



# BEACON<sub>2</sub>

ADVANCED ENERGY LASER SYSTEM

## BEACON™ Advanced Energy Laser System Instructions for Use

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To be used with: OmniGuide Catalog Numbers: 420060AA, 420030-AA

### OmniGuide, Inc.



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[www.omni-guide.com](http://www.omni-guide.com)

**Caution:** U.S federal law restricts this device to sale by or on the order of a licensed healthcare professional.

This article is covered by the following patents: U.S. Patent No. 7349589, 7167622, 7331954, 7991258.

OmniGuide, Inc. (OG) is not responsible for injury or damage resulting from improper use of the system. If there is any doubt concerning the use of the system or the User's Manual, contact OG immediately for assistance.

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## 1.0 PREFACE

This manual is designed to help the user understand and operate The BEACON Advanced Energy Laser System. BEACON is a surgical laser that delivers CO<sub>2</sub> energy via two modes of operation. The first is through OmniGuide's patented, polymer-based flexible fiber, which is utilized within a specialty-specific hand piece by the surgeon. The second modality is free-beam energy delivered via an articulating arm mounted on the laser system. This manual will outline operational features of both functions.

The system consists of the following versions:

Cat.# 420060-AA

BEACON Advanced Energy Laser System with 30W maximum power output , 120/230V, 50/60 Hz Electrical input

Cat.# 420030-AA

BEACON Advanced Energy Laser System with 60W maximum power output, 120/230V, 50/60 Hz Electrical input

The BEACON Advanced Energy Laser System will refer to all the units (unless the specific units are called out). This manual contains information on the performance and operation of the Laser as well as installation and control methods.

## 2.0 MANUFACTURING INFORMATION

Manufactured for  
OmniGuide, Inc.  
4 Maguire Rd.  
Lexington, MA 02421  
Tel: 1-888-666-4484 or 1-617-551-8444 US  
URL: <http://www.omni-guide.com>



**Caution** – Use of controls or adjustments or performance of procedures other than those specified in this manual may result in hazardous radiation exposure.

## 3.0 REGULATORY STATUS OF PRODUCT

The BEACON Advanced Energy Laser System includes all safety features required by the United States Food and Drug Administration (FDA) and Center of Devices and Radiological Health (CDRH). All required interlocks, warning labels

and indicators are in full compliance with 21 CFR 1040 and it has been 510(k) cleared for the following Indications for Use: The BEACON Advanced Energy Laser System is indicated for the incision, excision, ablation, vaporization and coagulation of body soft tissues in the following specialties:

- Dermatology
- General Surgery
- Gynecology
- Head & Neck Surgery
- Neurosurgery
- Oral Surgery
- Orthopedic Surgery in Soft Tissue
- Otolaryngology (ENT)
- Plastic & Reconstructive Surgery
- Podiatry
- Urology

The BEACON Advanced Energy Laser System device can be used only by trained medical professionals on general population of the patients. Applicability of the BEACON Advanced Energy Laser System to treatment of the patient is determined by a qualified physician based on the patient's medical history within cleared indications for use.

*Note: For fiber and laser accessories Indications for Use, see applicable fiber or laser accessories Instructions for Use. The Laser has been tested to the European Standards and Regulations, carrying the CE Mark affixed to the product. Information about the Management System can be obtained from the manufacturer.*

*Note: This product is not intended for neurosurgical/neurotology use in CE Mark recognized European Countries. Accessories used with articulating arm (e.g. micromanipulators and handpieces) comply with their respective regulatory requirements such as 510(k) and CE marking.*

*Note: This product is not intended for direct contact with the patient. Only fibers or laser accessories attached to the laser may contact the patient. Fiber and laser accessories are classified as applied part, type B.*

## Notice Concerning Warranty

Operating or handling of this medical laser, inconsistent with this manual, may void the warranty.

## 4.0 WARNING, CAUTION AND SYMBOLS

### Contraindications

Do not use OmniGuide Laser System if the medical history of the patient is not compatible with laser treatment.

### Adverse Effects

Potential complications could include:

- The general complications related to surgical procedures, such as local and systemic infections
- Thermal tissue damage
- Perforation of tissue or tissue adherence related to misuse of the device.
- Laser surgical procedures should be performed only by a licensed healthcare practitioner adequately trained to, and familiar with such surgical techniques and clinical use of CO<sub>2</sub> lasers, and hazards associated with it.
- Usage of gas can increase the chance of gas embolism, see OmniGuide fiber IFUs for additional information













### Definition of Warning

Warning is the term used to alert the user to possible injury, death, or other serious adverse reactions associated with the use or misuse of the device. Warning statements are placed at the appropriate sections of this User Manual.

### Definition of Caution

Caution is the term used to alert the user of the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunctions or device failure and may result in minor or moderate injury to the user and/or patient, damage to the device, or damage to other property. Caution statements appear at the appropriate sections of this User Manual.

## Symbols Used in this Manual

	This symbol is intended to alert the operator to the presence of dangerous voltages associated with the laser that may be of sufficient magnitude to constitute a risk of electric shock.
	This symbol is intended to alert the operator that there are specific warnings or precautions associated with the medical device, which are not otherwise found on the label.
	This symbol is intended to alert the operator to the danger of exposure to hazardous visible and invisible laser radiation.
	This symbol is to alert the operator to the danger of exposure to laser radiation being emitted from the aperture.
	Fiber port symbol
	Applied part type B connection
	Ground
	Emergency STOP button symbol
	Tipping hazard symbol
	Laser interlock symbol
	Food pedal connection symbol
	Read the manual before use
	Do not dispose as general waste

## Warning Signs and Laser Labels



Figure 4-1. Location of the labels





Figure 4-2. Main Labels for the 30W and 60W laser units








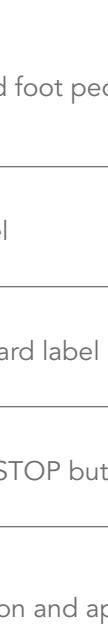







	Interlock and foot pedal label
	Ground label
	Tipping Hazard label
	Emergency STOP button label
	Laser emission and applied part connection label (fiber adapter)
	Laser emission and applied part connection label (articulating arm)
	Do not block air intake label
	Maximum gas pressure rating label for the gas management system label
	Fuses voltage and current rating label












Figure 4-3. Laser labels

## 5.0 WARNINGS









### General Warnings

-  No modification of this equipment by the user is allowed. Modification will void the warranty.
-  BEACON laser system is designed to be used only with OmniGuide fibers. Do not use fibers which are not approved for BEACON laser system.
-  Do not use laser accessories which are not approved for the BEACON laser system. Examine accessories for any sign of damage before use. Do not use damaged accessories.
-  If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment
-  To avoid risk of electric shock, this equipment must only be connected to supply mains with protective earth
-  BEACON Laser System weights more than 150 lbs and may cause injury if proper care is not used when moving it. The system should always be moved slowly and carefully

### Warnings for Laser Surgical Procedures







-  The BEACON Advanced Energy Laser System is a FDA Class 4 Laser device that produces invisible beams of high-energy infrared radiation at 10.6 microns wavelength (Class 4). Articulating arm has also an output of the laser beam at the visible wavelength of 635 nm (Class 2M). Improper use of the Laser could result in serious personal injury. Proper electrical and Laser safety training and strict observation of all safety precautions as specified in the Laser Instructions for Use or Operations Manual are required to operate the device and/or provide its maintenance.
-  Laser surgical procedures should be performed only by individuals adequately trained and familiar with such surgical techniques and hazards associated with it. Consult medical literature regarding techniques, complications, and hazards prior to performing these procedures.
-  All personnel in the immediate area of laser use must wear eye protection specifically rated for CO<sub>2</sub> Lasers (OD 4+). Failure to do so may result in serious and permanent damage to the eyes.
-  Laser beam coming out of the articulating arm is a non-divergent that should not be activated without an accessory attached to the articulating arm. Laser beam should not be aimed at the walls, floors or other object as it will create burn marks -even from a distance.
-  Before instruments and accessories from different manufacturers are employed in a procedure, the user must verify compatibility with the OmniGuide System. If in doubt, contact OmniGuide for assistance.
-  The laser should be activated only when the laser treatment site is clearly observable and the fiber tip is directed at it.
-  A fire extinguisher must be available in the operating room when the laser is being utilized. Saline solution or water should also be readily available.
-  Flammable prep solutions (e.g. alcohol-based prep solutions) must not be used during Laser procedures.
-  Follow established protocols for laser surgery to minimize the risk of airway fires.
-  A smoke evacuation system must be utilized to remove surgical plume.
-  Do not submerge any portion of The BEACON Advanced Energy Laser System in fluid.

## Warnings Specific to the Fiber







-  With most fiber assemblies, pressurized gas exits the fiber tip during the laser procedure and may cause venous gas embolism. To reduce the risk of embolism, do not bring the tip into contact with blood vessels or vascular tissue. The gas pressure delivered to the system should not exceed the pressures listed on the insert provided with each fiber. For airway cases, the fiber should not be used below the carina. See fiber IFU for additional fiber-specific warnings.
-  The pressurized gas exiting the fiber's tip during the laser procedure may cause temporary inflation and separation of sub-mucosal flaps or mild emphysema under superficial layers of tissue.
-  Only use medical-grade Helium gas.
-  Do not retract, probe, or manipulate tissue with the distal-end tip of the OmniGuide fiber.
-  Do not use excessive force while handling the OmniGuide fiber inside an endoscopic handpiece. The use of excessive force could potentially lead to fiber breakage or distal-end tip detachment.
-  The use of high laser power along with extensive bending of the fiber may result in gas temperatures exceeding 60oC, which can cause thermal damage to healthy tissue. Always use the minimum laser power possible for a given procedure and minimize the amount of bending of the fiber.
-  For sterile procedures, the use of the OmniGuide Gas Filter Unit (cat# ACC-GFU-100) is required.
-  There is a possibility that the OmniGuide fiber will fail to transmit light during the course of a surgical procedure. Therefore, it is recommended that you have at least two fiber assemblies available prior to starting a surgical procedure using the OmniGuide Laser System.

## Warnings Specific to Compressed Gas

*(Disclaimer: The supply of the gas per OmniGuide specifications, the gas delivery system, and the gas supply operation and maintenance procedures, including the observation of compressed gas safety precautions, are the responsibility of the healthcare-providing facility. Refer to general safety regulations for handling of compressed gases.)*









-  Only personnel trained in compressed gas safety procedures should be allowed to connect the compressed gas tanks to the system.
-  Using pressurized gas during some endoscopic procedures (e.g. gastrointestinal, gynecological, etc.) could lead to over-insufflations and the danger of tissue perforation. An approved system for pressure monitoring and gas evacuation, chosen by a physician, is required to prevent over-insufflations and ensure patient safety. Use of insufflators or other approved gas evacuation devices that are equipped with a sensor for internal pressure and a pressure relief valve are recommended. Refer to the manufacturer's instructions for equipment set up and detailed instructions.
-  For sterile cases where Gas Filter Unit is used, never exceed the maximum gas pressure rated for the Gas Filter Unit.
-  Always monitor the vital signs of the patient for symptoms of gas embolism.
-  Always monitor patient's blood oxygen level.
-  Before the start of a medical procedure using the OmniGuide Adapter and fiber, verify that the gas delivered to the system is of the proper type and pressure for the fiber being used. This information can be found on the insert provided with each fiber.

## Sterility Warnings



-  The OmniGuide fiber is supplied sterile for one-time use. The method of sterilization is radiation. Consult relevant OmniGuide fiber IfU for handling instructions
-  Do not use the fiber product if the package is damaged, opened, or if sterility is compromised.
-  Wear sterile gloves and observe proper surgical aseptic technique while handling the sterile fiber.
-  Do not use an OmniGuide Adapter in a sterile procedure without the Gas Filter Unit (cat# ACC-GFU-100).
-  Use sterile drape to cover articulating arm during sterile procedures.
-  *Accessories (micromanipulators and handpieces) must be cleaned and/or sterilized before the procedure using methods described in the IfUs provided for accessories.*

## 6.0 CAUTIONS




### Cautions for Laser Surgical Procedures

-  Physicians performing Laser procedures should be trained and compliant with their relevant health care facility requirements in:
  - Laser safety (ANSI-Z136.1)
  - Clinical use of CO<sub>2</sub> Lasers
  - The use of the OmniGuide System
-  Build-up of tissue or tissue debris on the distal-end tip of the OmniGuide fibers or handpiece can result in overheating of the device. If build-up/contamination occurs during use, clean the tip by dipping into saline solution. Refer to OmniGuide fiber IFUs for specific instructions on how to clean fiber tips during surgical procedures. Replace the fiber if performance does not improve.
-  The OmniGuide fiber is a single use device. Reuse of fiber voids all warranties of sterility and is prohibited.
-  Do not bend the OmniGuide fiber to a radius less than the minimum radius and maximum angle specified for the fiber (typically 3cm, 30 degree). Bending the fiber below this limit may cause fiber failure. Refer to fiber IFUs for more instructions on fiber usage.
-  To assure the proper functioning of the device, The BEACON Advanced Energy Laser System must be serviced be performed by an OmniGuide authorized representative.
-  After a surgical procedure, visibly inspect the integrity of the OmniGuide Fiber. In particular, verify that no portion of the fiber is missing or detached.
-  Excessive bending of OmniGuide fiber will lower its output power. Please consult fiber IFUs for the minimum allowable bending radius and angle of the fiber. Do not kink or pinch the Fiber.
-  The OmniGuide System is not currently compatible with optical scanners.




### Reflected Energy Protection

-  Do not aim laser beam at the reflective surfaces such as mirrors, polished metal, glass or polished ceramics to avoid uncontrolled beam reflection or scattering. All instruments used with the Laser system should have brushed, burnished, or blackened non-reflective surfaces.
-  Clinician and patient must use appropriate eye and skin protection. All personnel in the immediate area of laser use must wear eye protection specifically rated for CO<sub>2</sub> Lasers (OD 4+). Failure to do so may result in serious and permanent damage to the eyes.






## Fire Protection

-  Drape the surgical field with materials designed for use with lasers. The surgical drape must be flame retardant.
-  Keep combustible materials away from the area of laser use.
-  Take appropriate measures to prevent the possibility of a fire associated with anesthesia such as use of a laser safe tracheotomy tube at the 10.6 micron wavelength and maintaining oxygen levels at 30% or less of the anesthetic mixture while firing.




## Eye Protection

-  Everyone in the immediate area of laser use must wear eye protection specifically rated for CO<sub>2</sub> Lasers (OD 4+). Failure to do so may result in serious and permanent damage to the eyes.
-  Use special precautions when working around eyes.
-  Do not look directly at the laser beam, aiming beam or aim laser at the eye even when wearing eye protection.


## Tissue Protection

-  Start with low power and increase power gradually to achieve desired effect.
-  Use the shortest exposure time for the desired result.
-  Exposure of charred tissue to the laser radiation can heat and injure underlying tissue layer.
-  The clinician's skin should be protected from exposure and the patient's skin should be protected from overexposure to Laser radiation.
-  The CO<sub>2</sub> laser is approved for soft tissue only and can cause thermal damage to bones and teeth. Protect them from exposure to laser radiation as necessary.

## Smoke Control

-  Smoke from the procedure could contain biologically hazardous materials and has to be evacuated. Run smoke evacuator for 30 seconds after lasing stops.
-  The clinician should wear an appropriate mask/respirator specified by the safety procedures at your facility.
-  Refer also to the laser labeling for additional precautions.

## Gas Management System

-  Gas system is designed to be operated with two gas cylinders always in place. Do not operate the system with just one gas cylinder. This could result in the helium gas leaking into environment.

## 7.0 PRODUCT DESCRIPTION

In this section, the specifications and characteristics of The BEACON Advanced Energy Laser System will be discussed. Characteristics to be discussed include mechanical, thermal, electric and the laser system user interfaces. Also discussed are environmental requirements and limitations.

### The BEACON Advanced Energy Laser System

The Laser is FDA Class IV sealed, RF excited CO<sub>2</sub> Laser capable of producing CW or pulsed laser radiation at 10.6 μm wavelength. Laser radiation can be directed either through OmniGuide flexible fiber or through an articulated arm. Preferred laser modality can be selected from the user screen. The laser is operated via a foot pedal to allow laser radiation only when required. The back and front of the Laser are shown in Figure 7-1 and Figure 7-2 respectively.

The laser is designed to be operated in a general hospital environment and hospital OR rooms with environmental characteristics indicated in the laser specification, refer to section 7.20.



Figure 7-1: Front of the Laser

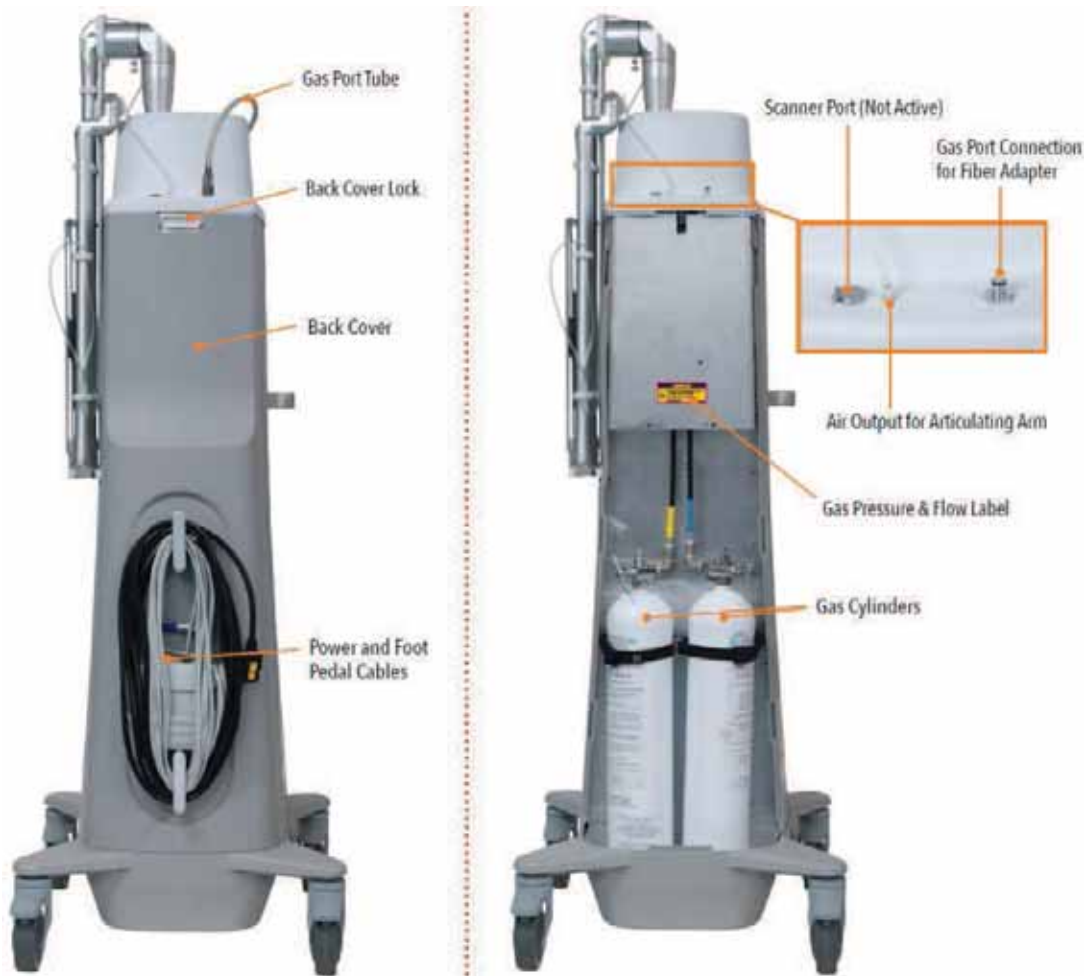


Figure 7-2. Back of the Laser: cover closed (left), back cover open (right).

## Delivery System

The Delivery System consists of a fiber adaptor and articulating arm. Either Fiber modality or Articulating Arm modality has to be selected by the user as the first step in operating the laser.

### 7.1.1 OmniGuide Fiber Adapter

To produce sufficient output power at the distal end of an OmniGuide fiber, the laser beam generated in the laser is delivered precisely to the input end of the fiber by means of fiber adaptor with a standard ST socket for fiber connection. The adaptor has a quick-disconnect gas port for the helium gas supply and incorporates an RFID antenna as shown in Figure 7.3.



### 7.1.1.1 RFID System

All Omniguide fiber are equipped with passive RFID tags that allow authentication and identification of fibers to the laser system. An RFID antenna is built into the fiber adapter (Figure 7-3) enabling the laser system to recognize specific Omniguide fiber when it is plugged in and to offer laser settings compatible with that specific fiber. The fiber type is displayed on the screen. The RFID system has the following characteristics:

Operating Frequency: 13.56MHz  
Bandwidth: 870kHz  
Transceiver output power: 100mW  
Read range: < 5cm  
RF communication data rates: 26.48 kbs (ISO 15693)



RF communications equipment (antenna on the fiber adapter) should be used no closer than 30 cm (12 inches) to any part of the medical equipment (other than BEACON laser system), including cables as specified by the manufacturer of that equipment. Otherwise, degradation of the performance of the other equipment could result.

### 7.1.2 Articulating Arm

The BEACON Advanced Energy Laser System is also equipped with articulating arm which can be connected with OmniGuide approved accessories such as micromanipulators and handpieces. Please, refer to OmniGuide website for the list of compatible accessories. The operator connects the micromanipulator or handpiece to the end-joint of the articulated arm prior to patient treatment, by threading it on, and disconnects it after treatment for cleaning and disinfection. Gas ports on the micromanipulator or handpieces can be connected with airline attached to the articulating arm. Please, refer to the IFUs of the specific accessory for installation and maintenance.

## The OmniGuide Fiber

The flexible OmniGuide fiber is a single use, sterile, disposable device which is supplied separately from the laser system. The OmniGuide fiber guides CO<sub>2</sub> Laser light with a wavelength of 10.6 microns and delivers energy from the laser to the surgical site, enabling minimally invasive procedures. A close up of the fiber connector at the proximal end, that is connected to the laser, is shown in figure 5-4. Fiber with RFID tag is required to operate The BEACON Advanced Energy Laser System.

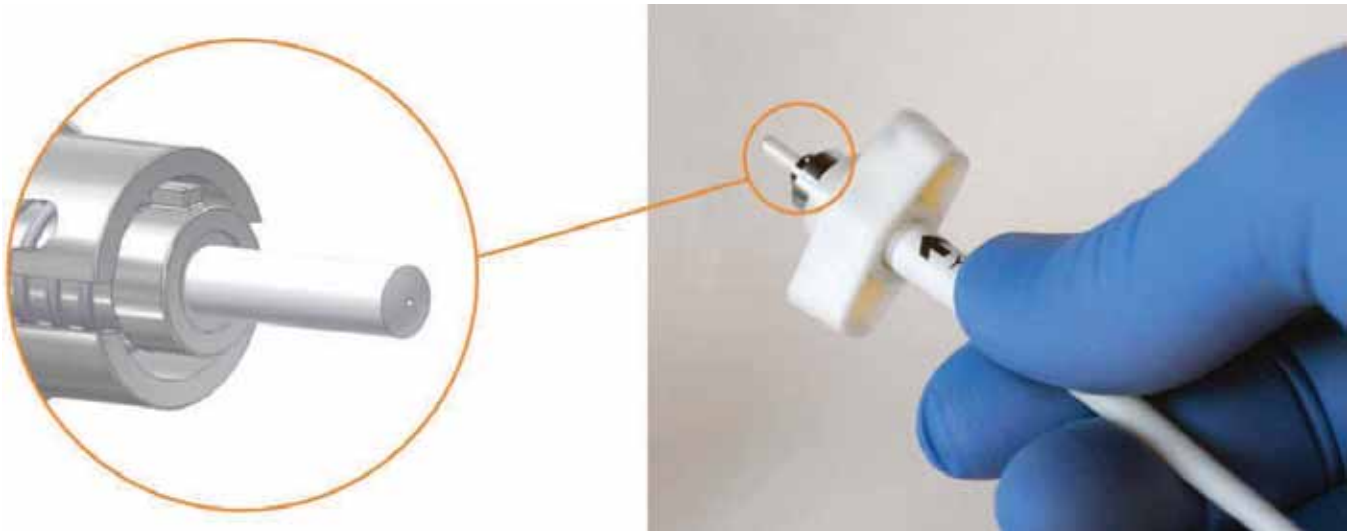


Figure 7-3: The proximal end ST connector on the OmniGuide fiber. Note the key that goes into the ST socket groove of the fiber adaptor.

## Description of AA accessories

The following accessories can be used with the BEACON laser system through the attachment to the articulating arm:

### Micromanipulators:

1. AccuBeam EasySpot (OmniGuide Cat.#420031)
2. AccuBeam MicroSpot (OmniGuide Cat.#420060)

### Handpieces:

3. Incisional Hand Piece 75 mm (OmniGuide Cat.#420035)
4. Incisional Hand Piece 100 mm (OmniGuide Cat.#420036)
5. Incisional Hand Piece 125 mm (OmniGuide Cat.#420037)
6. Incisional Hand Piece 200 mm (OmniGuide Cat.#420038)
7. Incisional Hand Piece 250-450 mm (OmniGuide Cat.#420039)

All accessories are manufactured by TTI Medical, San Ramon, CA and covered by the following 510(k)s: K864378 (Micromanipulators) and K945648 (Handpieces). Contact OmniGuide directly for more detailed information on the accessories.

## Touch Screen/Display Panel

The BEACON Advanced Energy Laser System has a touch screen panel mounted on the swivel joints. Position of the touch screen can be adjusted by the user. The high-resolution touch screen features a smart user interface that allows the operator to access and monitor the laser system operation functions.

## Foot Pedal Connection

The footswitch is connected to the laser by a cord 30 ft (10m) long. The footswitch cord should be plugged directly into the foot pedal connector receptacle on the bottom of the right side of the laser box (Figure 7-4). Open the protective cover, and align red dot indicators and the foot pedal connector and on the laser body before plugging the footswitch in. To remove the footswitch, firmly hold the footswitch connector at the connection point and pull outwards.



Figure 7-4. Foot pedal (left), and foot pedal and interlock connections (right)

## High Pressure Gas Input

The gas flow controller of the laser should be supplied with medical grade helium at a pressure ranging from 110 to 125 PSI. The laser is equipped with automatically triggering valves that read pressure and react prior to the mass flow controller. The Laser Gas Outlet pressure is controlled from the touch-screen interface. Helium gas is used only to operate flexible OmniGuide fiber. The Beacon laser has storage for two E size compressed Helium cylinders located under the back cover of the laser. Gas tanks can be connected with the gas management system using gas hoses with CGA-930 connectors. For country specific connectors, please, contact OmniGuide service.

When a fiber is used, the gas outlet on the top of the laser should be connected with the outlet on the fiber adaptor with supplied gas hose. An OmniGuide sterile gas filter unit should be installed on the fiber adaptor and connected to the gas outlet for sterile cases.

Laser has the ability to display the amount of gas available in the gas tanks on the laser touch screen.

## Removable Back Panel

The removable back panel of the laser provides access to the gas management system. The back panel must be closed during the normal operation of the laser. It can be removed only to install or to replace gas cylinders. To remove the back panel, press down the latch on the top of the panel and open the panel using cable storage hook as a handle. Removing the back panel will enable system interlock.



After closing the panel, make sure that the latch is locked. Otherwise system interlock will prevent laser system from operation.

## Gas Management System

The gas management system is fully integrated into The BEACON Advanced Energy Laser System (see Figure 7-2) and provides a convenient way to operate the laser. The gas management system consists of two gas tanks, hoses connectors for two gas tanks, pressure regulator, gas valves, pressure transducers to sense the amount of gas left in each of the gas tanks, electrical connections and gas supply quick-disconnect gas supply port. Most of the gas management system is not visible from the outside and must not be adjusted or accessed by the user. Storage for compressed gas tanks is located under removable back panel of the laser. Gas tanks can be accessed and replaced by the user. Only gas cylinder types specified by OmniGuide can be used with The BEACON Advanced Energy Laser System: filled with compressed helium 99.9+% purity, E size.

The user connects the gas port on the laser adaptor laser to the gas supply port located on the top of the laser by a hose supplied with the system (P/N 3-0162-012-00-01). The gas management system is designed to be always operated with two gas cylinders in place. Two cylinders act as a single reservoir of the gas: gas will be drawn from both cylinders and cylinders will be emptied at the same time.



Prior to starting the surgical procedure make sure that the gas tank valves are open and there is enough gas for the surgery. System is designed to operate with both gas cylinders in place. Do not operate the system with one cylinder.



Prior to replacing the compressed tanks make sure that valves on both gas tanks are closed.



Caution. Refer to OmniGuide fiber IFUs for instructions on choosing appropriate gas pressure settings.

## Door Interlock

The door interlock connection allows the use of the door interlock safety feature, as may be required at your health care facility. If the door to the room where the laser is being used is opened, this feature will automatically disable operation of the laser. If door interlock operation is not required, a door interlock plug (supplied with the system), can be plugged into the door interlock connection at the back of the laser to defeat the interlock and allow operation of the laser. The door interlock feature is implemented through the laser software.

## Locking Wheels

The laser system is equipped with wheels. All four wheels can swivel for maneuverability. All wheels have a locking mechanism which prevent the wheels from swiveling or moving. To lock or unlock the wheels, use your foot to press on the locking lever.



Do not attempt to move the laser with wheels locked. That may result in tipping.

## Emergency Switch

Emergency switch (red button) is located on the front panel. Pressing emergency switch will disable the laser tube and will stop laser radiation.

## Main Power Switch and Power Cable

The mains power switch (circuit breaker) and the mains power cable provide power to the laser system. The switch is located on the bottom of the laser system, on the left side (see Figure 7-5). The mains power switch must be in the ON position for the laser system to operate. Power on/off button located on the front panel of the laser can be then used to turn laser system on.

For the safe system shutdown use power on/off button on the front panel of the laser to turn laser system off first, before unplugging the laser power cord. After which the main switch can be tuned off.

The power cable is 20 ft. (6 m) long with a plug for power connection in the United States. Separate cable will be supplied for power connections outside of the United States.


 Using main switch for shutting down the laser system may result in corruption of system software.



Figure 7-5. Location of the main power switch

### Power On/Off Push Button

Energy is not delivered by the laser when the power is turned on. The power on/off button (Figure 7-6) must be in the On position before laser system starts. To turn laser system off always push power on/off button first, before unplugging the laser power cord or switching off the main power switch.



Figure 7-6. Location of the power on/off button, USB Port, Emergency Off Switch

## Laser Modality indicators

The laser system is equipped with two laser modality indicators: one on the fiber adaptor and one on the articulating arm. Solid or blinking light on the laser modality indicator shows which laser modality is engaged.

- So ght: laser is firing

## USB connection

Laser is equipped with USB port located on the front panel of the laser system. The USB port is used by OmniGuide personnel only, for diagnostics and software updates.

## Handle

There is a handle on the front panel of the laser system to help you easily roll the system around on its wheels. Handle should not be used to lift the laser system.

## Air Outlet

Outlet for the purge air flow is located on the top of the laser system. It should be connected to the gas hose attached to the articulating arm. Other end of the gas hose should be connected to the micromanipulator or the handpiece when line of sight (articulating arm) modality is used.

## Scanner Connection

This laser system is equipped with the connector for the scanner. Scanner is not available with the current model and will be available as future upgrade option.

## Operating Specifications for Laser

### 30 W Unit

<b>Laser wave length and classification:</b>	10 600 nm, Class 4
<b>Output Power:</b>	Maximum 30 Watt at Laser output from the fiber adaptor or articulating arm
<b>Power Stability:</b>	$\pm 20 \%$
<b>Laser modes:</b>	Waveforms: 8. Continuous wave (CW) or superpulse (SP) Laser output: 9. Continuous (continuous emission as long as foot pedal is kept pressed) 10. Single pulse with pulse duration of 50 msec -1000 msec (single pulse of laser emission per each foot pedal activation) 11. Repeat pulse with individual pulse duration of 50 msec -1000 msec (repeated pulses of laser emission as long as foot pedal is kept pressed)
<b>Spot size:</b>	FIBER: Fiber outputs a diverging laser beam. Exact laser spot size depends on fiber used and distance from the tissue. Please, refer to OmniGuide Fiber instructions for use (IFU). Beam divergence of the of the laser beam coming out of the fiber is $\leq 250$ mRad depending on the fiber type. ARTICULATED ARM: Articulating arm outputs a collimated laser beam with low divergence. Beam width out of the articulated arm without any accessories connected is $8.5 \pm 1.5$ mm, beam divergence is $1.5 \pm 0.5$ mrad Exact laser spot size depends on the used accessories. Please, refer to the accessories IFU for details.
<b>Laser safety:</b>	Optical Density: OD 4+ @ 10.6 $\mu$ m wavelength Nominal hazard zone (NHZ): 93 Meters Nominal ocular hazard distance (NOHD): 93 m Maximum Permissible Exposure (MPE): 0.1 W / cm <sup>2</sup>

<b>Aiming beam characteristics:</b>	Wavelength: 635 nm Power: < 1 mW Class 2M
<b>Connectors/Cords:</b>	FIBER: custom ST connector ARCTICULATED ARM: 15/16-12 female thread Power cord length: 6m Foot pedal cord length: 10m
<b>Weight:</b>	68 kg (150 lbs) Laser only
<b>Size (WxDxH):</b>	49 x 49 x 144 cm (20" x 20" x 59")
<b>Operating temperature:</b>	15 – 25° Celsius
<b>Operating pressure:</b>	Ambient pressure (700 hPa to 1060 hPa)
<b>Maximum humidity:</b>	75 %
<b>Operating voltage:</b>	120/240 volts
<b>Electrical:</b>	Class I
<b>Sterility:</b>	Dual laser system is not intended to be sterilized OmniGuide fibers are supplied sterile for a single use Accessories (micromanipulators and handpieces) are reusable and must be cleaned/sterilized before the procedure
<b>Applied parts:</b>	Fiber and laser accessories are classified as applied part, type B

#### 60 W Unit

<b>Laser wave length and classification:</b>	10 600 nm, Class 4
<b>Output Power:</b>	Maximum 30 Watt at Laser output from the fiber adaptor Maximum 60 Watt at Laser output from the articulating arm
<b>Power Stability:</b>	± 20 %
<b>Laser modes:</b>	Waveforms: 12. Continuous wave (CW) or superpulse (SP) Laser output: 13. Continuous (continuous emission as long as foot pedal is kept pressed) 14. Single pulse with pulse duration of 50 msec -1000 msec (single pulse of laser emission per each foot pedal activation) 15. Repeat pulse with individual pulse duration of 50 msec -1000 msec (repeated pulses of laser emission as long as foot pedal is kept pressed)



<b>Spot size:</b>	<p>FIBER: Fiber generates a diverging laser beam. Exact laser spot size depends on fiber used and distance from the tissue. Please, refer to OmniGuide Fiber instructions for use (IFU). Beam divergence of the of the laser beam coming out of the fiber is <math>\leq 250</math> mRad depending on the fiber type.</p> <p>ARTICULATED ARM: Cross-section of the collimated laser beam coming out of the articulated arm without any accessories connected <math>8.5 \pm 1.5</math> mm, beam divergence is <math>1.5 \pm 0.5</math> mrad</p> <p>Exact laser spot size depends on the used accessories. Please, refer to the accessories IFU for details.</p>
<b>Laser safety:</b>	<p>Optical Density: OD 4+</p> <p>Nominal hazard zone (NHZ): 93 Meters</p> <p>Nominal ocular hazard distance (NOHD ): 93 m</p> <p>Maximum Permissible Exposure (MPE): <math>0.1 \text{ W / cm}^2</math></p>
<b>Aiming beam characteristics:</b>	<p>Wavelength: 635 nm</p> <p>Power: <math>&lt; 1</math> mW</p> <p>Class 2M</p>
<b>Connectors/Cords:</b>	<p>FIBER: custom ST connector</p> <p>ARTICULATED ARM: 15/16-12 female thread</p> <p>Power cord length: 6m</p> <p>Foot pedal cord length: 10m</p>
<b>Weight:</b>	72 kg (159 lbs) Laser Only
<b>Size (WxDxH):</b>	49 x 49 x 144 cm (20" x 20" x 59")
<b>Operating temperature:</b>	15 – 25° Celsius
<b>Operating pressure:</b>	Ambient pressure (700 hPa to 1060 hPa)
<b>Maximum humidity:</b>	75 %
<b>Operating voltage:</b>	120/240 volts
<b>Electrical:</b>	Class I
<b>Sterility:</b>	<p>Dual laser system is not intended to be sterilized</p> <p>OmniGuide fibers are supplied sterile for a single use</p> <p>Accessories (micromanipulators and handpieces) are reusable and must be cleaned/sterilized before the procedure</p>
<b>Applied parts:</b>	Fiber and laser accessories are classified as applied part, type B

## 8.0 SAFETY

### Laser Safety Requirements



This laser conforms to the United States requirements for laser safety. These laser safety requirements are contained in 21 CFR, 1040.10 and 1040.11 and are administered by the FDA Center for Devices and Radiological Health.



A laser Report, detailing how the laser product complies with the federal laws is required to be submitted to FDA on an annual basis. The form of this report is covered in a pamphlet entitled: Guide for Preparing Product Reports for Lasers and Products Containing Lasers, Sept. 1995:

U.S. Department of Health and Human Services Public Health Service Food and Drug Administration Center for Devices and Radiological Health Division of Small Manufactures Assistance Rockville, MD 20857 Web Site: <http://www.fda.gov/CDRH>

For jurisdictions, outside of the United States, it is the responsibility of the buyer of this laser device to ensure that it meets the local Laser safety regulations.

### Optical Safety

The BEACON Advanced Energy Laser System has undergone extensive testing to ensure that, with proper usage, it is a safe and reliable device.

Laser light, because of its special properties, poses safety hazards not associated with light from other sources. The light from the BEACON Advanced Energy Laser System is invisible to the naked eye. The safe use of Laser requires that all operators be properly trained and the proper use of PPE be used in the operation of this device.



Laser energy exposure near the aperture may cause burns



Direct eye contact with the output beam from the Laser will cause serious damage and may cause blindness. CO<sub>2</sub> Laser Radiation is invisible. All personnel in the Laser Treatment Control Area, LTCA or anyone who may enter the LTCA should be informed that a Laser is in operation. All personnel within the Nominal Hazard Zone (NHZ) must wear Laser safety glasses (OD > 4), which protect against the wavelength (10.6 microns) in use.



The NHZ (Nominal Hazard Zone) is 2.4m from the exit of the fiber. The NHZ (Nominal Hazard Zone) and Nominal Ocular Hazard Zone (NOHZ) are 93m from the exit of the articulating arm. For laparoscopic cases, the NHZ is isolated within the patient. The proper use of appropriate optical filters on endoscopes are recommended.



Exercise caution to protect against reflections off shiny and mirror-like surfaces. Reflections of the BEACON Advanced Energy Laser System light are invisible to the naked eye. Eye, skin and fire safety is a great concern when using a high-power, FDA class IV Laser such as The BEACON Advanced Energy Laser System. There is potential for secondary beams present at various angles near the incident radiation site. While weaker than the main beam, such beams may still be sufficiently intense to cause eye damage and skin burns.



Laser beams are also powerful enough to burn skin, clothing or paint and can damage the light-sensitive elements in video cameras, photo multipliers and photo diodes.



Laser radiation produced during the normal use is powerful enough to some materials (e.g. cotton, wool when saturated with oxygen) and can ignite volatile substances such as alcohol, gasoline, ether and other volatile solvents. Solvents of the adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before laser radiation is applied.



Laser radiation may ignite endogenous gases.

OmniGuide provides the following recommendations to promote the safe use of The BEACON Advanced Energy Laser System. Operators are advised to adhere to these recommendations and employ sound Laser safety practices at all times.

Always follow the safe Laser usage guidelines, law or regulations relevant to the country, state, province etc., when you are operating or installing the Laser.

- Use protective eye wear when operating the Laser and guard against inadvertent exposure of skin or clothing to the laser radiation. Select eye wear which is suitable for use with the wavelengths and radiation intensity that the Laser emits – 10.6  $\mu\text{m}$ .
- Never look directly into the Laser output port when the power is on.
- Post warning signs to alert personal of the use of a Laser. When operating the Laser, limit access to the area to individuals who are trained in Laser safety.
- Do not use the Laser in the presence of flammable, explosives, or volatile solvents such as alcohol, gasoline or ether.
- For additional information on Laser safety, refer to the following publications:
  - ANSI Z136.1, ANSI Z-136.3 and IEC
  - 60825 Performance Standard for Laser Products. FDA, CFR 21 1040.10 and 1040.11
  - CAN/CSA-Z386-08: Laser Safety in Health Care Facilities

## Electrical Safety

The laser has Class I electrical rating, is ETL complaint and conforms to the following:

- UL STD 60601-1
- IEC STD 60601-1-2 & -1-4
- IEC STD 60601-2-22
- IEC STD 60825-1
- Certified to:
- CSA STD C22.2 NO. 601.1
- CSA STD C22.2 NO. 60601-1-2 & -1-4
- CSA STD C22.2 NO. 60601-2-22 & E60825-1

### 8.1.1 Door Interlock

The system has the capability to interlock the doors to the room where the Laser is operated. The interlock connection can be found at the rear of the laser (red colored rear input).

## Compliance to Standards Relevant to CE-Mark

The BEACON Advanced Energy Laser System meets the required standards of the European Union-Mark. Please see section 17 for more details.

## 9.0 TRANSPORTATION AND STORAGE



If the system has been transported or stored at temperatures below 10°C (50 F), unpack the device and leave it at normal room temperatures at least for half a day so that the laser reaches room temperature.

	<p>Store at temperatures: -30°C to 70°C</p>
	<p>Pressure: 525 hPa to 1060 hPa</p>
	<p>Humidity: 0-95%</p>
	<p>Indicates upper side. Keep upright.</p>
	<p>Fragile – handle with care.</p>
	<p>Keep dry</p>



For extended storage, The BEACON Advanced Energy Laser System is should be stored in dry environment at normal room temperatures.

Care should always be taken when moving the The BEACON Advanced Energy Laser System system. Before moving the laser, it is recommended to disconnect the footswitch from the laser and attach it to the back panel. A handle located on the front panel allows easy movement of the system, but take special care when manoeuvring over thresholds, elevator doors, ramps and other uneven or sloping floor surfaces. A severe physical shock could cause the alignment of the laser or the articulated arm to be disturbed resulting in personal injury or physical damage.

The BEACON Advanced Energy Laser System is not designed for mobile use. If it becomes necessary to relocate the laser, contact OMNIGUIDE Customer Support or your distributor for details. Failure to do so may result in personal injuries or damage to the system and may void any warranty.

## 10. UNPACKING AND INSPECTION

Before unpacking the Laser inspect the shipping container carefully for evidence of rough handling and note any damage. Immediately inform the shipping carrier and OMNIGUIDE or the distributor of any evidence of damage in shipment.

If there is any discrepancy noted, inform your distributor or OMNIGUIDE directly.

PLEASE NOTE THAT THE ACCESSORIES FOR ARTICULATING ARM WILL ARRIVE IN A SEPARATE SHIPPING CONTAINER.

### List of Items in the Box

- The BEACON Advanced Energy Laser System
- Power cord
- Foot pedal
- The BEACON Advanced Energy Laser System Instructions for Use.
- Gas hose
- Laser safety signage
- Laser goggles

If any items are missing, immediately report this to OmniGuide or the representative in your country. Report exactly the items missing and verify whether the Laser can be installed or the items missing will not allow you to install and operate the Laser.






If you need to ship the Laser back to OmniGuide, you **MUST** ship it in the OmniGuide shipping container and packing material. If the Laser is not packed properly and damage occurs during shipment, the customer will incur all charges for the repair of damaged or missing parts.









### Safety Issues in Laser Setup

Setup of The BEACON Advanced Energy Laser System must comply with all applicable electrical safety and Laser safety laws and regulations in the country the Laser is installed.

Review all the regulations which exist in your country.

Some information regarding safety based on international laws like in the EC (EN) or US (FDA) regulations is listed below.







-  Do not connect the Laser power cable to wall outlets without a proper ground.
-  Do not connect other instruments to the same wall outlet where the Laser is connected.
-  Check the fuse for the wall outlet with the rating given in this manual (The fuse installed is rated for a specific voltage used).
-  Do not use power cables other than those supplied with the instrument. If the connection to the main power socket is different than the cable supplied, contact your local electric supply office for guidelines on the power cable to be used with medical equipment.
-  Do not setup the unit close to any flammable material.

-  Do not set-up the unit stacked with any other equipment. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
-  Be sure the Laser is properly secured to avoid the possibility of the Laser moving during treatment, thus creating a hazardous condition.
-  Do not store any high reflecting material close to the Laser beam output to avoid any unwanted reflections. The Laser beam is invisible and can create skin and eye damage if not properly directed.
-  All people inside the room including the patient must wear protective eyewear to avoid unwanted Laser light directly, scattered or reflected entering the eye.
-  Do not fire the laser until the surgeon and the patient are positioned correctly.
-  The entrance to the room must be clearly marked with appropriate warning sign that laser is in use.
-  During surgery, the room should be interlocked in such a way that no one can enter the room without protective eye wear.
-  Only authorized and properly trained personnel are allowed operating the Laser. The laser must be turned off at all other times to prevent unauthorized usage.

## 11.0 FACILITIES REQUIREMENT

The dimensions of The BEACON Advanced Energy Laser System are given in section 7. Identify the laser room clearly. Post appropriate warning signs in prominent locations at all entrances to the laser room. When the laser system is in operation, limit entry to the room and limit access to the laser to the personal trained in operation of the laser.

Make sure that all laser room personnel are familiar with the laser system controls and know how to shut down the laser system instantly in an emergency.

-  Do not stress or bend the housing of the laser to avoid any misalignment of the laser beam.
-  The fiber adapter and articulating arm must be protected to ensure it is safe from inadvertent jarring that could cause laser beam misalignment.
-  Do not block the entrance of the air intake, located on the right side of the laser. Blocking of the air going through the laser will result in a misalignment of the laser head and consequently a drop of power.
-  Never operate the Laser without the air filter, do not use any other filter than the one provided by OmniGuide. Operating with dust, water or dirt in the environment around the laser or without the filter could result in damage to the laser. For filter replacement please contact OmniGuide service.
-  Do not install the laser on cartons or material that are flammable.
-  Do not position the laser in the way blocking access to power and emergency switches.

### Electrical Power Connection

The BEACON Advanced Energy Laser System requires AC voltage 120-240 Volts, 50/60 Hz.

The mains cable should be rated above 15A continuous AC current. Use mains cable supplied with the system.

Make sure that the mains ground connection is made. The mains cable is connected to the rear of the laser into the socket with the following characteristics:

Input voltage: 120-240 V, 50/ 60 Hertz Ground connection required Leakage current trip: less 500  $\mu$ A Fuses 120 V /15A (North America), 240 V / 10A (Europe)

The mains socket should be properly fixed to the wall; it is not allowed to use an extension cable between the Laser and the wall outlet.

#### 11.1.1 Fuse Specification for the Laser

Different input voltages require different fuses.

240 V 10A

120 V 15A

## Compressed Gas Requirement

The OmniGuide laser system is designed to be used with medical-grade Helium gas, delivered to the fiber at a pressure that depends on the type of fiber and the application. Please see fiber IFU for details. Adjustments of the setting will be automatically limited by the settings on the RFID tag of the particular fiber.

The gas flow is established by connecting the gas hose (connected to the system) to a Helium source (provided by the user). The gas hose has a CGA-930 fitting to facilitate this attachment. The gas outlet on the top of the laser has a 1/8 " quick disconnect port. The gas hose supplied with the system connects the gas outlet at the front of the laser to the fiber adapter. A Gas Filter Unit (P/N ACC-GFU-100-1) between the gas hose and the adapter is required for sterile procedures.

## Door Interlock

The Laser should be used only in a room which is clearly marked as laser room and could be interlocked through the laser console. To allow the door to be wired into the laser, the laser console has an interlock connector at the base of the housing next to the foot pedal (Figure 7-4).

The door interlock is a switch in normal open condition. The switch needs to be in closed condition for the laser to operate. When the door is closed or the interlock defeated the laser can be operated. If the switch is opened during laser operation, the laser will show an error condition and stop.



When door interlock is not mandated, a connector needs to be in place to defeat the door interlock in order for the laser to be started. A door interlock plug has to be used to allow laser operation (P/N 3-0142-015-31-00).

## Foot Pedal Connector

The foot pedal is directly attached to the base of the laser (Figure 7-4). The foot pedal can be removed by pulling the connector from the rear of the laser. The foot pedal is shielded with a protection cover.

## 12.0 SYSTEM OPERATION

### Use Preparation

12.1.1 The system should be first inspected for any loose, damaged, or missing hardware and accessories.

12.1.2 If a remote interlock will be used, the remote interlock connection is located at the base of the laser next to the foot pedal connection.

12.1.3 Proper laser safety, fire hazard, and electric safety precautions are required.

### Surgical Preparation

12.1.4 It should be determined prior to use if the system will utilize fiber or free beam / articulating arm modality.

12.1.5 Associated accessories should be procured prior to setup for respective modalities.

12.1.6 Proper positioning for the system should be reviewed prior to the procedure

12.1.7 Involved staff should be notified of proper safety precautions

12.1.8 Contingent equipment should be kept in reserve in the event of product failure

12.1.9 Plug in the system to an appropriate outlet and press the power button on the front of the unit

12.1.9.1 If the system will not power on, confirm that the mains power switch next to the power cord is on and that the Emergency Machine Off switch is pulled out.

### Fiber Mode Usage

12.1.10 Enter the password and review any notifications from system start-up

12.1.11 Select the "fiber" icon.

12.1.11.1 Note: plugging in an OmniGuide fiber will bypass the mode selection screen and take the user directly to the main Fiber interface

12.1.12 If a helium issue is reported on the screen remove the back panel of the laser and confirm there are two helium tanks attached and open. Reseat the back panel.

12.1.12.1 Note: two tanks are required to be attached at all times

12.1.13 If required attach a sterile gas filter unit in line between the helium supply hose and fiber port.

12.1.14 Attach a valid OmniGuide fiber to the fiber port and wait for the fiber tag to be recognized

12.1.15 Insert the fiber into the appropriate hand piece or scope and ensure the fiber is properly seated in accordance with the fiber IFU.

12.1.16 Position the laser so that there is sufficient slack to provide maneuverability but far enough from the surgical site to minimize loops and excessive bending. (laser distance approx. half the length of the fiber)



12.1.17 From the user graphical interface set the appropriate Pulse Mode, Helium Flow, and Power Level

12.1.17.1 Surgeon custom laser settings can be saved and recalled using "Save User Settings" and "Load User Settings" graphical interface features accessibly in the "Settings" menu

12.1.18 Provide the foot pedal to the surgeon

12.1.19 Place the laser in ready mode and press the foot pedal to activate the laser

12.1.19.1 It is strongly recommended the fiber be dipped in sterile saline to confirm gas flow and a test shot performed on a sterile tongue blade to confirm proper power setting prior to use

12.1.19.2 The fiber should be cleaned routinely during surgery to prevent tissue build up on the distal end

12.1.20 Power, gas, and pulse settings should be adjusted accordingly throughout the procedure at the discretion of the attending surgeon

12.1.21 Laser modality can be changed at any time by pressing the fiber icon in the upper left and choosing "change mode."

## Arm Usage Mode

12.1.22 Enter the password and review any notifications from system start-up

12.1.23 Select the "arm" icon

12.1.24 Determine what accessories will be used with the articulating arm

12.1.24.1 Consult section 5.4. of the current manual for the list of compatible accessories.

12.1.25 At the user screen set the Lasing Mode, Aiming beam brightness, and Power Setting

12.1.26 Position the laser so that mobility of the arm will not conflict or interfere with other equipment and will not pull on the laser body

12.1.27 Provide the foot pedal to the surgeon

12.1.28 Place the laser in ready mode and press the foot pedal to activate the laser

12.1.28.1 It is strongly recommended a test shot be performed on a sterile tongue blade prior to use to confirm the aiming beam and CO<sub>2</sub> beam are mutually aligned and that the power setting is appropriate

12.1.29 Power and pulse settings should be adjusted accordingly throughout the procedure at the discretion of the attending surgeon

12.1.30 Laser modality can be changed at any time by pressing the "Arm" icon in the upper left and choosing "change mode."

## Post Procedure Breakdown

12.1.31 Press the power button on the front of the laser to turn it off

12.1.32 When the unit has powered down it can be unplugged from the wall.

12.1.33 OmniGuide fibers are single use disposable as are sterile gas filter units.

12.1.34 OmniGuide handpieces can be cleaned sterilized and re-used in accordance with their corresponding IFUs

12.1.35 After use, the laser unit should be wiped with IPA wipes or equivalent as recommended by the hospital infection control procedures.

12.1.36 Consult the micromanipulator IFU for cleaning instructions

## Graphical User Interface

12.1.37 Password screen: occurs when system is first turned on

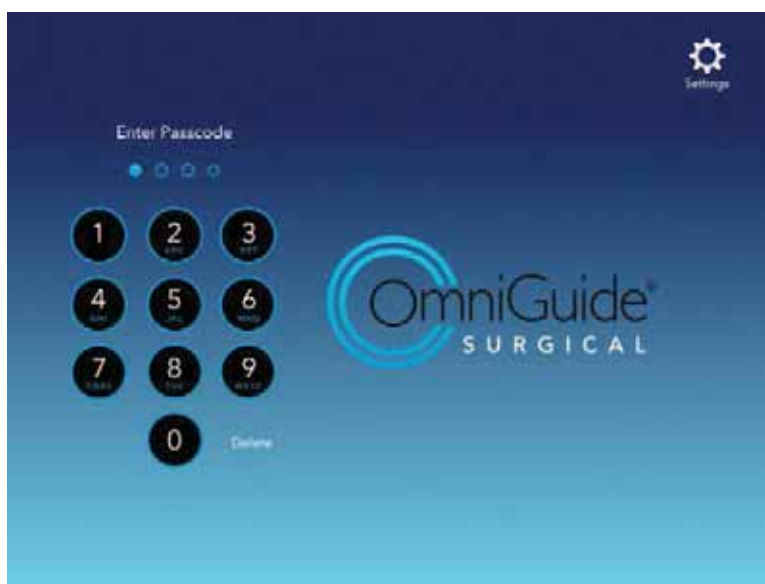


Figure 12-1: Password Screen

12.1.38 Home Screen: occurs after the password is input or whenever the “Home” button is pressed

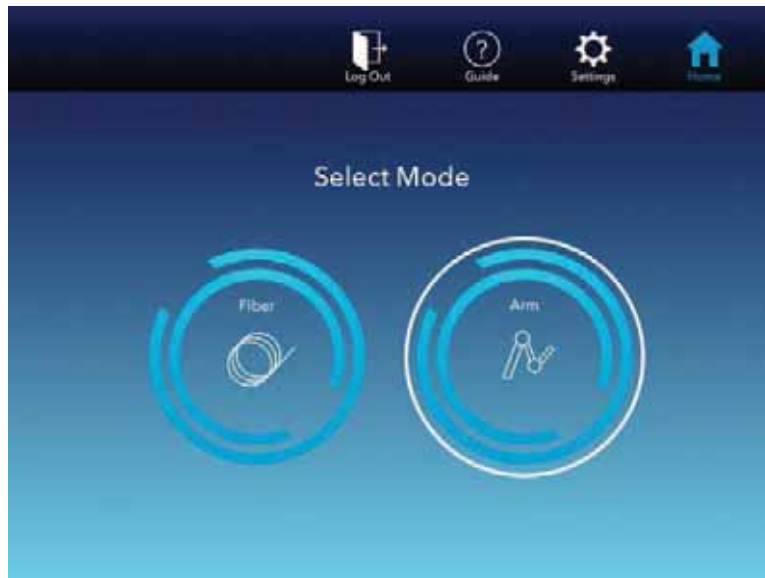


Figure 12-2 – Home Screen, Select Mode

12.1.39 Selecting Arm Accessories: Occurs after choosing “Arm” mode from the home screen

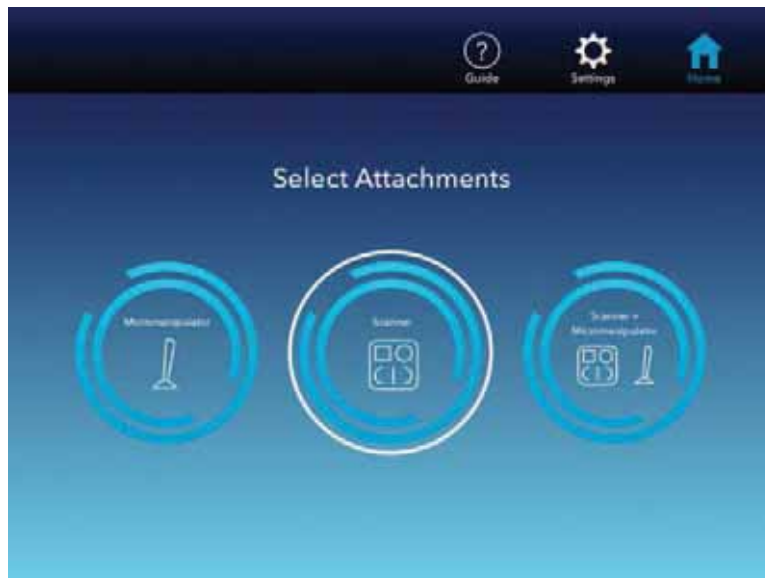


Figure 12-3

12.1.40 Arm Delivery Mode: Main Screen (Occurs after selecting Arm accessories)



Figure 10-4: Main Screen, Arm Mode

12.1.41 Fiber Delivery Mode: Occurs after selecting Fiber Mode from the Home Screen

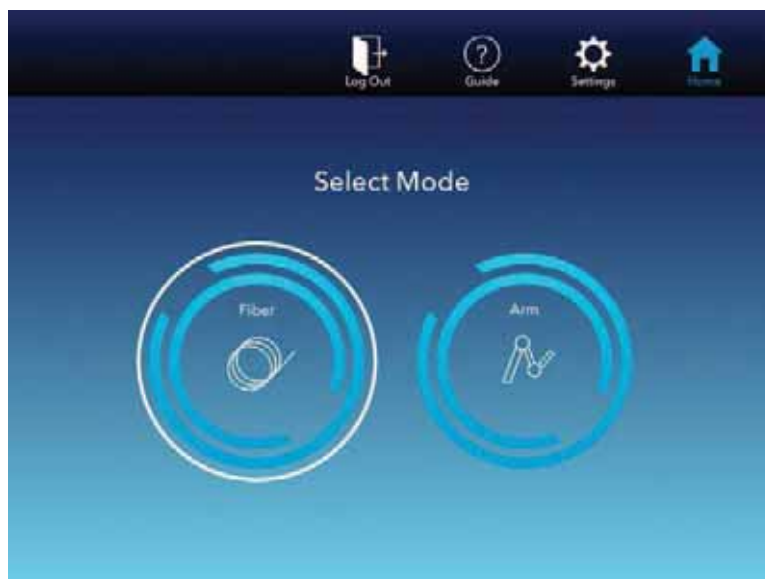


Figure 12-5: Select Mode

### 12.1.42 Fiber Delivery Mode: Main Screen

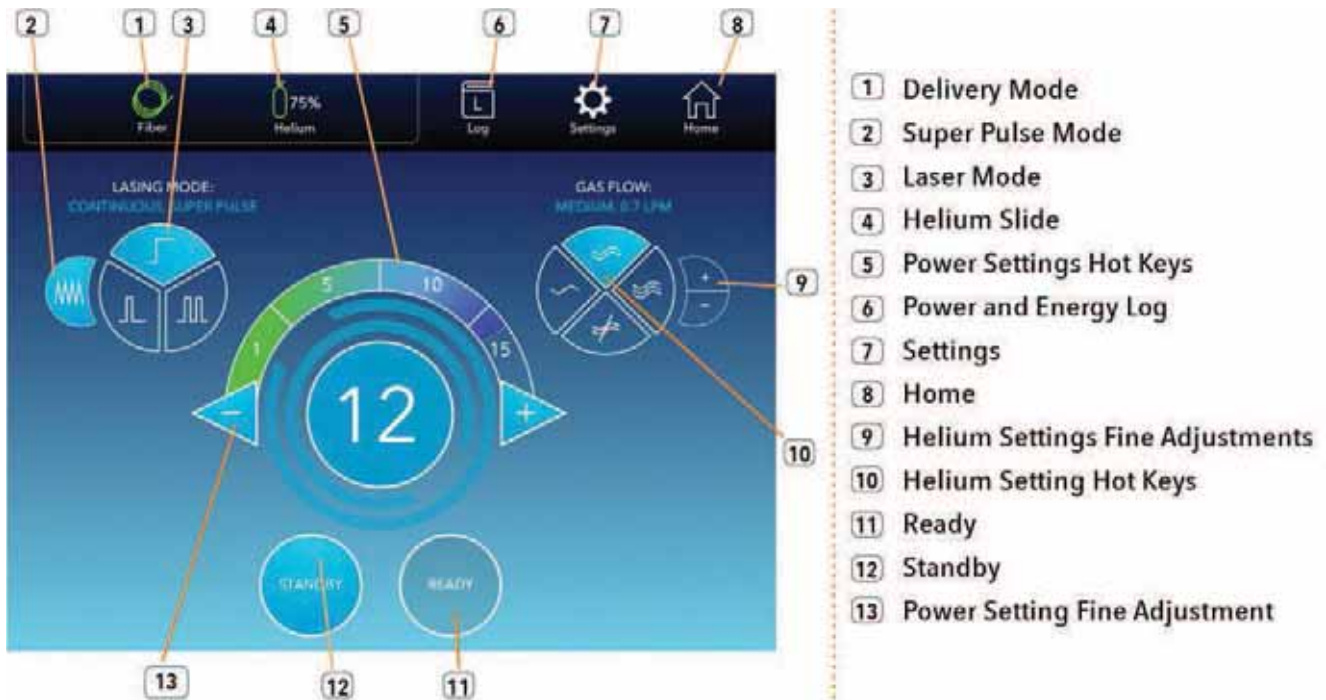


Figure 12-6

### 12.1.43 Helium Supply Details: Occurs when touching the Helium Supply icon.



Figure 12-7

12.1.44 Pulse Duration (Single Pulse): Occurs whenever the user touches the single pulse icon.



Figure 12-8

12.1.45 Pulse Duration (Repeat Pulse): Occurs whenever the user touches the repeat pulse icon.



Figure 12-9

12.1.46 Switching Modes: Occurs when touching the Delivery Mode icon and takes the user to the Home Screen.

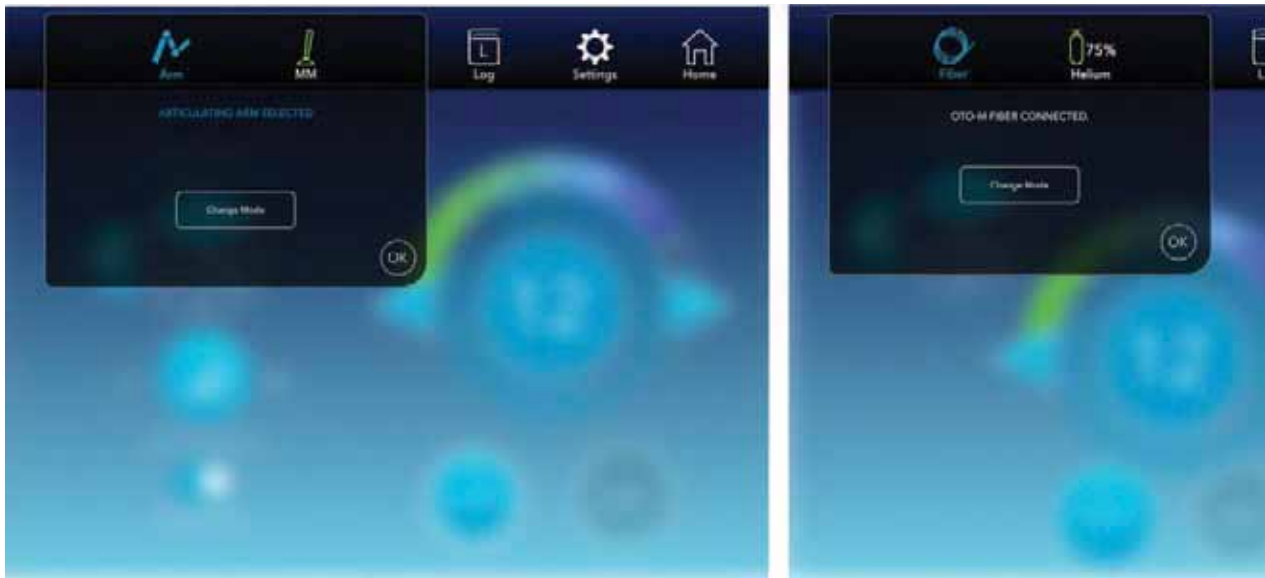


Figure 12-10

12.1.47 Laser Log: Occurs when the user touches the Laser Log icon

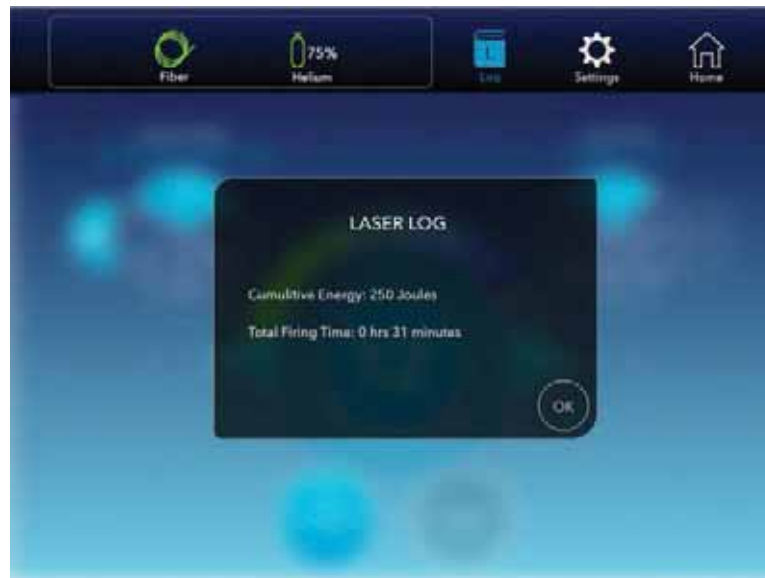


Figure 12-11

12.1.48 Settings Main Screen: Occurs when the user touches the settings button

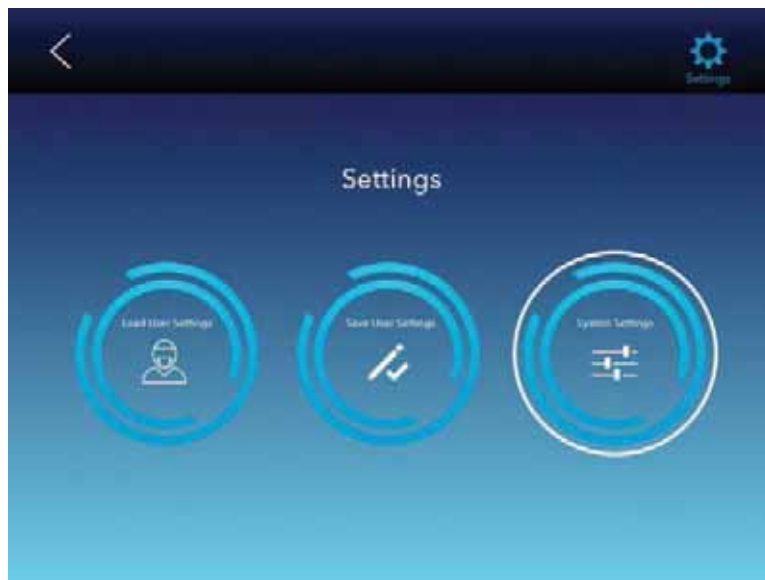


Figure 12-12

12.1.49 Load User Settings: Occurs when the user touches the Load User Settings Icon



Figure 12-13



### 12.1.50 Main System Settings: Occurs when the user touches the system settings icon



Figure 12-14

### 12.1.51 Language Settings: Occurs when the user touches the Language button



Figure 12-15

**12.1.52 Passcode Change:** Occurs when the user touches the Passcode Button. Allows the user to change the Main Password at Startup. User will be asked to confirm passcode.



Figure 12-16

**12.1.53 Note:** Rep and Service settings are only available to OmniGuide trained personnel.

## 13.0 CLEANING, STERILIZATION AND DISPOSAL

### Cleaning Instructions

The adapter, display screen, and articulating arm can be cleaned by wiping its exterior with a cloth moistened with 70% IPA or equivalent recommended by the hospital infection control procedures.

After use, articulating arm hand pieces are to be treated as biohazardous and to be cleaned in accordance with that specific accessories' IFUs.

Used fibers are biohazardous material and must be disposed in a manner consistent with hospital's procedure (Section 11.3)

### Sterilization Guidelines

Fiber is provided sterile and for the single use only. For sterile procedures, use the Gas Filter Unit (CAT# ACC-GFU-100) to sterilize the gas path. Please refer to the GFU instructions for use. For sterile procedures where the Articulating Arm may potential contaminate the sterile field cover the arm with a sterile drape. If the problem persists, contact OmniGuide service for assistance (1-888-666-4484 x3)

Articulating Arm hand pieces are to be sterilized prior to use in accordance with that specific accessories' IFU.

## Fiber Disposal Instruction

The used fiber should be disposed of as per routine healthcare facility procedures concerning biohazard materials. Refer to healthcare facility procedures on processing bio-hazardous materials.

# 14.0 MAINTENANCE

## Overview

It is strongly recommended the BEACON Advanced Energy Laser System undergoes a yearly Preventive Maintenance (PM) performed by an OmniGuide trained professional. While the laser itself is a standard CO<sub>2</sub> laser system, improper or inadequate maintenance will lead to an increased probability of poor system performance.



Only qualified personnel who are fully trained of the system's safety hazards should operate, maintain, and troubleshoot this equipment.

## Notification

A maintenance required notification will appear when the laser has passed its next maintenance date. This date is set in the service mode for the laser which is only accessible by OmniGuide trained technicians. This is a notification only and will not render the unit unusable. However, usage of the laser system without proper maintenance by an OmniGuide trained technician is highly discouraged and the user does so at their own discretion assuming full risk and liability.

## Alignment:

The OmniGuide optical adapter and articulating arm are to have its alignment confirmed and maximized to within specification. In addition, the laser beam should be inspected to ensure the beam profile (laser modes) and wavelength shifts are acceptable for optimal performance.

The Articulating Arm is to be inspected for beam walk off and co-linearity with the aiming beam. If the walk off is out of spec or the aiming and CO<sub>2</sub> beam are not collinear the beam is to be corrected at the source internal to the laser.

## Calibration

The power outputs of the laser are to be measured at several power levels from 1-60, measured using continuous, and super pulse waveforms. The power should be well within +/- 20% of the laser power setting measured at the exit of the fiber adapter.



Calibration shall be performed at an ambient temperature of 20°C ±2°C using calibrated power meter.

## Gas Management

The gas management assembly is to be measured for proper output pressure and inspected to ensure the tank levels are properly displayed. It is also to be inspected for any leaks or damaged connections. A remote interlock is activated when removing the rear panel of laser to access the gas management assembly.

## Functionality

The display screen, RFID antenna, articulating arm, wheels, emergency machine off, rear panel and foot switch are to be checked for routine functionality. The unit is to be inspected for any loose, missing or damaged hardware.

## Parts

The BEACON Advanced Energy Laser System cart, and accessories are to be inspected for any loose, damaged, or missing parts. The following parts are to be replaced annually:

**14.1.1 Fan filter element (located under the air intake enclosure panel on the right side of the laser), PN 1-0092-015-00-00**

**14.1.2 Yoke washers for the CGA-930 fitting that connects the inlet hoses for the gas management assembly to the tanks, PN 1-0090-017-00-00**

## OmniGuide Service

For additional information on the Yearly Preventive Maintenance please contact OmniGuide Service at 1-888-666-4484.

# 15.0 TROUBLESHOOTING

## System does not start

1. Check if electrical power cord is fully securely plugged into an individual outlet
2. Check if electrical power cord is fully plugged into the Laser
3. Check if mains switch at the laser base is in "ON" position
4. Check if emergency switch is pulled out all the way
5. Check if the door interlock connector is in place at base of Laser
6. Check fuses at the mains connector at base of the Laser. If the fuses are blown, exchange fuses with spare fuses supplied with the system.
7. Door is interlocked, and the door is open.

If the problem persists, contact OmniGuide service for assistance (1-888-666-4484)

## Password does not work

Retype the pin code (password). If you cannot get into the main menu, restart the system and retry. If you have no success entering the main menu contact OmniGuide service for assistance (1-888-666-4484).

## No effect on tissue

1. Prior to surgery the laser is to be test fired to confirm the aiming beam and CO beam are aligned and that there is no clipping or observed disfigured beam if the articulating arm is to be used.
2. Increase the power of the system
3. Is the "Ready" button pressed?
4. Increase the pulse length

5. Do you hear the laser firing tone when the foot pedal is pressed?

If the problem persists, contact OmniGuide for assistance

### **Low power or no power is observed out of the OmniGuide Fiber:**

1. Prior to surgery the laser is to be test fired with a fiber to confirm power output. If no energy is emitted from a fiber make sure the fiber is not clogged. Clean in sterile solution if necessary. Replace fiber if necessary.
2. Verify that the Laser is on and that it is set to "Ready".
3. Verify that gas of the proper type and pressure is being supplied to the gas hose of the Adapter. The proper gas type and pressure is shown on the insert provided with each fiber.
4. Verify that the Adapter is securely mounted on the Laser. If the Adapter exhibits any up-and-down, rocking, or rotational movement relative to the Laser, discontinue use and contact OmniGuide for assistance.
5. Set the Laser power to 4W in CW mode. Keep the cannula of the handpiece (if present) and the fiber as straight as possible and operate Laser for up to 5 seconds while the fiber's distal-end is 3mm from a moist tongue depressor. Use aseptic technique. If no visible burn spot appears, replace the OmniGuide Fiber and repeat this test.

If the problem persists, contact OmniGuide for assistance

### **System too hot**

1. Is the laser system wrapped too tightly in sterile wrap or the air inlet on the right side is blocked?
2. Is there restriction in the air flow at the bottom of the system?
3. Is the room temperature below 30° C (86F)?
4. Have you treated patients with full power more than 30 minutes?
5. Is the system close to any heat source, for example room heating?

If the problem persists, contact OmniGuide for assistance. Call OmniGuide Service at 888-666-4484 ext. 3.

## **16.0 WARRANTY**

### **Point of Sale Warranty**

For point of sale warranty on new and refurbished units please refer to OmniGuide's terms and conditions.

### **Parts and Service Warranty**

OmniGuide warrants that Parts installed and services performed by OmniGuide or OmniGuide-approved subcontractors, will be free from defects in material and workmanship respectively for a period of 90 days from the date of installation or performance of the service, respectively, provided that the warranty for parts purchased directly by the Customer from OmniGuide and not installed by OmniGuide is 30 days only from the date of purchase.

### **Services Remedy.**

If OmniGuide determines that any Service fail to meet the foregoing warranty, OmniGuide shall re-perform such Service to meet the foregoing warranty at its cost.

## Warranty Exclusions

Excluded from Warranty. This warranty will not apply to:

- 16.1.1 Product defects resulting from improper or inadequate maintenance by Customer or its agents;
- 16.1.2 Customer or third-party supplied parts, software, interfaces, or supplies not recommended or provided by OmniGuide;
- 16.1.3 Use or operation of the product other than in accordance with OmniGuide's applicable product specifications and written instructions;
- 16.1.4 Abuse, negligence, accident, loss, or damage to a Product in transit;
- 16.1.5 Improper site preparation; unauthorized maintenance or modifications to the Product;
- 16.1.6 Viruses or similar software interference resulting from the connection of the Product to a network.

## 17.0 PACKING PROCEDURE

### Packing of the system

If there is a need to send the system to the manufacturer the laser and the accessories must be properly packed and labelled in their original shipping box as shown in Figure 17-1.



Figure 17-1. OmniGuide laser in the shipping crate

## Shipping instructions

Before shipping the system back to OmniGuide please first contact OmniGuide or your distributor so that you will receive authorization to ship.

# 18.0 WARNINGS AND ALARMS

## Laser System Warnings

ID	Error	Condition	Displayed text
<b>FIBER</b>			
W-01	Fiber use attempts exceeded maximum	Fiber connected and fiber tag data use count per SW-056	Maximum fiber usage reached. Please replace with a new OmniGuide Fiber.
W-02	Invalid fiber connected	Fiber connected and fiber tag data authentication failed	Invalid fiber. Please replace with a new OmniGuide Fiber.
W-05	Ready mode selected without fiber connected	READY selected with no fiber present	No fiber detected. Attach valid OmniGuide fiber before entering READY mode.
<b>LASER OPERATIONAL MODE</b>			
W-07	Minimum Gas Flow for Current Power	User attempted to decrease the gas flow below the minimum allowed in the fiber tag data for the current power setting.	Action Required Laser is set at minimum gas flow for the current power setting. Please adjust power setting in order to reduce gas flow.
W-08	Maximum Power for Current Gas Flow	User attempted to increase the power above the maximum allowed in the fiber tag data for the current gas setting.	Action Required Laser is at maximum power setting for current gas flow. Please increase gas flow in order to increase power settings
W-09	Power settings changed	When changing from one operation mode to another, and the power settings are automatically updated.	Settings have been modified. Please adjust power and gas setting in accordance with procedural setting recommendations
<b>GAS SYSTEM</b>			
W-10	Possible gas leak	POST (Power on self-test) failure comparing previous gas level with current gas level	Possible loss of helium gas. Check valves and gas tank connections. If the problem persists, call OmniGuide Service at 888-666-4484 ext 3.
W-12	Gas supply below Warning Level	Total gas supply below the <i>Gas supply low level warning threshold</i> .	Helium gas supply approaching minimum requirements. Please replace gas supply soon.
W-13	Tank Replacement Required. Laser Operation Limited	Both tanks below the <i>Gas cylinder empty pressure level</i> while in Fiber modality	Helium gas supply below minimum requirements. Gas tank replacement required.
W-14	No Gas supply	Gas pressure at or below the <i>Gas cylinder valve closed threshold</i> in one or both tanks.	No helium gas pressure found. Check valves and gas tank connections. If the problem persists, call OmniGuide Service at 888-666-4484 ext 3.

ID	Error	Condition	Displayed text
W-16	Tank Replacement Required. Laser Operation Limite	POST (Power on self-test) failure: Both tanks below the <i>Gas cylinder empty pressure</i> level at startup	Helium gas supply below minimum requirements.
<b>FOOT PEDAL</b>			
W-20	No Foot Pedal Connected	Attempt to transition to Ready mode with no foot pedal connected	READY mode not allowed - No footpedal detected.
W-21	No Foot Pedal Connected	No foot pedal connected following successful system login	No footpedal detected. Please connect footpedal to operate the laser.
W-22	Foot pedal pressed when entering READY	FP Pressed when READY button selected OR FP Pressed while in READY PENDING state.	READY mode not allowed when footpedal is pressed.
<b>SYSTEM</b>			
W-25	Maintenance Required	Current date later than the prescribed next maintenance due date	Maintenance required. Call OmniGuide Service at 888-666-4484 ext 3.
W-26	Refer to Instructions for Use for Micro-Manipulator Connection	Micro-Manipulator selected in line-of-sight modality	Refer to Instructions for Use for Micro-Manipulator Connection.
W-28	Incomplete service call	System powered up following being powered down in the middle of a service call.	Service call not completed. Maintenance Required. Call OmniGuide Service at 888-666-4484 ext 3.

## Laser System Alarms

ID	Error	Condition	Displayed text
<b>FIBER</b>			
A-01	Fiber Removed During Use	RFID presence lost by laser controller when in Ready mode	Fiber disconnected. Please reconnect OmniGuide Fiber.
A-02	RFID Communication Failure	No communication with RFID sensor when Fiber modality selected.	Communication error. Please re-start the laser system. If the problem persists, call OmniGuide Service at 888-666-4484 ext 3.
<b>LASER CONTROLLER INTERFACE</b>			
A-06	Laser Controller not responding.	No response from Laser Controller after Allowed Successive Replies Timeout Count attempts.	System error. Please restart the laser. If the problem persists, call OmniGuide Service at 888-666-4484 ext 3.
A-07	Laser Controller: Not responding to Standby Request	SBC sends STANDBY request to laser controller, but reported state is still READY after more than Allowed Successive Command Failed Count attempts.	System error. Please restart the laser.
A-08	Laser Controller: Ready State Dropped	SBC expected laser state is READY, Laser Controller reported state is STANDBY	System error. Please restart the laser. If the problem persists, call OmniGuide Service at 888-666-4484 ext 3.
A-09	Laser Controller: Power Monitoring Error	Following a change request: The SBC requested power setting differs from the Laser Controller actual power setting more than Allowed Successive Power Change Failed Count attempts	System error. Please restart the laser.
A-11	Laser Controller: Command Error	Following a change request not covered above, the SBC expected values and settings differ from the Laser Controller values and settings after Allowed Successive Command Failed Count attempts.	System error. Please restart the laser.



ID	Error	Condition	Displayed text
A-12	Parameter verification error	One or more LC parameters has changed from its expected value (condition present for more than 500ms).	System error. Please restart the laser. If the problem persists, call OmniGuide Service at 888-666-4484 ext 3.
GAS SYSTEM			
A-15	Gas Overflow error	Gas flow exceeds max specified in Gas Flow Critical Overflow deviation while in READY state	Helium gas overflow error. Please check fiber, filter and gas connections.
A-16	Gas Underflow error	Gas flow below minimum specified in Gas Flow Critical Underflow deviation while in READY state.	Helium gas underflow error. Please check fiber, filter and gas connections. If problem persists, replace with a new OmniGuide fiber or call OmniGuide Service at 888-666-4484 ext 3.
A-17	MFC Communication Failure	No communication with MFC when operating in Fiber modality	Flow controller error. Please re-start the laser system. If the problem persists, call OmniGuide Service at 888-666-4484 ext 3.
A-18	Tank input pressure out of range (one or both tanks)	Laser Controller reports 0 (zero) value for tank pressure of one or both tanks (below 0 converted value per SW-034)	Flow controller error. Please re-start the laser system. If the problem persists, call OmniGuide Service at 888-666-4484 ext 3.
A-19	MFC Failed to tare during POST	During POST, the tare function of the MFC did not correctly zero the device.	Flow controller error. Please re-start the laser system. If the problem persists, call OmniGuide Service at 888-666-4484 ext 3.
FOOT PEDAL			
A-20	Foot Pedal Malfunction	LC asserts fault bit – Foot pedal failure	Foot pedal error. Please reconnect or replace the foot pedal. If the problem persists, call OmniGuide Service at 888-666-4484 ext 3.
SYSTEM			
A-25	System Watchdog Timeout	System watchdog times out	Software error. Please re-start the laser system. If the problem persists, call OmniGuide Service at 888-666-4484 ext 3.
A-26	Thread Watchdog Timeout	Thread watchdog times out	Software error. Please re-start the laser system. If the problem persists, call OmniGuide Service at 888-666-4484 ext 3.
A-27	System Clock Failure	POST failure checking clock accuracy	Software error. Please re-start the laser system. If the problem persists, call OmniGuide Service at 888-666-4484 ext 3.
A-28	EMO Pressed	Laser Controller reports that EMO (E-Stop) is pressed	EMO (Emergency Machine Off) button pressed. Disengage EMO button to continue.
A-29	Door Interlock Active	Laser Controller reports that Door Interlock (Remote E-Stop) is active	Door interlock active. Check interlock connection or close door.
A-30	Laser Enclosure Opened	Laser enclosure is opened while in READY mode	Back panel enclosure is open. Please close back panel to continue.
A-31	Software Failure: Data Corruption	Verification of data CRC or other data validation method fails	Software error. Please re-start the laser system. If the problem persists, call OmniGuide Service at 888-666-4484 ext 3.
A-32	Software Failure: Other	Software detects a memory leak, resource failure, or some such failure	Software error. Please re-start the laser system. If the problem persists, call OmniGuide Service at 888-666-4484 ext 3
ENVIRONMENTAL			
A-35	Humidity Too High	LC asserts Humidity fault bit and Humidity reading is above 95%.	Ambient humidity too high to operate the laser. If the problem persists, call OmniGuide Service at 888-666-4484 ext 3.

ID	Error	Condition	Displayed text
A-36	Ambient Temperature Too High	LC asserts Temperature fault bit and Temperature reading is above the max operational temperature.	Ambient temperature too high to operate the laser. If the problem persists, call OmniGuide Service at 888-666-4484 ext 3.
A-37	Ambient Temperature Too Low	LC asserts Temperature fault bit and Temperature reading is below the min operational temperature.	Ambient temperature too low to operate the laser. If the problem persists, call OmniGuide Service at 888-666-4484 ext 3.
A-38	Moisture Condensation Risk	LC asserts Humidity fault bit and humidity is over 85% and temperature is over 25 C.	Ambient conditions present a high risk of moisture condensation. If the problem persists, call OmniGuide Service at 888-666-4484 ext 3.
<b>LASER TUBE OR POWER SUPPLY</b>			
A-40	Laser Tube Temperature Too High	LC HW Status: RC1 = 0; RC2 = 0; Voltage OK = 1;	Laser tube error. Call OmniGuide Service at 888-666-4484 ext 3.
A-41	Power Supply Failure	LC HW Status: RC1 = 0; RC2 = 0; Laser Voltage OK = 0 (> one second after RC1 & RC2 = 0)	Laser tube error. Call OmniGuide Service at 888-666-4484 ext 3.
A-42	SWR Fault	LC HW Status: RC1 = 0; RC2 = 0; Voltage OK = 1; Laser OK = 0;	Laser tube error. Call OmniGuide Service at 888-666-4484 ext 3.
A-43	Power Supply Did Not Start	During POST, the HW Control status relay contacts indicate that the laser power supply is not enabled (RC1 != 0 or RC2 != 0)	Laser tube error. Call OmniGuide Service at 888-666-4484 ext 3.
A-44	Power Supply Failure	During operation, the HW Control status relay contacts indicate that the laser power supply has been disabled (RC1 != 0 or RC2 != 0)	Laser tube error. Call OmniGuide Service at 888-666-4484 ext 3.
<b>LASER POWER</b>			
A-45	Tube Current Too High	Tube current higher than specified limit (20% above nominal) when laser is firing.	Laser tube error. Call OmniGuide Service at 888-666-4484 ext 3.
A-46	Tube Current Too Low	Tube current lower than specified limit (20% below nominal) when laser is firing.	Laser tube error. Call OmniGuide Service at 888-666-4484 ext 3.
A-47	Tube Current Sensor Broken	Tube current is 0	Laser tube error. Call OmniGuide Service at 888-666-4484 ext 3.
A-48	Output Power Too High	Pre-Ready power check indicates power and tube current exceed nominal value by more than 20%	Laser tube error. Call OmniGuide Service at 888-666-4484 ext 3.
A-49	Output Power Too Low	Pre-Ready power check indicates power and tube current below nominal value by more than 20%	Laser tube error. Call OmniGuide Service at 888-666-4484 ext 3.
<b>POWER DETECTOR</b>			
A-50	Power Detector Too Low	Power detector signal is more than 20% below nominal when tube current is valid for specified power	Power monitoring error. Call OmniGuide Service at 888-666-4484 ext 3.
A-51	Power Detector Too high	Power detector signal is more than 20% above nominal when tube current is valid for specified power	Power monitoring error. Call OmniGuide Service at 888-666-4484 ext 3.
A-52	Power Detector Failure (1)	Power Detector Fail fault bit asserted.	Power monitoring error. Call OmniGuide Service at 888-666-4484 ext 3.

ID	Error	Condition	Displayed text
HARDWARE			
A-60	Power Supply Relay Contacts Failure	Relay contacts are shorted	System error. Call OmniGuide Service at 888-666-4484 ext 3.
A-61	Shutter Failure (1)	Shutter does not move from Open/Close position when commanded	System error. Call OmniGuide Service at 888-666-4484 ext 3.
A-62	Shutter Failure (2)	Shutter stuck between open/close position	System error. Call OmniGuide Service at 888-666-4484 ext 3.
A-64	Laser Modality Selector Failure (1)	Laser modality selector does not move from Fiber/Arm position when commanded	System error. Call OmniGuide Service at 888-666-4484 ext 3.
A-65	Laser Modality Selector Failure (2)	Laser modality selector stuck between Fiber/Arm position	System error. Call OmniGuide Service at 888-666-4484 ext 3.

## 19.0 GUIDANCE AND MANUFACTURER'S DECLARATION

The BEACON laser system was designed to comply with IEC/EN 60601-1-2 (Group 1, Class A). "Electromagnetic Compatibility Requirements and Tests".

### Electromagnetic Emission

GUIDANCE AND MANUFACTURER'S DECLARATION ELECTROMAGNETIC EMISSION		
The Laser is intended for use in a typical commercial or hospital environment. The customer or the user of the Laser should assure that it is used in such an environment		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11 ed5.0 (with A1:2010) CISPR 32 ed2.0	GROUP 1	The Laser uses RF energy only for its internal function. Therefore, its RF emissions are very low and are unlikely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11 ed5.0 (with A1:2010) CISPR 32 ed2.0	CLASS A	The Laser is suitable for use in all establishments other than domestic and those directly connected to the low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics emissions IEC 61000-3-2 ed4.0 (2014-05)	CLASS A	If it is used in a residential environment this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Flicker emissions IEC 61000-3-3 ed3.0 (2013-05)	PASS	

## Electromagnetic Immunity

GUIDANCE AND MANUFACTURER'S DECLARATION ELECTROMAGNETIC IMMUNITY			
The Laser is intended for use in a typical commercial or hospital environment. The customer or the user of the Laser 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 ed2.0 (2008-12)	± 8 kV contact ± 15 kV air	complies with IEC 60601	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 ed3.0 (2012-04)	± 2 kV for AC mains power lines  ±1 kV for signal input/output lines	complies with IEC 60601	Mains power quality should be that of a typical commercial or hospital environment.
Surges Immunity IEC 61000-4-5 ed3.0 (2014-05)	± 2 kV	complies with IEC 60601	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 ed2.0 (2004-03)	0 % UT (100% dip in UT) for 0.5 cycle  0 % UT (100 % dip in UT) for 1 cycle  70 % UT (30 % dip in UT) for 25 cycles  110VAC/60Hz 240VAC/50Hz	complies with IEC 60601	Mains power quality should be that of a typical commercial or hospital environment. If the user of the laser requires continued operation during power mains interruptions, it is recommended that the Laser be powered from an uninterruptible power supply or a battery.
Power frequency magnetic field IEC 61000-4-8 ed2.0 (2009-09)	30 A/m 50/60 Hz	complies with IEC 60601	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: $U_r$ is the AC main voltage prior to the application of the test level			

## Electromagnetic Immunity II

Immunity test	IEC 60601-test level	Compliance level
Radiated, Radio-Frequency, Electromagnetic Immunity IEC 61000-4-3 ed3.0 (with A1:2007+A2:2010)	3 V/m $V_{off}$ 80 MHz to 6000 MHz	3 V/m $V_{off}$ conforms to IEC 60601
Conducted, Radio-Frequency, Electromagnetic Immunity Test IEC 61000-4-6 ed2.0 (with A1:2004+A2:2006)	3V <sub>rms</sub> / 6V <sub>rms</sub> 150 kHz to 80 MHz	3V <sub>rms</sub> / 6V <sub>rms</sub> conforms to IEC 60601

Immunity test	IEC 60601-test level	Compliance level																																																																
Immunity to Proximity Fields from FR Wireless Communications Equipment  IEC 60601-1-2, Table 9	<b>Table 9 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment</b>																																																																	
	<table border="1"> <thead> <tr> <th>Test frequency (MHz)</th> <th>Band <sup>a)</sup> (MHz)</th> <th>Service <sup>a)</sup></th> <th>Modulation <sup>b)</sup></th> <th>Maximum power (W)</th> <th>Distance (m)</th> <th>IMMUNITY TEST LEVEL (V/m)</th> </tr> </thead> <tbody> <tr> <td>385</td> <td>380 – 390</td> <td>TETRA 400</td> <td>Pulse modulation <sup>b)</sup> 18 Hz</td> <td>1.8</td> <td>0.3</td> <td>27</td> </tr> <tr> <td>450</td> <td>430 – 470</td> <td>GMRS 460, FRS 460</td> <td>FM <sup>c)</sup> ± 5 kHz deviation 1 kHz sine</td> <td>2</td> <td>0.3</td> <td>28</td> </tr> <tr> <td>710</td> <td rowspan="3">704 – 787</td> <td rowspan="3">LTE Band 13, 17</td> <td rowspan="3">Pulse modulation <sup>b)</sup> 217 Hz</td> <td rowspan="3">0.2</td> <td rowspan="3">0.3</td> <td rowspan="3">9</td> </tr> <tr> <td>745</td> </tr> <tr> <td>780</td> </tr> <tr> <td>810</td> <td rowspan="3">800 – 960</td> <td rowspan="3">GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5</td> <td rowspan="3">Pulse modulation <sup>b)</sup> 18 Hz</td> <td rowspan="3">2</td> <td rowspan="3">0.3</td> <td rowspan="3">28</td> </tr> <tr> <td>870</td> </tr> <tr> <td>930</td> </tr> <tr> <td>1 720</td> <td rowspan="3">1 700 – 1 990</td> <td rowspan="3">GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25; UMTS</td> <td rowspan="3">Pulse modulation <sup>b)</sup> 217 Hz</td> <td rowspan="3">2</td> <td rowspan="3">0.3</td> <td rowspan="3">28</td> </tr> <tr> <td>1 845</td> </tr> <tr> <td>1 970</td> </tr> <tr> <td>2 450</td> <td>2 400 – 2 570</td> <td>Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7</td> <td>Pulse modulation <sup>b)</sup> 217 Hz</td> <td>2</td> <td>0.3</td> <td>28</td> </tr> <tr> <td>5 240</td> <td rowspan="3">5 100 – 5 800</td> <td rowspan="3">WLAN 802.11 a/n</td> <td rowspan="3">Pulse modulation <sup>b)</sup> 217 Hz</td> <td rowspan="3">0.2</td> <td rowspan="3">0.3</td> <td rowspan="3">9</td> </tr> <tr> <td>5 500</td> </tr> <tr> <td>5 785</td> </tr> </tbody> </table>	Test frequency (MHz)	Band <sup>a)</sup> (MHz)	Service <sup>a)</sup>	Modulation <sup>b)</sup>	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	385	380 – 390	TETRA 400	Pulse modulation <sup>b)</sup> 18 Hz	1.8	0.3	27	450	430 – 470	GMRS 460, FRS 460	FM <sup>c)</sup> ± 5 kHz deviation 1 kHz sine	2	0.3	28	710	704 – 787	LTE Band 13, 17	Pulse modulation <sup>b)</sup> 217 Hz	0.2	0.3	9	745	780	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation <sup>b)</sup> 18 Hz	2	0.3	28	870	930	1 720	1 700 – 1 990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25; UMTS	Pulse modulation <sup>b)</sup> 217 Hz	2	0.3	28	1 845	1 970	2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation <sup>b)</sup> 217 Hz	2	0.3	28	5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation <sup>b)</sup> 217 Hz	0.2	0.3	9	5 500	5 785	Conforms to IEC 60601, Table 9
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	870																																																																	
	930																																																																	
	1 720	1 700 – 1 990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25; UMTS	Pulse modulation <sup>b)</sup> 217 Hz	2	0.3	28																																																											
	1 845																																																																	
	1 970																																																																	
	2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation <sup>b)</sup> 217 Hz	2	0.3	28																																																											
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation <sup>b)</sup> 217 Hz	0.2	0.3	9																																																												
5 500																																																																		
5 785																																																																		
NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT OR ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.																																																																		
<sup>a)</sup> For some services, only the uplink frequencies are included.																																																																		
<sup>b)</sup> The carrier shall be modulated using a 50 % duty cycle square wave signal.																																																																		
<sup>c)</sup> As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.																																																																		

## 20. REFERENCES

Lasers: The Perioperative Challenge, Kay A. Ball, Mosby Publishing, ISBN 081510524X

- Lasers and Optical Fibers in Medicine, Abraham Kazir, Academic Press, ISBN 0124019404
- Laser Surgery and Medicine, Principles and Practice, Carmen A. Puliafito, John Wiley & Sons, ISBN 0471120707
- Medical Laser Endoscopy, Dennis M. Jensen, Kluwer Academic Publisher, ISBN 07920305795
- Medical Lasers and Their Safe Use, D.H. Sliney & S.L. Trokel, Springer-Verlag, ISBN 3540978569

## 21.0 PRODUCT INFORMATION

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