main components

(1) Laser system

(2) Color touch screen

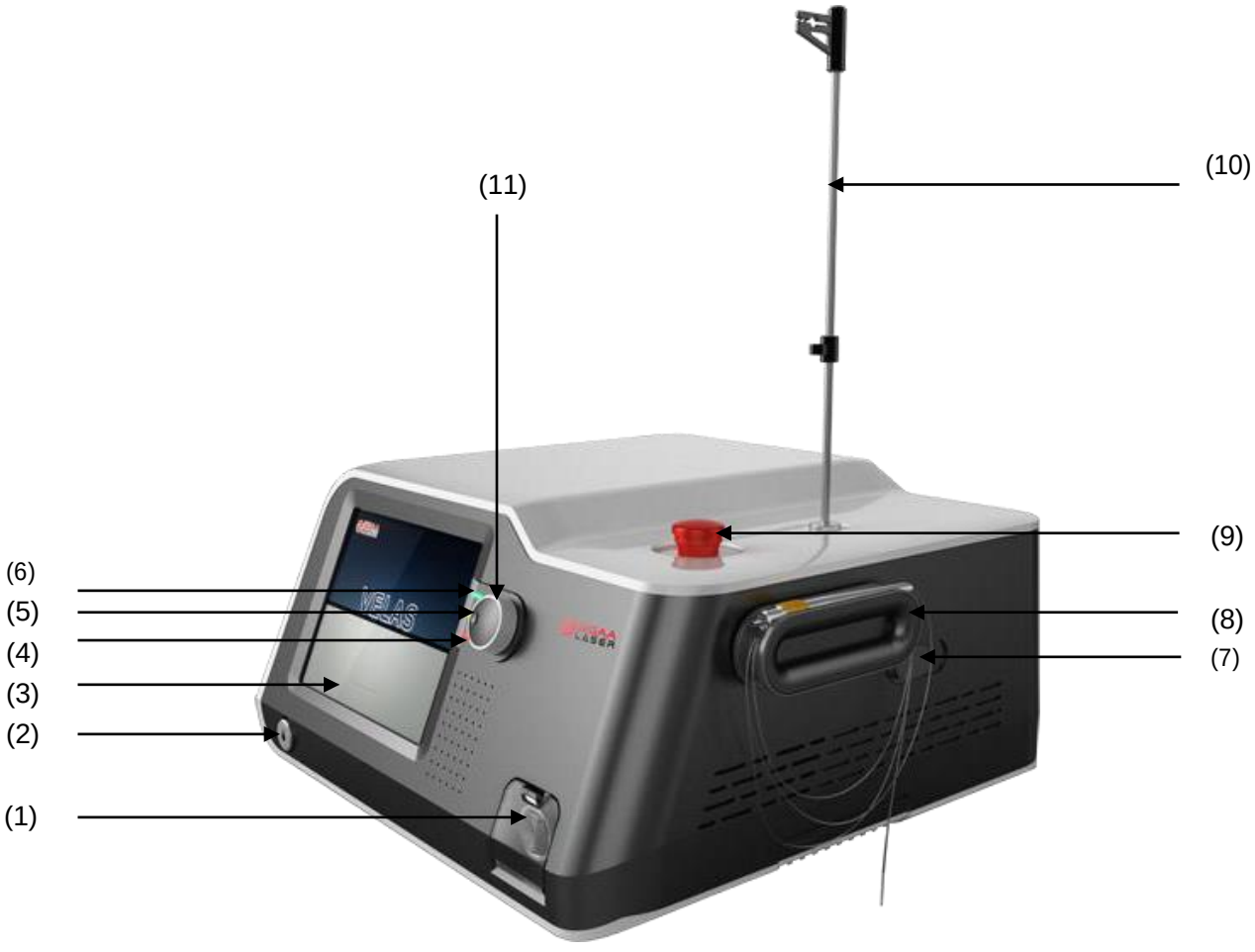
(3) Fiber and the handpiece

(4) Foot switch

(5) Power detector

The laser system consists of the fiber-coupled diode laser module, power supply, control panel, safety shutter and the embedded computer control system.

8.2 Front



At the front of the unit you will find:

(1) Laser Aperture

(2) Key Switch

(3) Color Touch Screen

(4) Alarm Indicator (RED)

(5) Laser Emission Indicator (YELLOW)

(6) Power Indicator (GREEN)

(7) Power Detect Aperture

(8) Handpiece Holder

(9) Emergency Stop

(10) Fiber Holder

(11) Encode Knob

8.2.1 Laser Aperture

Laser aperture

The laser aperture is designed with a standard SMA-905 connector. Make sure that the fiber connection is right and well. The alarm indicator will give warning when the fiber is wrongly connected.

Warnings!

Do not remove the fiber during the use of the device.
Fiber cannot be steeply bent; the bend radius must more than 15cm.

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

Attention!

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.

8.2.2 Key Switch

The key switch for the unit is at the front of the device. The device is equipped with two keys and can't be operated without a key. The key should only be carried or be available by the physician who operates the device.

The key switch serves as the main system activator. Turning the key switch into "|" position, the system will boot and the power indicator is on. Then the system will perform a self-check. Turn the key switch into "O" position the whole unit will be switched off.

Attention!

Remove the key from the key switch when the system is not in use and store it in a safe place.

8.2.3 Color Touch Screen

The LCD touch screen of the unit features high sensitivity and high resolution. It is the man-machine interface. You can touch the icons on the screen with finger or professional pen to open the corresponding program.

Attention!

Do not put heavy objects or apply excessive pressure on the touch screen to prevent distorting the touch screen display. Also avoid touching the screen with sharp materials in case there's any scratch to the surface.

Cautions have to be taken that don't sprinkle any liquid directly on the surface of the touch screen.

8.2.4 Alarm Indicator

The alarm indicator will be red, when system alarms.

8.2.5 Laser Emission Indicator

The Laser emission indicator will be yellow when the laser is emitting. The action of the indicator synchronizes with the laser.

The laser emission indicator will still be on if the system is in an emergent or a non-normal status. At that time the system will stop all the output and the touch screen will show the error information, meanwhile the system alarms.

Attention!

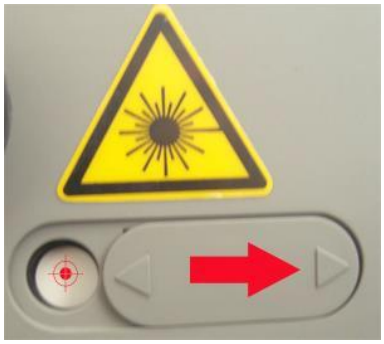
Press the emergency stop to terminate laser emission if the laser emission indicator constant light.

8.2.6 Power Indicator

The power indicator will be green if the power supply of the laser is normal.

8.2.7 Power Detect Aperture

Closed



Open

At the right side of the ELLI 810/980, there is a power detect aperture. You can easily test the power of the laser with the power detect aperture. When testing, firstly remove the aperture protective hat and then make the fiber direct to the middle of the aperture, keep the distance about 0.5 cm, and fix the fiber.

Attention!

(1) Please wear safety goggles when testing laser power.

(2) Before testing, you must open the laser power detect aperture.

(3) Please make sure that the testing fiber is clean and the fiber tip is very good.

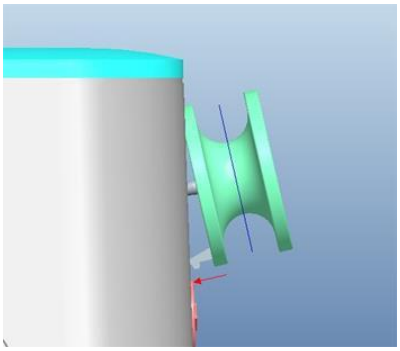
(4) Make the fiber tip at the middle of the laser power detect aperture (Aim at the red dot as the picture "Open" shows above with the fiber perpendicular to the laser power detect aperature) and fix it.

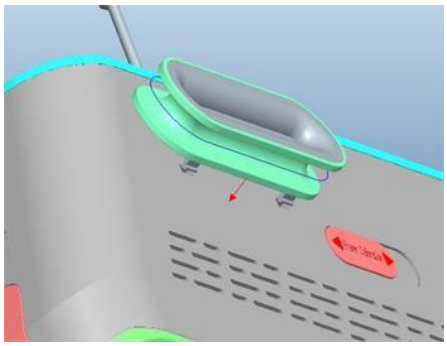
(5) Please make sure the laser beam entirely goes into the laser power detect aperture and the distance is about 0.5cm between the fiber tip and power meter.

(6) Don't use hands to hold the fiber during testing. Otherwise the test result will not be accurate.

8.2.8 Handpiece Holder

You can place the handpiece on the handpiece holder when you do not need to use it. The following picture will help you to install the handpiece holder:





8.2.9 Emergency Stop

The emergency stop connects to the system's power supply. In the event of an emergency, pressing the emergency stop will immediately stop laser emission. Before restarting, turn as the arrow shows at the knob to bounce up the emergency stop.

8.2.10 Fiber Holder

Make fiber as a circle bundle, use the clip which on the top of the fiber holder to clamp the fiber bundle, and use the hook to hook the below of the fiber bundle.

8.2.11 Encode Knob

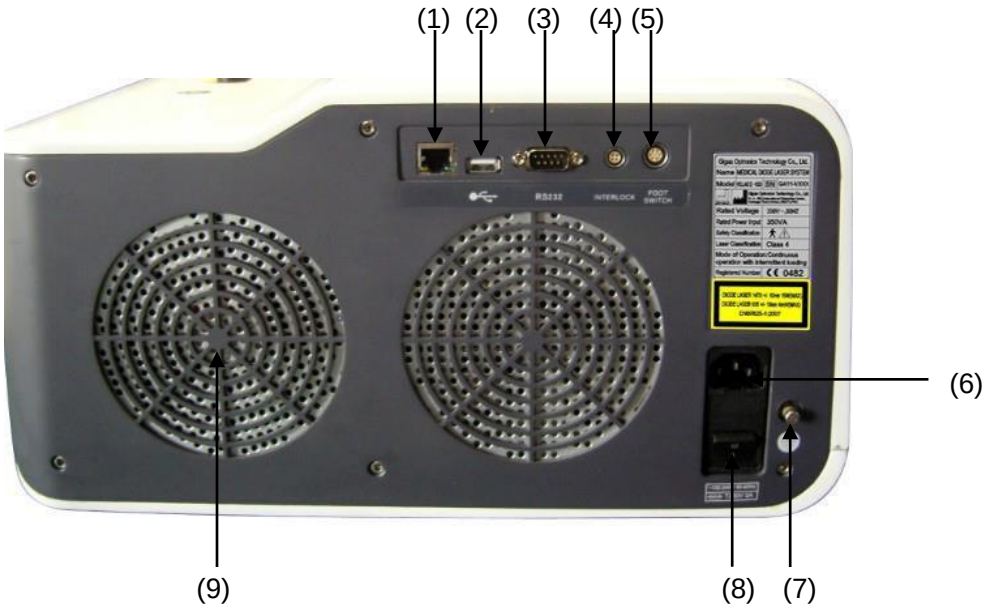
The encode knob are used for adjusting the parameter value. In different condition, the step is not the same.

8.2.12 Fiber

Single used sterile fiber which has already passed CE certification is applied. The parameter must satisfy the following:

- bare fiber, long as 3m
- Fiber core diameter ≥200μm
- NA ≥0.22
- With SMA905 connector
- CE marked.
- Single used

8.3 Rear Panel



(1) Network port – for future use

(2) USB port – for update program

(3) RS232 port – for computer control

(4) Foot switch outlet

(5) Remote interlock

(6) Power outlet

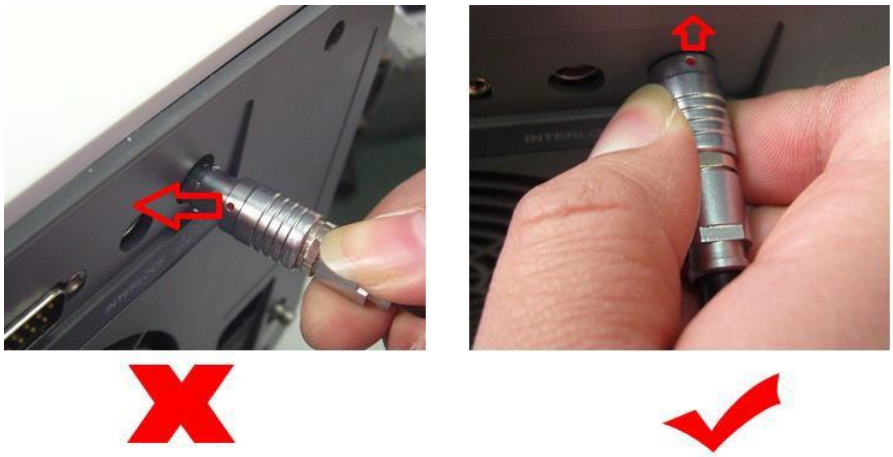
(7) Ground

(8) Main switch

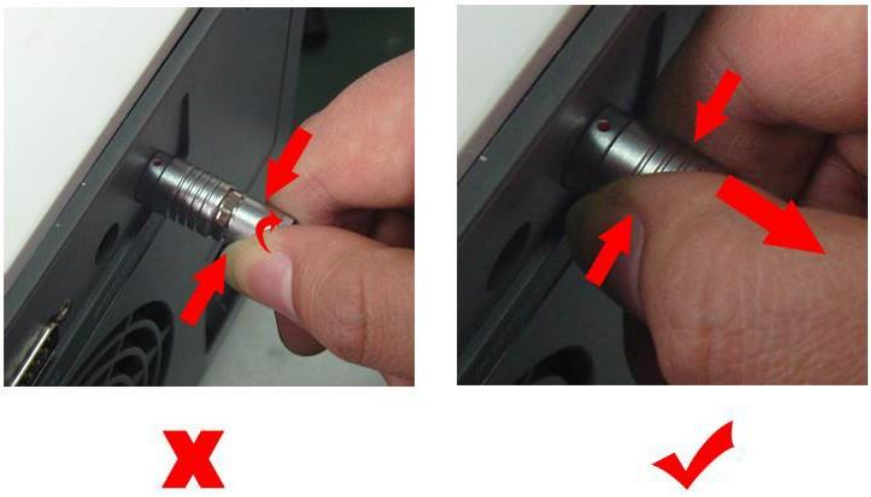
(9) FAN

Attention!

Please pay attention to inserting and pulling out the footswitch and the interlock.



There is a red dot on the connector. Insert the footswitch or interlock with the red dot facing upward as the picture shows above.



When pulling out the footswitch or interlock, please hold the right place.

9 Specifications

(Temperature is 5℃ ~ 40℃, relative humidity is no more than 80%, and atmospheric pressure is 860hPa ~ 1060hPa.)

Laser type	GaAlAs diode laser
Model	ELLI 810/980
Wavelength	ELLI 810: 810nm±10nm ELLI 980: 980nm±10nm
Output power	1-30W
Operation mode	CW, single pulse, repeat pulse
Pulse width	10μs-10s
Pulse repetition rate	0.05Hz-20 KHz
Application systems	Fiber core diameter ≥200μm NA ≥0.22 With SMA905 connector Before use must sterile CE Marking
Transmission system	contact: fibers of 400μm, 600μm and 1000μm with SMA905 connector; Non-contact: fibers and tips
Aiming beam	Diode laser of 635nm, power < 5mW, adjustable brightness.
Operation interface	Color LCD touch screen
Power supply	230VAC, 5A, 50Hz
Laser Class	4

Safety classification	Class Ⅰ Type B
Cooling	Air
FUSE	F 250V 5A
Dimensions	400(W)*385(L)*200(H)mm
Weight	12.9kg
Waterproof level	IPX1
Footswitch Waterproof level	IPX8
Safefy Compliance	CE 0483

10 Operating the Instrument

Attention!

The "ELLI 810/980" should only be operated by a physician who has been instructed in the use of the instrument during installation.

Don't touch the device signal port when another hand contact with the patient.

This part of the manual only describes the technical use of the instrument without detailing the medical use.

10.1 Introduction

To guarantee a faultless operation of the device during surgery the following requirements have to be met:

- The device has already been plugged into electricity.
- The safety goggles are available for the people in the room.
- The fiber has already been fixed to the laser aperture (Connect the handpiece when necessary).
- The remote interlock connector has been used.
- The footswitch has already been connected.
- The emergency stop has already been popped out.

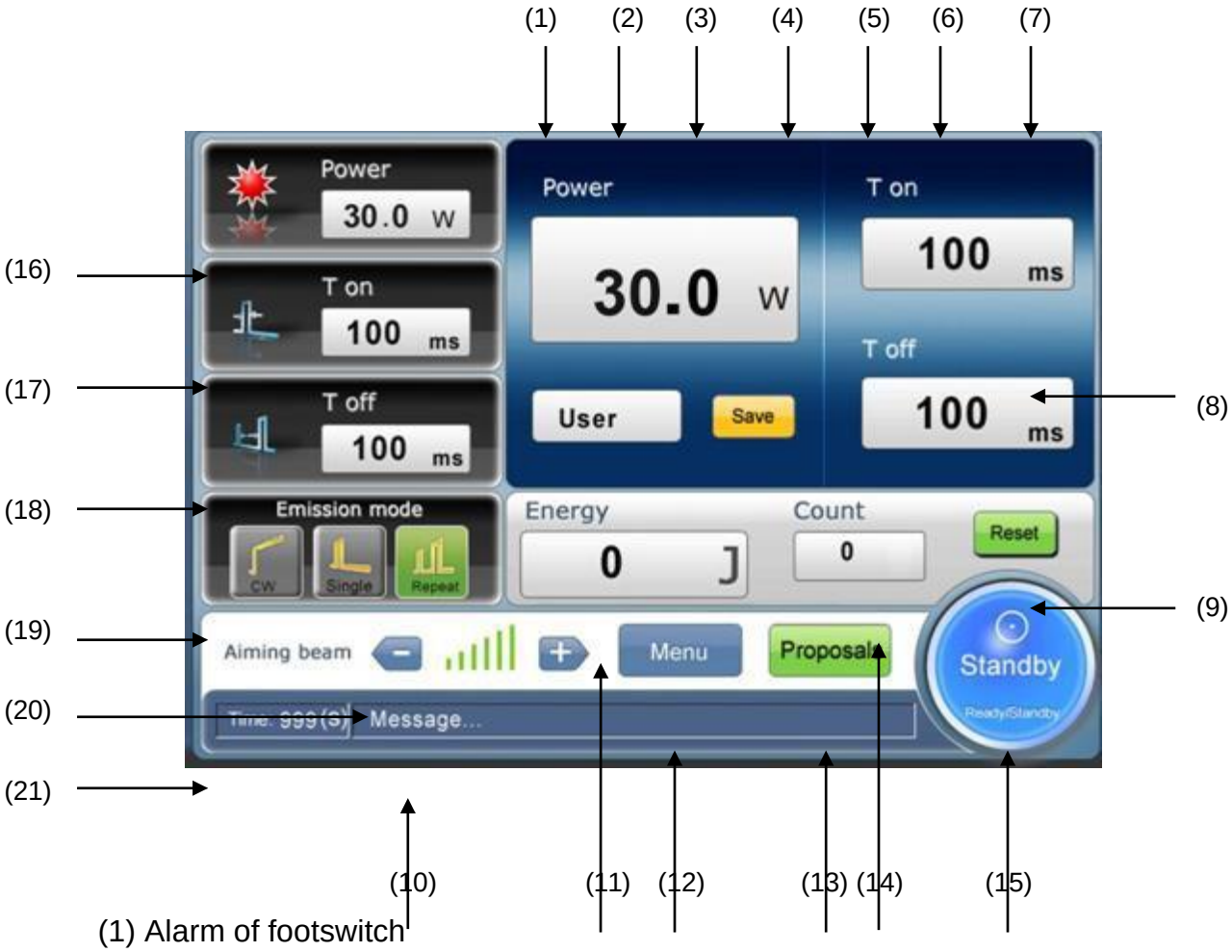
10.2 Starting of the Unit

To start the laser unit, turn the main switch ON and turn the key switch clockwise into "I" position. Immediately the power indicator will be green with the system fans working. At the same time, the LCD screen lights up as the picture shows below.

After showing the information, the system will perform a self-check. If there are problems during startup, the system will inform you at the display about the problems. For more information, please see chapter 11 "Failure Detection".

System will take about 90 seconds to start up.

10.3 Main Menu



(1) Alarm of footswitch

(2) Alarm of interlock

(3) Alarm of fiber

(4) Timer on

(5) Sound on

(6) Aiming beam on

(7) Wavelength

(8) Parameter area, not as a touch area

(9) Reset the energy

(10) Help message or alarm message

(11) Total energy

(12) Menu

(13) Preset proposals

(14) Pulse count

(15) Standby/Ready

(16) Set laser power

(17) Set Ton time. At Ton time laser is emitting.

(18) Set Toff time. At Toff time laser is paused.

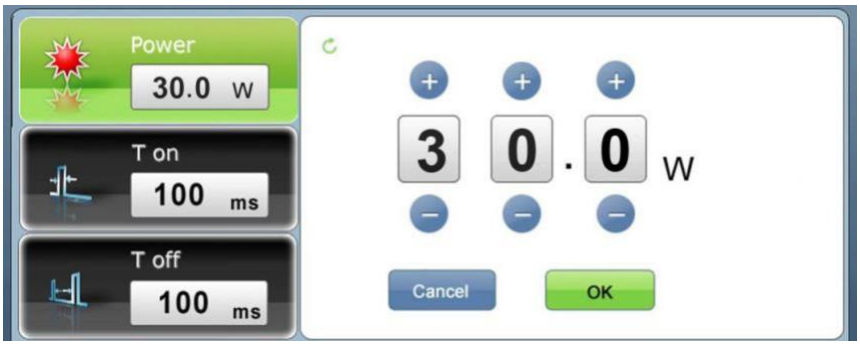
(19) Laser emission mode
CW - continuous laser output
Single - press the footswitch, only one pulse laser out
Repeat - press the footswitch, multiple pulses laser out

(20) Aiming beam intensity

(21) Show the timer setting value

10.4 Set parameter

10.4.1 Set laser output power



The peak power is the output MAX power when laser emitting and the range is 1W to 30W. By pressing the “+” and “-” button, you can set the laser output power conveniently. Also you can use the encode knob to adjust it. When finishing adjusting, “ELLI 810/980” will save the parameter into the proposal.

10.4.2 Select laser emission mode

There are altogether 3 emission modes. When selected, the corresponding button will turn green:

(1) CW

In this mode, the laser will continue emitting unless you release the footswitch.

Attention!

For safety in this mode, after emitting 5 minutes (when peak power is above 12W), the laser should be stopped 1 minute at least.

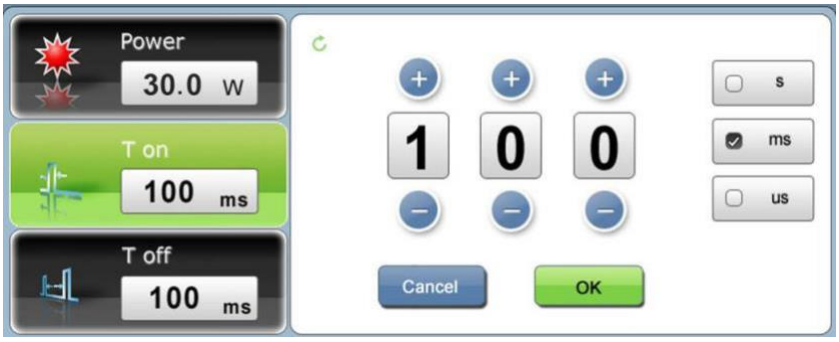
(2) Single

In this mode, the laser will emit one pulse when you don't release the footswitch.

(3) Repeat

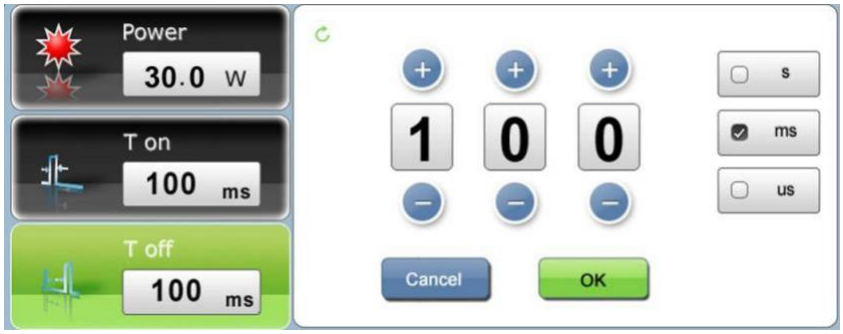
In this mode, the laser will emit by pulse when you don't release the footswitch.

10.4.3 Set laser Ton time



The Ton time is the laser emission time during one pulse period. It ranges from 10μs-10s. By pressing the "+" and "-" button, you can adjust the value conveniently. Also you can use the encode knob to adjust. When finishing, "ELLI 810/980" will save the parameter into the proposal.

10.4.4 Set laser Toff time



The Toff time is the laser off time during one pulse period. It ranges from 25μs to 10s. By pressing the “+” and “-” button, you can adjust the value conveniently. Also you can use the encode knob to adjust. When finishing, “ELLI 810/980” will save the parameter into the proposal.

10.4.5 Adjust aiming beam

Adjust density of the aiming beam. [+] is increase and [-] is decrease.

There are 7 levels of the aiming beam from 0 to 6. When the level is selected, it turns green, otherwise it is black. If the aiming beam level is 0, it means that the aiming beam is closed.

At the main menu, the item 6 is active (see chapter 10.3) only when the value is more than 0.

Attention!

Only in Ready status, you can see the density of the aiming beam. In standby status you can adjust the density, but can’t see it.

10.4.6 Save the parameter

When finishing the parameter setting, you can press the “Save” button to save the current parameters to current selected proposal.

10.4.7 Reset the total energy

When laser working, the energy is summated. The total energy ranges from 0 to 99999J. If you want reset the total energy please press the “RESET” button. When the total energy is more than 99999J, it will back to 0 automatically.

Count: Pulse count.

Single: In this mode, the count is the total count of footswitch pressed.

Repeat: In this mode, treading down and then releasing the footswitch the count will be automatically accumulated. If you press the footswitch again, the count will be suspended.

10.4.8 Menu and Proposal

When you press the “Menu” button, you will enter into the menu interface. And the “Proposals” button is to the proposals interface. Details please refer to paragraph 10.4.10 and 10.4.11.

10.4.9 Standby and Ready

When you press the Ready/Standby button, it changes from a status to another status.

Standby: in this status, the laser power supply is disabled. When you press the footswitch, it can’t send out laser.

Ready: in this status, the laser power supply is enabled. When you press the footswitch, it can send out laser.

10.4.10 Menu interface

10.4.10.1 Setting

In menu interface pressing “Settings” icon, you will go into user setting interface. In this interface, you can set the speaker sound, LCD back light. And you can enable/disable the timer. When timer is on you can set the timer value. In this interface by pressing “Back” icon, you can back to the main menu.

10.4.10.2 System information

If you want to learn about the system information, please press the “Settings” icon in menu interface.

10.4.10.3 Test laser power

By pressing the “Test Power” button, you will enter into the test power interface.

Set Power: the power you want to test.

Test Power: the value of the tested power.

Testing step:

(1) Open the laser power detect aperture;

(2) Fix the fiber;

(3) Wear the safety goggles;

(4) Press the “Test” button, the button will turn yellow meanwhile the aiming beam will be on;

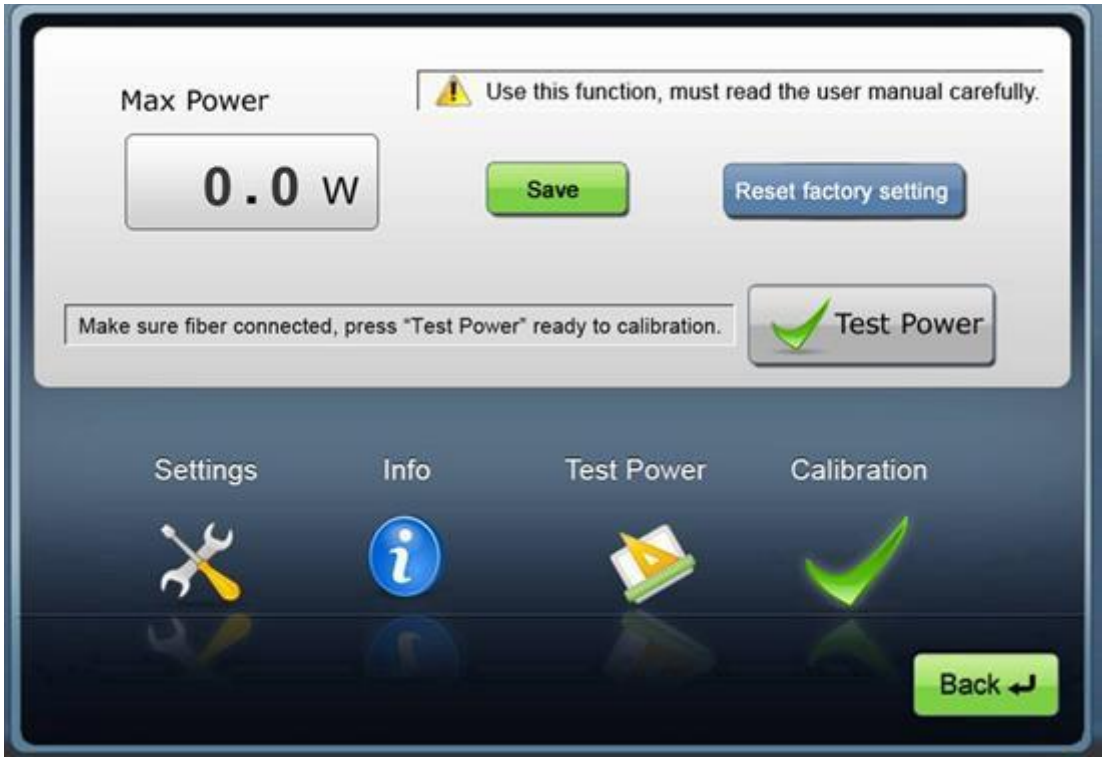
(5) Press the footswitch, and hold it.

(6) When the process bar is over, the power detect is finished. And then you can release the footswitch and read the value of the laser power.

Attention!

The test value may be different to the set value, if the difference is in 20%, this is normal.

10.4.10.4 Calibrate laser power



Attention!

Before calibration, please make sure that there is an accurate power meter. Only when the ELLI 810/980 testing result is near to the power meter testing power, can you begin to calibrate.

If you press the “Calibration” button, the calibration interface will show above.

Test Power: Before laser test, this power is the MAX power of the ELLI 810/980.

Max Power: the value of the tested power.

Saved: After you make sure the ELLI 810/980 testing power is near to the power meter testing result, save the result to the memory and finish the calibration.

Reset factory setting: Restore the laser power setting as the factory setting, don’t keep the calibration result.

Calibration step:

(1) Open the laser power detect aperture.

(2) Fix the fiber.

(3) Wear the safety goggles.

(4) Press “Test Power” button, the button will turn yellow meanwhile the aiming beam will be on.

(5) Press the footswitch, and hold it.

(6) When the process bar is over, the power detect is finished. And then you can release the footswitch and read the value of the laser power.

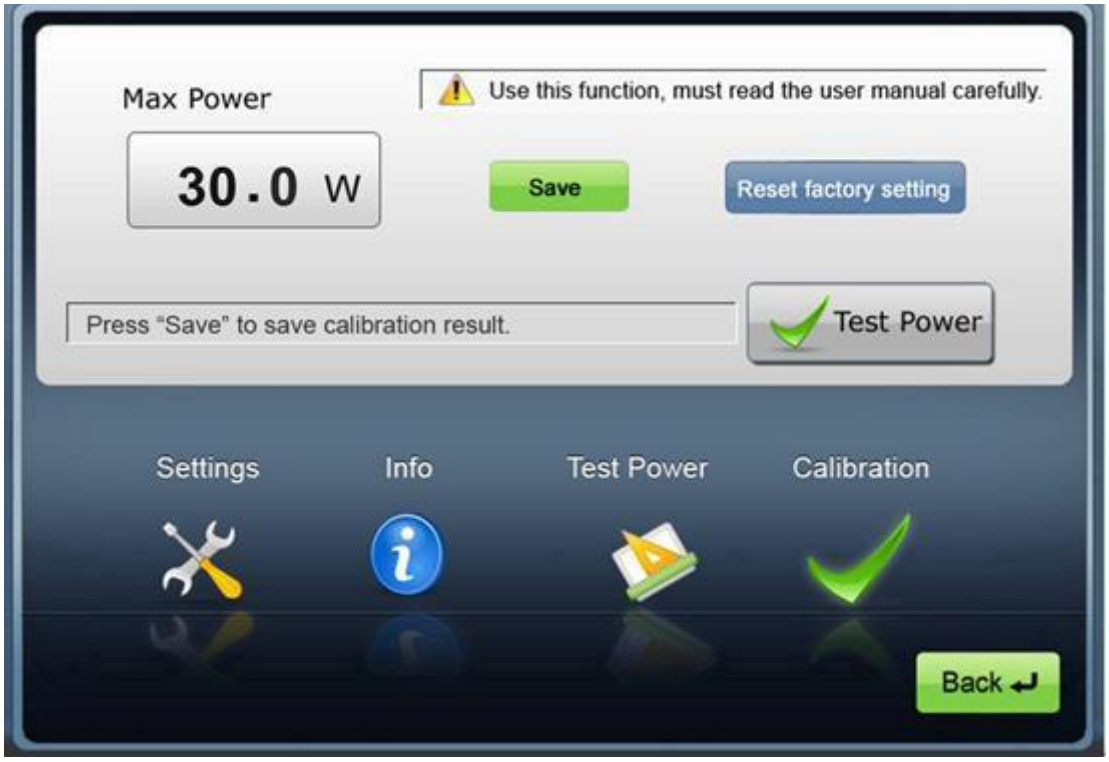
(7) Use the power meter to test the laser power again.

(8) If the test results are very nearly, you can make sure the test result is correct. Press the “Saved” button to save the test result.

Attention!

(1) If the test power is too low (<50%), the calibration will not be going on.

(2) After calibration, the ELLI 810/980 MAX power will be changed. If the calibration power is lower than the old MAX power, you can only save the lower as the MAX power.



10.4.11 Proposals interface

When going into the proposal interface, there are 16 items. you can change the proposal parameter as the following step:

(1) Select the proposal you want to change.

(2) See the old parameter at the bottom of the screen.

(3) Press “OK” button return to the main menu.

(4) Change the parameter in the main interface.

You can rename the proposals easily, just by tapping the “Rename” button.

10.5 Laser Emission

After finishing setting the parameters, press the “Ready” button and the system will remind you to wear the safety goggles (protect wavelength from 800nm to 1100nm). At this time when you press down the footswitch, the laser will emit.

11 Failure Detection

Problem	Eventually Cause	Problem Solving
When put on the main switch, the unit does not start, and the power indicator is off	1) "Emergency Stop" button is pressed 2) The fuse is burned	1) Turn the "Emergency Stop" button back to the normal position 2) Take off the power line to cut off the power, and check the fuse.
Alarm information on the screen	1) The fiber is not plugged in or plugged in an improper way 2) Safety interlock switch is on 3) Footswitch not connect 4) System is wrong	1) Plug the fiber in tightly 2) connect the safety interlock switch. 3) connect the footswitch 4) Write down the wrong code, and contact LYSISTECH AG.
TEMPERATURE is HIGH	Temperature more than 35 ℃	Stop the laser and wait for a few minutes
TEMPERATURE is LOW	Temperature less than 10	Make room temperature more high
POWERSUPPLY ERROR	Laser current too high	Exclude the interference of high-power electrical to the device, and then restart the device.
Remote INTERLOCK	Not connect the interlock	Connect the interlock
FIBER NOT CONNECTED	Not connect the fiber	Connect the fiber
Footswitch opened	Not connect the footswitch	Connect the footswitch
Fiber temperature is high	The fiber connector temperature is high	May be the fiber tip or the laser output lens is dirty, please check the fiber tip and the laser output lens
MOSFET temperature is high	MOSFET temperature is high	Stop the laser output
no electricity when opening the laser	not plug in the external power	plug in the external power
no electricity when opening the laser	Press down the emergency stop switch	Turn around clockwise, pop-up the emergency stop switch
no electricity when opening the laser	The inner power supply has no output	Check the supplied pressure and the required pressure
no electricity when opening the laser	The inner power supply has no output	The power supply have already destroy, must sent back the system to LYSISTECH AG

cannot start up, no display	the screen wire break off or the data wire fall off	take apart the machine to check the the screen wire and the data wire
cannot start up, no display	The control board cannot output	The control board broken, send back to LYSISTECH AG
no take aim light	Didn't connect the fiber	Check if the fiber is connected or not
no take aim light	The intensity is too low	The take aim light broken, send back to LYSISTECH AG
no take aim light	The laser keeps standby situation	Only the laser is in the ready situation, people could see the light
no take aim light	Caused by the fiber or optical parts	Change the fiber or the handpiece
no take aim light	The diode laser problem	Contact LYSISTECH AG
no take aim light	The aim beam status is "OFF"	Set aim beam status to "ON"
no take aim light	The diode laser output lens in the SMA connector is destroyed	Contact LYSISTECH AG
has take aim light, no laser light	Foot switch didn't insert in	Check if the switch connected well
has take aim light, no laser light	Something wrong with the foot switch	Check the foot switch wire
no take aim light, no laser light	The fiber didn't connect to the laser	Check if the fiber connected well
no aim beam, no laser light	Something wrong with the fiber part	Contact with LYSISTECH AG
no aim beam, no laser light	Foot switch didn't insert in	Check if the switch connected well
no aim beam, no laser light	Something wrong with the foot switch	Check the foot switch wire
Have aim beam, but no laser light	Something wrong with the foot switch	Replace the foot switch of the same model
Have aim beam, but no laser light	Diode laser module is destroyed	Contact with LYSISTECH AG
The alarm info. appears	Inappropriate operating environment or wrong operating method.	Restart the laser to see if failure still appears. If still appears, read the info. Description, analyse the reason or contact LYSISTECH AG

12 Maintenance

12.1 Fiber's Maintenance

(1) One of the fiber ends which connects with SMA905 connector is the output of the fiber-coupled diode laser. Any dirt or material on the fiber end will burn the fiber or even damage the diode laser.

(2) If fiber end face is not flat or be contaminated, the output power of laser will be affected. When the laser release high power, the end face will even be melted or carbonized which will lower down the output power of the laser drastically. We strongly recommend that check, trim and clean the fiber each time before using.

(3) The fiber can't be bended too much in case it is broken.

12.2 The Main Unit's Maintenance

"ELLI 810/980" is precise medical instrument and should only be maintained by professional engineer authorized by LYSISTECH AG.

(1) When the fiber is removed, please cover the aperture with protective hat. The protective hat should be cleaned by alcohol in advance.

(2) Don't touch the screen with hard or sharp materials. Don't scrub the screen with reagent. You can clean it softly with soft tissue.

(3) The unit should avoid drastic shaking and hitting during movement.

(4) The laser output power is yearly calibrated by professional engineer from LYSISTECH AG.

12.3 Planned preventative maintenance

The "ELLI 810/980" should be checked annually by a Lysistech AG Laser-accredited technician, the results of the maintenance should be recorded in the instrument log book. (See also the section Annual Maintenance) Failure to use a Lysistech AG Laser or other authorized Lysistech AG Laser technician during the guarantee period will result in the warranty being invalid.

13 Service

- ➢ Provide professional training about laser and clinic.
- ➢ Quick response within 24 hours, readily available accessories and equipment.
- ➢ Regular maintenance and technique support on the spot.

Lysistech AG

Add.: Lettenstrasse 39, 9491 Ruggell, Liechtenstein

Tel: +423 230 20 22

Mail: kontakt@lysistech.li

14 Attachment

14.1 Device Master Record

DEVICE MASTER RECORD			
Model:		Operator:	
S/N:		Location:	
Inventory-No.:			

14.2 Training Protocol

Responsible: Name / Signature:	
Date:	
Checked:	
Name of person trained / signature:	

14.3 Annual Maintenance

Protocol – No.:	Responsible / Date	Notes	Device status	Signature

1.	Visual Inspection	Passed	Failed	comment
1.1	Laser labels/Laser warning (laser class, max. power, wavelength) cp. Section Labels			
1.2	All labels are firmly in place cp. Section Labels			
1.3	User manual			
1.4	Equipment complete			
1.5	Ports			
1.6	Outer device surface			
2.	Inspection of functional capability			
2.1	Foot switch			
2.2	Optical Input/ Output /Aiming Beam			
2.3	Interlocks			
2.4	Display and Key Pad			
3.	Inspection of Monitoring and Safety System			
3.1	Laser Safety Goggles			
3.2	Control LED			
3.3	Main power Switch			
3.4	Emergency stop			
4.	Electric Safety VDE 0750 / VDE 0751			
4.1	Insulation Resistance			
4.2	Earth Leakage Current			
4.3	Protective Conductor Continuity			
5	Measurement of Output Parameters Relevant to Safety			

Caution!

Always wear safety goggles when performing this procedure.

Laser Calibration Test:

Connect a new Lysistech AG Bare Fiber to the output port of the laser. Put the distal end of the delivery system into the specific power meter adapter. Enable the laser, fire the laser and record the values.

Put the laser into Continuous Mode. Fire the laser and verify with the power meter that the output is in the tolerances:					
Power selected only till the max Laser Power		Power selected Value (W) +/-20% Min / Nominal / Max	Actual Value	Passed	Failed
1 W		0.8~1.0~1.2			
2 W		1.6~2.0~2.4			
3 W		2.4~3.0~3.6			
4 W		3.2~4.0~4.8			
5 W		4.0~5.0~6.0			
6 W		4.8~6.0~7.2			
7 W		5.6~7.0~8.4			
8 W		6.4~8.0~9.6			
9 W		7.2~9.0~10.8			
10 W		8.0~10.0~12.0			
11 W		8.8~11.0~13.2			
12 W		9.6~12.0~14.4			
13 W		10.4~13.0~15.6			
14 W		11.2~14.0~16.8			
15 W		12.0~15.0~18.0			
20 W		16.0~20.0~24.0			
25 W		20.0~25.0~30.0			
30 W		24.0~30.0~36.0			

If the results fall within the expected 20% range then the laser is deemed recalibrated. No further action is needed.

Caution!

If the laser falls outside the 20% range than Lysistech GmbH Laser or an authorized representative should be contacted.

5.	Measurement of Output Parameters Relevant to Safety	Passed	Failed	Evaluation
5.1	Result according to 5.			

6.	Inspection of Internal Error Messages			
6.1	Interlock			
6.2	Excess Temperature Indication: Inspection via Software			

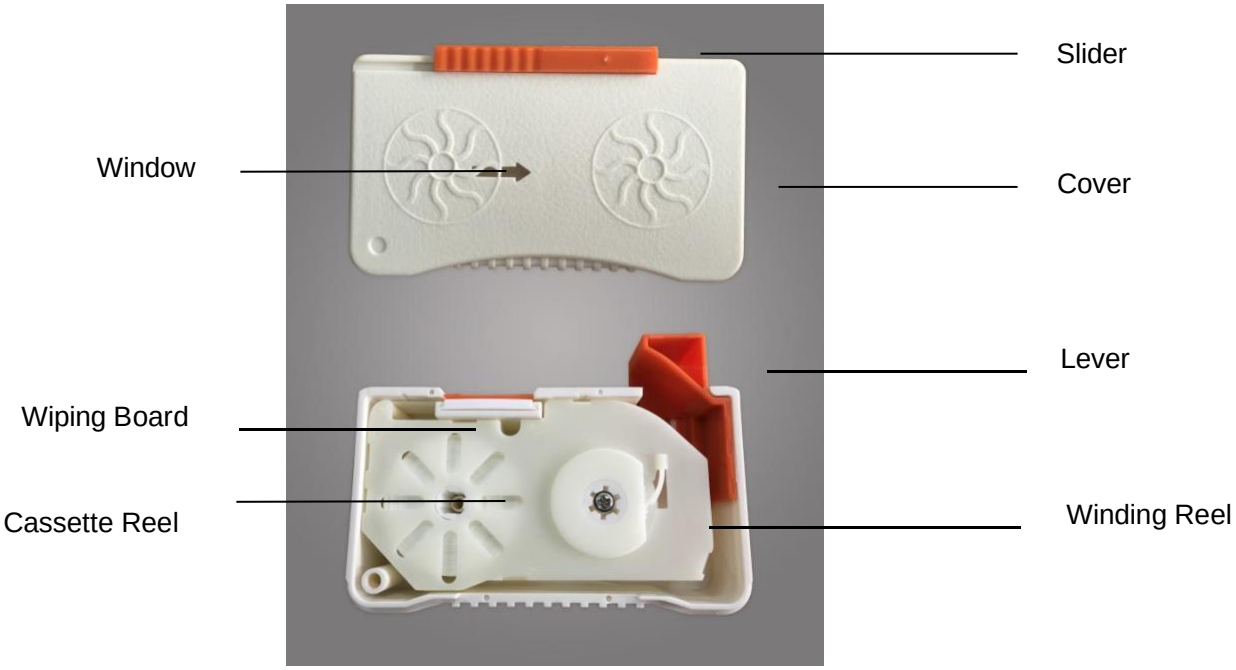
Warnings!

In case of any parameters relevant to safety failing the annual maintenance the device should be disused immediately.

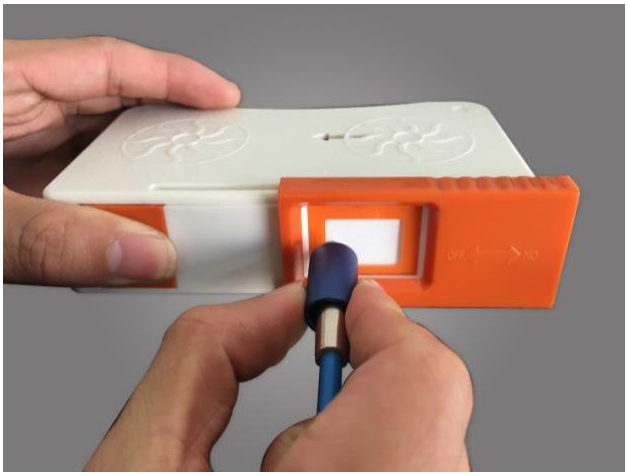
Actions taken:			
Service informed on:		Device disused on:	
Device repaired on:		Entry in Instrument log book:	
Inspector:			
Notes:			
Status:	Date:	Inspector:	

CLE-BOX

Optical Connector Fiber Cleaner Operation Manual



1. How to use



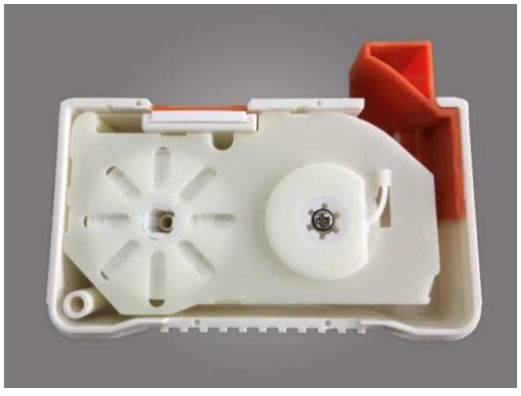
①. Slide the slider to the “ON” side, then new cleaning tape will ②appear.

. Push and slide a ferrule end face while gripping the lever.

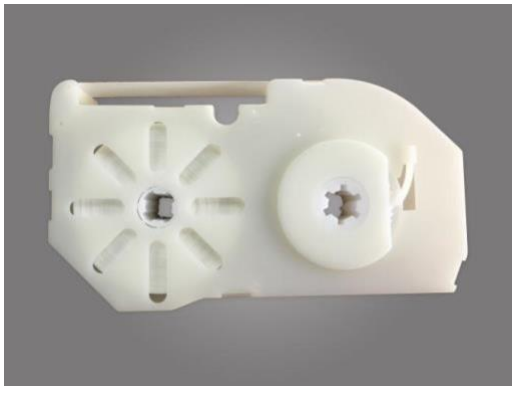
2.How to replace the tape

①.Slide the slider to the direction which is opposited from the lever, until uninstall the slider.

②. Open the cover by slide the cover downside.



③. Take off the cover.



④. Pull out the tape and replace a new one into the cleaner.

⑤. Install the cleaner, and grip the lever 2 or 3 times and to check the tape is moving smoothly.

Caution!

When the lever becomes difficult to press, it indicates a new refill is needed. Repeated forceful depression of lever can cause damage to cleaner mechanism. Be careful not to place this product at more than 60℃ for long times, and it may loose its functionary. Replace the new reel in manual way. If you do not, a damage may result. LYSISTECH AG LASER strongly suggests for CLE-BOX users to use replacement reel manufactured by LYSISTECH AG LASER in order to optimize the cleaning performance. CLE-BOX cannot be warranted when improper replacement installed.