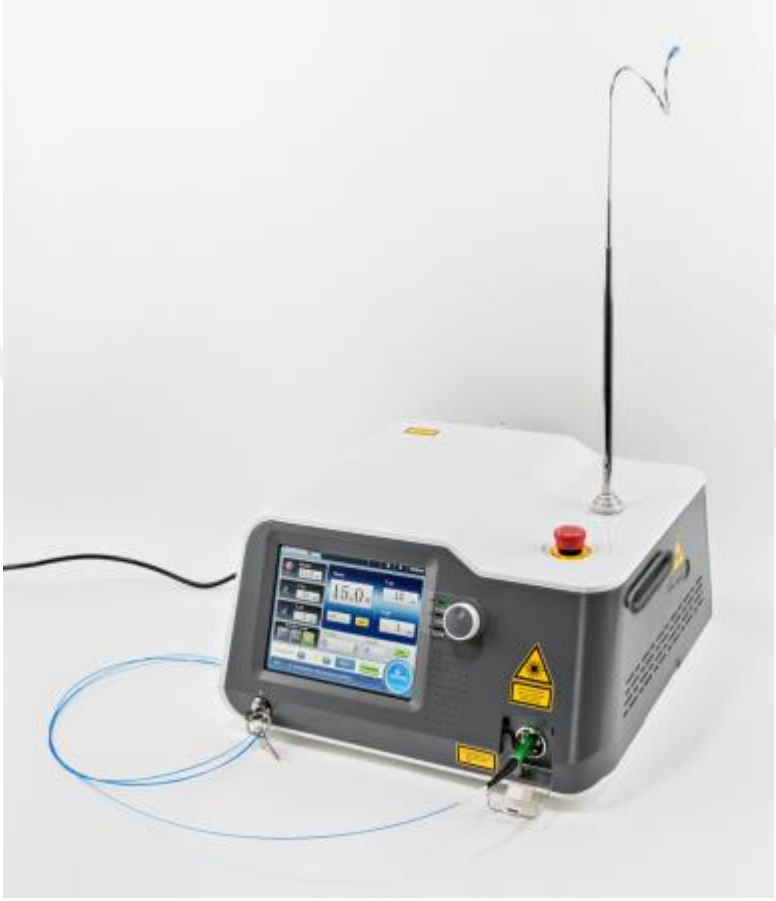
FIBERNEX FN II

Medical Diode Laser System

Operating Manual



Manufactured For: Typenex Medical
303 East Wacker Drive, Suite 1030
Chicago, Illinois 60601
866-897-3639
www.typenex.com

Fibernex Medical Laser System

1. Model	Fibernex FN II, 1470nm,15W
2. Manufactured For:	Typenex Medical, LLC 303 East Wacker Drive, Suite 1030 Chicago, Illinois 60601 866-897-3639 www.typenex.com

Typenex Medical, LLC.

Fibernex Medical Laser System

Medical Device: Fibernex FN II, 1470 nm ± 10nm/ 15W

We declare that the above mentioned product meets 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 60601-1:2006/A1:2013 / IEC 60601-1:2005+AMD1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

EN 60601-1-2:2015 / IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances- Requirements and tests.

EN 60601-2-22:2013 / IEC 60601-2-22:2007+AMD1:2012 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.

EN 60825-1:2014 / IEC 60825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements.

EN 60601-1-6: 2010 / IEC 60601-1-6:2010+AMD1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability.

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

Content

1 Introduction

Thank you for using the Fibernex FN II Medical Diode Laser System.

The Fibernex FN II is a class 4 laser. Care is required to avoid hazards or injuries. Read the operation manual carefully before operating. If this manual does not answer all your questions regarding safety measures or device operation/application, contact your Typenex Medical representative.

The intended use of the Fibernex FN II Medical Diode Laser System is to treat reflux of the saphenous veins associated with varicose veins and varicosities, including endovenous laser ablation (EVLA).

1.1 Copyright

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

1.2 Warnings and safety precautions

Visible and Invisible Laser Radiation
Avoid Eye or Skin Exposure to Direct or Scattered Radiation

CLASS 4 LASER PRODUCT

DIODE LASER 1470 +/-10nm cw 15W

EN/IEC 60825-1:2014

EN 60601-2-22:2013/IEC 60601-2-22:2007+A1:2012

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, and should only be operated by qualified personnel who have familiarized themselves with the operating parameters of this product prior to use.

Caution: Federal law restricts this device to sale, by or on the order of a physician/surgeon.

The Fibernex FN II is a class 4 laser according to EN/IEC 60825-1:2014.

A class 4 laser is hazardous to the eyes in both direct beam and diffused 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 where the laser is being used.

Near infrared light (1470nm) from the Fibernex FN II 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 eyewear designed for protection from cw-diode laser radiation at a wavelength of 1470nm +/-10nm with an optical density of **OD ≥ 4** should be used. Protective eyewear not designed to this specification is not suitable for eye protection. Compatible protective eyewear is available from your Typenex Medical 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 any area outside the target tissue may result in laser burn.

Attention!

The Fibernex FN II is to be used in combination with a fiber with a SMA-905 connecter and fiber core diameter ⩾ 400µm.

Attention!

Avoid simultaneous contact with the patient and the footswitch / door contact /service connector socket.

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 performed by qualified personnel authorized by Typenex Medical. At the end of warranty period servicing can be performed by trained, qualified technicians.

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

Separate the unit from the power supply before cleaning and disinfecting.

Caution!

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

NOTE!

When not in use, remove key from key switch to avoid unqualified use of laser equipment.

1.3 Vigilance

The manufacturer adheres to procedures during the post-production phase that include a review of user experience and subsequent implementation of any necessary corrective actions or improvements. This medical device vigilance system is designed to optimally protect the health and safety of patients, users, and others by reducing the likelihood of adverse incidents recurring. This is achieved through the evaluation of reported incidents, and where appropriate, the dissemination of information to prevent recurring adverse events, 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 cooperation 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 Typenex Medical immediately:

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 directed to:

Typenex Medical
303 East Wacker Drive, Suite 1030
Chicago, Illinois 60601
866-897-3639
www.typenex.com

2 Technical information

The diode laser includes a semiconductor, a cavity resonator, and a power source. The diode laser for this unit is the manufacturer’s diode bar with a wavelength of 1470nm.

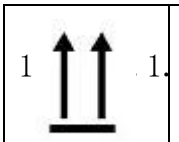
3 Transportation and Storage

3.1 Information on the packaging

NOTE:

Keep the packaging in the event you will 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 dry.
	Do not turn over.
	Temperature limitation
	Fragile – handle with care.
	Do not stow under other equipment.

The Fibernex FN II should be transported and stored only in its original container to prevent damage. Handle the device with care; jolting during transport or otherwise should be avoided.

Do not expose the device to acidic, alkaline, or caustic material. Protect it from direct exposure to sunlight or water.

3.2 Transportation and storage conditions

Store in dry, clean conditions at temperatures between 131°F (55°C) and -4°F (-20°C), relative humidity less than 80%, and an atmospheric pressure range of 500hPa to 1060hPa.

4 Installation

4.1 Unpacking and installation

The device should be unpacked and installed by qualified staff who are responsible for testing and inspection.

Upon product receipt, check for damage to the laser unit and any of its components using the installation checklist in section 14.2.

During unpacking, use the packing list (see section 14.2) to ensure all items are included. Preserve all items; do not discard. If you have any questions, contact Typenex Medical.

4.2 Procedure room requirements

The use of a medical Class 4 laser requires that warning signs are displayed on the unit itself and at the entrances to the room where it will be used. Refer to the information below for additional instruction.

4.2.1 Procedure room entrance labelling

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

Every entrance door to the room in which the laser is used must be clearly marked with a laser warning sign and laser wavelength information to denote laser usage inside.

Every entrance door to the room in which the laser is used must be equipped with a warning light. Each time the laser is switched on, the warning light must illuminate to the room's exterior.

4.2.2 Laser protection at windows

It is critical that no laser light escapes the room during surgery.

All openings to the laser room, including windows, must be properly secured to prevent laser beams from escaping. Typenex Medical can provide additional information as well as help in safeguarding the room.

4.2.3 Protection against highly reflective materials

To avoid any direct or indirect scattered radiation from the laser beam, the procedure room should be devoid of any highly reflective material including mirrors, picture frames, polished chromium surfaces, and windows. All such surfaces must either be removed or protected by non-reflective material.

4.2.4 Safety indicators

Safety signs must be affixed to all entrances, exits, windows, and other openings from which laser light or radiation could escape.

5 Safety Tips and Technical Acceptance

5.1 General

The Fibernex FN II is a medical laser device and should only be used for medical application. The system is thoroughly tested before shipping. Read this section thoroughly; it contains information vital to maximizing the product's functionality throughout its lifetime and protecting your personnel from laser radiation.

Note: All laser operators should be trained before using the unit.

The Fibernex FN II is classified as a class 4 laser. As such, certain precautions are necessary before operating the equipment.

Keep flammable materials away from the laser.

Caution!

Using the equipment in any manner outside of those specified in this manual may result in hazardous radiation exposure.

5.2 Eye Protection

Attention!

To avoid damage to the retina, do not look directly at or into the laser beam or at its reflected or scattered light. Never look directly into the output of the fiber optic or the output of the laser handpiece.

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

To avoid eye injuries, each person in the procedure room (including patients) is required to wear safety protective eyewear at all times that the laser is on. Safety protective eyewear must be stored in a clearly marked, easily accessible area.

Only protective eyewear designed for protection from cw-diode laser radiation at a wavelength of 1470 nm +/-10 nm with an optical density of **OD ≥ 4** should be used. Protective eyewear not designed to this specification is not suitable for eye protection. Compatible protective eyewear is available from your Typenex Medical representative.

The Fibernex FN II offers a remote interlock connector, which directly connects to the room door's switch. The laser unit automatically shuts off when the door is opened. It is recommended that the door remain closed and cannot be opened from the outside when the laser is in use. Opening the door will terminate laser operation.

5.3 Electrical protection

- Opening the device for repair or maintenance should only be carried out by certified technicians recommended by Typenex Medical. Typenex Medical assumes no responsibility for devices that have been opened without the approval of Typenex Medical.
- The Fibernex FN II Medical Diode Laser System is designed to limit current output.
- Make sure that the device is grounded when it is in operation.
- The room where the device is installed should be clean and dry. Make sure the room is free of excessive moisture and vapor when the device is turned on.

Warnings!

To avoid risk of electric shock, this equipment must be connected to a grounded outlet.
Modification of this equipment is prohibited.

Attention!

Never attempt to operate the laser when a failure code is displayed. In the event of a failure code, contact Typenex Medical.

5.4 Fire Hazards

Danger!

Keep the device and the laser beam far away from flammable solvents, anesthesia, or any other flammable materials. Make sure paper and plastics are removed from the laser working area. These materials absorb considerable energy and can be ignited.

When the laser is not in use switch the device into “stand-by” mode. In this mode the laser cannot be activated by the footswitch.

5.5 Protection against scattered light

To prevent triggering of the laser while connecting handpieces or fiber optics, follow the sequence below:

1) Install the fiber optic.
2) Connect the laser handpiece.
3) Switch the laser on.

Take care not to focus the laser beam near or towards flammable materials.

The footswitch must be placed and used in the doctor’s working area and can only be controlled by the doctor responsible for the treatment. Never trigger the laser via a third person.

5.6 Main switch and key switch

The main power switch is located at the back of the device and the key switch is located on the front panel. The device is equipped with two keys. The device can’t be operated without a key. The doctor who is operating the device should be in sole possession of the key.

Turning both the main switch and the key switch to the “on” position will turn the laser system on. The system will perform a series of self-checks. Once complete, the main operating interface will be displayed.

5.7 Manual reset

Any improper function of the system will immediately cut the power supply to the laser and the unit will power off. To restart the unit the main switch has to be pressed to “O” and then “I” position. If the failure shows up repeatedly, contact Typenex Medical.

5.8 Remote interlock connector

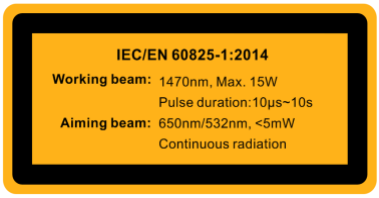
The remote interlock connector at the back panel of the unit connects to the procedure room’s door interlock via a cable. The unit will shut off as soon as the door is opened. By default, the remote interlock connector will disconnect.

5.9 Safety signs

Warning: Laser Beam

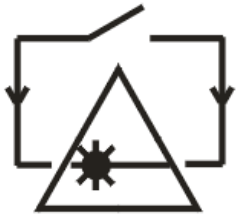
Laser Equipment Warning Label

Class 4 Laser Radiation

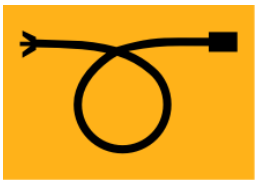


Laser Product Information

Emergency Laser Stop



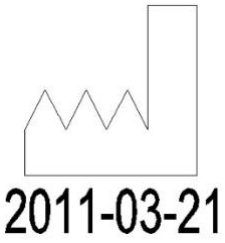
Remote interlock connector



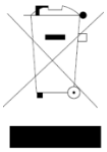
Optical Fiber Applicator

B type device

Refer to operate manual

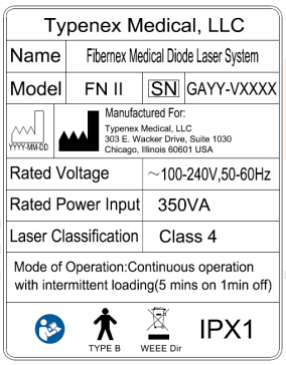


Production date



WEEE Dir

Manufactured by



Product nameplate

Unique Device Identifier (UDI)

5.10 EMC guidance

1) This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.

2) **DO NOT** use a mobile phone or other devices that emit electromagnetic fields near the unit. This may result in incorrect operation of the unit.

3) **Caution:** This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacture's declaration – electromagnetic emission		
The Fibernex FN II is intended for use in the electromagnetic environment specified below. The customer of the user of the Fibernex FN II should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Fibernex FN II use 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 emission CISPR 11	Class A	The Fibernex FN II 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	Complies	

Guidance and manufacture's declaration – electromagnetic immunity			
The Fibernex FN II is intended for use in the electromagnetic environment specified below. The customer or the user of Fibernex FN II should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	±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) for 5 sec	<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) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Fibernex FN II requires continued operation during power mains interruptions, it is recommended that the Fibernex FN II be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity			
The Fibernex FN II is intended for use in the electromagnetic environment specified below. The customer or the user of the Fibernex FN II should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Fibernex FN II, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
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) telephones 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 Fibernex FN II is used exceeds the applicable RF compliance level above, the Fibernex FN II should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Fibernex FN II.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Fibernex FN II

The Fibernex FN II is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Fibernex FN II can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Fibernex FN II 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)		
	150 KHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
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.

6 Environmental Protection

After its final use, the Fibernex Fiber should be discarded in accordance with the regulations regarding the disposal of medical waste.

7 Clinical Indications

The Fibernex FN II can be applied in vascular surgery. The intended use of the Fibernex FN II Medical Diode Laser System is to treat reflux of the saphenous veins associated with varicose veins and varicosities.

7.1 Vascular Surgery

EVLA (Endovenous Laser Ablation)

Product usage exclusions:

The Fibernex FN II laser should not be used in patients with the following conditions:

- Heart trouble
- Psychosis
- Hypertensive diseases
- Or any patient who has been proven not to be suitable for laser therapy.

8 Product Description

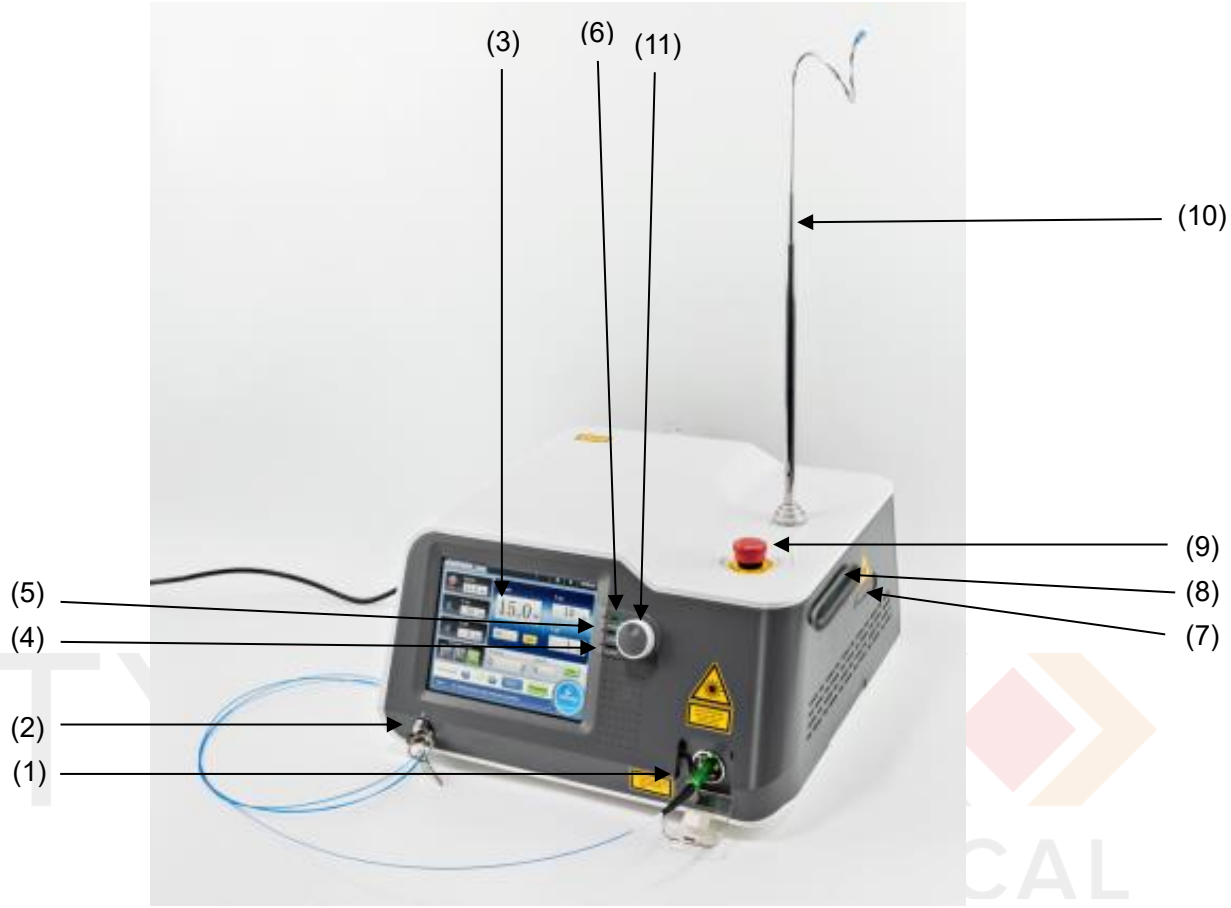
8.1 General overview

The Fibernex FN II consists of five main components

1) Laser system
2) Color touch screen
3) Fiber and handpiece
4) Footswitch
5) Power detector

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

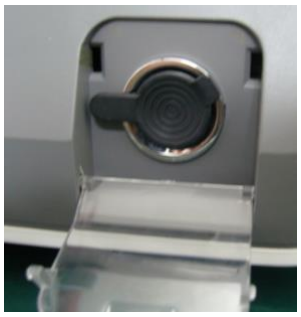
8.2 Front



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 Meter
(8) Handpiece Holder
(9) Emergency laser 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. Ensure that the fiber connection is secure. The alarm indicator will alert you to an improper fiber connection.

Warnings!

Do not remove the fiber while using the device.
Do not bend fiber drastically; the bend radius must not exceed the requirement stated in the Fiber Manufacturer's Instructions for use (IFU).

When the Fibernex FN II laser is not in use, remove the fiber and immediately cover the laser aperture with the external shield to prevent contamination.

Attention!

Protect the laser aperture from contamination by dust, liquid, oil, and other materials. Otherwise, failure to do so may result in damage to the laser output power and/or damage to the laser system.

Clean the aperture external shield with alcohol prior to use.

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 individual operating the device should have sole possession of the key.

The key switch serves as the main system activator. Turning the key switch to the "|" position will start the system and turn the power indicator on. The system will perform a series of self-checks. When the key switch is turned to the "O" position, the entire unit will be powered 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 unit features a high-sensitivity, high-resolution LCD touch screen. The interface allows you to touch the icons on the screen with your finger or stylus to open the corresponding program.

Attention!

Do not place heavy objects on or apply excessive pressure to the touch screen as it could damage it or distort the screen display. Avoid touching the screen with sharp objects that could scratch the surface.
Do not allow the surface of the touch screen to get wet.

8.2.4 Alarm Indicator

The alarm indicator will be illuminated red when the alarm is activated.

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 remain on if the system is not functioning properly. The system will stop all output and the touch screen will show error information as the system alarm sounds.

Attention!

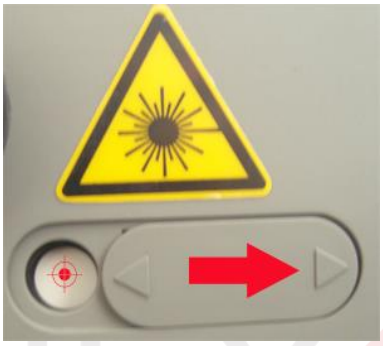
If the system alarm sounds, press the Emergency laser stop button to terminate laser emission.

8.2.6 Power Indicator

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

8.2.7 Power Meter

Closed



Open

The power meter is located on the right side of the Fibernex FN II. The laser power can be tested using the power meter. When testing, first slide the external shield open. Then ensure the fiber is directed at the middle of the power meter while keeping a distance of 0.5cm.

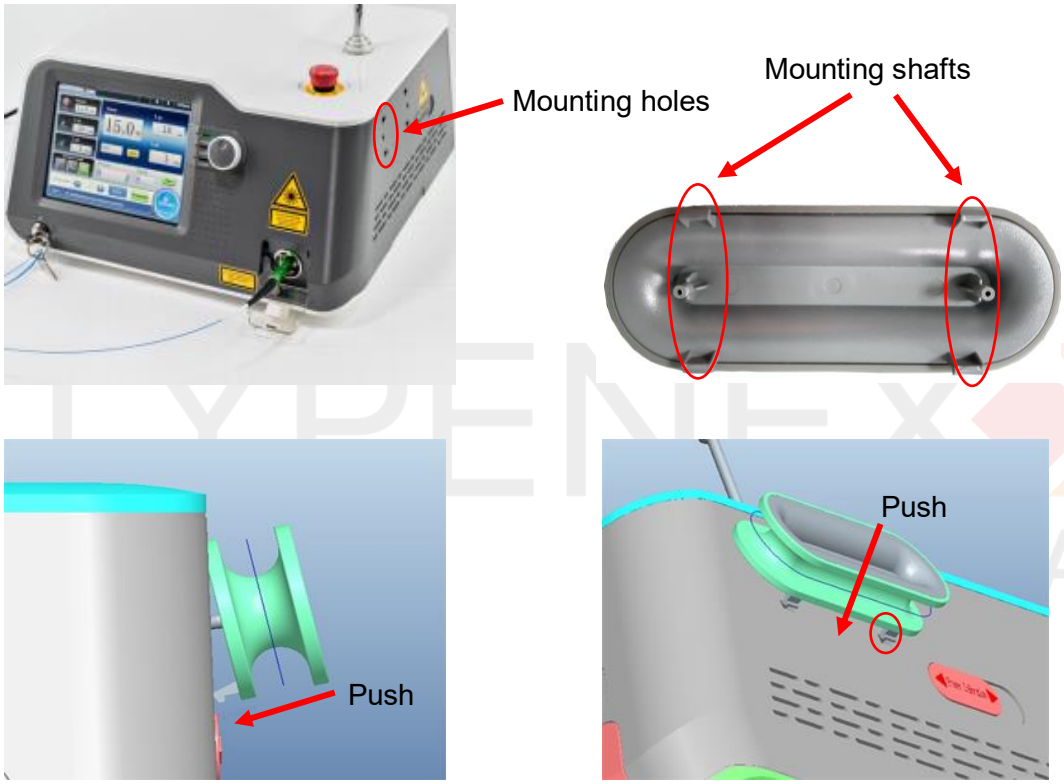
Attention! Test the laser:

(1) Wear safety protective eyewear when testing laser power.
(2) Before testing, you must open the laser power meter.
(3) Make sure the testing fiber is clean and the fiber tip is in good condition.
(4) Aim the fiber tip towards the middle of the laser power meter (aim at the red dot shown in the above picture labeled “Open”).
(5) Ensure the entire laser beam goes into the laser power meter and that a distance of 0.5 cm is maintained between the fiber tip and power meter.
(6) Don’t use your hands to hold the fiber during testing. Use of hands during testing may result in inaccurate readings.

The output power of the unit is calibrated by 400 μm fiber. The actual output power will be two to three watts higher if 600 μm or 1000 μm is selected.

8.2.8 Handpiece holder

The handpiece can be placed on the handpiece holder when not in use. The following pictures will help you to install the handpiece holder. On the right shell of the device, there are six mounting holes for installing the handpiece holder. On the back side of the handpiece holder, there are six corresponding mounting shafts. When installing, pay attention to the position and correspondence between holes and shafts

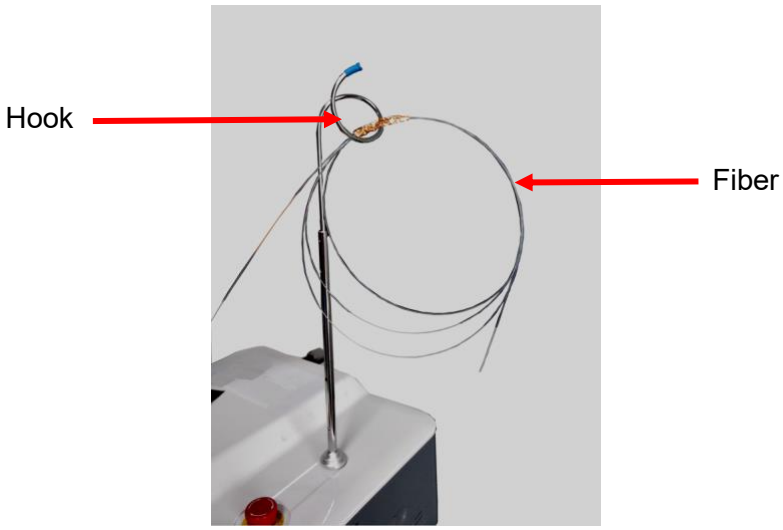


8.2.9 Emergency laser stop

The Emergency laser stop connects to the system's power supply. In the event of an emergency, pressing the Emergency laser stop will immediately stop laser emission. Before restarting, turn the knob in the direction shown by the arrows, located on the knob, to reset the Emergency laser stop.

8.2.10 Fiber holder

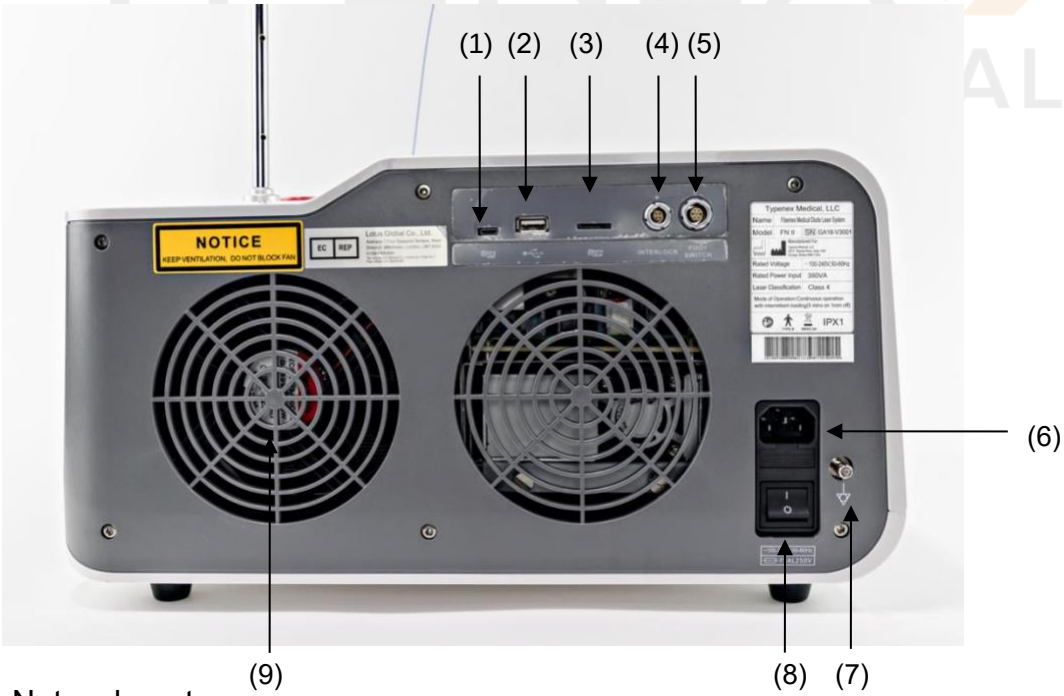
Shape the fiber into a circular bundle and hold the fiber in place using something that will have no impact on the fiber. Then, hook the fiber onto the Fiber holder.



8.2.11 Encode knob

Use the encode knob to adjust the parameter value. In different modes, the selections will be different.

8.3 Rear panel



(1) Network port

(2) USB port – for update program

(3) RS232 port – for computer control

(4) Remote Interlock outlet

(5) Footswitch outlet

(6) Power outlet

(7) Ground

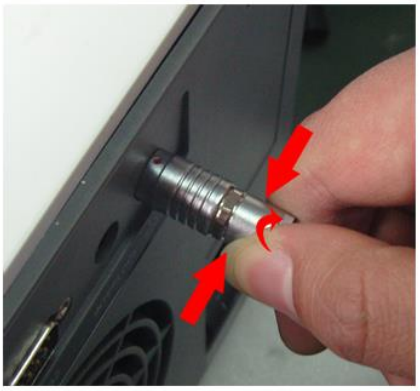
(8) Main switch

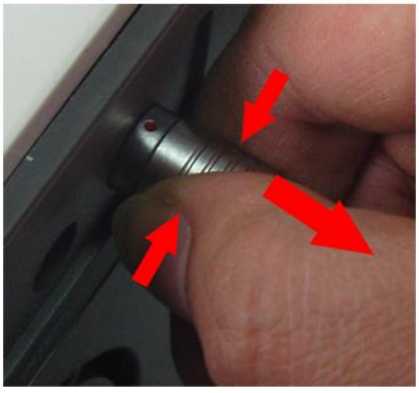
(9) FAN

Attention!

Pay close attention when inserting and removing the footswitch and the interlock.

Find the red dot on the connector. Insert the footswitch or interlock with the red dot facing upward as shown in the picture above. (The picture on the left shows incorrect position and the picture at right above shows proper position.)





When pulling out the footswitch or interlock, ensure the red dot is facing upward.

9 Specifications

Store in dry, clean conditions at temperatures between 131°F (55°C) and -4°F (-20°C), relative humidity less than 80%, and an atmospheric pressure range of 500 hPa to 1060 hPa.

Laser type	GaAlAs diode laser
Model	Fibernex FN II
Wavelength	1470 nm ± 10 nm
Output power	1–15 W
Operation mode	CW, single pulse, repeat pulse
Pulse width	10 μs–10 s
Pulse repetition rate	0.05Hz - 20 KHz
Application systems	Fiber core diameter ≥ 200 μm NA ≥ 0.22 With SMA-905 connector Must sterilize before use
Transmission system	Contact: fibers of 200 μm, 400 μm, 600 μm and 1000 μm with SMA-905 connector; Non-contact: fibers and tips
Aiming beam	Diode laser of 650 nm, power < 5 mW, adjustable brightness
Operation interface	Color LCD touch screen
Power supply	230 VAC, 5 A, 50 Hz
Laser Class	4
Safety classification	Class Ⅰ Type B
Cooling	Air
FUSE	F 250 V 5A
Dimensions	400(W) x 385(L) x 200(H)mm
Weight	12.9 kg
Waterproof level	IPX1
Footswitch Waterproof level	IPX8
Safefy Compliance	CE 0197

10 Operating the Instrument

Attention!

The Fibernex FN II should only be operated by a physician who has been instructed in the use of the instrument.
This section of the manual describes the technical use of the instrument only; medical use specifications are not included.

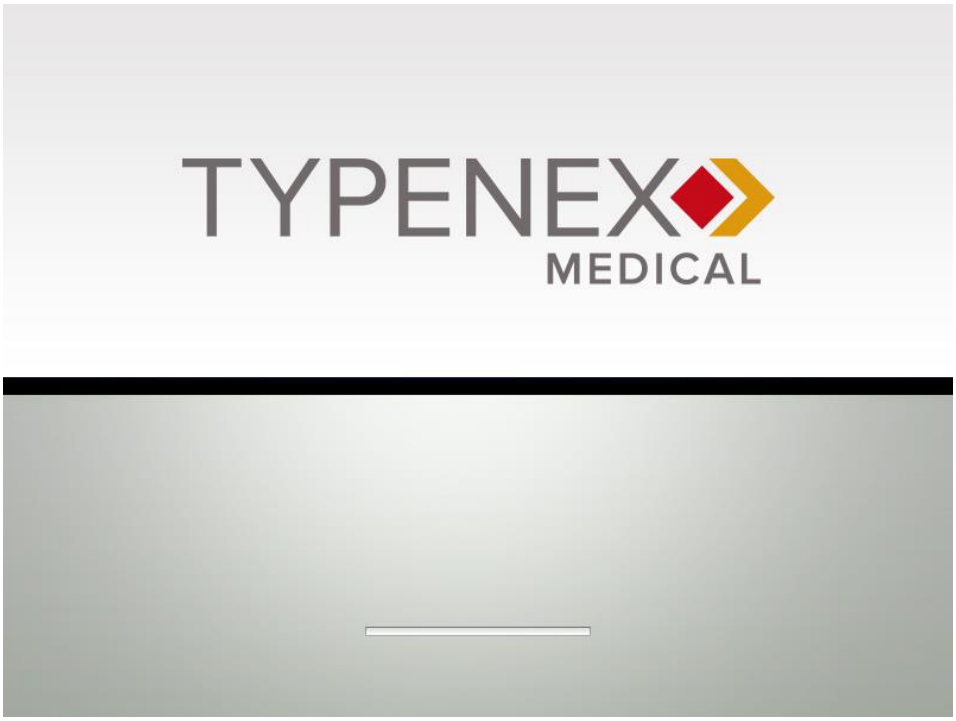
10.1 Introduction

To guarantee an optimal operation of the device during surgery, the following requirements must be met:

- The device is plugged into an electrical outlet.
- Safety protective eyewear is provided for each person in the room.
- The fiber is affixed to the laser aperture (connect the handpiece when necessary).
- The remote interlock connector has been employed.
- The footswitch is connected.
- The Emergency laser stop is disengaged.

10.2 Starting up the unit

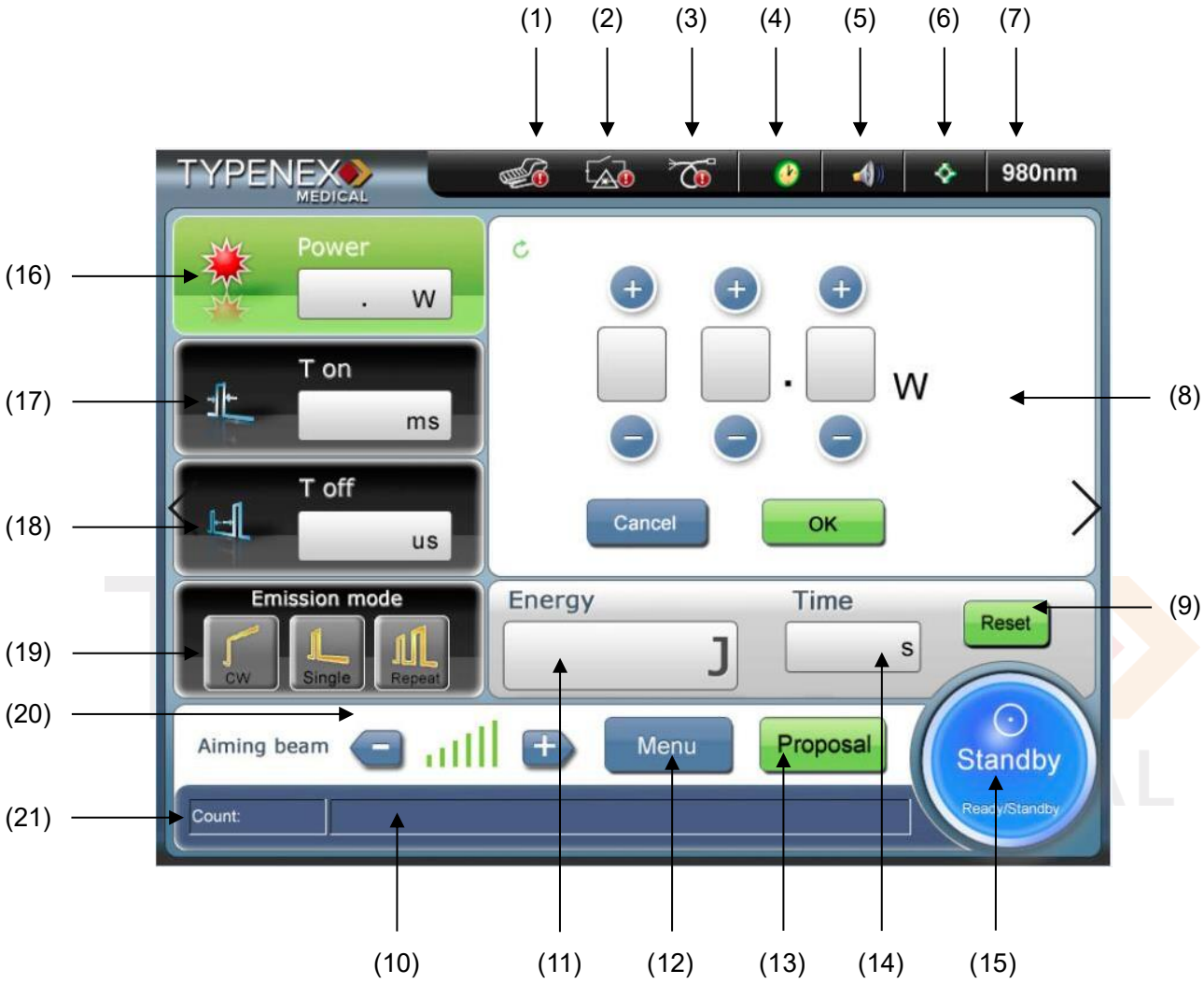
To start the laser unit, press the main switch located in the back ON and turn the key switch located at the front of the laser clockwise into the “I” position. The power indicator will immediately illuminate green and the system fans should also power on. At the same time, the LCD screen illuminates as the picture shows below.



After the loading screen appears, the system will perform a series of self-checks. If problems are encountered during startup, the system's display will inform you. For more information, see section 10 "Failure Detection."

The system will take approximately 90 seconds to start up. The main screen will be displayed.

10.3 Main menu

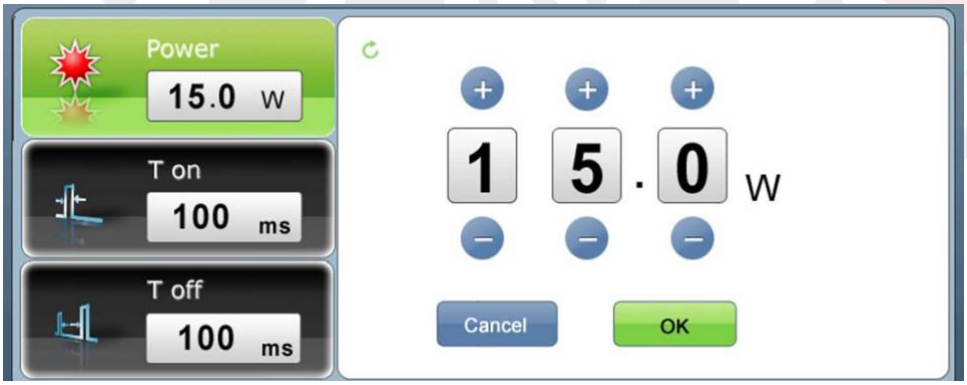


(1) Footswitch alarm
(2) Interlock alarm
(3) Fiber alarm
(4) Timer on
(5) Sound on
(6) Aiming beam on
(7) Wavelength
(8) Parameter area, not a touch area
(9) Reset energy
(10) Help message or alarm message
(11) Total energy

(12) Menu
(13) Preset proposals
(14) Show the timer setting value
(15) Standby/Ready
(16) Set laser power
(17) Set “Timer on” (Ton) time / T on laser emitting
(18) Set “Timer off” (Toff) time / T off laser is paused
(19) Laser emission mode
CW = continuous laser output
Single = press the footswitch, a single pulse laser emits
Repeat = press the footswitch, multiple pulses laser emits
(20) Aiming beam intensity
(21) Pulse count

10.4 Set parameter

10.4.1 Set laser output power



The peak power is the maximum output power when laser is emitting and the range is 1 W to 15 W. By pressing the “+” and “-” buttons, the laser power output can be adjusted. Additionally, the encode knob can be used to adjust the laser power output. When the laser power output adjustment has been completed, the Fibernex FN II will save the parameters into the proposal.

10.4.2 Select laser emission mode

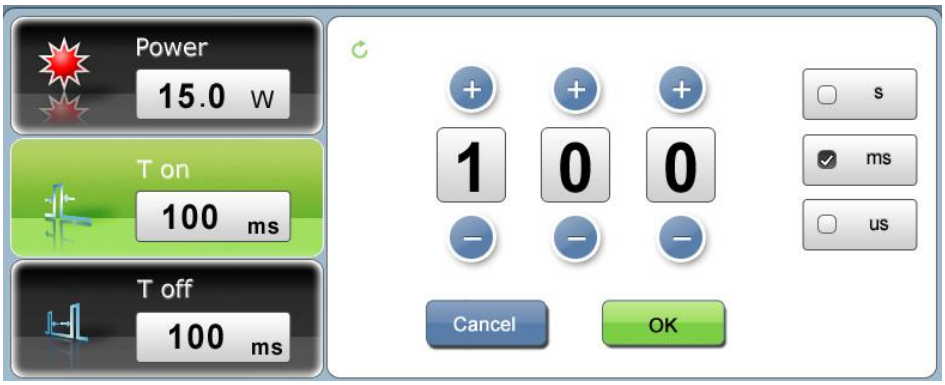
There are three emission modes. When selected, the corresponding button will turn green:
(1) CW
In this mode, the laser will continue emitting until you release the footswitch.

> **Attention!**
>
> **For safety in the CW (continuous) mode, after emitting for 5 minutes (when peak power is above 12 W), the laser should be stopped for a minimum of 1 minute.**

(2) Single
In this mode, the laser will emit a single pulse when you hold the foot pedal down. A single pulse will emit regardless of how long the foot pedal is pressed.

(3) Repeat
In this mode, the laser will emit multiple pulses when you hold the foot pedal down.

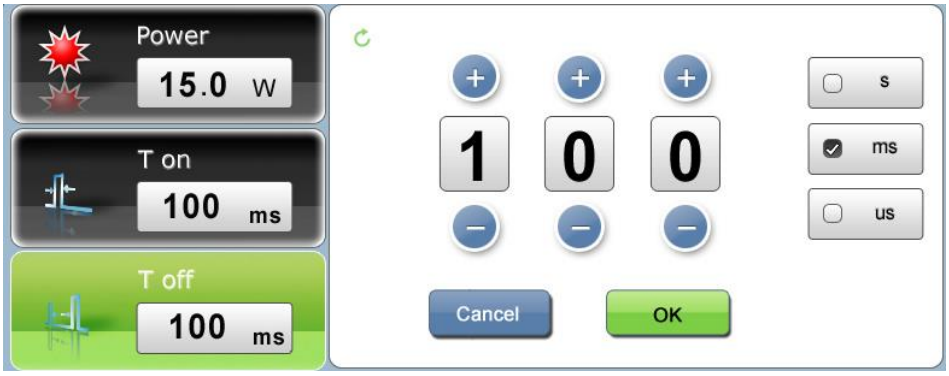
10.4.3 Set laser time on (T on)



The Time On (T on) value is the laser emission time during one pulse period. It ranges from 10 μs–10 s. By pressing the “+” and “-” buttons, the value can be adjusted. The encode knob can also be used to adjust the value as well. When

the adjustment has been completed, Fibernex FN II will save the parameter into the proposal.

10.4.4 Set laser time off (T off)



The Time Off (T off) value is the time the laser is not emitting during one pulse period. It ranges from 10 μs to 10 s. By pressing the "+" and "-" buttons, the value can be adjusted. In addition to using "+" and "-" buttons, the encode knob can be used to adjust the value. When the adjustment has been completed, Fibernex FN II will save the parameter into the proposal.

10.4.5 Adjust aiming beam

When adjusting the density of the aiming beam, use [+] to increase the density and [-] to decrease the density.

There are 7 levels of the aiming beam from 0 to 6. When a specific the level is selected, it turns green (otherwise it is black). If the aiming beam level is set at 0, the aiming beam is closed.

In section 10.3, the aiming beam indicator is labeled as item 6 (active when greater than 0).

Attention!

Only in "Ready" mode, can the density of the aiming beam be seen. In "Standby" mode the density can be adjusted, but can't be seen.

10.4.6 Save the parameter

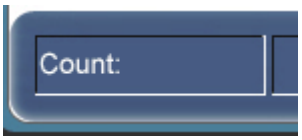
When finishing the parameter setting, you can press the “Save” button to save the current parameters to current selected proposal (see sections 10.4.10 and 10.4.11 for complete information on proposals).

10.4.7 Reset the total energy

When the laser is working, the energy is summated. The total energy ranges from 0 to 99999 J. To reset the total energy press the “RESET” button. When the total energy is more than 99999J, the laser will automatically reset to 0.

Time: Time the laser has been emitting in seconds.

Count: Pulse count.



Single: In this mode, the count is the total number of times the footswitch is 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 the menu interface. The “Proposals” button will lead you to the proposals interface. For additional details refer to sections 10.4.10 and 10.4.11.

10.4.9 Standby and ready

When you press the Ready/Standby button, the laser changes from one status to another.

- *Standby:* In this mode, the laser power supply is disabled. When you press the footswitch, the laser won't emit.
- *Ready:* In this mode, the laser power supply is enabled. When you press the footswitch, the laser can be emitted.

10.4.10 Menu interface

10.4.10.1 Setting

In menu interface, selecting the "Settings" icon directs the operator to the user setting interface. In this interface, you can set the speaker sound and LCD back light, and enable/disable the timer. When the timer is on you can set the timer value. Pressing the "Back" icon leads the operator back to the main menu.

10.4.10.2 System information

To find the system's information, press the "Settings" icon in the menu interface.

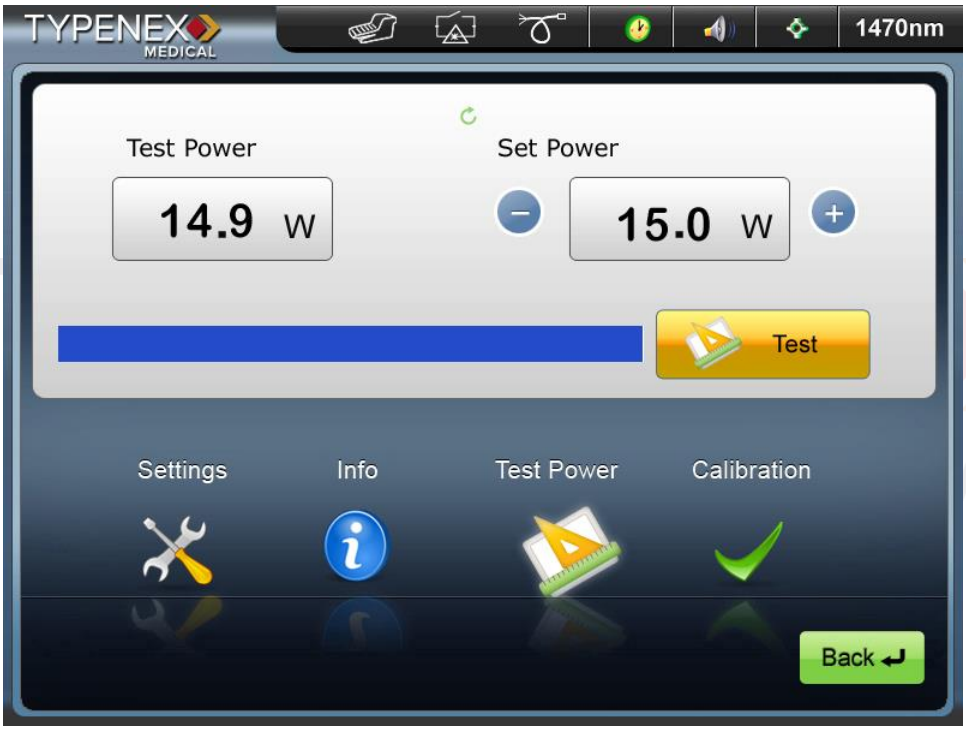
10.4.10.3 Test laser power

By pressing the "Test Power" icon, 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 steps:

(1) Open the laser power meter;
(2) Align the fiber;
(3) Wear the proper safety protective eyewear;
(4) Press the “Test” icon. (The icon will turn yellow, indicating the aiming beam is on);
(5) Press the footswitch, and hold it down.



(6) When the process bar (purple bar shown above) has finished processing, the power analysis is complete. Now you can release the footswitch and read the value of the laser power.

Attention!

The test value may be different than the set value. If the difference is within ± 20% this is normal.

10.4.10.4 Calibrate laser power

Attention!

Before performing laser calibration, ensure the power meter has been calibrated. You can begin to calibrate only when the Fibernex FN II testing result is near to the power meter testing power.

If you press the "Calibration" button, the calibration icon will display above.

- **Test Power:** Before a laser test, this power is the maximum power of the Fibernex FN II.
- **Max Power:** The value of the tested power.
- **Saved:** After you make sure the Fibernex FN II testing power level is similar 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; discard the calibration result.

Calibration steps:

(1) Open the laser power detect aperture.
(2) Affix the fiber.

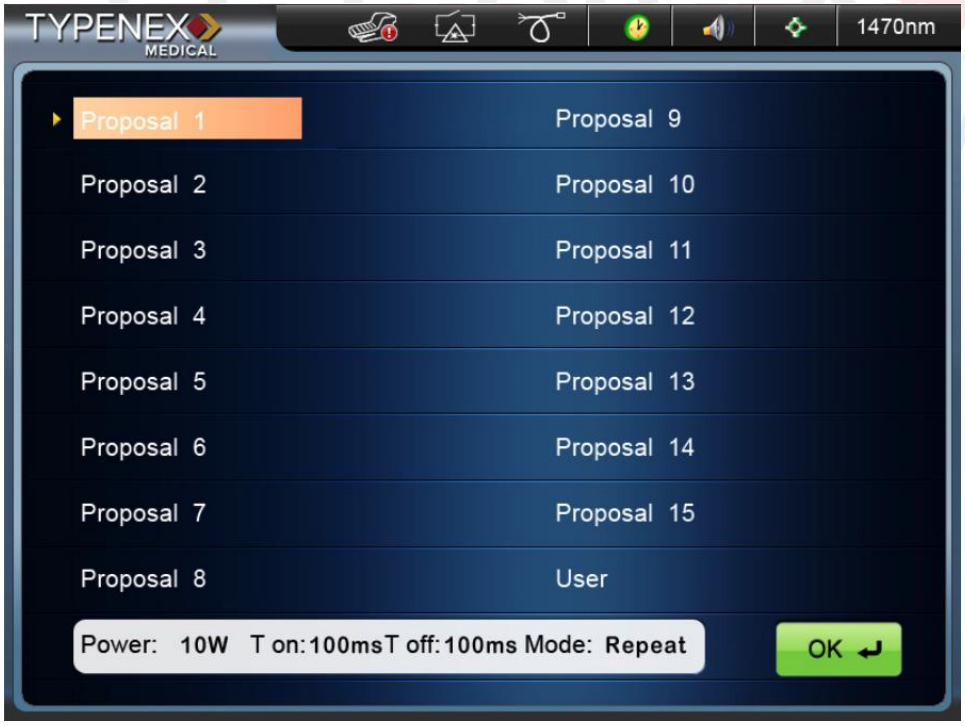
(3) Wear the proper safety protective eyewear.
(4) Press the “Test Power” icon; the icon will turn yellow (the aiming beam will be on).
(5) Press the footswitch, and hold it.

(6) When the process bar (purple bar as shown above) is processing, the power analysis is complete. Now 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 difference between the calibration result showed in the above interface and the result tested by the power meter is within ± 20%, you can confirm 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 unit will fail to calibrate.
(2) After calibration, the Fibernex FN II power will be adjusted. If the calibration power is lower than the former MAX power, the unit will save the lower calibration as the new MAX power.

10.4.11 Proposals interface



In the proposal interface, you can edit up to 16 items in the proposal parameter by following these steps:

(1) Select the proposal you want to edit.

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

(3) Press the “OK” button to return to the main menu.
(4) Change the parameter in the main interface.

The proposals can be renamed by pressing the “Rename” button and inputting the new name.

10.5 Laser emission

After the parameters have been set, press the “Ready” button. The system will remind you to wear the appropriate safety protective eyewear (the protect wavelength is from 800 nm to 1700 nm). When the laser is in “Ready” mode and the footswitch is depressed, the laser will emit.

11 Failure Detection

Problem	Possible Cause	Troubleshooting
When the laser is turned on using the main switch, the unit does not start, and the power indicator is off	1) "Emergency Stop" button is pressed 2) Fuse is burned 3) Power cord not connected	1) Turn the "Emergency Stop" button back to the normal position 2) Power down the unit. Unplug the unit and check the fuse. Refer to section 11.1 3) Connect the power cord
Alarm/Alert on the screen	1) Fiber is not plugged in or Incorrectly plugged in an improper way 2) Safety interlock switch is on 3) Footswitch not connected 4) System error	1) Securely connect the fiber 2) Connect the safety interlock switch. 3) Connect the footswitch 4) Write down the code, and contact Typenex Medical.
TEMPERATURE is HIGH	Temperature more than 35°C	1) Stop the laser and wait for about 15 minutes 2) Ensure the correct distance of the rear panel from the wall
TEMPERATURE is LOW	Temperature less than 10°C	Adjust room temperature to make it warmer
POWERSUPPLY ERROR	Laser current too high	Connect the device to the appropriate power supply source, and then restart the device.
Remote INTERLOCK	Interlock not connected	Connect the interlock
FIBER NOT CONNECTED	Fiber not connected	Connect the fiber
Footswitch opened	Footswitch not connected	Connect the footswitch
Fiber temperature is high	Fiber connector temperature is high	Check the fiber tip and the laser output lens to ensure they are clean and undamaged
No electricity when turning on the laser	Power cord is not plugged in	Plug in the power cord

No electricity when turning on the laser	1) Emergency stop switch is depressed 2) Inner power supply has no output	1) Rotate the emergency stop button clockwise until it pops-up or check the supplied power and the required power 2) Check the supplied power against the required power
No electricity when turning on the laser	Inner power supply has no output	The power supply is unusable; contact Typenex Medical
System not starting up / No display	1) Screen wire broke off or the data wire fell off 2) Control board is unable to provide output	1) Disassemble machine to check screen wire and data wire 2) Control board broken; contact Typenex Medical
No aiming beam	1) Fiber isn't connected 2) Intensity is too low 3) Laser stays in standby mode 4) Faulty fiber or optical parts 5) Diode laser problem 6) Aiming beam status is "OFF" 7) Diode laser output lens in the SMA-905 connector is damaged	1) Check fiber connection 2) Aiming beam broken; contact Typenex Medical 3) Contact Typenex Medical 4) Change the fiber or the handpiece 5) Contact Typenex Medical 6) Set aiming beam status to "ON" 7) Contact Typenex Medical
No laser light (but aiming beam works)	1) Footswitch isn't inserted. 2) Footswitch malfunction	1) Check if footswitch connection 2) Check the footswitch wire
Both laser and aiming beam lights not functioning	1) The fiber isn't securely connected to the laser 2) Something is wrong with the fiber part 3) Footswitch isn't inserted 4) Footswitch malfunction	1) Check fiber connection 2) Contact Typenex Medical 3) Check if the footswitch is securely connected 4) Check the footswitch wire. 5) Replace the footswitch of the same model.
No laser light indicator but aiming beam works	Diode laser module is damaged	Contact Typenex Medical
Alarm info appears	Incompatible operating environment or method	Make sure all components are connected securely and try restarting laser to see if failure message still appears. If error message still appears, contact Typenex Medical.

11.1 Checking the fuse

Unplug the laser, then remove the fuse cover located below the power supply input (shown below) using a flat-tip screwdriver.

The fuse can now be removed for testing with a multimeter. If an issue is found with the fuse, it can be replaced using one of the four replacement fuses included with each laser system.

12 Maintenance

12.1 Fiber maintenance

1) One of the fiber ends that connects with the SMA-905 connector is the output of the fiber-coupled diode laser. Any dirt or material on the fiber end can burn the fiber or even damage the diode laser.
2) If the fiber end face is not flat or is contaminated, the laser power output will be affected. When the laser releases a high power output, the end face can melt or be carbonized, which will drastically lower the laser power output. It is highly recommended that the fiber is trimmed, cleaned, and checked for any damage prior to each use.
3) Care should be taken when bending the fiber; too sharp of a bend angle will break the fiber.
4) During clinical use, the fiber will come into direct contact with the patient and can become highly contaminated. To avoid transmission of disease, the fiber must be properly decontaminated and sterilized prior to re-use (re-usable fibers only) or discarded per the facility's protocol.
5) Re-usable fibers must be re-sterilized per the product's Instructions for use.

After multiple use and sterilization cycles, the transmission efficiency of fiber may degrade. In these instances, the fiber should be replaced.

NOTE:

Strictly avoid dipping the SMA-905 connector into liquid when cleaning the optical fiber. Strictly avoid removing the fiber protective cap when the fiber is not connected.

12.2 Main unit maintenance

Fibernex FN II should be maintained only by technicians authorized by Typenex Medical.

1) When the fiber is removed, cover the aperture with the external shield. The external shield should be cleaned with alcohol and a lint free wipe prior to use.
2) Do not touch the screen or allow sharp objects to come into contact with it. Do not use a reagent to clean the screen. Use a soft cloth to gently clean the touch screen.
3) Use extreme care when moving and handling the unit.
4) The laser output power should be calibrated annually.

12.3 Planned preventative maintenance

Typenex Medical can recommend qualified service technicians upon request. If interested, please reach out to your Typenex Medical Representative.

13 Service Pledge

- Typenex will provide specialists and technicians who are thoroughly trained in using the manufacturer's laser.
- Typenex guarantees a response within 24 hours, and will promptly provide any accessories and equipment.
- Regular operator and maintenance support is readily available.

Typenex Medical
303 East Wacker Drive, Suite 1030
Chicago, Illinois 60601
866-897-3639
www.typenex.com

14 Attachment

14.1 Product Information

Product Information			
Model:		Operator:	
S/N:		Location:	
Inventory-No.:			

14.2 Installation Checklist

1) Ensure that all components are present using the packing list below:

	Component	Quantity	Confirmation
1	Medical Diode laser system	1	
2	Safety goggles	3	
3	Fiber holder	1	
4	Foot switch	1	
5	Fiber cutter	1	
6	Fiber stripper for 400um	1	
7	Fiber stripper for 600um	1	
8	Interlock	1	
9	Key	2	
10	Handpiece holder	1	
11	Power cord	1	
12	Carrying case	1	
13	Fuses	4	

2) Check the exterior of the laser to ensure there is no physical damage.
3) Check to ensure that there is no physical damage to any additional components.
4) Place the laser on a flat, sturdy surface with the ventilation slots at least 25 cm from the wall.
5) Start up the laser per section 10.2 and check to ensure that the correct main screen is displayed per section 10.3.
6) Installation completion may be documented in the log below.

Installation Date:	
Responsible: Name / Signature:	

14.3 Training protocol

Below is an example log to record users who have been trained on the Fibernex FN II laser.

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

14.4 Annual maintenance

Below is an example checklist to utilize when performing preventative annual maintenance on the Fibernex FN II laser system.

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

Maintenance		Passed	Failed	Comment
1.	Visual Inspection			
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	Footswitch			
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 Protective eyewear			
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			
6.	Inspection of Internal Error Messages			
6.1	Interlock			
6.2	Excess Temperature Indication: Inspection via Software			

Caution!

Always wear safety protective eyewear when performing this procedure.

Laser Calibration Test:

Connect a new Fibernex bare fiber to the output port of the laser. Insert the distal end of the delivery system into the specific power meter adapter. Power on 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 within 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			

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 contact Typenex Medical.

Warnings!

If any of the safety parameters fail the annual maintenance, use of the device should cease immediately.

Actions taken:			
Informed of Service on:		Device disused on:	
Device repaired on:		Entry in Instrument log book:	
Inspector:			
Notes:			

Status:	Date:	Inspector: