GreenLight HPS™

high performance system

Laser Operator's Manual

Manufactured by

LASERSCOPE®

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Preface

About This Manual

This manual contains the safety, installation, operation, and maintenance instructions for the GreenLight HPS™ laser system. It also provides information on the use and care of the system components, proper eye protection, troubleshooting, and warranty for the GreenLight HPS™ laser system.

- **Safety** provides recommendations to avoid bodily injury, especially the use of protective eyewear. Read this section before attempting to operate the equipment when treating a patient.
- **Section 1: Introduction** describes the basic components of the system and describes the interface features.
- **Section 2: System Installation** provides the physical and environmental requirements necessary to operate the GreenLight HPS™ laser system, as well as information on how to move the instrument should you need to.
- **Section 3: Operating the System** gives you step-by-step instructions on how to start up the system, select treatment parameters, operating procedures, and how to turn the system off.
- **Section 4: Physician Information** contains information regarding indications, contraindications, possible complications, precautions, and post-treatment care.
- **Section 5: Maintenance** provides instructions on cleaning the system.
- **Section 6: Troubleshooting** presents a list of error messages and codes, and gives suggestions on how to solve the problem.
- **Specifications** lists the product specifications. This section also includes the labels found on the GreenLight HPS™ laser system console and provides the meaning of each symbol found on the system and the labels.
- **Warranty** contains warranty information and specific instructions for returning the GreenLight HPS™ laser system and GreenLight HPS™ fiber optic for repair.
- **Support Materials** contains documents to help you organize the operation and management related to the GreenLight HPS™ laser system.

Conventions

■ **NOTE:** Points out additional information that may be helpful.

▲ **CAUTION: Alerts you to situations that could result in instrument damage, failure in a procedure, or incorrect results.**

◆ **WARNING: Alerts you to situations that could result in bodily harm or irreparable damage to the equipment.**

Who Should Read This Manual?

All users of the GreenLight HPS™ system should read this manual thoroughly before attempting any surgical procedure. Pay particular attention to all warnings, contraindications, and precautions noted in this manual and other related materials. Failure to do so may result in harm to a patient or the user of the system.

Obtaining Help

1. Read through the section of the guide specific to the operation you are performing. Refer to the table of contents to locate information.
2. See **Section 6: Troubleshooting** for a list of problems and suggested solutions.
3. For additional information covering installation, medical applications, or any other questions, contact Laserscope Customer Response Center at:
   - (800) 356-7600 from inside the US, or
   - Outside the US, contact your local distributor.

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Safety

◆ **WARNING: Laser light presents a severe eye hazard and a potential for burns or fire. The system's aiming beam may be viewed by an unprotected eye. Never activate the system treatment beam without eye protection. It presents a severe eye hazard if viewed directly or by reflection. Avoid exposure to the laser beam. Take all necessary protective measures in areas where the laser is being used.**

Introduction

This section describes specific laser hazards and appropriate precautionary measures.

Guidance for the safe use of lasers is given in IEC 825-1. It is also given in two equivalent American National Standards. The first is ANSI Z136.1-2000, *The Safe Use of Lasers*, and covers general use of lasers. The second standard is ANSI Z136.3-1996, *The Safe Use of Lasers in Health Care Facilities*, and covers specific use of lasers in medical applications. Refer to the general ANSI Z136.1-2000 standard for the actual calculations for eye protection.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

▲ **CAUTION: Changes or modifications not expressly approved by Laserscope could void the user's authority to operate this equipment.**

EYE INJURY

RECOMMENDED PRACTICE V: ALL PEOPLE IN THE NOMINAL HAZARD ZONE SHOULD WEAR APPROPRIATE EYEWEAR APPROVED BY THE LASER SAFETY OFFICER.[1]

Visible light and near-infrared laser energy passes through the transparent components of the eye (cornea, lens, aqueous and vitreous humor), and is focused on the retina. This light can cause an accidental retinal burn. The degree of injury to the eye will depend upon the power of the beam, how focused the beam is, and how long the eye is exposed to the beam.

[1] 2006 Standards, Recommended Practices and Guidelines: Recommended Practices for Laser Safety in Practice Settings. AORN. Denver 2006: pg 565-570

Precautions against eye injury should include wave-length specific laser protective eyewear for the operating room staff. Patient's eyes and eyelids should be protected from the laser beam in a method deemed appropriate by the laser safety officer. [2] See the Eye Protection Information Guide in this section for more information regarding eye protection. Laser eyewear is not interchangeable for a variety of lasers.

Eye Protection Information Guide

It is the responsibility of the hospital or medical institution where the laser surgery is performed to establish a written policy on eye protection.

Several articles have been published stating the strong OSHA and JCAHO (Joint Commission on Accreditation of Hospital Organizations) position to adhere to ANSI Standards. Refer to ANSI Z136.1-2000 and ANSI Z136.3-1996, in conjunction with the recommendations of your Laser Safety Officer (LSO) to develop your facility's laser policy.

This guide will address some common questions raised on the issue of laser eye protection. The information contained in this guide is designed to assist you in tailoring a policy to fit the needs of your institution, particularly in relation to the use of the GreenLight HPS™ laser system.

Laser Protective Eyewear

There are several products available for use with the GreenLight HPS™ laser system to protect both eyes and video equipment. This section describes the laser protective eyewear and the video camera filters that have been designed to meet ANSI Z136.3-1996, ANSI Z136.1-2000 and DIN standards for safe viewing in a medical facility. All the filters have optical densities greater than 5.0 at 532 nm. The OD of the filters indicates how much the light is attenuated and is defined as:

Optical Density = OD = $-\text{Log}_{10}$ (Filter Transmission)

A filter with an OD of 2 has a transmission of 1/100 or 10^{-2} while a filter with an OD of 5 has a transmission of 1/100,000 or 10^{-5}.

- **NOTE**: It is required for everyone in the room to wear protective eyewear.

[2] American National Standards Institute, Laser Institute of America, American National Standard for Safe Use of Lasers in Health Care Facilities. (Orlando, FL: The Laser Institute of America. 1996)

Two different types of eyewear have been designed to protect operating room personnel from the GreenLight HPS™ laser energy. These include:

- The Surgeon Glasses (catalog number 10-1350 and 10-0008). They have a min. optical density (OD) of 5.0 at both 532. The essentially clear lens material has very high visible light transmission and minimal color distortion.

- The 532nm Surgeon Protective Goggles (catalog number 10-7030). Have a min. optical density (OD) of 5.0 at 532 nm. Although they have good visible light transmission, the orange color of the plastic lens causes some color distortion.

Eye Protection Product Reorder Information

- 532nm Surgeon Protective Glasses, Large Frame (catalog number 10-0008)
- 532 Surgeon Protective Glasses, Small Frame (catalog number 10-1350)
- 532nm Surgeon Protective Goggles, Standard Frame (catalog number 10-7030)

COMMON QUESTIONS ABOUT EYE PROTECTION

1. "O.D." is marked on the laser eyewear. What does it mean?

O.D. stands for optical density. It is specific to the spectral wavelength marked on the eyewear and represents the capability of the eyewear to block out laser light. The higher the O.D., the greater the amount of light blocked out. The O.D. marked on the eyewear is sufficient to provide protection for the use described in the associated product insert.

Eyewear is not interchangeable for different wavelengths. Eyewear designated for use at 532 nm should only be used when viewing the 532 nm wavelength. For more information about the O.D. of Laserscope's eyewear, consult the product insert shipped with the specific eyewear.

2. Why is the eyewear for the GreenLight HPS™ laser system 532 nm laser tinted?

The human eye is very sensitive to light in the green portion of the spectrum. Since the GreenLight HPS™ 532 nm laser system operates in the visible green light wavelength, protective eyewear for 532 nm must block a portion of this green light to provide adequate eye protection.

3. Does my eyewear protect me if I can see green light during lasing?

Laserscope eyewear is designed to block out a specific portion of the light spectrum in green, and allow other parts of the spectrum to pass through. There is nothing dangerous about viewing green light at low intensity or the red aiming beam. The eyewear is designed to protect against the high intensity of the green laser light used to perform surgery.

4. Why do goggles fog and what can be done to prevent this from happening?

The fogging of goggles is a common problem experienced by many laser users. The warmth of the wearer, stress of the case, and coolness of the procedure room are ideal conditions for condensation to form on all eyewear, despite manufacturing design. The use of anti-fogging agents after cleaning and before each case should reduce the fogging problem.

5. What is the potential for a fiber to break during a procedure and cause eye injury?

During normal use, a fiber may incur stress when it is inserted into the cystoscope. Stress is a concern when fibers are being used because small nicks in the nylon jacket of the fiber can result in increased fragility.

The probability that a person without eyewear will directly view a fiber breaking is low, but can occur. The probability of the fiber breaking while actually aimed at someone's eye is low. The following factors must all occur simultaneously in order to result in hazardous exposure:

- Alignment of the laser beam with the eye
- Close proximity of the eye to the source of the laser light
- Exposure time in excess of damage threshold

With proper use of the laser equipment, the chance of these events occurring simultaneously is remote, but may occur. Laserscope supports the ANSI recommendation that all personnel in the operating room wear appropriate eyewear when the laser is being used for open or endoscopic procedures.

6. Do I need laser eyewear with endoscopic cases?

Yes, protective eyewear is routinely required for most laser cases. In an editorial article published by Rockwell Laser Industries, the use of eye protection during endoscopic laser surgery was addressed. According to Rockwell's interpretation of ANSI Z136.1 (Section 4.3.6.2), Class 1 conditions shall be considered as fulfilled for those limited open beam path lasers or laser systems where measurements and analysis confirm that the accessible levels during operation are at or below applicable maximum permissible exposure (MPE) levels. By this definition, endoscopic laser surgery (ruling out the possibility of a broken fiber) could be considered a Class 1 condition.

Laserscope supports the ANSI and AORN recommendations that protective eyewear be available and worn during all laser procedures by all personnel present.

7. What are some appropriate ways to protect the patient's eyes during laser surgery?

The patient should always be educated on the laser procedure and eye protection requirements prior to the start of the procedure.

In addition, the following protective measures should be taken:

- Use moist towels where appropriate.
- If the patient is awake, use suitable protective eyewear, and instruct the patient not to remove the eyewear.
- If the patient is anesthetized, lubricate and tape the patient's eyelids shut.
- Use a combination of moist towels, gauze eye pads, eyeshields, and drapes to protect the eyes when the surgical site is on or near the face.

8. Where can I find additional information about eye safety and protection?

Current literature on laser applications is available in medical libraries.

Additional information on terms, definitions and reference materials may be obtained by reviewing ANSI Z136.1-1986 and ANSI Z136.1-2000 and ANSI Z136.3-1996, or by contacting:

- Laser Institute of America
  12424 Research Parkway, Suite 130
  Orlando, FL 32826
  Phone: (800) 34-LASER or www.laserinstitute.org

- Rockwell Laser Industries
  P.O. Box 43010
  Cincinnati, OH 45243
  Phone: (800) 94-LASER or www.rli.com

BURNS

RECOMMENDED PRACTICE VIII: ALL PERSONNEL IN THE LASER TREATMENT AREA SHOULD BE PROTECTED FROM FLAMMABILITY HAZARDS ASSOCIATED WITH LASER USE. [3]

Personnel using lasers should be knowledgeable of the fire hazards associated with laser use. Accidental irradiation of tissue other than the target tissue may result in a burn or vaporization, regardless of the wavelength. Surrounding the target area with moist drapes or saline-soaked sponges will keep it moist and greatly reduce this hazard.

Flammable or combustible items in the laser environment may include: flammable liquids or combustible ointments, gases, plastics, paper or gauze materials, adhesive or plastic tapes, and endotracheal tubes.

Laser appropriate fire extinguishers and water should be available where lasers are utilized. Care and precision in aiming and applying laser energy is of paramount importance.

◆ **WARNING: Never use a clamp to secure the laser fiber optic to a drape. The use of a clamp to secure a fiber may cause the fiber to bend at sharp angles and damage the fiber. To do so can result in an unsafe condition. The fiber can break and release laser energy causing a burn in the protective jacket. If undetected, this condition will result in a burn or ignition of flammable materials.**

When using the fiber with the laser, the fiber device connector should never be allowed to touch the floor or any wet surface. If the fiber connector does contact a surface other than the laser device port, dispose of the fiber in accordance with hospital safety regulations.

REFLECTION OF THE BEAM FROM INSTRUMENTS

RECOMMENDED PRACTICE V: ALL PEOPLE IN THE LASER TREATMENT AREA SHOLD BE PROTECTED FROM UNINTENTIONAL LASER BEAM EXPOSURE. [ibid]

Care should be taken when aiming the laser beam to prevent reflection of the beam off metallic surgical instruments. Mirror-finish instruments are especially dangerous as they have highly reflective surfaces. The laser light reflected from such instruments is intense and potentially very harmful.

Matte, dull, satin-finished, or ebonized instruments have less glare and those with curved surfaces do not reflect light as intensely. While these instruments usually produce a more diffused reflection that is less harmful,

[3] 2006 Standards, Recommended Practices and Guidelines: Recommended Practices for Laser Safety in Practice Settings. AORN. Denver 2006: pg 565-570

this reflection can still be damaging. Protective eyewear should be worn at all times to prevent eye damage.

◆ **WARNING: When using anodized, black chrome finished, or ebonized instruments during a surgical procedure, additional care should be taken to prevent burns. These instruments will become extremely hot when they come in contact with a laser beam and are not able to quickly dissipate heat. When any tissue is touched under these conditions, a burn may result.**

IGNITION OF FLAMMABLE MATERIALS

The laser can ignite many materials used during a surgical procedure. Use of non-flammable materials is strongly recommended. See **Operating Room Environment** in this section for more information regarding flammable materials.

VAPOR/SMOKE PLUME

RECOMMENDED PRACTICE VI: PERSONNEL WORKING IN THE LASER ENVIRONMENT SHOULD AVOID EXPOSURE TO SMOKE PLUME GENERATED DURING LASER SURGERY.[ibid]

There is considerable concern about the biological plume created by electrocautery units, bone saws and lasers. Current medical literature recommends that a smoke evacuator and in-line filter be used to capture this plume. The plume should be regarded as a source of active biological material and a possible carcinogen.

ELECTRICAL

RECOMMENDED PRACTICE VII: ALL PEOPLE WORKING IN THE LASER TREATMENT AREA SHOULD BE PROTECTED FROM ELECTRICAL HAZARDS ASSOCIATED WITH LASER USE.[ibid]

Electrical hazards with the laser are the same as with any electrical device. Care should be taken when plugging the unit into the wall outlet. The area must be free of water and your hands must be dry. Always disconnect the laser by grasping the plug and not the power cord. Examine the electrical cord routinely; if signs of wear are noted, contact the Laserscope Customer Response Center at (800) 356-7600 to have it repaired or replaced. When performing a surgical procedure that requires large amounts of irrigation, protect the foot pedal in a plastic bag.

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ibid

ibid

OPERATING ROOM ENVIRONMENT

This section describes specific safety measures for the operating room to aid in the safe operation of the laser system.

Laser Warning Signs

RECOMMENDED PRACTICE III: ALL PEOPLE SHOULD KNOW WHERE LASERS ARE BEING USED AND ACCESS TO THESE AREAS SHOULD BE CONTROLLED.[4]

The area where the laser is operated should be clearly labeled. Warning signs that specify the laser wavelength being used should be posted at all operating room and access-door entrances. Figure S-1 is an example of a sign suitable for use with the GreenLight HPS™ laser system.

◆ **WARNING: Warning signs are not interchangeable. Select a sign that is appropriate for the wavelengths in use.**

Figure S-1 GreenLight HPS™ laser system Warning Sign

[4] 2006 Standards, Recommended Practices and Guidelines: Recommended Practices for Laser Safety in Practice Settings. AORN. Denver 2006: pg 565-570

Remote Door Interlock

Always limit personnel in the operating room to those essential to the procedure. To protect intruding personnel from exposure to the laser beam, an optional remote door interlock can be connected from the laser system to the operating room entrance door. This interlock will automatically put the laser in STANDBY if the door is opened during a procedure. The laser will remain in STANDBY until the door is closed and the interlock is reconnected. Once reconnection is made, the operator can place the system back in READY and reactivate the surgical beam. The laser cannot be placed in READY unless the interlock is reconnected.

If the use of the remote door interlock is desired, the biomedical personnel at the user's facility can connect it. Access to the laser unit's interlock is made via a socket located on the back panel of the laser (see **Section 1.1. System Overview**).

Safety Recommendations

The following are general safety recommendations for the operating room and are not specific to the GreenLight HPS System:

- Keep drapes and towels moist to prevent their ignition and burning.
- Use non-flammable prepping solutions.
- Prevent combustion of methane gas by packing the rectum during perineal procedures.

■ **NOTE:** All lasers operate with a keyswitch. Keep the laser key in a designated place and allow only trained personnel access to the key.

◆ **WARNING: Do not fire the laser unless the aim beam is clearly visible and directed at the targeted tissue.**

REFERENCE SOURCES

Reference material and additional information regarding laser safety may be obtained from the following sources:

ANSI Z136.3
The Safe Use of Lasers in Health Care Facilities
American National Standards Institute, (ANSI), 1988.

AORN: Standards, Recommended Practices and Guidelines. 2006 edition: Recommended Practices for Laser Safety in the Practice Settings. Pg 565-570

Safety Considerations for the Use of Medical Lasers
The Nursing Spectrum of Lasers
Pfister, Kneedler, Purcell, Education Design, 1988, Pg. 70-72.

Lasers: The Perioperative Challenge
Ball, Kay A.. 3rd edition, Denver, AORN, Inc. 2004

Diffuse Reflections
Endoscopic Surgery: Is Laser Safety Eyewear Really Needed?
Radiant Resources Newsletter, Winter 1992, Rockwell Laser Industries.

SAFETY FEATURES OF THE GreenLight HPS™ LASER SYSTEM

Safety Regulations

The United States Code of Federal Regulations, CFR Title 21, Ch. 1, Sections 1040.10, and 1040.11, requires that lasers have certain safety features. It further requires that labels be affixed to each laser unit identifying the manufacturer, the class or classes of radiation produced, and the location of the laser aperture(s) on the unit.

The safety features of Laserscope's GreenLight HPS™ laser system are described in the following sections. All required labeling information is also provided in these sections.

System Safety Features

Laserscope's GreenLight HPS™ laser system incorporates the following safety features:

- The laser will stop firing when the pressure is removed from either footswitch.
- An automatic circuit breaker shuts the system completely off in the event of an electrical overload.
- The laser provides an operating room door interlock connection, which must be set up by the hospital personnel.
- The key can only be removed when the keyswitch is in the OFF position.
- An on-board microprocessor continuously monitors the status of the system, and displays messages on the video screen along with appropriate operator prompts.
- Laser energy cannot be emitted from the system unless a fiber optic has been connected.
- Laser will go into ready when the READY button is touched, or when the button on top of the footswitch is pressed.
- A fiber support pole elevates and positions the fiber in a safe and unobtrusive position.
- A continuous audible tone is heard when the surgical beam is activated (i.e., foot pedal is pressed). A higher frequency tone is heard for vaporization and a lower tone for coagulation.
- A 2-second delay occurs before laser energy is emitted after the laser is placed in READY status.
- An Emergency Laser Stop switch is available to disable the system immediately, in the case of an emergency situation
- When switching between READY and STANDBY, a voice will announce the current mode.

IMPORTANT NOTE: Do not attempt to remove any panel from the laser console. All panels are fitted with tamper-proof fastenings. Any attempt to remove the panels, unless instructed by authorized Laserscope personnel, can damage the laser and will void the manufacturer's warranty.

◆ **WARNING: Unauthorized use of internal controls, adjustments to the equipment, or performance of procedures other than those specified herein, may result in hazardous radiation exposure.**

SAFETY CLASSIFICATIONS

In accordance with UL 2601-1/IEC 60601-1, the product is classified as Class I equipment at continuous operation with intermittent loading, which is not protected against ingress of liquids. The product is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Performance & Safety Standards:

The GreenLight HPS™ laser system and accessories comply with U.S. Federal regulations and the performance standards 21 CFR 1040.10 and 1040.11 for medical laser systems. In addition, the information below identifies Standards (European Norms and other Regulatory Guidelines) deemed as relevant for addressing particular aspects of the Quality System, the requirements for Medical Lasers, the Requirements for Medical Devices, and the Essential requirements of the EU Medical Device Directive (Annex I).

ANSI Z136.1;200	EN 60601-1-4:1997	ISO 8600-3:1997
ANSI Z136.3:2005	EN29001	ISO 8600-4:1997
21 CFR Part 820	ISO 11135	ISO 60601-2-18
21 CFR Part 1040.10-11	ANSI/AAMI ST81:2004	CB Scheme
MDD 93/42/EEC	AAMI TIR 12:2004	ISO 13485:2003
WEEE 2002/96/EEC	AAMI TIR 30:2003	CMDCAS
EN60601-2-22:1996	ISO 8600-1:1997	

This equipment has been tested and found to comply with the limits for medical devices to the IEC 601-1-2:1994. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

LABELING

This figure shows the location of all labels on the laser unit. The actual labels used in these locations are also shown.

Figure S-2 Labeling of Front Panel of Laser

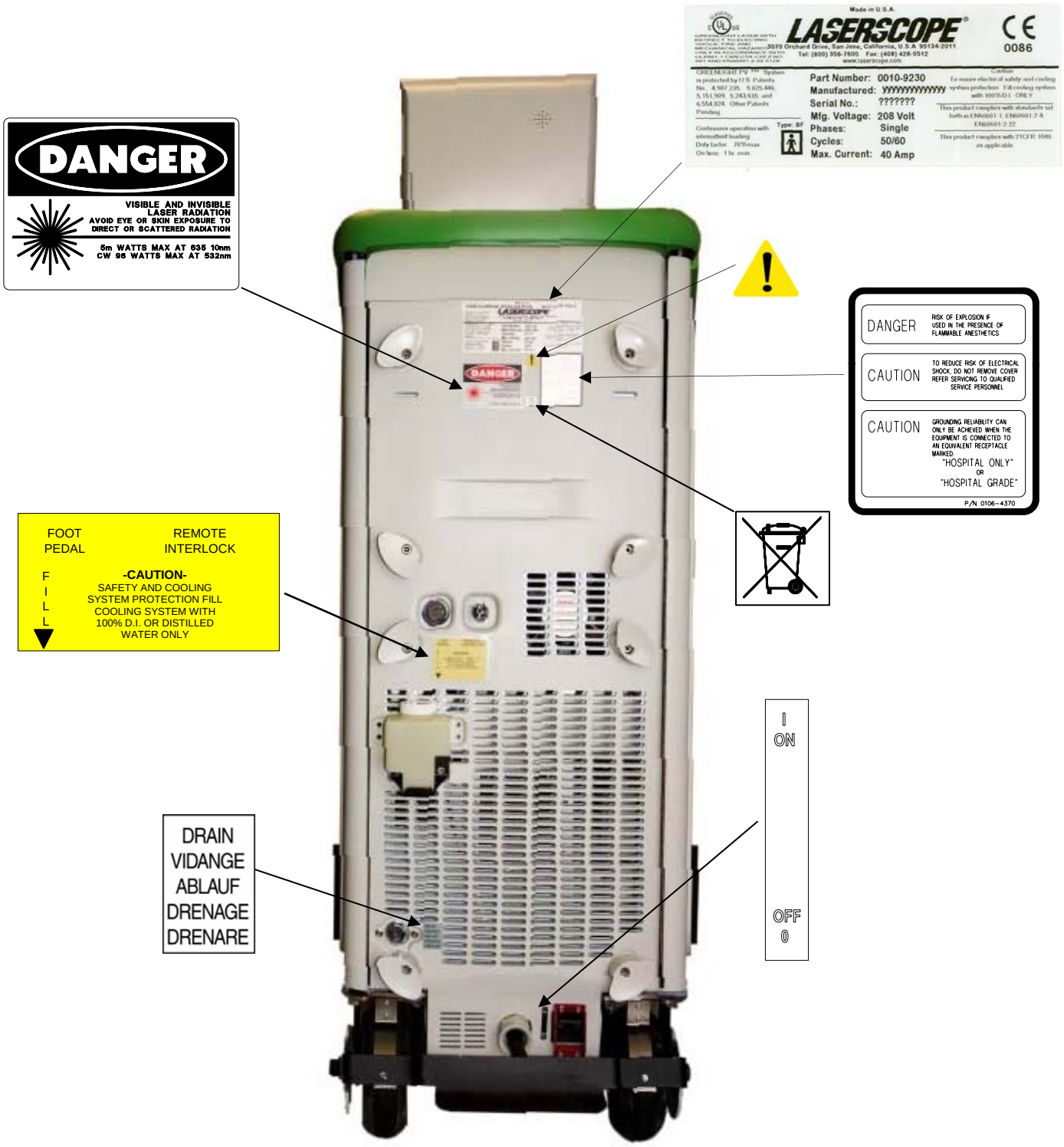


Figure S-3 Labeling of Rear Panel of Laser

Section 1
Introduction

1.1 SYSTEM OVERVIEW

The GreenLight HPS™ laser system is a diode-pumped, frequency-doubled Nd:YAG solid state laser. The laser system delivers a visible 532nm laser light with a power setting range of 20 to 120W, in 10W increments.

The GreenLight HPS laser system features a “Plug and Play” capability that self-adjusts to the facility’s individual voltage requirements, eliminating the need for electrical modifications.

The laser system also consists of an air-cooled internal mechanism, ensuring safe operating temperatures with no external water connections. Laser energy emission and system status selection is activated through a surgeon-controlled, color-coded footswitch or system touch screen feature located in the laser console.

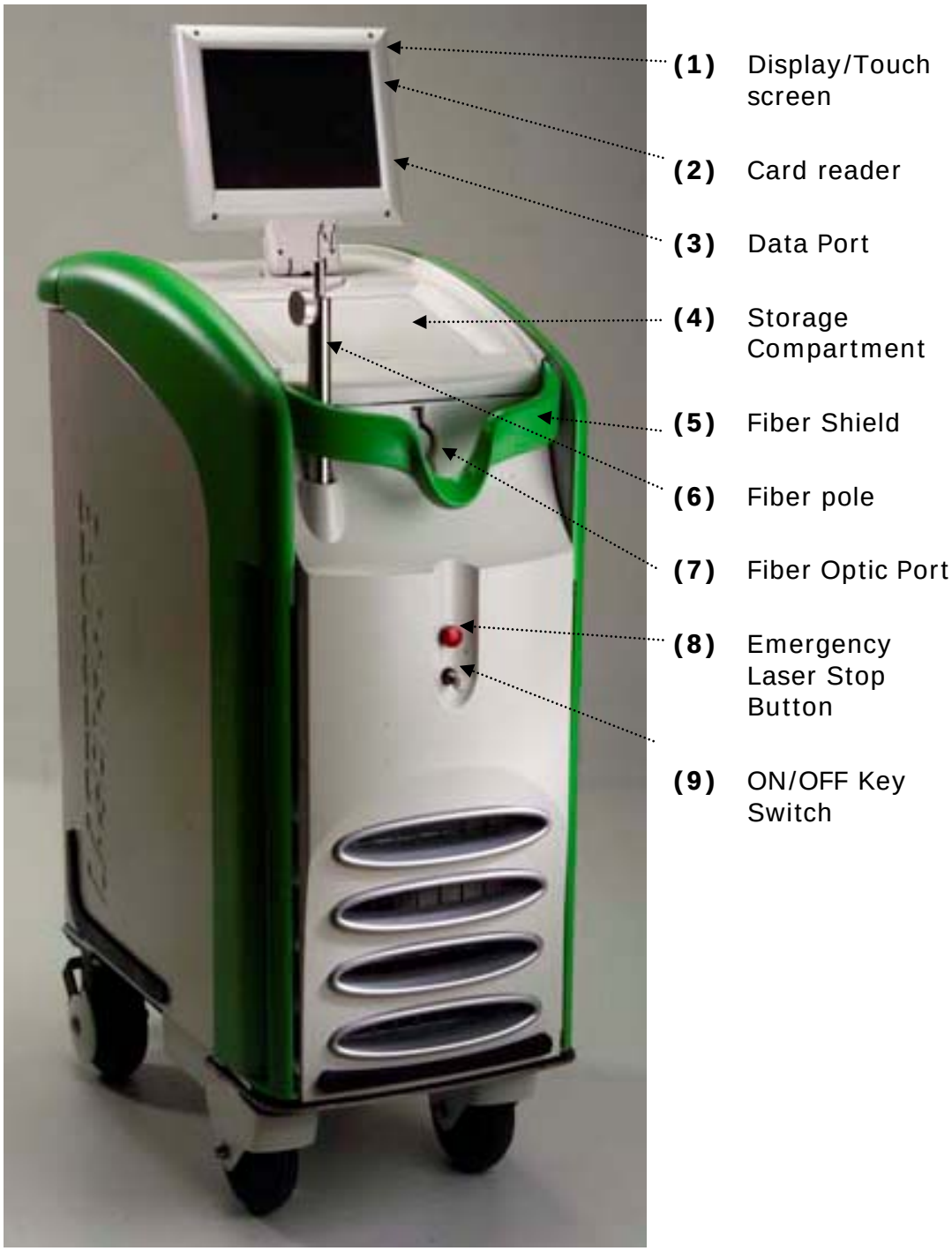


Figure 1-1 Front View of Laser

Front View of Laser

(1) Display / Touch Screen - Displays operator information:

- System status (Standby, Ready)
- Laser output (in Watts). Separate display for vaporization and coagulation.
- Lights up when surgical beam is fired and indicates vaporization or coagulation
- Aiming beam brightness level
- Joule meter (displays total number of Joules delivered)
- Exposure time (displays total time light is emitted)
- Button to arm and disarm the laser
- Error codes and screen prompts

(2) Card Reader - Reads fiber card

(3) Data Port

(4) Storage Compartment

(5) Fiber Shield- Protects the fiber hub from inadvertent damages

(6) Fiber Pole - Secures and protects the fiber (retractable)

(7) Fiber Optic Port - Connection for fiber

(8) Emergency Laser Stop button - Shuts the entire system off in case of emergency

(9) ON / OFF Keyswitch

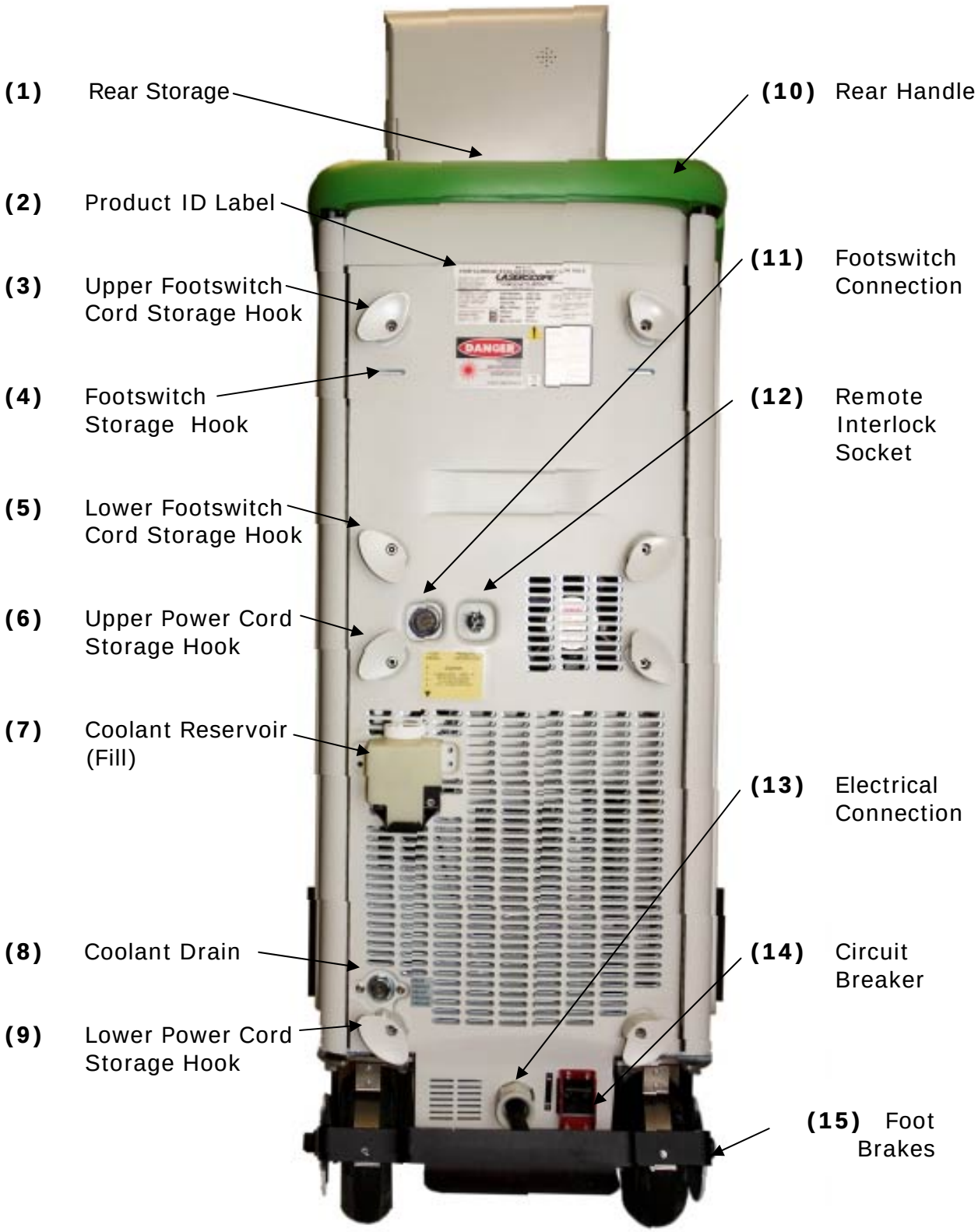


Figure 1-2 Rear View of Laser

Rear View of Laser

(1) Rear Storage

(2) Product ID Label

(3) Upper Footswitch Cord Storage Hook – 2 upper hooks for coiling footswitch cord

(4) Footswitch Storage Hook – 2 hooks for footswitch storage

(5) Lower Footswitch Cord Storage Hook – 2 lower hooks for coiling footswitch cord

(6) Upper Power Cord Storage Hook – 2 upper hooks for coiling power cord

(7) Coolant Reservoir – for refilling the internal cooling liquid (see section 5.2 Coolant Refill Instructions)

(8) Coolant Drain - for draining the internal cooling liquid (see section 5.2 Coolant Refill Instructions)

(9) Lower Power Cord Storage Hook – 2 lower hooks for coiling power cord

(10) Rear Handle – for easy positioning and movement

(11) Footswitch Connection

(12) Remote Interlock Socket - can be connected to the room door so the footswitch will be disabled in the event of entry during lasing.

(13) Electrical Connection

(14) Circuit Breaker - automatically trips in the event of a power overload, shutting off power to the system

(15) Foot Brakes

(16) Vent (under chassis) - might release small amounts of water when system is in longer use

1.2 GREENLIGHT HPS FIBER OPTIC

Product Description

The GreenLight HPS fiber (catalog number 10-2090) features a "side firing" mechanism delivering up to 120W of 532nm light to tissue. The fiber is guided to the treatment site by the continuous flow cystoscope, consisting of an inner and outer sheath set, 30º forward oblique telescope, and visual obturator.

The GreenLight HPS fiber is used to cut, coagulate and vaporize tissue in endoscopic and open surgical procedures at a 70º forward defection angle to the fiber axis. It can rotate 360-degrees, allowing tissue access in multiple planes; and it is used in surgical applications where lateral delivery of laser energy is desired. GreenLight HPS fibers are sterile and designed for single use only.

GreenLight HPS Fiber Optic Specifications

Fiber size	600 microns
Fiber length	12 feet (3.66m)
Laser beam	Side fire
Sterilization	Single use

Fiber Optic Handling Guidelines

If the tip of the fiber accumulates tissue debris during a procedure, turn the laser to STANDBY, remove the fiber from the cystoscope and carefully wipe the tip clean with moistened sterile gauze.

The correct method of removing debris from the fiber is to gently wipe from the tip of the fiber toward the control knob. When the procedure is complete, dispose of the fiber using the standard hospital procedure for bio-hazardous material. GreenLight HPS fibers are single use devices and are not designed to be re-sterilized or re-used.

▲ **Caution**: **Improper cleaning of the fiber tip may cause damage to the fiber.**

Calibration Information

GreenLight HPS fibers are tested at the factory to insure they have the proper transmission factor. They do not have to be calibrated by hospital personnel.

1.3 GENERAL INSTRUCTIONS FOR USE

1. Remove the GreenLight HPS fiber optic from its sterile package using aseptic technique. Be sure to bend back all the tabs from the fiber package nest prior to removing the fiber.
2. Before starting the surgical procedure, the GreenLight HPS fiber optic should be checked for damage.
3. Connect fiber hub into the fiber port on the laser system console.
4. Place the laser in READY mode to activate the aim beam**. CAUTION: Do not press the footswitch while checking the aim beam.** Place the distal end of the fiber on a non-reflective sterile surface and turn slightly until the aim beam can be visualized. If the aim beam is not seen, the fiber may be defective and should not be used.
5. Check for kinks or bright areas along the entire length of the GreenLight HPS fiber. **Do not use the fiber if it has been damaged.**
6. Once the GreenLight HPS fiber has been checked, return the laser to the STANDBY mode.
7. Position the GreenLight HPS fiber optic at the targeted treatment site. The tip of the GreenLight HPS fiber should be in clear view and extended approximately 1 to 2 cm. beyond the distal end of the endoscope. The output beam of the fiber is aligned with the raised surface on the handle. Therefore, the direction of the laser energy can always be determined.
8. Place the laser in READY mode to enable the footswitch control.
9. Laser software automatically corrects for fiber losses such that the power level shown on the system video display indicates the actual amount of power delivered to tissue.
10. Treatment times vary based on distance to tissue, power settings, and other factors. The fiber should be maintained at a distance of 3 mm from the tissue for maximum vaporization. The efficiency of vaporization will decrease with increasing distance from the tissue and coagulation may result.
11. **Avoid contact of fiber tip with tissue**. If, during the procedure the tip accumulates debris, turn the laser to the STANDBY mode, remove the GreenLight HPS fiber from the cystoscope, and carefully wipe the tip clean with a sterile gauze or towel. Begin at the end of the fiber and wipe along the fiber tip.
12. Never bury the cap of the fiber in tissue while firing the laser.

1.4 STERILIZATION

Laserscope recommends that GreenLight HPS fibers be used in only **one** surgical procedure. The GreenLight HPS fiber is a sterile, single-use, disposable device and should not be re-used or re-sterilized. After the completion of the procedure, dispose of the GreenLight HPS fiber following the standard hospital protocol for bio-hazardous material. The GreenLight HPS fiber is ethylene oxide sterilized and is not designed or certified for multiple use.

Do not re-sterilize. Do not reuse.

ADDITIONAL INFORMATION ABOUT REUSING THE GreenLight HPS FIBER

If you need more information on this subject, we recommend the AAMI Technology Assessment Report on the Re-Use of Disposables. It can be ordered from the *Association for the Advancement of Medical Instrumentation* at: (703) 525-4890 (Part Number: TAR6-058). Other questions can be directed to the Laserscope Customer Response Center at (800) 356-7600 or (408) 943-0636.

STORAGE

The GreenLight HPS fiber should be stored under ambient conditions.

WARRANTY

The warranty for the GreenLight fiber optic covers only defects in the material and workmanship. Should you need to return this product, call the Laserscope Customer Response Center for "Return Authorization". Instructions for returning a product to Laserscope are detailed in the Accessory Return/Repair Policy included with each device.

◆ **WARNING: Never secure a fiber optic using a clamp as doing so can result in an unsafe use condition. Use of a clamp can result in the fiber optic being bent at sharp angles or fiber damage which, in turn, can also result in an unsafe use condition. The fiber optic can break causing a burn in the protective jacket and the release of laser energy. If undetected, this condition can result in a burn or ignition of flammable materials.**

When using the fiber with the laser, the fiber device connector should never be allowed to touch the floor or any wet or non-sterile surface. If the fiber connector does come into contact with a surface other than the laser device port, dispose of the fiber in accordance with hospital safety regulations.

Section 2
System Installation

2.1 RESPONSIBILITY

This section provides general guidelines for the installation of the GreenLight HPS™ laser system. This laser system has specific installation requirements. It is the customer's responsibility to fulfill these requirements prior to the installation of the system. Failure to do so can result in intermittent operation and even damage to the laser system. Please read the following information carefully.

> ▲ **CAUTION: The crated system should be stored in a protected area in temperatures between 50°F (10°C) and 104°F (40°C).**

Laserscope's Responsibility

A Laserscope Service Representative will install the laser system. Upon arrival at the installation site, the representative will perform the following:

1. Verify appropriate power.
2. Uncrate the system and inspect for damage.
3. Perform all optical, electronic, and system checks necessary to bring the laser into operation.
4. Inventory all shipped accessories.

Customer's Responsibility

Provisions for proper power must be made prior to the receipt and installation of the system. Return visits by service personnel for installation will not be covered under warranty. Upon completion of the pre-installation site preparation, call Laserscope to check shipment date and schedule installation of the system.

Because the GreenLight HPS™ system uses standard electrical service and has built-in cooling systems, installation requires minimal site preparation.

> ▲ **CAUTION: Do not attempt to turn on the system until it has been installed and tested by a Laserscope Service Engineer. Severe damage to the system will result.**

2.2 SPACE AND POWER REQUIREMENTS

POSITIONING OF THE LASER CONSOLE

- Power connections must be within a radius of 6 feet from where the laser console will be positioned in the treatment room.
- The laser console, in turn, must be able to be positioned not more than 5 feet from the center line of the treatment table to ensure proper handling of the fiber.

ENVIRONMENTAL REQUIREMENTS

The recommended temperature range for the room where the laser will be operated is 55 to 85°F (13 to 30°C).

The laser unit's dimensions are:

	Inches	Centimeters
Width:	16.50	41.9
Depth:	33.75	85.7
Height:	43.25	109.9

POWER REQUIREMENTS

The power source for the GreenLight HPS™ laser system must be 200, 208, 220, 230 or 240 VAC, 30 Amp., 50/60 Hz. The laser will automatically adjust to the voltage and frequency within this range.

The laser can function when some voltage change is present in the service line, however the voltage may not vary by more than ± 10%.

In order for Laserscope to provide the correct electrical plug, the customer must provide information about the installed receptacle in the facility to the Customer Service Department prior to installation. A 250 VAC, 30 Amp, 2 pole, 3 wire receptacle can be used as long as it meets the system's electrical requirements; meets facility, city, county, state, and country ordinances; complies with UL544/UL60601 for leakage current; and is ETL certified.

Section 3
Operating the System

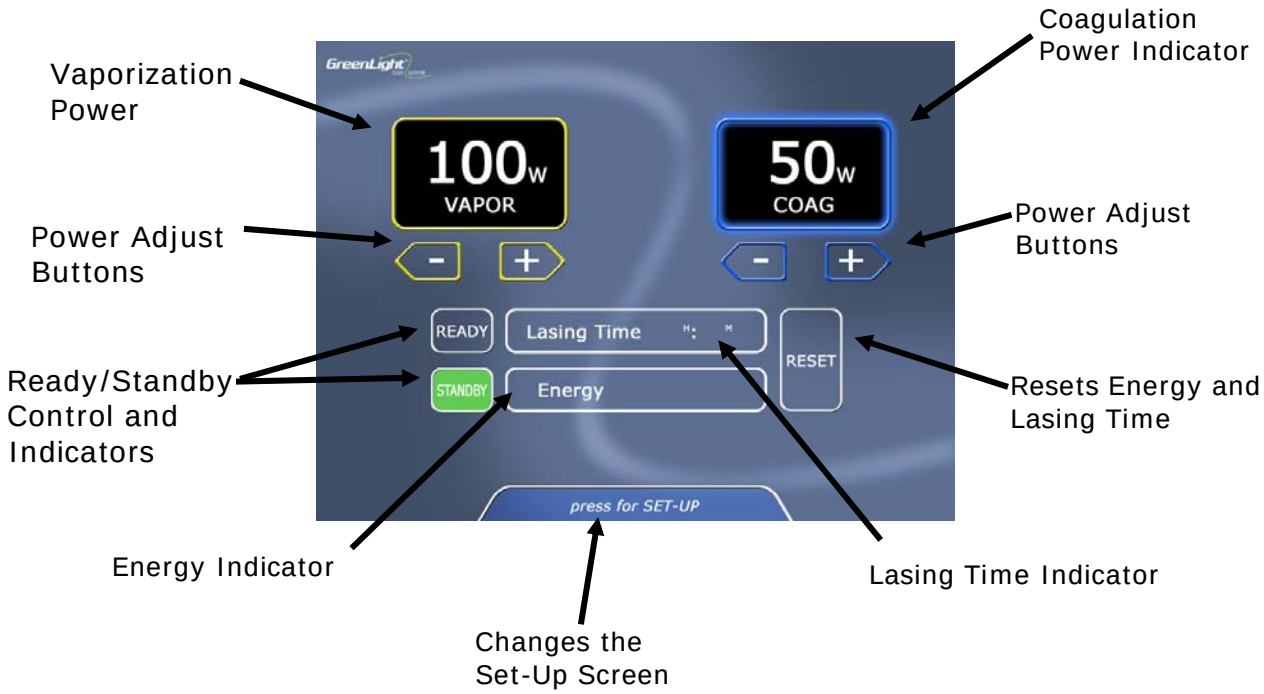
3.1 THE TOUCH SCREEN AND FOOTSWITCH

This section describes the touch screen and footswitch used to control the GreenLight HPS™ laser system, and provides step-by-step instructions on how to operate the system.

Laser parameters are selected and the system status is changed by using a touch screen. You may also use the button on top of the footswitch to go from READY to STANDBY laser status. The aiming beam is activated when the system is changed from STANDBY to READY and the surgical beam is activated by pressing the foot pedal. Press the yellow pedal for VAPOR and the blue pedal for COAG.

Power is set by touching the – or + buttons on the display screen. An audible tone will be heard when maximum or minimum levels are reached. If at any time the laser is unable to deliver the requested power, an alert tone is sounded and the actual power being delivered is displayed.

THE TOUCH SCREEN



THE FOOTSWITCH

3.2 TURNING THE SYSTEM ON

The following procedure is recommended for system start-up:

1. Confirm the system circuit breaker is in the OFF position to prevent a power surge to the system.

2. Connect the power cord to the wall outlet.

3. Turn the system circuit breaker to the ON position.

4. Turn the Keyswitch ON. The following screen will appear:

5. The system will go through a series of self-tests. When the tests are completed, the following screen will be displayed:

6. Located inside of each fiber box attached to the sterile fiber pouch is a fiber card. Insert the card into the card reader. The screen will then prompt you to attach the fiber.

7. Attach the fiber. Connect the fiber optic by pushing the connector into the fiber optic port (arrow on connector facing up) and turning it ¼-turn clockwise until it locks. The following screen will appear:

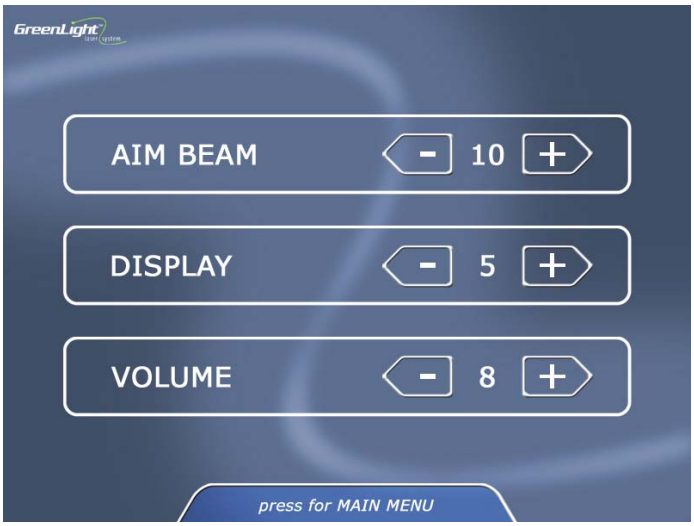
8. To select the treatment parameters, adjust the power by touching − or + under the **VAPOR** and **COAG** indicators.

9. The laser system has both an automatic joule counter and a lasing time indicator, which displays the accumulated Joules and the lasing time. To reset both counters, touch **RESET**. The following screen will appear:

10. Touch the appropriate box to select either **Yes** or **No**.

11. The main screen will re-appear:

12. To change the system's settings, touch **press for Set Up** at the bottom of the main screen. The following screen will appear:



13. Adjust the desired setting by touching the − or + indicators. Press **MAIN MENU** to get back to the main screen.

3.3 OPERATING PROCEDURE

14. Press the **READY** button to activate the red aiming beam and set up the laser for emission. READY will change to orange.

15. The system is now ready for use in a procedure. Laser energy will be emitted when the footswitch is pressed. The **VAPOR** or **COAG** buttons will become active and an audio tone (adjustable) heard during an emission. The system will return to STANDBY mode after two minutes without any exposures. To go back to STANDBY**,** press **STANDBY** or step on the **Ready/Standby** footswitch**.**
16. Treatment power may be changed at any time by touching the - or + buttons.
17. The laser emission can be disabled and the aiming beam turned off at any time by pressing the **STANDBY** button or stepping on the **Ready/Standby** footswitch.
18. (Press the red **Emergency Laser Stop** button **for emergencies only**).
19. Take care not to cut or damage the cord between the footswitch and the laser.

20. If the fiber card or fiber optic is removed, the screen will display:

(or Please Attach a Device)

- If less than 24,000 joules of accumulated energy has been used, then re-insert the fiber card or fiber optic and continue.
- If more than 24,000 joules of accumulated energy has been used, a **NEW** fiber card and fiber optic must be inserted.

The GreenLight HPS fiber can be used up to the energy limit printed on the seal of the fiber package. The user is alerted by an audible tone and a screen message when less then 50,000 joules remain. If the energy limit has been reached, a new fiber card and fiber optic must be inserted.

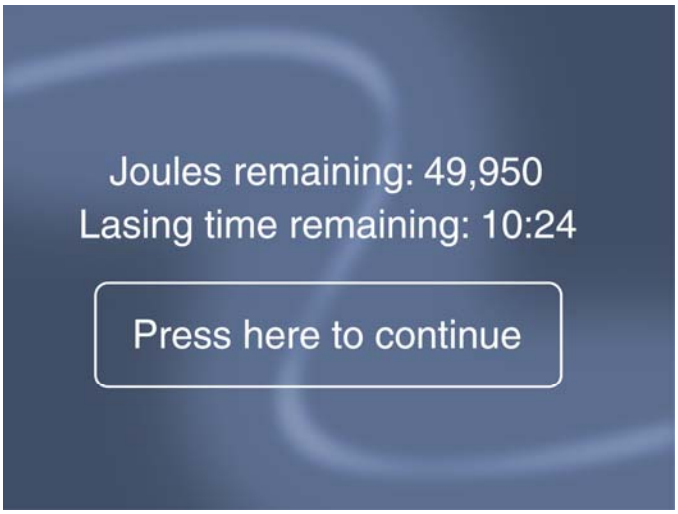
◆ **WARNING: You will not be able resume the procedure with the current fiber card if more than 24,000 joules have elapsed AND the fiber card or fiber are removed or the system is turned off.**

NEVER REMOVE THE FIBER OR THE FIBER CARD PRIOR TO COMPLETING THE PROCEDURE.

The following sequence of alerts will appear:

1. An audible tone will alert the user when 50,000 joules of usage remain on the fiber. The remaining energy will be displayed on the screen.

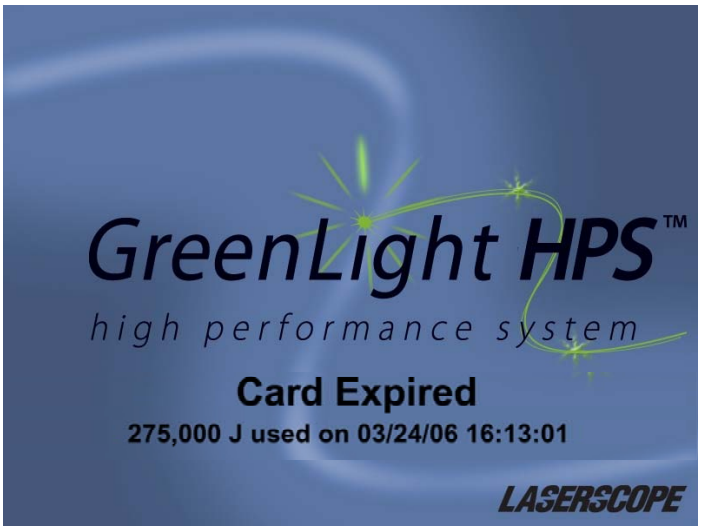
2. The following message will appear on the screen when the user lifts the foot off the pedal for the first time after less then 50,000 joules remain:



3. Press the screen as indicated to continue. The main screen will appear. Joules and lasing time remaining will be displayed.

4. To get the laser into Ready Mode, press the Ready/Standby button.

5. The following message will appear when the energy limit has been reached:



6. To continue a procedure when the energy limit has been reached, a new fiber card and fiber optic must be inserted.

3.4 TURNING THE SYSTEM OFF

After the completion of the procedure, please follow the shut down instructions as follows:

1. Record the Joule Meter total and lasing time, if desired.

2. Disconnect the fiber and discard in accordance to hospital policy for biohazard waste. The fiber is a single use device.

3. Remove the used fiber card. Information on recycling cards is on the back of the card. Accidental insertion of a used card will display a "Card Expired" message with the date and time the card was used.

4. Turn the Keyswitch to the OFF position and remove the key. Store the key in a safe place.

5. Coil the footswitch cable around the designated hooks and hang foot-switch onto the rear panel of the laser.

6. Switch the circuit breaker on the rear panel of the laser to the OFF position.

7. Disconnect the power cable from the wall outlet, observing appropriate precautions for handling electrical equipment.

8. Coil the power cable around the designated hooks on the rear panel of the laser.

▲ **CAUTION*:* Attach fiber port Dust Plug whenever a fiber is not attached to the fiber port.**

■ **NOTE:** If the laser is going to be stored for a long period of time, the storage temperature must be between 50°F (10°C) and 104°F (40°C).

Chapter 4
Physician Information

4.1 TRAINING REQUIREMENTS

The GreenLight HPS™ laser system should be used only by practitioners who have been trained in its proper use. All users and support staff must have thorough knowledge of its operation and its effects. Users should familiarize themselves with this operator's manual and with this device in a non-clinical setting before using it for the treatment of patients in a clinical situation.

4.2 INDICATIONS

▲ CAUTION: Federal (USA) Law restricts this device to sale by or on order of a Physician.

The GreenLight HPS™ laser system and accessories are intended for use in endoscopic (cystoscopic) 532 nm laser resection of the prostate for the treatment of benign prostatic hypertrophy/hyperplasia (BPH). The device is not intended to treat prostate cancer. The laser system has also been cleared for use on various other soft tissue applications including bladder tumors and urethral strictures.

4.3 CONTRAINDICATIONS

The GreenLight HPS™ laser system and fiber optic should only be used by a qualified and trained surgeon. The use of the laser system is contraindicated for patients:

- Whose general medical condition contraindicates surgical intervention
- Where appropriate anesthesia is contraindicated by patient history
- Where tissue (especially tumors) has calcified
- For hemostasis of vessels over approximately two millimeters in diameter
- Where laser therapy is not considered the treatment of choice
- Bleeding disorders and coagulopathy
- Prostate cancer
- Acute urinary tract infection (UTI)
- Severe urethral stricture

4.4 POTENTIAL COMPLICATIONS AND RISKS

The same complications and risks that exist for conventional or traditional surgery exist for laser surgery. These include, but are not limited to, the following:

Pain: Short-lived pain may occur immediately following endoscopic/ cystoscopic laser therapy and may persist for as long as 48 hours.

Fever and Leukocytosis: Immediately after laser therapy, the patient may experience fever and leukocytosis, which are commonly associated with tissue destruction. These generally resolve without treatment. Cultures may be indicated to exclude the possibility of infection.

Bleeding: Patients may experience bleeding at the site of the laser therapy during or after laser therapy. Post-treatment hemoglobin and hematocrit are recommended to assess the severity of the bleeding.

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 any endoscopic/cystoscopic procedure. To clinically diagnose perforations, patients must be closely monitored post-operatively through physical assessment of clinical symptoms, hematology studies as deemed appropriate, and radiography.

Other complications may include:

- Allergic reaction to medication
- Ulceration
- Edema
- Chills
- Urethral stricture
- Delay in healing
- Sloughing
- Bladder neck contracture
- Epididymitis

4.5 PRECAUTIONS

- The GreenLight HPS™ laser system is a surgical device to be used by surgeons who have been trained in laser surgery through courses, preceptorships, and under the guidance of other surgeons knowledgeable in laser use. No claim is made that the laser will cure any medical condition.
- No claim is made that the GreenLight HPS™ laser system will cure any medical condition, or entirely eliminate the diseased entity. Repeated treatment or alternative therapies may be required.

- The surgeon should become fully acquainted with the unique surgical effects produced with the GreenLight HPS™ laser system prior to clinical use. These effects include coagulation, depth of penetration, and cutting intensity.
- Prior to turning the laser system on, operating room personnel and the patient should be wearing protective eyewear suitable for 532nm laser energy.
- Laserscope has no clinical information or experience concerning the use of Laserscope's laser systems on pregnant women or nursing mothers.
- The risk of combustion, perforation, and laser-induced hemorrhage, all of which could cause serious or fatal complications, must be fully explained to the patient.
- As with conventional endoscopic treatment, adverse reactions such as fever, chills, sepsis, edema and hemorrhage may occur following laser treatment. In extreme cases, death may occur due to procedural complications, concurrent illness, or the application of the laser. In the case of the treatment of BPH, reported adverse events have been: decreased or retrograde ejaculation; urinary retention; bladder neck contracture; urethral strictures; hematuria; renal insufficiency; incontinence; potential for re-treatment and shortness of breath.
- Use of lower power levels and shorter exposure times are required in order to prevent thermal damage to underlying structures; for example, to thin-walled structures, such as the bladder.
- The surgeon should carefully assess the target and surrounding tissue. Then begin at the lowest power, with short duration exposures. Note the surgical effect and adjust the settings until the desired effect is obtained.
- Before operating the laser system, surgeons and all staff operating the laser should carefully read and become familiar with the Operator's Manual.
- Careful assessment of the target and surrounding tissue should be made, and appropriate power should always be used.
- Tissue perforation can occur if excessive laser energy is applied. This can occur through the use of excessive laser power or the application of power for excessive periods of time, particularly on diseased tissue.
- Aim and use the laser only on tissues that are in full view.
- Extra caution should be used when lasing tissue in close proximity to known arteries, nerves and veins.
- Flash fires can occur. A basin of water should be available in case a fire should occur.
- The laser may not be effective for coagulation in massive hemorrhage situations. The surgeon must be prepared to control hemorrhages with

- strident alternative non-laser techniques, such as ligature or electrocautery.
- Alterations in surgical approach or technique may be required to accommodate laser use.
- The surgeon should schedule follow-up visits in the same manner as for any patient undergoing such surgery with other modalities.
- Use caution when treating patients who have had difficulty with previous endoscopic/cystoscopic procedures.
- Extra precaution should be taken when radiation therapy and laser therapy are to be used concurrently, including more stringent post-operative monitoring. Clinical studies have shown that patients who have undergone radiation therapy present a greater risk of perforation or tissue erosion.
- To avoid damage from the treatment beam or treatment beam backscatter, it is recommended that the fiber be fully in the visual field. Do not fire the laser unless the aim beam is visible and directed at the intended target.

Chapter 5
Maintenance

Introduction

The GreenLight HPS™ laser system has been designed to provide trouble-free operation with minimal maintenance. This section provides information on the routine maintenance and care required for these laser systems.

The laser, cooling system, and control electronics are enclosed in a tamper-resistant console. The console does not contain any user serviceable components.

5.1 CARE OF THE CONSOLE

The console may be wiped down periodically with a cloth dampened with a weak solution of water and mild detergent or a mild cleaning agent.

When cleaning the console, never do the following:

- NEVER use harsh or abrasive cleansers, especially on the LCD display screen panel. Damage to the finish will result.

- NEVER pour water or any other liquid over the console. If any liquid is spilled on the console and it is thought that some may have gone inside, TURN THE UNIT OFF and call the Laserscope Customer Response Center.

5.2 COOLANT REFILL INSTRUCTIONS

The GreenLight HPS™ laser system uses a vented internal cooling system that uses distilled or de-ionized water. Over time, some evaporation can occur resulting in a “Water Low” system prompt. The following instructions describe the water filling process for restoring the proper coolant level.

INSTRUCTIONS FOR USE

- **NOTE*:*** The laser holds approximately 1,700 ml of distilled or deionized water.

The following procedure is to be used to top off the water level for the GreenLight HPS™ laser system only if a low water fault occurs.

1. Turn the circuit breaker off and unplug the laser.
2. Remove the reservoir cap in the rear of the laser.
3. Pour water into the filler reservoir until its level stops falling. Fill the reservoir to just beyond the half way point, stop, and repeat until the level stops falling.
4. Plug system in, turn on circuit breaker, and turn the laser key switch to on.
5. Make sure that the filler reservoir is still about half full. Add water if necessary.
6. Replace cap.
7. Continue with laser start up. If a "water low" message is still present, call Laserscope Customer Service at (800) 356-7600 from inside the US or +1 (408) 943-0636 from outside the US; or call your local Laserscope distributor.

5.3 PREVENTATIVE MAINTENANCE SCHEDULE

For optimum performance of the GreenLight HPS™ laser system, preventative maintenance needs to be performed every six (6) months.

Please contact the Laserscope Customer Service at (800) 356-7600 or (408) 943-0636 or your local Laserscope distributor for more information concerning preventative maintenance or to schedule an appointment with a Laserscope service repair representative.

Chapter 6
Troubleshooting

Introduction

The GreenLight HPS™ laser system's self-check mechanism will alert operating room staff if there is a mechanical or software problem. A message will appear on the screen at the time of system malfunction. Depending on the severity of the problem, the system will either maintain status (Information Messages) or require a solution before reactivating (System Prompts and Service Prompts).

6.1 SYSTEM PROMPTS

A system prompt will appear and replace the main display. The following messages require that corrective action be taken.

Message	**Corrective Action**
Emergency Stop	Touch the "Press Here to Continue" prompt.
Not In Ready	Press the Ready/Standby button
Attach a Fiber	Attach a valid device.
Invalid Fiber Type	Device attached is not valid GreenLight HPS™ device.
Remote Interlock Open	Close the Remote Interlock on the rear panel of the system.
Device Port Overheat	Wait for device port to cool off. Contact Laserscope Customer Service if problem persists.
Please Wait	The system is warming up (this should not take longer than 5 minutes)
Water Low	Restore coolant level (see **Section 5.2 Coolant Refill Instructions**). Turn system off, and add distilled water.
Check Card Insertion	Reinsert fiber card. If problem persists, use one of the spare fiber cards shipped with the system and Contact Laserscope Customer Service.

6.2 SERVICE PROMPTS

An Error Code will appear and replace the main display. When these error codes appear, the operator should note the problem number and contact Laserscope Customer Service at (800) 356-7600 or call your local Laserscope distributor.

NOTE:

System Prompts:	**Correct the problem as indicated in the System Prompt table above and continue the procedure.**
Service Prompts:	**The system can be reset if you see the message "Press Here to Continue". If the system cannot reset itself, then it will require servicing before it can be used again. In any event, Service should always be notified of any Service Prompt Errors.**

Specifications

Product specifications

Laser Type	Solid State, Frequency Doubled
Wavelength	532 nm
Average Power Levels	20-120 Watts in 10 Watt increments
Aiming Beam	Diode laser, red, 635 nm, <5mW adjustable
Output Beam Divergence	0.05 - 0.15 radians full angle at half minimum
Electrical Requirements	200-240 VAC @ 60 Hz or 50 Hz, 30 A
Operating Temperature	55° F (13° C) – 85° F (30° C)
Storage/Transport Temperature	50° F (10° C) – 104° F (40° C)
Humidity	10% - 90%, non-condensing
Dimensions	Width: 16.5 inches (41.9.1 cm) Depth: 33.75 inches (85.7 cm) Height: 43.25 inches (109.9 cm)
Weight	335 pounds (152 kg)

Warranty

WARRANTY POLICY

Laserscope warrants its products against defects in materials and workmanship. The warranty period begins on the date of installation or ninety days after the date of shipment, whichever is first, where installation is included in the purchase price; and on the date of shipment where installation is not included in the purchase price. The duration of the warranty period and the extent of the warranty vary from product to product. Every Laserscope product is assigned a warranty code that defines the nature and duration of the warranty provided for the particular product. A copy of Laserscope's Warranty Policy, which defines the warranty codes in detail and assigns a code to each product, is available from Laserscope without charge and is incorporated herein.

If Laserscope receives notice of such defects during the warranty period, Laserscope shall, at its option, either repair or replace equipment or components that prove to be defective. Equipment or components shipped under this agreement or used as replacements under this warranty may be refurbished or new equipment or components at Laserscope's option.

Warranty service is performed either on-site or at a Laserscope facility at Laserscope's option. Where warranty service is provided on-site, the work will be performed at the Buyer's facility, or a location that is mutually agreed upon, at no charge. Where warranty service is provided at Laserscope, products must be returned to a Laserscope service facility designated by Laserscope.

Products may only be returned with the prior approval of Laserscope. A valid Return Material Authorization Parts Request (PR) number must evidence such approval. Buyer shall prepay shipping charges (and shall pay all duties and taxes) for products returned to Laserscope. Laserscope shall pay for return of products to Buyer.

Where warranty work is performed at the Buyers facility, such work will be performed during normal working hours. If Buyer requests work to be performed outside of normal working hours then Buyer shall pay reasonable charges for the incremental cost of such work. Buyer agrees to make the Equipment available to Laserscope during normal business hours.

Limitation of Warranty

The foregoing warranty shall be voided where, in Laserscope's sole judgment, there has been:

1. Improper or inadequate maintenance by Buyer, or service performed by anyone other than Laserscope or a party authorized by Laserscope to perform service on the specific item covered under this warranty.
2. Unauthorized modification or misuse.
3. Operation outside of the environmental specifications for the product.
4. Improper site preparation and maintenance, including but not limited to improper electrical utilities.
5. Use of delivery devices or accessories not manufactured by Laserscope or approved by Laserscope for use with Laserscope Systems.

Additional Terms, Mobile Systems Warranty

Due to the special situations surrounding GreenLight HPS™ laser systems that are moved to numerous sites of service, the following conditions apply in addition to the above:

1. Every mobile provider must have a clinical trainer on staff. This person must be certified by Laserscope to provide clinical support to physicians for their first cases and beyond.
2. Every mobile provider must have qualified (as certified by Laserscope) technicians on staff to transport, setup and operate the GreenLight HPS™ during all cases. Annual re-certification is required.

Transport of the System

1. Every mobile provider must have suitable transportation for moving the laser from site to site.
2. The vehicle must have a lift gate or ramp, depending on the height of the vehicle, to load and unload the system.
3. The system must be transported in the original shipping crate or other suitable method designed to absorb road shock (both vertical and horizontal loads) to protect the system during transport. To absorb vertical shock and vibration the floater (plywood base supported by foam blocks) can be removed from the original shipping crate and installed in the transport vehicle.
4. Exposure to freezing temperatures: The laser must be protected from temperatures below 32 degrees Fahrenheit.

THE WARRANTY SET FORTH ABOVE IS EXCLUSIVE AND NO OTHER WARRANTY, WHETHER WRITTEN OR ORAL OR IN ANY COMMUNICATION WITH BUYER, IS EXPRESSED OR IMPLIED. LASERSCOPE SPECIFICALLY DISCLAIMS THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR USE.

THE REMEDIES PROVIDED HEREIN ARE BUYER'S SOLE AND EXCLUSIVE REMEDIES. IN NO EVENT SHALL LASERSCOPE BE LIABLE FOR DIRECT, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, (INCLUDING LOSS OF PROFITS) WHETHER BASED ON CONTRACT, TORT OR OTHER LEGAL THEORY.

Warranty Codes

Table W-1 summarizes the warranty codes assigned to Laserscope products, and lists the warranty period for each code.

Warranty Code	Warranty Period	Commencement Date
12	12 months	Installation
6	6 months	Shipment
3	3 months	Shipment
1	1 procedure	Shipment
0	None	N/A

Table W-1 Warranty Codes

- **NOTE:** All warranty periods are expressed in months or number of procedures.

Product Warranties

Table W-2 summarizes the product warranties and the products to which they apply.

■ **NOTE:** The products listed under Warranty Code 1 in Table 2 are examples only. This list is not inclusive.

Warranty Code	Products Covered	Notes
12 Parts & Labor for 12 months from Installation not to exceed 15 months from shipment	GreenLight HPS™ laser system	--
3 Parts & Labor for 3 months from Shipment	Adapter Plates & Rings Eye Protection Filters Surgeons Glasses & Goggles	Replacement parts will be warranted for the remaining amount of the 90-day warranty or 30 days, whichever is the longest.
0 No Warranty Provided	Manuals and Literature Products Not Listed	--

Table W-2 Product Warranties

In addition to the above warranties, service visits will warranty Parts & Labor for 30 days from completion of the billable service repair or shipment of part(s).

PRODUCT RETURNS

Accessory Return / Repair Policy

Laserscope's product insert, *Accessory Return/Repair Policy*, is contained in this section. Please refer to this insert for answers to questions on return and repair policies and procedures for end-users of Laserscope accessories.

All returns are handled by the Laserscope Customer Response Center at (800) 356-7600 or (408) 943-0636. After hours response will be handled on a call back basis.

Accessory Return/ Repair Policy

English

Return/Repair Policy and Procedures for End-Users of Laserscope Accessories

Overview of Laserscope's Return/Repair Policy:

Generally, any Laserscope accessory that fails during its warranty period because of defects in materials or workmanship—NOT MISUSE—may be returned by the customer to Laserscope for replacement. Additionally, certain accessories that fail after the warranty period has expired may be returned for repair. Warranty policy for returned products may be obtained from your Laser System Operator's Manual. After warranty, the customer may be responsible for repair costs.

The policies and procedures outlined below are not a complete explanation of Laserscope's return and repair policies and procedures. Please refer to the Laserscope Terms and Conditions of Sale (on the back of the Laserscope Sales Order) for a complete explanation or contact the Laserscope Customer Response Center for this information.

Procedure For Returning Laserscope Accessories:

All products returning to Laserscope must have a signed Sterilization Certificate and a Return Materials Authorization (RMA) number. The Sterilization Certificate must be attached to the outside of the returning package. RMA numbers and Sterilization Certificates may only be obtained by calling the Customer Response Center at 1-800-356-7600 Monday through Friday, 7:00 am to 4:30 pm Pacific Standard Time. If you return a failed product that is under warranty, Laserscope will credit your account or replace the product only if you first obtain an RMA number. Products not covered by warranty must also have an RMA number, and, upon receipt, your return request will go through Laserscope's determination process before being accepted for credit consideration.

If a *Warranty Return Form* or any *return questionnaire* was supplied with the device or is provided by Laserscope's Customer Response Center when advised of the intent to return, the form must be completed and returned with the product.

Sterile/Non-Sterile Products:

In order to protect everyone who may come in contact with a "Returned Product", a Sterilization Certificate must be attached to the outside of the returning package.

If a product has not been used and is in its original unopened package, it may be returned non-sterile once an RMA number has been issued. Products must be returned within 30 days of the original shipment date to be given credit consideration. A 20% restocking fee will be charged for all unused and unopened returned products.

Products returned without the Sterilization Certificate on the outside of the returning package will be returned unopened. Boxes that are opened and found to be inappropriately decontaminated shall be contained and isolated from all other materials. The customer shall be notified by Customer Response of charges levied for the disposal of goods in accordance with OSHA Standards or, goods will be repackaged in accordance with DOT regulations and returned to the customer as hazardous material at customer's expense.

Unused and Unopened Disposable Accessories:

Sterile disposable products can only be returned if the seal on the original package is not broken. A 20% restocking fee will be charged for all unused and unopened disposable accessories. Products must be returned within 30 days of the original shipment date to be given credit consideration.

Obtaining a Return Material Authorization (RMA) Number:

When calling Laserscope's Customer Response Center to request an RMA number, please be prepared to provide the following information:

1. Your facility: Customer name, address and contact person.
2. Your Laserscope Customer Number.
3. Your Laserscope Sales Order Number.
4. Your original Purchase Order Number.
5. Catalog Number and quantity of product to be returned.
6. Serial or Lot Number of product to be returned.
7. Reason for return (including laser system error codes displayed, if available).
8. Your "replacement" Purchase Order Number.

Shipping Procedures:

Ship the package, postage pre-paid. Indicate the RMA number on the outside of the package. Insure the package for its appropriate value (as indicated on the original purchase order), as Laserscope will not be financially responsible for the loss of any product being returned.

Note:

IF THE PRODUCT IS NOT RECEIVED BY LASERSCOPE WITHIN 30 DAYS OF ORIGINAL SHIPMENT DATE, THE RETURN PRODUCT WILL NOT BE ACCEPTED FOR CREDIT CONSIDERATION.

Replacement Products Out of Stock or Not Timely Delivered:

If, as a result of unforeseen events, Laserscope does not have the appropriate replacement product in stock or the replacement product is not timely delivered, Laserscope assumes no responsibility for monetary loss or damage resulting to the customer/end-user.

Determining if Credit is Due:

Within 30 days of receipt of a returned product, Laserscope will evaluate and test the returned item to determine if credit is due to the customer. Laserscope warrants products only for defects in materials and workmanship and only for a specific period, so it is possible that returned products may not be credited to a customer's account.

Support Materials

To help you and your staff organize the operation and management related to the GreenLight HPS™ laser system, Laserscope has developed a package of practice assistance documents. Listed below are the forms that are included in this chapter. For printing and customizing purposes, the forms are also included on the CD supplied with this manual.

- **Clinical Competency Check List**
- **Equipment Check List** (OR equipment needed for the procedure)
- **Laser Log** (Check list and log for operation of the GreenLight HPS™ Laser System)
- **Operative Record Template**. (The document is a template and must be customized for each individual patient treatment. The document **must not** be used as a preprinted operative record.)
- **Pre-Procedural Patient Instructions**
- **General Post-Procedural Instructions for Patients**

Clinical Competency Validation Checklist
GreenLight HPS™ Surgical Laser System

Name/Title_____Date_____

Unit/Department _____

	Performance Criteria	Criteria Met	Initials and Date	Comments
1.	Completed basic training course highlighting laser safety and physics specific to the GreenLight HPS™ laser system and procedures performed in the facility.			
2.	Prepares surgical suite for laser use: • Covers all windows with opaque covering (placed on inside of window) • Posts laser warning signs, specific to the laser being used on all access doorways • Inspects laser safety eyewear for scratches or damage • Has laser wavelength specific safety eyewear posted at all access doors to surgical suite • Fire extinguisher and basin of water are immediately available			
3.	Performs proper laser system setup steps: • Knows location of laser serial number • Inspects power cord for damage prior to connection to wall outlet. • Demonstrates connection of foot pedal to laser • Turns on circuit breaker at rear of laser • Powers laser on • Observes self-test • Inserts fiber card successfully • Connects GreenLight HPS™ fiber to laser correctly • Identifies fiber serial number (located at machine connection of laser fiber) • Places GreenLight HPS™ fiber in fiber support pole • Knows location of Emergency Laser Stop Button			
4.	Laser Safety During Procedure • Ensures that all personnel in room wear wave-length specific laser safety goggles • Ensures that patient's eyes are appropriately protected. Patients who are awake are given wave-length specific goggles. Patients who undergo general anesthesia are provided with other appropriate protection such as wet eye pads or laser-specific eye shields. • Demonstrates proper placement of foot-pedal and black connecting hose in a position convenient to the surgeon; preventing unintended footswitch activation or potential damage to the cord by the laser, personnel, or other equipment.			

	• Removes unneeded footswitches from the vicinity of the laser footswitch, preventing possible surgeon confusion and inadvertent firing of the laser. • Demonstrates use of "READY/STANDBY" button on touch screen and footpedal • Knows how to adjust laser power settings			
5.	Knowledge/assistance during procedure • Recognizes when a fiber needs cleaning • Knows proper method of cleaning fiber (from distal to proximal end of fiber) • Recognizes importance of keeping blue arrow in visual field at all times, and reminds surgeon appropriately • Understands safety implications of placing laser in STANDBY/READY modes when not being actively used. • Verifies relative fiber degradation status by requesting that aiming beam be examined at appropriate times during procedure			
6.	Laser Shut-down • Records Joules, power settings and duration of laser time used during procedure on laser log • Powers laser off • Turns off circuit breaker • Disconnects power cord and stores it properly at rear of laser • Returns key to designated secured area • Collects and accounts for all laser protective eyewear and stores them in protective cases • Removes window coverings from access doors/windows • Removes laser warning signs and stores them in appropriate location. • Cleans and stores foot pedal on rear panel storage rack.			

Evaluator Name _____

Title _____

Evaluator Signature _____

Date _____

GreenLight HPS™

SUPPLIES NEEDED

The following is a list of supplies needed to perform a procedure with the *GreenLight HPS*™ laser system.

STERILE SUPPLIES

- Continuous flow laser cystoscope (22-24 Fr) consisting of:
  - Outer sheath
  - Inner sheath (laser bridge)
  - Visual or blunt obturator
  - 30º telescope
- Seal for fiber port of cystoscope
- Video camera or sterile camera drape
- Fiberoptic cable
- De-fogging agent (anti-fog) for telescope, camera, and video camera insert(*optional)*
- Laserscope *GreenLight* HPS™ side-fire laser fiber optic
- 0.9% Saline solution for irrigation (approx. 8-12 units of 3 liter bags at room or body temperature)
- TUR-Y irrigation tubing
- Suction tubing
- Cystoscopy pack
- Cover for back table (instrument trolley)
- Sterile gauze (4'' x 4'')
- K-Y Jelly
- Sterile towels (4)
- Sterile gowns
- Prep solution of choice
- Sterile gloves
- Sterile bowl for irrigation (if desired)
- Have available:
  - Van Buren sounds
  - Foley catheter (16 - 20Fr. 5cc 2-way)
  - Urinary drainage bag
  - 10 cc syringe

NON-STERILE SUPPLIES

- GreenLight HPS™ Surgical Laser System
- GreenLight HPS™ fiber card (supplied in fiber package)
- Laserscope video camera insert marked O.D. 5 at 532 nm (diam. 1.25'' [Part No. 10-0721] or diam. 0.95'' [Part No. 10-0722] dependent on video camera and telescope model). Both video camera inserts are delivered with each GreenLight HPS™ surgical laser system. Soak insert in alcohol to clean and let it dry prior to the procedure.
- Eye protection glasses for 532 laser labeled O.D. (optical density) 5.0 at 532 nm (for everyone in room including the patient).
- Laser warning signs on all entrance doors to the room
- Opaque window covering for laser safety required for all windows
- Light source
- Video cassette recorder (VCR, CD-RW, DVD-RW) *(optional)*
- G.U. Stirrups
- Irrigation collection bottles (or floor drain)
- Irrigation/suction pump (optional)

If you have any questions, please contact our Customer Service Department at (408) 943-0636 or (800) 356-7600 (inside the US and Canada only). International customers, please dial ++1 (408) 943-0636.

GreenLight HPS™
high performance system

Laser Log

Date:		**OR #**	**Patient**		
Surgeon		**Anesthesiolgist**			
Pre Op Dx		**Anesthesia**	General ☐		
			Spinal: ☐		
Post Op Dx			Pudendal Block ☐		
			IV Sedation ☐		
Procedure		**Laser s/n**			
Prostate Gland Size:		**Fiber lot #**	10-2090-		
		Fiber lot #	10-2090		
Circulating Nurse		**Fiber lot #**	10-2090		
		If more than one fiber used, please note joules expended per fiber under comments section			
Scrub Nurse		**Total # of fibers used**	-		
		Laser On	**AM/PM**		
Laser Operator		**Laser Off**	**AM/PM**		
		Lasing Time	**min**	**sec**	
LASER SAFETY PROCEDURES		**Power Settings Used:**			
			watts		**time**
Laser Warning Signs on Doors	Yes ☐ No ☐		**watts**		**time**
			watts		**time**
Wavelength-specific eyewear used	Yes ☐ No ☐		**watts**		**time**
			watts		**time**
Fire Protection	Yes ☐ No ☐		**watts**		**time**
(Fire extinguisher and water basin in room)			**watts**		**time**
			watts		**time**
Windows covered	Yes ☐ No ☐		**watts**		**time**
COMMENTS:					

GreenLight HPS™ OPERATIVE RECORD TEMPLATE

The operative record must be customized for each individual patient treatment. The document must not be used as a preprinted operative record.

PATIENT'S NAME AND DATE OF TREATMENT.

_____anesthesia for the procedure was jointly selected by the patient and his anesthesiologist. The patient was taken to the operating room, placed in the dorsal lithotomy position and prepped and draped in the usual sterile manner. The prostate size was estimated to be _____ g during previous examination.

A ___Fr continuous-flow cystoscope was connected to saline solution irrigation and inserted into the bladder without difficulty in the usual fashion. A preliminary cystoscopic examination was performed during which the ureteral orifices, bladder neck and verumontanum were identified. The GreenLight HPS™ laser was set at ___watts. The GreenLight HPS BPH™ laser fiber was introduced through the working channel of the cystoscope. The median lobe was identified and it was vaporized down to capsular fibers. The bladder neck was then vaporized as far laterally as possible to open up the prostatic urethra. The median lobe was vaporized from the bladder neck to the verumontanum. The left and right lateral lobes were vaporized from the bladder neck to the verumontanum,. Vaporization was continued until the capsular fibers were visualized or until the lateral lobes were adequately vaporized. The proximal adenoma was vaporized first, then the scope was withdrawn to the verumontanum and the most distal adenoma was vaporized, always ensuring that the verumontanum was well isolated. By serially vaporizing the obstructing tissue, a wide open prostatic urethral channel was created. A total of _____ joules were used during the procedure.

During the procedure, any bleeding vessels were effectively controlled. At the end of the procedure, the bladder neck, ureteral orifices, and verumontanum were again inspected, and found to be intact, and without evidence of incidental laser beam damage. The bladder was filled with saline solution irrigation, and the continuous flow cystoscope was removed. External pressure was applied to the dome of the bladder to ascertain the quality of the urinary stream. A strong urine flow was achieved, with minimal evidence of bleeding. A ___Fr (5cc) Foley catheter to straight drainage was inserted. The patient was transferred to the PACU (Perianesthesia Care Unit) in good condition.

GreenLight HPS™
high performance system

PRACTICE NAME HERE PRE-PROCEDURAL PATIENT INSTRUCTIONS

1. Call your doctor if your condition changes, or if you develop a cold, infection or fever.
2. Let your doctor know if you are taking any blood thinners such as aspirin, aspirin-containing medications, Coumadin® or Plavix®. Your doctor may recommend that you stop taking these medicines several days prior to the GreenLight HPS™ procedure.
3. Take any antibiotics as prescribed by your doctor.
4. Ask your doctor to write prescriptions for any medications he thinks you should take before the day of your scheduled procedure. This will allow you to have those medications "on hand" when you leave the surgery center, instead of having to depend on someone else to take them to a pharmacy for you.
5. Write down any questions you have about the procedure. Bring them with you. There will be plenty of time to answer your questions before, during, or after your procedure.
6. You may eat and drink as usual the night before. Your urologist or anesthesiologist may allow a clear liquid breakfast, depending upon the time of day your procedure is scheduled. If you are scheduled to have your procedure before noon, do not take anything by mouth after 12:00 midnight the night before.
7. Wear comfortable, loose-fitting clothing to the hospital or ambulatory surgery center on the day of your procedure.
8. Bring all medications with you on the day of the procedure.
9. Ask your urologist or the anesthesiologist if you should take your regularly prescribed medications on the day of the procedure.
10. Please plan to be at the hospital/ASC at least 2 hours prior to your scheduled treatment. Remember that you will also need to spend some time post procedure to recover from anesthesia prior to being discharged to home. If your doctor has indicated that you will need to stay overnight in the facility, please arrange for someone to pick you up the next morning at _____a.m.
11. Arrange for transportation home; you may not drive or operate dangerous equipment for 24 hours after the procedure. (If you have spent the night in the healthcare facility, you will still need to arrange for a ride home.)
12. If you have any questions, or cannot keep this appointment, please call:

_____ _____

Practice/MD/RN Name Phone

GreenLight HPS™
high performance system

PRACTICE NAME HERE **GENERAL POST-PROCEDURAL INSTRUCTIONS**

1. You may need to wear a catheter to drain your bladder after the procedure, depending upon how much swelling your doctor thinks may occur immediately following the PVP procedure. This catheter is generally removed within 24 hours.
2. Do not drive or operate dangerous equipment for 24 hours following anesthesia.
3. Avoid beverages containing caffeine as they may cause bladder spasms.
4. Activity level: Take it easy for 2 to 3 days. Do not engage in activities requiring heavy lifting, gardening, bicycling etc. This will increase the pressure your abdomen puts on the bladder, and may result in blood in your urine.
5. Take all medications as directed. Typical medications *may* include:
    a. Antibiotic (prevents infection).
    b. Non-steroidal anti-inflammatory drug (reduces inflammation).
    c. A drug to reduce bladder spasms.
    d. Mild over-the-counter pain reliever as needed.
6. Do not engage in sexual activity for 2 weeks.
7. Unless you have been advised to limit your fluid intake due to another medical condition, drink one glass (8 oz. or 1/4 liter) of water for every hour you are awake, about 64 oz. (or 2 liters) per day.
8. Please call the office at _____ to schedule a follow-up appointment.
9. Please call the office immediately if any of the following symptoms appear:
    a. Bright red bleeding in urine with a heavy clot.
    b. Fever over 101º F (38°C).
    c. Inability to urinate for more than 4 hours.
    d. Feeling of bladder fullness that does not go away after urinating.

YOUR CONTACT PERSON, _____, CAN ANSWER ANY NEEDS OR CONCERNS YOU MAY HAVE.

THE TELEPHONE NUMBER IS: _____.