

Odyssey 30/XE User's Manual



CONVERGENT LASER TECHNOLOGIES

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Odyssey 30 B/XE User's Manual
Convergent Document No. 210627 Version 2.3

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Convergent Laser Technologies is a subsidiary of Xintec Corporation.
900 Alice Street, Oakland, CA 94607 USA

Printed in U.S.A.
May 2002

Odyssey 30/XE User's Manual

Introduction

The Odyssey surgical laser system and accessories are designed for use in the treatment of soft tissue disease and urinary stones. The laser system emits a concentrated beam of invisible radiation that may cause injury to the user or patient if improperly used. Prior to operating the laser system, the user and operating room personnel should be familiar with laser safety and the proper use of the laser system and its accessories. The user should carefully read and understand the contents of this Manual and accompanying documentation before using the laser to treat a patient.

How to Use This Manual

Chapter 1, "Introduction," introduces the Odyssey laser system and its theory of operation.

Chapter 2, "Installation," outlines the procedure for site preparation and installation of the laser system.

Chapter 3, "Safety," provides information on regulatory compliance and the safe use of the laser system.

Chapter 4, "Indications" provides the physician with precautions, indications, and contraindications related to the intended use of the laser system.
















Chapter 5, "Operation," describes laser system controls and indicator signals. This chapter also outlines standard operating procedures.

Chapter 6, "Maintenance," provides maintenance procedures and a troubleshooting guide.

Chapter 7, "Customer Service," contains contact information for ordering accessories, obtaining warranty repair, or general service requests.

Symbols

The following table lists the symbols used on the laser system and within this Manual. The placement of the labels are diagrammed in Chapter 3. Additional symbols used on the touch screen interface are described in Chapter 5.

		
Refer to Manual for additional instructions or warnings	WARNING Dangerous voltage	WARNING—Visible and invisible laser radiation
		
Non-AP equipment	Type BF medical equipment	Emergency Stop
		
Alternating current	Mains ON <i>isolation transformer energized</i>	Mains OFF <i>no power to entire laser system</i>
		
Key switch OFF <i>isolation transformer may be energized</i>	Standby state	Ready state
		
Remote interlock	Optical fiber applicator	Foot switch <i>laser activation device</i>

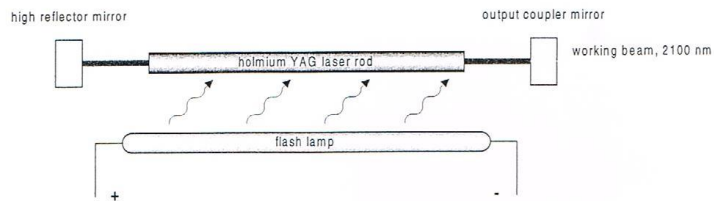
Holmium Laser Theory of Operation

The Odyssey is a pulsed holmium YAG laser emitting laser radiation at 2100 nm. The holmium wavelength is highly absorbed by water making it superior for tissue ablation with minimal lateral thermal damage. In the case of laser lithotripsy, laser energy vaporizes water in the calculus causing it to crumble into smaller particles that pass easily through the urinary tract.

A laser, an acronym for Light Amplification by Stimulated Emission of Radiation, produces a highly concentrated beam of light of a given wavelength. In contrast, white light, such as sunlight, is composed of light throughout the electromagnetic spectrum—from ultraviolet (UV), through visible light (i.e. the rainbow), to infrared (IR).

Laser energy is generated by converting electrical energy to light energy using a flash lamp. The flash lamp energy is then used to excite the lasing medium, in this case a holmium YAG laser rod. The laser energy is amplified in the laser resonator cavity and a small portion of the energy is allowed to leak out. This becomes the working laser beam.

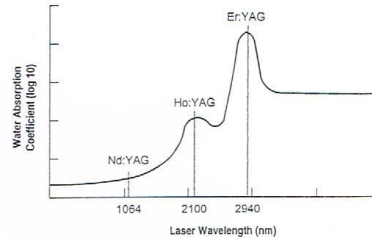
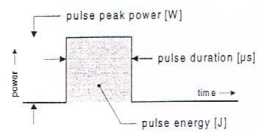
The Odyssey is a flash lamp pumped solid-state laser. The flash lamp converts electrical energy to optical energy and the resonator mirrors amplify the optical energy.



Laser Power Parameters

Lasers are useful in medical applications because of selective absorption of their energy by tissue. Since a laser emits light energy at a distinct wavelength, a laser wavelength is chosen that best matches the desired absorption characteristics for the target tissue.

In general, holmium lasers (2100 nm) are better at ablating tissue than Nd:YAG lasers (1064 nm) because the holmium wavelength is readily absorbed by water, which constitutes a major portion of tissue. However, the Nd:YAG wavelength transmits easily through water, making it more suitable for coagulation and for generating thermal effects. The erbium laser (2940 nm) is superior at ablation, but the lack of commercially available fiber-optics makes it unsuitable for endoscopic procedures.



A laser's water absorption characteristics coupled with the mode of laser delivery governs its clinical efficacy.

Though laser wavelength is the primary governing factor in tissue interaction, the mode of laser delivery, or power parameter, determines its clinical effectiveness. For pulsed lasers like the Odyssey, the mode of laser delivery depends on the pulse peak power, energy density, pulse duration, and repetition rate.

Most pulsed laser systems are rated by their highest attainable average power. Average power (P , measured in Watts) is calculated by multiplying the pulse energy (E , measured in Joule per pulse) with the repetition rate (f , measured in pulses per second or Hz). For example, the Odyssey 30 is capable of delivering 3.0 J/pulse at 10 Hz making it a 30 Watt laser system. Note that useful laser power should be measured at the operating plane and not out of the laser resonator cavity.

Energy Density

Energy density is one of the most important laser operating parameters for safe and effective laser surgery. Energy density is proportional to the pulse energy and inversely proportional to the square of the beam diameter.

$$\text{energy density [J / cm}^2\text{]} \propto \frac{\text{pulse energy [J]}}{\text{beam diameter [mm]}^2}$$

For example, switching from a 400 micron core fiber (0.4 mm) to a 200 micron core fiber (0.2 mm) results in an energy density that is four times greater than before.

The selection of appropriate power parameters is dependent on the procedure, the selection of delivery system, and the specific conditions of the patient. Before using the laser system on a patient, the user should have attended a training course on the specific procedure and have consulted fellow physicians on the latest clinical techniques, indications, and contraindications.

Unique Features of the Odyssey 30/XE

- *Controlled Delivery*—Microprocessor controlled delivery insures precise power delivery and pulse-to-pulse uniformity.
- *Ease of Use*—Touch screen user interface reduces the number and type of controls to a bare minimum. A status line at the bottom of the screen alerts the user in the event of a safety hazard or system error. Motorized blast shield facilitates blast shield changes without removing any access panels.
- *200 Micron Fiber Capable*—Specially designed optics and mounts allow laser energy to be delivered into a straight 200 micron core fiber without the need for expensive tapered fibers.
- *Variable Pulse Duration*—Allows the user to easily change the mode of laser delivery and shift between ablative or coagulative tissue effects.
- *Safety*—A safety monitor continuously monitors every subsystem and automatically sets the laser system to Standby state in the event a potential hazard is detected.

System Specifications

<i>Model</i>	Odyssey 30	Odyssey XE
<i>Laser Type</i>	Pulsed CTH:YAG (holmium:YAG)	
<i>Laser Wavelength</i>	2100 nm	
<i>Maximum Average Power</i>	30 W ¹	15 W
<i>Pulse Peak Power</i>	1.14 to 7.1 KW	1.14 to 3.5 KW
<i>Pulse Duration</i>	350, 700 μ s	
<i>Pulse Energy</i>	0.4 to 3.0 J	0.4 to 1.5 J
<i>Repetition Rate</i>	5 to 20 Hz	5 to 12 Hz
<i>Visible Aiming Beam</i>	Variable intensity 3 mW green, 532 nm	
<i>Laser Activation</i>	Foot switch	
<i>Cooling System</i>	Self-contained water-to-air	
<i>Physical Dimensions</i>	102 cm H x 40 cm W x 84 cm D (40" H x 16" W x 33" D)	
<i>Weight</i>	90 Kg (200 lb)	
<i>Electrical Requirements²</i>	115/230 V~, 15 A single-phase 50/60 Hz, 2.3 KVA	
<i>Regulatory Compliance</i>	US CFR 1040.10, 1040.11	
<i>Safety Compliance</i>	UL/CSA 2601, EN 60601-1-1, EN 60825-1, EN 60601-2-22, EN 60601-1-2 (EMC)	

¹ 30 W average power achievable with 230 V~ input and 600 micron core fiber.
² See Chapter 2 for more complete electrical requirements.

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2

Installation

Unpacking the Laser System

Your Odyssey laser system is shipped from the factory in a wooden crate to protect the laser system from damage during shipping. Before uncrating, inspect the crate for damage. If there is evidence of damage, save all packing materials and notify the shipping company by filing an insurance claim report.

A Convergent sales or service representative will help you with the installation of your new laser system upon request. If you have any questions, please contact customer service (see Chapter 7). After the laser system has been unpacked, please store the shipping crate and packing materials in a safe location in case the laser system has to be transported in the future.

Component Checklist

The Odyssey laser system is delivered with the following components or accessories. Please take inventory of the below items and contact customer service if there are any missing items.

- Odyssey 30 or XE laser system
- User's manual
- Product performance certificate
- Dust cover
- Detachable power cord with NEMA L6-30P plug
- Detachable foot switch
- Remote interlock connector (attached to laser system)
- 2 keys
- Top panel key
- 600 micron core test fiber assembly with flat tip

Optional Accessories

The following list includes the most common accessories used with the Odyssey. Please refer to Convergent's product catalog for additional information and pricing.

AR2430	Laser Safety Sign, 40 W CTH:YAG, 3 mW 532 nm
AR2060	Laser Safety Spectacles (1.064 to 10.4 mm), clear lens
AR2050	Laser Safety Goggles (1.064 to 10.4 mm), clear lens
SMH1020F	SMA IQ 200 micron core low OH fiber assembly with flat tip
SMH1040F	SMA IQ 400 micron core low OH fiber assembly with flat tip
SMH1060F	SMA IQ 600 micron core low OH fiber assembly with flat tip
SMH1010F	SMA IQ 1000 micron core low OH fiber assembly with flat tip
SMH6060A	SMA IQ 600 micron core low OH angled delivery fiber assembly
LP3015	Blast shield assembly, 6 per disk
TE3050M	Energy probe calibrated for 2100 nm
TE3040M	Energy meter for use with TE3050M

Registering Your Laser System

Once installed, please be sure to register your laser system. You can register your laser system by calling Customer Service or send an e-mail to service@convergentlaser.com. Please include the serial number of your laser system when contacting us.

By registering your laser system, you will be notified of product safety bulletins and updates to the software and documentation. In addition, timely registration will allow you access to Convergent's technical support staff and on-line knowledge base.

The laser system must be registered within 30 days of installation in order to activate and qualify for the manufacturer's warranty. The manufacturer's warranty is only applicable to the original owner of the laser system and is non-transferrable except by prior written consent from Convergent Laser Technologies. See Chapter 7 for additional warranty information.

Electrical Requirements

The Odyssey is equipped with a worldwide tappable isolation transformer, which can be configured to suit your line voltage conditions. The laser system will perform optimally if has its own dedicated, stable electrical supply line. Measure the alternating current (“AC”) line voltage with and without load to verify that the electrical supply line is stable. Please contact customer service to request the technical bulletin on reconfiguring the transformer.



DANGER—High Voltage—Only a qualified service technician or biomedical engineer can reconfigure the isolation transformer. A mistapped transformer may cause serious harm to the technician and/or damage the laser system.

<i>Nominal Outlet Voltage</i>	115 V~	230 V~
<i>Voltage Range</i>	103-127 V~	207-253 V~
<i>Current Rating</i>	15 A	10 A
<i>Maximum Output Power</i>	15 W	30 W

The maximum output power is dependent on the line voltage. When the input voltage is 115 V~, the software limits the output power to 15 W. At 230 V~, the laser system is capable of delivering full power.

Ambient Operating Conditions

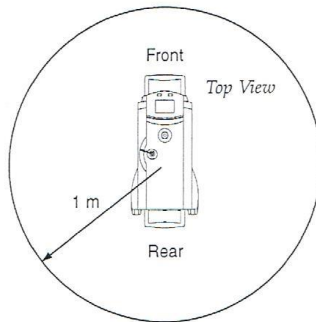
The laser system should be used in a well-ventilated, air-conditioned operating room. The procedure room temperature should be kept between 18-22 C (65-72 °F) for optimum system performance. Holmium lasers in general are very sensitive to temperature, and the output can vary by up to 15% depending on the room temperature. The laser system is factory calibrated at 21 C (70°F).

When the laser system reaches above 38 C (100 °F), the safety circuits will prevent the laser system from operating. The touch screen status readout will display "11: System Overheat." The laser system overheats for the following reasons:

- the ambient operating room temperature is above 24 C (74 °F),
- the laser system has been running at high power for an extended period of time (greater than 20 minutes), or
- the input line voltage is lower than normal causing the cooling fans or water pump to under-perform.

Space Requirements

The laser system requires adequate space to reduce potential operating hazards and allow for proper air ventilation. The cooling system contains two radial fans located at the bottom of the laser system. Cooling air is drawn from the bottom of the unit and exhausted through the vents located on the right, left, and back sides of the laser system. There should be a clearance of at least a 1 meter (3 ft) on each side of the system to allow for proper airflow.



Allow about 1 meter on all sides of the laser to allow for adequate ventilation.

To reduce potential operating hazard, the laser system should be positioned at least 1 meter (3 ft) from the patient.



The procedure room should be in a controlled access area. If necessary, install the remote interlock switch to prevent inadvertent laser exposure to unsuspecting personnel entering the operating room. A laser danger sign must be posted on each operating room access door. Please consult your Laser Safety Officer for applicable laser safety procedures.

Initial System Power ON

Review the previous sections in this chapter and verify that all site installation requirements have been met. The laser system should only be operated in a restricted access area. Post a laser danger sign on each access door.

- 1 Plug the detachable power cord into the laser system.
- 2 Verify that the Mains switch is in the OFF (O) position.
- 3 Verify that the key switch is in the OFF (O) position.
- 4 Plug the outlet end of power cord to a suitable electrical outlet.
- 5 Verify that the remote connector is secured.
- 6 Plug the detachable foot switch into the connector on the back panel.
- 7 Raise the fiber mast to the upright position.
- 8 Lift the laser aperture door and insert the 600 micron test fiber into laser aperture.



Do not overtighten the delivery system connector. The connector only needs to be finger-tight for proper operation.

- 9 Turn ON (I) Mains switch.
- 10 Turn ON (I) the key switch. The yellow Standby LED is lit. After 5 seconds, the touch screen displays the user power settings screen. The touch screen status displays "STANDBY." An icon appears on screen indicating that a 600 micron core fiber has been properly connected.

- 12 Press the Ready button. The green Ready LED is lit.
- 13 If the touch screen status displays "READY" after 2 seconds, then the system is operating normally. If not, please consult the troubleshooting guide in Chapter 6 or call Convergent technical support.
- 14 Follow the instructions in the next section to verify the alignment and calibration.

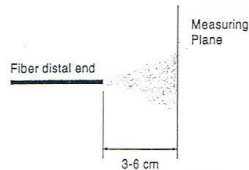
Verifying Alignment and Calibration

The laser system has been designed with many safeguards to prevent optical misalignment due to shipping and normal operation. However it is important to verify the alignment and calibration of the laser system to insure peak system performance. The following test requires a calibrated energy or power meter. Please contact Convergent technical support if you would like to know if your energy or power meter is compatible with the Odyssey.

The test below is intended for laser systems operating at 230 V~ nominal. Skip step 12 if you are operating the laser system using a 115 V~ electrical outlet.



- 1 Setup laser system for lasing.
- 2 Verify that the 600 micron test fiber has clean surfaces on both the connector and distal ends.
- 3 Insert the 600 micron test fiber into the laser aperture.
- 4 Setup energy/power meter probe in front of and parallel to the distal face of the test fiber. Be careful not to place the fiber tip too close to the probe as the energy density may damage the probe's sensitive surface.



Do not place the distal tip of the fiber too close to the probe as the high energy density may destroy the probe's sensitive coatings.

- 5 Wear appropriate safety eyewear.



All personnel in the operating room while the laser is in operation must wear appropriate laser eyewear. The working beam is invisible and can cause irreparable eye damage. Do not stare into the beam even through laser eyewear.

- 6 Set the power parameters to 350 μ s, 7 Hz, 0.5 J (3.5 W).
- 7 Press the Ready button and wait 2 seconds.
- 8 Depress the foot switch for 5-10 seconds until you get a stable reading on your energy/power meter.
- 9 If the power reading is not within 10% of the displayed power, the laser system is either misaligned or out of calibration. Please contact Convergent technical support.
- 10 Repeat steps 7-9 for 350 μ s, 10 Hz, 1.5 J (15 W).
- 11 Inspect connector end of fiber for burn marks. If there is a burn mark, the laser system is out of alignment. Please contact Convergent technical support.
- 12 (230 V~ systems only) Repeat steps 7-9 & 11 for 350 μ s, 10 Hz, 3.0 J (30 W).
- 13 Follow instructions in Chapter 5 to shut down the laser system.



If you receive an under-power warning message, the most likely cause is that the resonator mirrors are slightly out of alignment. The laser will continue to operate normally. Contact Convergent service at next opportunity

3

Safety

Introduction

This chapter contains important safety information related to the use of the laser system. All operating room personnel should familiarize themselves with the contents of this chapter before operating or assisting in the operation of the laser system. All efforts have been made to minimize hazardous conditions during system design. But since the laser system is high power equipment, it is impossible to eliminate all potential hazards that may result in user and patient injury.

The Odyssey is classified as a Class IV laser system by the National Center for Devices and Radiological Health (CDRH). Class IV represents the highest class of laser devices. Laser energy should only be applied to the intended treatment area.

Optical Hazards



- The working beam is invisible and can cause irreparable eye damage. Only direct the optical fiber at the intended surgical site.
- Do not look directly at the distal end of the optical fiber or into the laser aperture.
- All persons in the operating room must wear appropriate safety eyewear while the laser is in operation. Eye damage can occur not just by direct viewing of the working beam but also through scattered laser radiation when reflected off smooth surfaces such as operating room walls, floors, and other surgical equipment.

Electrical Hazards



- Only a qualified service technician may remove the enclosure covers. Removing the enclosures exposes personnel to potential electrical hazards. **There are no user serviceable parts within the laser system.**
- Do not touch areas marked HIGH VOLTAGE. These and surrounding components in the laser system contain charge voltages of up to 1000 VDC.
- Do not operate the laser system if the procedure room floor is flooded.

Other Hazards

- RISK OF FIRE—Do not direct the distal end of the fiber on flammable materials such as surgical drapes.
- RISK OF EXPLOSION—Do not operate the laser system in the presence of flammable substances including flammable anesthetics.

Safety Indicators

- Standby state yellow LED, located on the Standby button on the control panel, indicates that the laser system is in Standby state. Depressing the foot switch will NOT activate the laser.
- Laser Ready indicator green LED, located on the Ready button on the control panel, indicates that the laser system is in Ready state—no system errors are present and the touch screen is displaying the user power settings screen. Depressing the foot switch will activate the laser.

When switching from Standby state to Ready state, there is a two second delay to allow time for laser operator to give adequate notice to operating room personnel.



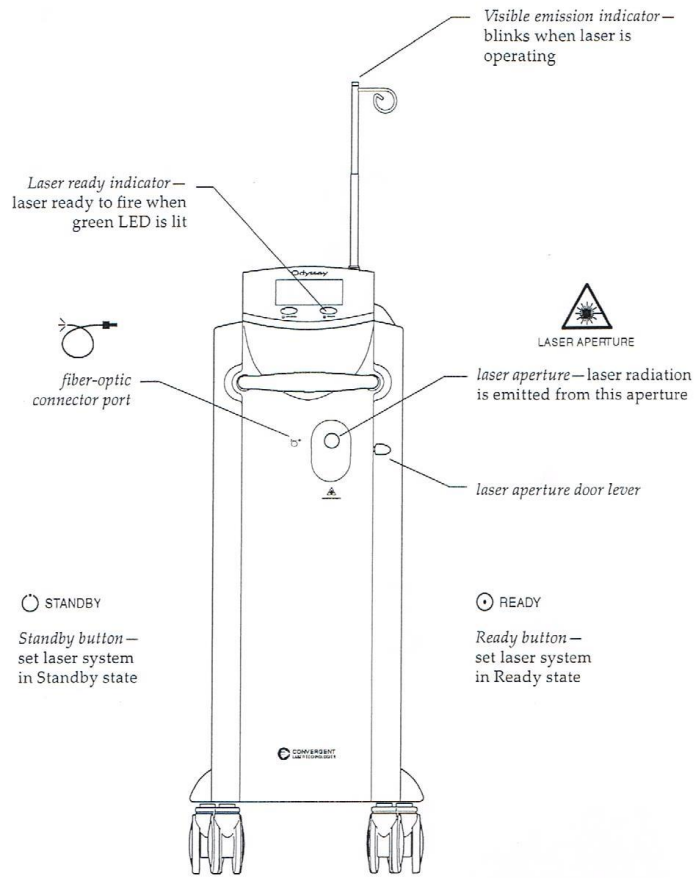
- Capacitor charge indicator icon, located on the lower right corner of the touch screen display, indicates whether the main capacitor bank has no charge, is half charged, or is fully charged.
- Audible emission warning alerts operating room personnel that the laser is firing.
- Visible emission indicator (blinking amber LED), indicates that the laser is firing. The audible and visible emission indicators operate simultaneously.
- Status readout, located on the lower left corner of the touch screen display alerts the user of any internal system errors. The error codes are referenced in Chapter 6.

In the event of a system error, the laser system will immediately return to Standby state and the Status readout will display a corresponding error code.

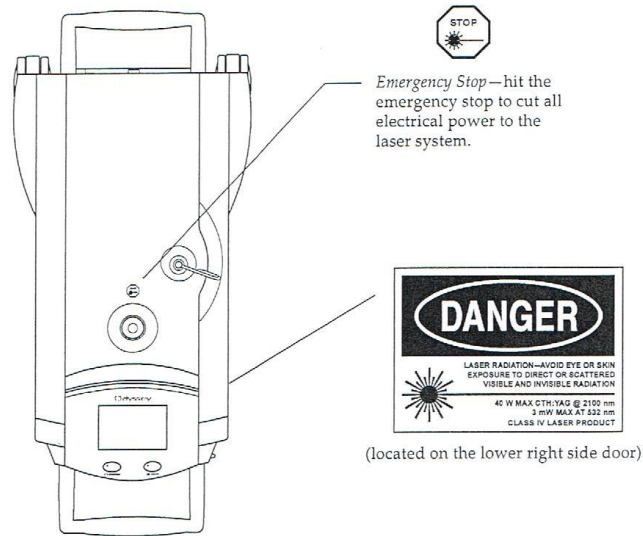


Labeling

The Odyssey contains all appropriate labels to satisfy U.S. Food and Drug Administration (FDA), Underwriter's Laboratory (UL), European Union (CE), and Canadian Standards Association (CSA) medical laser device labeling requirements.

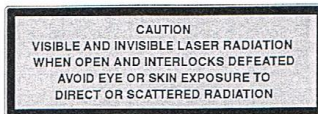


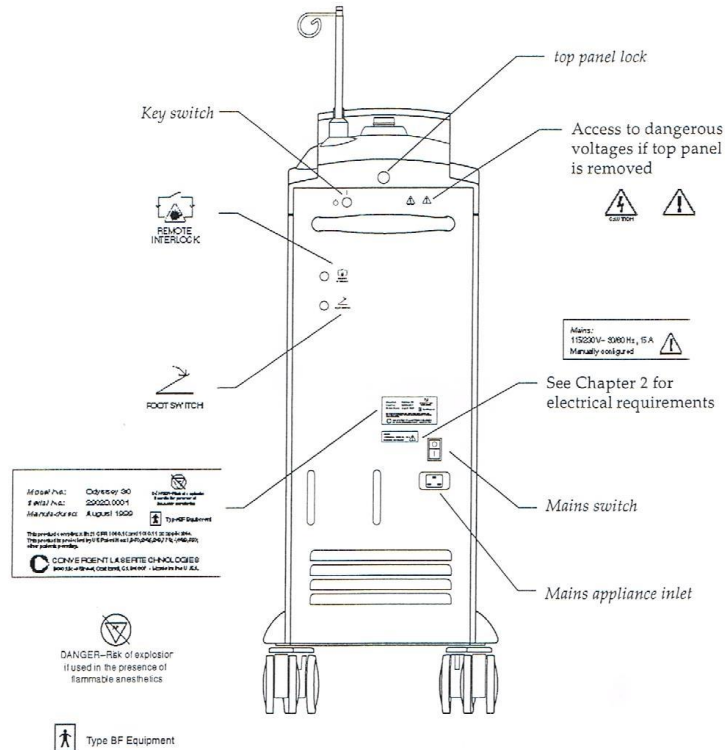
Odyssey 30 Front View



Odyssey 30 Top View

The following explanatory label is located on the cover to the optical platform. When this interlocked cover is removed, hazardous laser radiation may be emitted from the laser head into the operating room. Access to this panel is restricted to authorized service personnel.





This equipment is designed to provide an adequate degree of protection against electric shock particularly regarding allowable leakage currents and reliability of the protective earth connection

Odyssey 30 Back View

4

Indications

Physician Training

Physician training should include all of the following areas, which are often performed chronologically in the order listed below:

- 1 The physician should thoroughly review published literature related to the holmium laser procedures. These include literature pertaining to general laser biology and specific treatment techniques for a particular disease entity. The physician should also review similar modalities in related specialties and similar indications using other types of lasers such as Nd:YAG, Er:YAG and CO₂ wavelength lasers.
- 2 The physician should attend training courses and seminars at medical conferences related to holmium laser procedures. At these conferences, there are a number of courses on laser therapy which discuss the latest surgical techniques, precautions, indications, and contraindications.
- 3 The physician should attend hands-on workshops offered at medical conferences or available in your local area.
- 4 The physician should attend didactic courses that include both seminar and laboratory sessions.
- 5 Where possible, the physician should visit other physicians who are performing similar or related laser therapy to observe cases and discuss different aspects of the procedures.

General Information and Precautions

Indications

The Odyssey laser system and accessories are intended solely for the use of properly trained and qualified physicians. The laser system is indicated for use in ENT, oral and thoracic surgery, soft tissue dentistry, neurosurgery, GI/GU, gynecology, general and plastic surgery, dermatology, orthopedics, podiatry, and related procedures where laser incision, hemostasis, vaporization, and ablation are indicated.

The use of the laser system for an application is at the physician's discretion except in cases where contraindicated.

Warnings

- Unexpected or uncontrolled tissue damage can sometimes occur due to excessive power application. Use only the lowest pulse energy settings required to achieve the desired tissue effects. Extreme caution should be employed until the biological interaction of the laser energy with tissue is fully understood by the physician.
- As with conventional endoscopic and laparoscopic treatment, the possibility of adverse reactions such as chills, fever, edema, and hemorrhage may occur following treatment. In extreme cases, death may occur either due to procedural complications, concurrent illness, or laser application.

Precautions

- Use caution with patients who have had difficulty with previous endoscopic or laparoscopic procedures.
- The laser should be used only on tissue target that is fully observable either by direct sight or through an endoscope.
- Vaporization or excision of anatomical structures in proximity to known critical structures such as large arteries, veins, bowel, ureter, bladder, etc. should be performed carefully to avoid lasing of such structures.
- Electrocautery should be easily accessible in the event that a bleeding artery or vein needs to be cauterized.

- The flammability of methane gas must be considered when treating in the perianal area.

Clinical Parameters

- The holmium laser wavelength (2100 nm) has been shown to be a safe and effective tool for ablation, excision, and coagulation of a variety of soft tissues as demonstrated by numerous clinical studies and pre-clinical experience. The depth of laser incision is dependent on the power parameters (see Chapter 2). The rate of incision is dependent on the pulse frequency or repetition rate. Optimum incision of tissue is accomplished by balancing the depth and rate of the incision being formed.
- If a surgical probe is used in contact mode with the tissue, the localized heating may cause the distal end of the fiber to deform.
- Please consult the specific sections of this chapter for additional clinical information. The most up-to-date clinical indications can be collected through the sources listed in the Physician Training section of this chapter.

Usage Recommendations

- The holmium laser wavelength is strongly absorbed by water and is generally considered as an effective tool for tissue ablation with minimal lateral thermal damage.
- When the surgical probe is used in non-contact mode, the working beam is diverging at approximately 30°. The energy density decreases as the distal tip moves further from the target tissue (see Chapter 2). Approximately 2-30% of the working beam may be lost to backscatter of which a portion may be absorbed by non-targeted peripheral tissue.
- When using the surgical probe in non-contact mode, place the distal tip in contact with tissue before activating the laser. Discontinue power delivery as the fiber tip is being disengaged from the tissue to minimize the adhesion of tissue to the fiber tip.
- When selecting power parameters, always select the lowest power parameters to achieve the desired tissue effect. Start with the lowest reasonable setting and gradually increase power if necessary.

Urology

Indications

Incision, excision, coagulation, ablation, therapeutic thermal or photodisruption of all tissue and treatment of tumors and stones in the pulmonary, gastroenterology, and genitourinary tracts, and specifically for the fragmentation of upper and lower tract urinary calculi including cystine, calcium oxalate, monohydrate, and calcium oxalate dihydrate stones.

Warnings

- Extreme caution should be used until the physician is completely familiar with the biological interactions of laser with various tissue types.
- Do not operate the laser if the operating plane is not visible either by direct sight or via an endoscope.
- Steady the distal tip of the fiber at the intended treatment target before depressing the foot switch.
- Tissue perforation can occur if excessive laser energy is applied, whether through excessive pulse energy or extended laser application dwell time.
- When risk of air embolism is present, such as cutting/vaporizing organs with large vascular structures, always use fluid cooling.
- Screen tumors that are in close proximity to know arteries or veins by pretreatment workups to precisely locate the tumors.
- "Flash" fire can occur during pulmonary procedures. Do not use general inhalation anesthetics. Oxygen levels in the procedure room must not be higher than 30%.
- The risk of combustion, perforation, and laser-induced hemorrhage, any of which can cause patient death, must be fully explained to the patient prior to surgery.
- Endoscopic treatment may result in adverse reactions such as fever, chills, sepsis, edema, and hemorrhage. In extreme cases, death may occur due to procedural complications, concurrent illness, or the application of laser radiation.

Precautions

- Use caution when treating patients who have had difficulty with previous endoscopic procedures.
- When radiotherapy and laser therapy are used concurrently, extra precautions should be taken including conducting a more stringent postoperative monitoring. Patients who have undergone radiotherapy present a greater risk of perforation and tissue erosion.
- Use caution with patients who have had previous esophageal/tracheal fistulae or episodes of aspiration.
- Discontinue laser therapy immediately if the patient develops any cardiopulmonary problems.
- Convergent Laser Technologies has no clinical information or experience concerning the use of the Odyssey on pregnant women or nursing mothers.
- Patients who have experienced discomfort during previous laser treatment may require analgesics.

Complications & Risks

- The following complications can cause patient death:
 - Non-thermal**—Perforation, aspiration, induced hemorrhage, allergic reaction to medication, hypertension, arrhythmia, pain, gas over-distention, pneumothorax, and infection.
 - Thermal Acute**—Induced hemorrhage, ulceration, perforation, edema, pain, fever, leukocytosis, and chills.
 - Thermal Chronic**—Delay in healing, perforation, delayed hemorrhage, and sepsis.
- After esophageal procedures, swallowing may be paradoxically worsened rather than immediately improved. This is caused by secondary tissue edema. This potential problem should be explained to the patient prior to surgery.

- *Pain*—Short-lived pain may occur immediately following endoscopic laser therapy and may persist for as long as 48 hours.
- *Fever & Leukocytosis*—Immediately after laser therapy, the patient may experience fever and leukocytosis, which are commonly associated with tissue destruction. These conditions are generally resolved without treatment. Tissue cultures are indicated to exclude the possibility of infection.
- *Bleeding*—Patients may experience bleeding at the surgical site or from erosion of a tumor during or after laser therapy. Post treatment blood studies, such as hematocrit levels, may be necessary.
- *Sepsis*—Laser-ablated tissue may become infected after therapy. If a question of sepsis exists, a culture should be taken and other appropriate evaluations made.
- *Perforation*—Perforation can occur as a result of excessive exposure to laser radiation. Perforation can also occur from tumor erosion, or as a result of endoscopic, cystoscopic, or bronchoscopic procedures. To clinically diagnose perforation, patients must be monitored postoperatively through physical signs, hematocrit, and radiography.
- *Gas Over-distention & Pneumothorax*—Patients may experience gastrointestinal distension or pneumothorax during or after therapy.

Contraindications

The use of the holmium laser is contraindicated for patients:

- who are inappropriate candidates for laser surgery
- who are intolerant of anesthesia

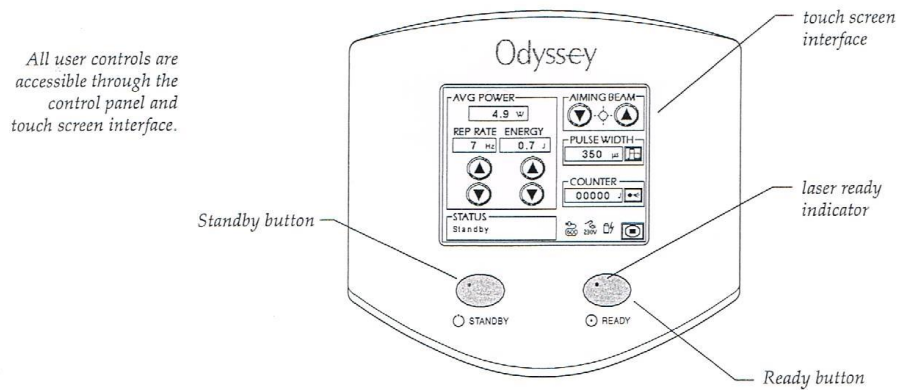
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5

Operation

Introduction

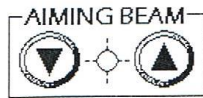
The Odyssey laser system user interface is feature-rich and intuitive. The touch screen display allows you to precisely control your laser parameters. The laser system is intended for use only by physicians trained in the therapeutic use of holmium lasers. Before operating the laser, the user should be familiar with the safety precautions noted in Chapter 3 and the clinical indications noted in Chapter 4. In addition, all operating room personnel should be trained in laser safety.



Navigating the User Interface

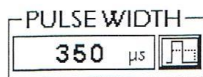
The user mode touch screen interface is separated into two screens: user power settings screen and user options screen. All necessary operating controls are located on the user power settings screen. To prevent inadvertent laser exposure, the laser system can only lase when the touch screen is displaying the user power settings screen and the laser ready indicator is ON (lit green).

User Power Settings Screen



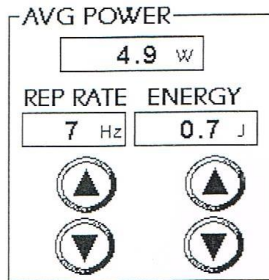
Visible aiming beam control

- defaults to OFF in Standby state and defaults to ON in Ready state
- adjustable in 10 step increments
- lowest step is OFF



Pulse width (pulse duration) control

- toggle  between 350 μs and 700 μs



Average power display

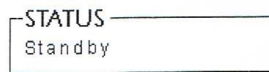
- average power calculated by multiplying rep rate (pulse frequency) with pulse energy.

Repetition rate control

- increase or decrease the pulse repetition rate

Energy control

- increase or decrease pulse energy in 0.1 J increments




Status display

- under normal conditions, displays the operating state of the system: STANDBY or READY
- under error state, displays the error identification number



Joule counter











- counts the amount of energy delivered
- reset button  sets the counter back to zero



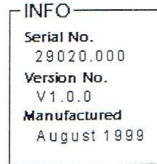
User options screen button

- jump to user options screen

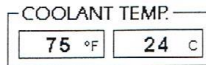
Status Icons

<i>Input line voltage indicator</i>		115 V~ line input
		230 V~ line input
<i>Delivery system indicator</i>		no delivery system connected
		SMH1020F fiber assembly connected
		SMH1040F fiber assembly connected
		SMH1060F fiber assembly connected
		SMH1010F fiber assembly connected
<i>Capacitor charge indicator</i>		capacitor voltage between 50 to 400 V
		capacitor voltage between 400 to 600 V
		capacitor voltage between 600 to 1000 V

User Options Screen



- System information*
- System serial number
 - Software version number
 - Manufactured date



- Coolant temperature display*
- displays the cooling water temperature in degrees Fahrenheit and Celsius



- Screen contrast adjustment*
- increase or decrease the touch screen contrast



- Blast Shield Control*
- Advance or reverse blast shield disk position between positions 1 through 6



- Return button*
- return to the user power settings screen

Power Matrix

350 μ s pulse width (power in W)

	5 Hz	7 Hz	10 Hz	12 Hz	15 Hz	20 Hz
0.4 J	2.0	2.8	4.0	4.8	6.0	8.0
0.6 J	3.0	4.2	6.0	7.2	9.0	12.0
0.8 J	4.0	5.6	8.0	9.6	12.0	16.0
1.0 J	5.0	7.0	10.0	12.0	15.0	20.0
1.2 J	6.0	8.4	12.0	14.4	18.0	—
1.5 J	7.5	10.5	15.0	18.0	22.5	—
1.8 J	9.0	12.6	18.0	21.6	—	—
2.2 J	11.0	15.4	22.0	26.4	—	—
2.6 J	13.0	18.2	26.0	—	—	—
3.0 J	—	—	30.0	—	—	—

700 μ s pulse width (power in W)

	5 Hz	7 Hz	10 Hz	12 Hz	15 Hz
0.4 J	2.0	2.8	4.0	4.8	6.0
0.6 J	3.0	4.2	6.0	7.2	9.0
0.8 J	4.0	5.6	8.0	9.6	12.0
1.0 J	5.0	7.0	10.0	12.0	15.0
1.2 J	6.0	8.4	12.0	14.4	—
1.5 J	7.5	10.5	15.0	18.0	—
1.8 J	9.0	12.6	18.0	—	—
2.2 J	11.0	15.4	22.0	—	—

For 30 Watt systems, the software limits the output power to 15 W using 115 V~, 10 W using a 200 micron core fiber, and 20 W using a 400 micron core fiber. Full power is achievable using 230 V~ with a 600 micron or larger core fiber. 15 and 20 Hz are not achievable using a 200 micron core fiber.

For Odyssey XE, the maximum output power parameter is at 15 W, 1.5 J/pulse, and/or 12 Hz.



Preparation

- 1 Make sure that all persons in the operating room have appropriate laser safety eyewear.
- 2 Verify that the power cord is plugged into to a suitable electrical outlet. For additional details, please review the installation procedures in Chapter 2.
- 3 Verify that the Mains switch, located on the back panel, is in the ON (I) position.
- 4 Verify that the foot switch is properly connected. The foot switch connector is located on the back panel.
- 5 Verify that the remote connector is attached. The remote connector is located on the back panel above the foot switch connector.



In case of an emergency, hit the emergency stop button located on the top panel. When the button is engaged, all electrical power to the laser system will be cut immediately. Remember to release the emergency stop button before attempting to restart the laser system.

Start-up Sequence

- 1 Turn ON the key switch. The key switch is located on the back panel.
- 2 The laser system powers ON and the touch screen displays the welcome screen. After 2 seconds, the power setting screen appears.
- 3 Connect an SMA IQ fiber delivery system into the fiber-optic port, located on the front panel. Make sure that the connector is screwed down finger-tight. The touch screen displays a fiber icon corresponding to the fiber core size.



Do not overtighten the fiber connector onto the laser.

If a fiber delivery system is connected when the laser is initially turned ON, the status displays "RECONNECT FIBER." Remove and reconnect the fiber. The Status display will change to "STANDBY."

- 4 Adjust the screen contrast as necessary. See Adjusting the Screen Contrast below.

The aiming beam can be turned on in Standby state by pressing the aiming beam UP arrow button. In Ready state, the aiming beam will turn on automatically unless it has been manually set in the OFF position.



Adjusting the Screen Contrast

- 1 From the power setting screen, touch the options button.
- 2 If the screen is too bright, touch the DOWN arrow until the contrast is optimum. If the screen is too dark, touch the UP arrow until the contrast is optimum.
- 3 Touch the back button to return to the power setting screen.

Setting Power Parameters

- 1 Select the pulse duration for the given procedure. In general, 350 μ s (higher peak power) is optimum for ablation and 700 μ s (lower peak power) is optimum for coagulation. Please review the Holmium Laser Theory of Operation in Chapter 2 for more information.
- 2 Select the pulse energy. Keep in mind that the fluence, or energy density, is the operating parameter and depends on the chosen fiber type and distance from distal tip to operating plane.
- 3 Select the repetition rate. The repetition rate governs the rate of energy delivery. In general, higher repetition rates mean shorter operating times but also less control.
- 4 The laser system automatically calculates the average power by multiplying the pulse energy with the repetition rate. Keep in mind that

Treatment

- 1 Set the laser system into Ready state by pressing the Ready button located on the control panel. After 2 seconds, the Ready light should be lit green.
- 2 Carefully position the fiber-optic probe at or near the intended surgical site.
- 3 Adjust the aiming beam intensity by using the UP/DOWN arrows on the touch screen display.
- 4 Aim and steady the fiber tip at the surgical target.
- 5 Depress the foot switch while laser energy is desired. The Joules counter adds the amount of energy delivered. Adjust power as necessary.
- 6 Return the laser system to Standby state by pressing the Standby button.



The laser system automatically returns to Standby state when changing any power parameter.

Shut-down Sequence

- 1 Note down the clinical parameters and Joule count as necessary.
- 2 Disconnect and dispose of the delivery system.
- 3 Close the laser aperture door.
- 4 Turn the key switch to the OFF position.
- 5 Remove the key from the key switch and store in safe place.
- 6 Turn OFF the Mains switch
- 7 Unplug the power cord from the wall outlet.
- 8 Cover the laser system and store in a safe, dry area.

Resetting the Emergency Stop

- 1 Verify that the Mains switch is in the OFF position.
- 2 Verify that the key switch is in the OFF position.
- 3 Twist counterclockwise to release the emergency stop button.
- 4 Turn ON the Mains switch.
- 5 Turn ON the key switch.

The laser system will not power ON unless the emergency stop is in the UP (released) position.



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6

Maintenance

Preventive Maintenance

The Odyssey has been designed to operate trouble free for thousands of procedures. To maintain peak performance, the laser system should undergo a preventative maintenance procedure every six to twelve months depending on usage. The procedure should also be repeated if the laser system has not been used for over two months.

The preventative maintenance procedures are as follows:

- inspect and replace cooling water if necessary
- inspect and replace water filter if necessary
- inspect and replace blast shield if necessary
- clean optics
- verify optical alignment
- verify power calibration
- inspect and replace air filter if necessary
- clean external surfaces with alcohol



Only an authorized service technician may conduct the preventative maintenance procedures.

Troubleshooting Error Codes

<i>Code</i>	<i>Description</i>	<i>Probable Cause</i>	<i>Solution</i>
03	WARNING: Optical deck interlock override	Optical deck interlock override switch engaged	Call or service; Re-engage optical deck interlocks using the switch located on the optical deck interface board
07	WARNING: Energy output 20% below set point	Laser resonator out of alignment or laser mirror damaged	Continue procedure; call for service at next opportunity
08	WARNING: Energy output 20% above set point	System requires re-calibration	Continue procedure; verify power calibration at next opportunity
10	Cooling water over temperature (above 38 C, 100 °F)	Ambient operating room temperature has exceeded 24 C (74° F)	Place system in Standby state until error disappears or lower ambient temperature
		Laser operating duty cycle exceeded	Place system in Standby state until error disappears or lower output power
		Low line voltage	Have an electrician verify that the electrical outlet meets the system's electrical requirements
		Cooling system component failure	Call for service
12	Foot switch stuck; foot switch in down position while attempting to place system in Ready state	Foot switch failure or an object is causing the foot switch to remain in the down position	Check foot switch operation for obstruction and/or replace foot switch

<i>Code</i>	<i>Description</i>	<i>Probable Cause</i>	<i>Solution</i>
14	Top panel interlock disengaged	Top panel signal connector is not properly connected	Check to make sure the top panel signal connector is seated securely
15	Optical deck interlock defeated	Optical deck covers are not properly seated or optical deck interlock failure	Call for service
16	Delivery system not connected	An appropriate delivery system is not in place	Verify that the delivery system uses a Convergent compatible connector Verify that the connector is screwed down finger tight
17	Remote interlock open	An external device has cause the remote interlock circuit to disable the laser system Remote connector missing	Re-engage the remote interlock with the external source Verify that the remote connector, located on the back panel, is seated securely
18	Foot switch not connected	An appropriate foot switch is not in place	Verify that the foot switch connector, located on the back panel, is seated securely
27	Blast shield error	Blast shield motor or optical sensor error	Call for service
28	Laser output below minimum	Laser resonator out of alignment or laser mirror damaged	Call for service

<i>Code</i>	<i>Description</i>	<i>Probable Cause</i>	<i>Solution</i>
29	Laser output 100% above set point	System requires re-calibration Error spike injected into high power electronics	See Power Calibration in this chapter Turn OFF laser system and restart after 30 seconds
30	Cooling fan failure	1 of 2 cooling fans operating below performance	Continue procedure; call for service at next opportunity
32	IGBT failure	High power electronics failure	Turn OFF laser system and restart after 30 seconds; if error persists, call for service
34	Main power supply overload	Low line voltage condition causes power supply to draw too much current	Verify that the voltage meets the performance specifications in Chapter 2
35	Main power supply over temperature	Power supply cooling fan failure	Call for service
37	Laser timer repetition rate error	Laser timer error	Turn OFF laser system and restart after 30 seconds; if error persists, call for service
38	Laser timer pulse width error	Laser timer error	Turn OFF laser system and restart after 30 seconds; if error persists, call for service
42	Main power supply charge error	Power supply failure	Turn OFF laser system and restart after 30 seconds; if error persists, call for service

<i>Code</i>	<i>Description</i>	<i>Probable Cause</i>	<i>Solution</i>
44	Safety shutter error	Safety shutter stuck in incorrect position	Call for service
		Safety shutter sensor error	Call for service
46	Laser flash lamp simmer error	Low line voltage condition	Verify that the voltage meets the performance specifications in Chapter 2
		Flash lamp failure	Turn OFF laser system and restart after 30 seconds; if error persists, call for service
50	Foot switch error	Foot switch in short circuit situation or foot switch failure	Replace foot switch
52	Computer error	At least one microcontroller has stopped responding	Turn OFF laser system and restart after 30 seconds; if error persists, call for service
53	External watchdog error	External watchdog microcontroller failed to communicate with main computer	Turn OFF laser system and restart after 30 seconds; if error persists, call for service
56	Laser cavity water pressure error	Water pressure across laser cavity is out of range	Call for service
		Cavity pressure sensor error	Call for service
57	Cooling water flow rate error	Water pump failure	Call for service
		Cooling system leaking	Call for service
		Water flow rate sensor failure	Call for service

Blast Shield Maintenance

The Odyssey is preinstalled with a blast shield to protect the output lens from flashback debris. There are six blast shields per disk. After one blast shield is soiled, the next one can be activated simply by rotating the disk to the next position from the user power setting screen. After the last blast shield is exhausted, the blast shield disk will have to be replaced. You can reorder a blast shield by calling Convergent sales and asking for part number LP3015.

Under normal operating conditions, a blast shield should last for over 100 cases. Typically, a blast shield gets soiled for the following reasons:

- the internal optical system became misaligned
- the delivery system connector face became soiled due to mishandling
- an inappropriate delivery system was used

Using a non-Convergent delivery system on the Odyssey may damage the laser system and will void the manufacturer's warranty.



Inspect the blast shield whenever you notice a drop in output power. This can be noticed clinically—it takes a higher energy setting to achieve the same clinical result—or verified quantitatively using an appropriate energy or power meter.

The following procedures expose the biomedical engineer to high voltages. Please observe all safety precautions. The following procedures should only be attempted by a qualified biomedical engineer or service technician.



Inspecting the Blast Shield

- 1 Unplug the laser system. If the laser system has been idle for over 10 minutes, then proceed, otherwise wait 10 minutes to allow for all high voltage circuits to discharge.
- 2 Remove the top panel using the supplied key. Disconnect the top panel wire connector as you lift off the top panel.

- 3 Remove the optical platform cover by loosening two screws on either side of the optical platform.
- 4 Using a flash light and a small 12 mm (1/2") mirror, inspect the blast shield for damage. If the blast shield is damaged, the glass will be frosted white.
- 5 If necessary, rotate the blast shield to the next position, by pressing the blast shield forward arrow in the user power setting screen.
- 6 Replace the optical platform cover and top panel.



If the optical platform cover is removed in a dusty room, carefully dust off the mirrors using canned air before replacing the optical platform cover.

- 7 Verify the calibration by following the procedures in Chapter 2.

Power Calibration


As the laser system ages, the efficiency of certain components may decrease. Power calibration should be verified as part of the preventative maintenance program.

Only an authorized service personnel may calibrate the laser system. The calibration procedures permit access to service mode functions which, if used improperly, may damage the laser system.





Always conduct the calibration in a restricted access room with laser safety signs posted at all entrances. Wear appropriate safety eyewear at all times during power calibration.

- 1 Plug laser system into a 230 V~ electrical outlet. Power calibration can only be conducted using a 230 V~ line input. Reconfigure the transformer if necessary.
- 2 Turn the Mains switch ON (I).
- 3 Simultaneously turn ON the key switch and depress the foot switch. This will allow you to gain access to the software's service mode functions.

- 4 When prompted for the pass code, enter in the pass code supplied with your laser system and touch the  button.

The pass code is issued to the registered owner of the laser system. Please contact customer service if you have forgotten or misplaced your pass code. Each laser system has a unique pass code.



- 5 If the pass code is entered correctly, the service menu will be displayed on the touch screen.
- 6 Insert a new 600 micron core fiber (SMH1060F) into the fiber-optic port.
- 7 Set up a compatible energy or power meter to read the laser output at the distal end of the fiber.
- 8 Touch the calibration button .
- 9 Referring to the power matrix in Chapter 4, step through each value and confirm output power. The power setting should be within 5%.
- 10 If necessary, adjust the output power by increasing or decreasing the power supply voltage. After the correct voltage is set, touch the save button  to store the current value in static memory.

Do not set the power supply program voltage over 4.80 V.



- 11 Return to the service menu and then to the user power settings screen.
- 12 Step through each power setting and confirm output power. Note down any discrepancies and re-calibrate specific data points as necessary.

Always verify every output power combination in user mode after calibration. An incorrectly set data point may cause unexpected levels of output energy.



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7

Customer Service

Customer Service by Phone

A Convergent customer service representative can provide you with the following:

- help with registering your laser system,
- assistance with ordering delivery systems and service parts,
- scheduling a preventative maintenance, and
- redirect a technical problem to Convergent technical support.

Customer service is available weekdays between 8:00 am and 5:00 PM Pacific Standard Time at 800-848-8200 or 510-832-2130. For service calls, please have the serial number of you laser system ready. For general inquires, please visit our website at www.convergentlaser.com.

Customer Service On-line

After registering your laser system either via phone or on-line, Convergent will issue the primary contact of the laser system a user name and password to access Convergent's customer care website. At this website, you will find the latest clinical and technical information regarding your Odyssey laser system. In addition, you will find the following information:

- running log of your laser system's service records,
- access to Convergent's searchable service knowledge base, and
- on-line ordering of delivery systems and service parts.

Customer service can also be contacted via e-mail at service@convergentlaser.com.

Warranty

Convergent Laser Technologies warrants the Odyssey laser system to be free from defects in material and workmanship, at the original purchaser's location for 12 months. The optical deck assembly including the laser resonator chamber will be under warranty for 1 million pulses (as indicated by the pulse counter) or 12 months, whichever occurs sooner. To activate the warranty, the owner of the laser system must register the laser system within 30 days of receiving the product.

In order to comply with this warranty, all internal adjustments or modifications must be made by a Convergent authorized service person or with express permission of a Convergent service representative. The warranty does not apply in the event of misuse, negligence, or accidental damage. Tampering with the optical system or any electronic safety circuits will null the warranty.

The liability of Convergent under valid warranty claims is limited to repair or replacement at Convergent's facilities or purchaser's place of business, at the option of Convergent.

To avoid damage to the optical system, only Convergent accessories may be used with the Odyssey laser system. Using other than Convergent accessories may compromise the safety of the laser system and will nullify the above warranty or service contract.



The above warranty is exclusive and in lieu of all other warranties, whether written, oral or implied.

Warranty Claim

To obtain warranty repair, contact Convergent technical support. A support engineer will determine whether the product can be serviced on-site or needs to be returned to Convergent's facilities. If it becomes necessary to return a product for repair and/or adjustment, a customer service representative will issue you a return material authorization number (RMA) to be included with the returned product.

Returned products need to be shipped pre-paid to Convergent's facilities and properly decontaminated per US law. If the equipment is not properly decontaminated, the purchaser will be assessed with a cleaning cost. Shipping charges for returned or replacement products will be the sole responsibility of the purchaser.