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Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING: Users of the GreenLight XPS™ Laser System should read this manual thoroughly before attempting surgical procedure. Pay attention to all warnings, contraindications, precautions, and adverse events in this manual and other related material. Failure to thoroughly understand and follow all instructions may result in harm to the patient or the user of the laser system.

1 DEVICE DESCRIPTION
The GreenLight XPS Laser System is designed for the vaporization and coagulation of soft tissue using light. One example procedure is the endoscopic (transurethral) resection of the prostate for the treatment of Benign Prostatic Hyperplasia (BPH). The laser system consists of a console, which generates the green laser light and a fiber optic delivery device that transmits laser light from the console to the patient. This laser system is not intended to treat prostate cancer.

1.1 Console
The console is a diode-pumped solid-state laser utilizing Nd:YAG laser gain medium and Acousto-Optic Q Switch. The primary wavelength is 1064 nm. Frequency-doubling crystal is used to generate a 532 nm output beam. Quasi-CW pulse repetition rate is 23.6 kHz. Pulse duration is approximately 100 ns. Pulse energy is approximately 8 mJ at maximum power (180 W). The console generates visible green 532 nm laser light. In vaporization mode, the power settings range from 20 W to a maximum power determined by the fiber delivery device. In coagulation mode, the power settings range from 5 W to 40 W. The console features a plug and play capability that self-adjusts to the facility’s supply voltage, eliminating the need for electrical modifications of the operating facility. The console includes internal cooling mechanisms ensuring safe operating temperatures with no external water connection. Laser energy emission and console status changes are activated through a surgeon-controlled, color-coded footswitch or console touchscreen feature.

1.2 FiberLife
The console is equipped with the FiberLife feature. The FiberLife feature continuously monitors the temperature of the tip of the fiber and momentarily stops the laser emission when the fiber gets too hot. In most cases, this will prevent damage to the fiber if tissue or vapor bubbles accumulate on the tip or there is excessive heating of the fiber.

In most cases, the laser will turn back on immediately and the procedure continues without interruption. There will be noticeable blinking of the working beam. If the FiberLife feature is activated continuously, vaporization efficiency will be significantly reduced. In this case, the fiber should be cleaned or replaced. The console will automatically detect this condition, put the laser in Standby mode, and display a message.

The FiberLife feature will stop laser emission if the laser is accidentally fired while inside the cystoscope. Generally, this will prevent serious damage to the cystoscope. Some discoloration of the metal may still occur, which can increase the possibility of corrosion.

1.3 Vaporization
The console uses photo-selective vaporization for the resection of soft tissue. The 532 nm green laser light emitted is strongly absorbed by oxyhemoglobin in red blood cells. Absorption of the laser light energy results in the generation of heat, which bursts cells, effectively vaporizing the targeted tissue. Additionally, the heat can coagulate blood vessels near the resected tissue, allowing for a clear surgical field. If bleeding occurs, the console also has a pulsed coagulation feature.

1.4 Coagulation
The console has a pulsed coagulation feature. In this mode, activated when the coagulation (coag) footswitch is pressed, laser emission is pulsed at a rate of ~12.5 Hz with a duty cycle of ~25 %. This pulse mode improves the coagulative effect.

1.5 User Information
Only persons trained in the use of the laser console and who have sufficient medical knowledge should use the GreenLight XPS Laser System. The user should have a demonstrated understanding of the laser console’s operation and the risk associated with improper use.

1.6 Contents
• Laser Console
• Footswitch
• Fiber Pole
• Key Chain
• Laser In-Use Sign
• Physician Protective Eyewear
• Spectator Protective Eyewear

2 INTENDED USE/INDICATIONS FOR USE
The GreenLight XPS Laser System is intended for the surgical incision, excision, vaporization, ablation, hemostasis, and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs, and glands.

Suggested applications include:
• General Surgery: Vaporizing, coagulating, incising, excising, debulking, and ablating of soft tissue as well as in endoscopic (for example, laparoscopic) or open surgeries.
• **Gastroenterology:** Tissue ablation and hemostasis in the gastrointestinal tract; esophageal neoplastic obstructions, including squamous cell carcinoma and adenocarcinoma; gastrointestinal hemostasis (including varices, esophagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, angiodysplasia, stomal ulcers, non-bleeding ulcers, gastric erosions); gastrointestinal tissue ablation (benign and malignant neoplasm, angiodysplasia, polyps, ulcers, colitis, hemorrhoids).

• **Gynecology:** Vaporizing, incising, or coagulating tissue associated with treatments of conditions such as endometriosis; cervical, vulvar, and vaginal intraepithelial neoplasia; condyloma acuminata; uterine septum; intrauterine adhesions; submucosal fibroids.

• **Head and Neck/Otorhinolaryngology (ENT):** Tissue incision, excision, ablation, and vessel hemostasis.

• **Neurosurgery:** Incising, excising, coagulating, and vaporizing neurological tumors of the firm textured type.

• **Ophthalmology:** Post-vitrectomy endophotocoagulation of the retina.

• **Plastic Surgery:** Vaporizing, coagulating, incising, excising, debulking, and ablating soft tissue in endoscopic and open procedures.

• **Spinal Surgery:** Percutaneous lumbar discectomy.

• **Thoracic Surgery:** Vaporizing, coagulating, incising, debulking, and ablating soft tissue, including lung tissue in thoracoscopic or open procedures.

• **Urology:** Cutting, coagulating, or vaporizing urologic soft tissues. Open endoscopic minimally invasive urological surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including treatment of bladder, urethral and ureteral tumors; condylomata; lesions of external genitalia; urethral and penile hemangioma; urethral strictures; bladder neck obstructions; and vaporization of prostate tissue for men suffering from Benign Prostatic Hyperplasia (BPH).

The GreenLight XPS™ Laser System is intended for the hospital, office, and outpatient surgery center markets.

3 CONTRAINDICATIONS

The laser system is contraindicated for patients with the following conditions:

• General medical condition that contraindicates surgical intervention
• When appropriate anesthetics is contraindicated by patient history
• Calcified tissue (especially tumors)
• Hemostasis of vessels over approximately two millimeters in diameter
• When laser therapy is not considered the treatment of choice
• Uncontrolled bleeding disorders and coagulopathy
• Prostate cancer
• Acute urinary tract infection (UTI)
• Severe urethral stricture

The GreenLight XPS Laser System is contraindicated in the presence of severe urethral strictures; however, the system can be used in the treatment of urethral strictures with proper cautions. A severe stricture shows visible narrowing on urethrography or ultrasonography, with near total obstruction that makes passage of instruments difficult or dangerous. Use caution to avoid injury to urethral tissue.

4 WARNINGS

• Everyone in the room is required to wear protective eyewear.
• Never use a clamp to secure the laser fiber to a drape. The use of a clamp to secure a fiber may cause the fiber to bend at sharp angles, which can damage the fiber, causing 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.
• Do not fire the laser unless the aiming beam is visible and directed at the targeted tissue.
• Never activate the laser energy unless the fiber tip extends visibly beyond the tip of the endoscope.
• Unauthorized use of internal controls, adjustments to the equipment, or performance of procedures other than those specified therein, may result in hazardous radiation exposure.
• Warning signs are not interchangeable. Select a sign that is appropriate for the wavelengths in use.
• 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 dissipate heat quickly. When tissue is touched under these conditions, a burn may result.
• Unauthorized modification of this equipment is not allowed. Do not attempt to repair or alter any components/parts of the GreenLight XPS Laser System. All repairs and servicing are to be performed only by Boston Scientific Corporation (BSC) or personnel authorized by BSC.

5 PRECAUTIONS

• Before operating the laser system, surgeons and all staff operating the laser should carefully read and become familiar with the User’s Manual.
• Do not attempt to turn on the laser system until it has been installed and tested by a BSC service engineer. Severe damage to the laser system may result.
• Alterations in surgical approach or technique may be required to accommodate laser use.
• The laser system is a surgical device used by surgeons who have been trained in laser surgery through courses, preceptorships, or under the guidance of other surgeons knowledgeable in laser use.
• The surgeon should become fully acquainted with the unique surgical effects produced with the laser system before clinical use. These effects include coagulation, depth of penetration, and cutting intensity.
• 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 non-laser treatments, adverse reactions such as fever, chills, sepsis, edema, and hemorrhage may occur after laser treatment. In extreme cases, death may occur due to procedural complications, concurrent illness, or the application of the laser.
• Caution should be taken when radiation therapy and laser therapy are to be used concurrently, including more stringent post-operative monitoring. Patients who have undergone radiation therapy may present a greater risk of perforation or tissue erosion. Use caution with patients who had previous esophageal/tracheal fistulae or episodes of aspiration.
• Use caution when treating patients who had difficulty with previous endoscopic/cystoscopic procedures.
• No claim is made that the laser system will cure the medical condition or eliminate the diseased entity. Repeated treatment or alternative therapies may be required.
• BSC has no clinical information or experience concerning the use of the laser system on pregnant women or nursing mothers.
• Before turning the laser system on, operating room personnel and the patient should be wearing protective eyewear suitable for the laser energy.
• A basin of water should be available in case a fire should occur.
• Do not press either footswitch while checking the aiming beam.
• To avoid damage from the treatment beam or its backscatter, it is recommended the fiber be fully visible in the visual field. Do not fire the laser unless the aiming beam is visible and directed at the intended target. Aim and use the laser only on tissues that are in full view.
• Avoid firing the laser if the fiber tip is in an air pocket.
• Do not bury the fiber in tissue. Do not use the fiber as a probe.
• Firing the working beam continuously at one location (not sweeping the beam) may result in difficult to control bleeding or perforation.
• If extended contact between the fiber tip and tissue is unavoidable, use the lowest power at which acceptable vaporization can be achieved, but no more than 80 W.
• If the working beam or aiming beam exits the fiber in an unusual direction, cease firing immediately, determine if there has been unintended tissue damage and take appropriate action. Replace the fiber before continuing with the procedure.
• The surgeon should carefully assess the target and surrounding tissue, and then begin at the lowest appropriate power, with short duration exposures. Do not adjust the power of the laser until the effect of the laser on the tissue has been evaluated. Note the surgical effect and adjust the settings and sweeping speed until the desired effect is obtained.
• Use of lower power levels and shorter exposure times are required to prevent thermal damage to underlying structures, for example, to thin-walled structures, such as the bladder.
• Tissue perforation can occur if excessive laser energy is applied. This can occur using excessive laser power or the application of power for excessive periods of time, particularly on diseased tissue. Examples of diseased tissue include tissue that has undergone brachytherapy, tissue that is infected, or tissue that has thinned due to another underlying disease other than BPH.
• Use caution when lasing tissue in close proximity to known arteries, nerves, and veins.
• Use caution to protect endotracheal tubes from laser radiation. Ignition or perforation of endotracheal tubes by the laser beam could result in serious or fatal patient complications.
• 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 ligation or electrocautery.
• The surgeon should schedule follow-up visits in the same manner as for patients undergoing such surgery with other modalities.
• Exercise care for special risks related to the disposal of the device. See End of Useful Life section.
• The laser system must be kept dry during storage and transport with temperatures between:
  • 32 °F to 104 °F (0 °C to 40 °C) with all water drained from system
  • 39 °F to 104 °F (4 °C to 40 °C) with cooling system charged with distilled or deionized water
Improper storage or transport of the laser system may result in damage to the cooling system, optical resonator, and other critical components.

6 ADVERSE EVENTS
Users should read and understand the specific indications, contraindications, warnings, precautions, and current adverse events included with the fiber used in conjunction with the GreenLight XPS™ Laser System. Potential adverse events associated with the GreenLight XPS Laser System are, but not limited to, the following:
• Abdominal bloating (intestinal gas)
• Acute renal failure
• Allergic reaction
• Aspiration
• Bladder neck contracture
• Bladder spasm
• Bleeding
• Burn
• Chills
• Clot retention
• Contamination of the device may lead to injury, illness, or death of the patient
• Deep venous thrombosis
• Delay in healing
• Dysuria
• Edema
• Embolism
• Epididymitis
• Erectile dysfunction (ED)
• Fatigue or weakness
• Fever
• Fluid overload/hyponatremia
• Gas over-distension
• Hematosperma
• Hematuria
• Infection
• Leukocytosis
• Malfunction of laser fiber or console resulting in an injury or prolonged procedure
• Nocturia
• Overactive bladder
• Pain:
  • Abdominal pain unresponsive to Nonsteroidal Anti-inflammatory Drugs (NSAIDs)
  • Arm or leg pain
  • Headache
  • Back/low back pain
  • Body aches
  • Pelvic
  • Penile
• Pelvic hematoma
• Penile urethral injury
• Perforation
• Pneumothorax
• Profuse perspiration (not fever-related)
• Prostatitis
• Pulmonary embolus
• Retrograde ejaculation
• Sepsis
• Stricture
• Tissue damage
• Tissue sloughing
• Ulceration
• Unretrieved device fragment
• Ureteral orifice injury
• Urethral stricture
• Urgency
• Urinary frequency
• Urinary incontinence
• Urinary retention
• Urinary tract infection

6.1 Some Adverse Events Further Explained

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

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.

Pain: Short-lived pain may occur immediately after endoscopic/cystoscopic laser therapy and may persist for 48 hours.
Perforation: Perforation can occur as a result of excessive exposure to laser radiation. Perforation can occur from tumor erosion, or as a result of 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.

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.

As with conventional endoscopic treatments, adverse reactions such as fever, chills, sepsis, edema, and hemorrhage are possible after laser treatment. In extreme cases, death may occur due to procedural complications, concurrent illness, or the application of the laser. Use caution when treating patients who had difficulty with previous endoscopic procedures.

6.2 Complications And Risks By Indication
For all indications, see Intended Use/Indications for Use section.

General Surgery
Complications and Risks: See Adverse Events for general information. There is a potential risk of thermal damage at the site of the incision.
For endoscopic/laparoscopic procedures, there are no known complications and risks specific to general surgery other than those associated with laparoscopy procedures in general (that is, over-distension, subcutaneous emphysema).
See Contraindications for general information. There are no known contraindications specific to general surgery at this time. Endoscopic/ laparoscopic procedure patients should be treated with alternative methods when laparoscopy is contraindicated.

Gastroenterology
See Adverse Events for general information.
The risk of combustion, perforation and laser-induced hemorrhage, all of which could cause serious or fatal complications, must be fully explained to the patients.
Use caution when radiation therapy and laser therapy are to be used concurrently, including more stringent post-operative monitoring. Patients who have undergone radiation therapy may present a greater risk of perforation or tissue erosion. Use caution with patients who had previous esophageal/tracheal fistulae or episodes of aspiration.
Discontinue laser therapy immediately if the patient develops cardiopulmonary problems.
To avoid the potential risk of endoscopic ignition or damage from the treatment beam or treatment beam backscatter, it is recommended that the fiber extend 1 to 2 cm beyond the distal port of the endoscope, so it is entirely in the visual field.
After esophageal procedures, swallowing may be paradoxically worsened, rather than immediately improved. This is caused by secondary tissue edema. Explain this potential problem to the patient before therapy.
See Contraindications for general information. There are no known contraindications specific to gastroenterological use at this time.

Gynecology
See Adverse Events for general information. There are no known complications and risks specific to gynecology at this time.
See Contraindications for general information. These procedures may be contraindicated for women who are pregnant or have a suspected pregnancy, and for whom hysteroscopy or laparoscopy, or open abdominal surgery would not be appropriate. These procedures may be contraindicated for women with other medical or surgical conditions that would contraindicate laparoscopic or hysteroscopic surgery.

Head and Neck/Otorhinolaryngology (ENT)
See Adverse Events for general information. For cosmetic purposes, it is recommended that initial incisions be performed with conventional scalpels or that skin edges incised with the laser be cut back by approximately 0.5 mm to 1.0 mm with a scalpel before closing the skin.
Use caution to protect the endotracheal tubes. Contact with the laser beam could result in serious or fatal patient complications. When using the laser for coagulation in ENT applications, it is essential to de-focus the laser beam spot to preclude tissue damage beyond the desired coagulation site. Unintended tissue damage could result from a focused treatment beam. While clinical experience to date has demonstrated that lasers can be safely used for hemostatic in ENT, there have been reports of serious complications when lasers are used inappropriately.
The main risk of laser use is thermal damage to the surrounding vital structures, which is risky for oval window surgery as energy applied directly to the open oval window will pass directly through the perilymph and be absorbed by the inner ear structures. Other complications related to laser surgery include, but are not limited to burns, scarring, hemorrhage, perforations, fires and explosions, eye injury, electrical shock, swelling, and obstruction. Thermal damage caused by laser treatment has been related to adverse side effects and other risks. For example, where laser tissue welding is used, such as in laser-assisted myringoplasty, a low strength astenomosis or thermal damage to tissue are the main concerns. Delayed post-operative pain and slow healing are both thought to be related to thermal damage caused by the laser during tonsillectomy.
Compared to traditional scalpel cutting surgery, laser treatment has sometimes resulted in slower healing in procedures such as uvulopalatoplasty and tonsillectomy. Tissue necrosis, post-operative edema, or bleeding was rarely seen. Slow healing increases the risk of infection. The presence of necrosis could leave the tonsillar bed more vulnerable to infection.
See Contraindications for general information. There are no known contraindications unique to ENT.

Neurosurgery
Particular care must be exercised in heating the brain stem area. Flushing with cool saline in such areas will reduce heat build-up and related bradycardia.
See Adverse Events for general information. There are no known specific complications and risks to neurosurgery use at this time.
See Contraindications for general information. These procedures are contraindicated for the treatment of necrotic or calcified tumors.

Ophthalmology
See Adverse Events for general information. There are no known specific complications and risks to ophthalmology use at this time.
See Contraindications for general information. These procedures are contraindicated for the treatment of necrotic or calcified tumors.
Spinal Surgery
See Adverse Events for general information. Some patients have reported an inflammatory response four to ten days post-operative at the site of surgery. This has occurred in patients who have reported a successful procedure post-operatively and are otherwise asymptomatic.

The occurrence of this adverse event has reportedly been significantly reduced by the administration of an anti-inflammatory agent, into the surgical site, at the completion of the procedure.

With surgical procedure in the spine, there is the potential risk of infection, inflammation and post-operative pain. The injection of antibiotics, anti-inflammatory drugs, and analgesics into the surgical area at the completion of the procedure has been reported to reduce the occurrence of these adverse events.

See Contraindications for general information. General anesthesia is specifically contraindicated for this procedure.

This procedure is contraindicated, if the following conditions exist:
- Non-contained disc herniation (leakage of dye into epidural space by discogram)
- Radiographic evidence of spinal stenosis > 50% 
- Progressive neurological loss
- Cauda Equina Syndrome
- Tumor
- Infection
- Fracture
- Spondylolisthesis
- Spinal instability
- Free fragments or other significant pathologies
- Significant (> 30%) narrowing of disc space, possible facet damage
- Patients with previous surgery/chemonucleolysis at the indicated level may be a candidate for laser disc decompression.
- All other factors should be considered.

Plastic Surgery
The laser is not intended for use for skin incision or liposuction. See Adverse Events for general information. Initial skin incision using the laser may result in undesirable scar formation.

See Contraindications for general information. There are no known contraindications unique to plastic surgery.

Thoracic Surgery
The use of contact delivery devices (for example, sculptured fibers) on lung tissue, in conjunction with the wavelength, is considered investigational. When performing thoracoscopic surgery it is vital for the surgeon to appreciate that the view provided is monocular (not binocular) and that depth perception is decreased. Practice on the part of the surgeon to get the feel of operating through a monocular scope is strongly recommended before clinical use.

In surgery of a body cavity that is insufflated, the surgeon and the anesthesiologist must appreciate the risk of embolism, should a blood vessel be opened. Most surgeons prefer CO2 as the pressurizing gas of choice, as it is readily absorbed and does not lead to embolism. The anesthesiologist should monitor the patient for unusually high CO2 absorption, and adjust procedures, as necessary.

See Adverse Events for general information. There are no known specific complications and risks to thoracic surgery use at this time.

See Contraindications for general information. There are no known contraindications unique to thoracic surgery.

Urology
See Adverse Events for general information.

7 HOW SUPPLIED
Do not use if the package is opened or damaged.
Do not use if labeling is incomplete or illegible.

7.1 Handling and Storage
- Storage and transport temperature with all water drained from the system: 32 °F to 104 °F (0 °C to 40 °C)
- Storage and transport temperature with cooling system charged with distilled or deionized water: 39 °F to 104 °F (4 °C to 40 °C)
- Store in a dry place

When in storage or transport outside of the recommended temperature ranges, damage may occur to the cooling system, optical resonator, and other critical components. The console should be drained using the field drain procedure. For complete draining procedure, contact BSC technical support.
When the console is drained and in storage, the desiccant pack should be replaced on a six-month interval.

8 SAFETY
8.1 Eye Injury
Visible light 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.

Protective eyewear for the operating room staff and patient should be provided. Laser eyewear may not be interchangeable between lasers of different wavelength, power, or divergence angle.
WARNING: It is required for everyone in the room to wear protective eyewear.

Eyewear has been designed to protect operating room personnel from the 532 nm laser energy. The eyewear has a minimum optical density (OD) of 6.0 at 532 nm. The eyewear requirements for EU are 532 D L6. These types of laser protective eyewear include:

- Nearly clear physician laser protective eyewear — The essentially clear lens material has high visible light transmission and minimal color distortion.
- Orange protective eyewear — Although it has good visible light transmission, the orange color of the plastic lens causes some color distortion.

8.2 Burns

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. 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 used. Care and precision in aiming and applying laser energy are important.

WARNING: Never use a clamp to secure the laser fiber 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.

8.3 Reflection of the Beam From Instruments

Use caution 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 harmful.

Matte, dull, satin-finished, or ebonized instruments have fewer glares, and those with curved surfaces do not reflect light as intensely. While these instruments usually produce a more diffused reflection that is less harmful, 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 caution 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 tissue is touched under these conditions, a burn may result.

8.4 Ignition of Flammable Materials

The laser can ignite many materials used during a surgical procedure. Use of non-flammable materials is strongly recommended.

8.5 Electrical

Electrical hazards with the laser are the same with any electrical device. Use caution when plugging the unit into the wall outlet. The area must be free of water and user’s 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 BSC technical support to have it repaired or replaced.

8.6 Operating Room Environment

This section describes specific safety measures for the operating room to aid in the safe operation of the laser system. Medical Electrical Equipment (MEE) is not intended to be used in an oxygen-rich environment.

Laser Warning Signs

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

Figure 1. Laser Warning Sign
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 console to the operating room entrance door. This interlock will automatically put the console in Standby mode if the door is opened during a procedure. The console will remain in Standby mode until the door is closed and the interlock is reset. Once reset, the user can place the console back in Ready mode and reactivate the surgical beam. The console cannot be placed in Ready mode, unless the interlock is reset.

If the use of the remote door interlock is desired, the biomedical personnel at the user’s facility can connect it. The user should test the remote interlock before each use. Access to the console’s interlock function is made through a socket located on the back panel of the console (see Figure 3).

Safety Recommendations
The following are general safety recommendations for the operating room and are not specific to the laser system:
• When using accessories, tools, disposables, or materials that were in contact with the patient, take protective measures to prevent cross-contamination.
• 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.
• Do not use the laser in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.

WARNING: Do not fire the laser unless the aiming beam is visible and directed at the targeted tissue.

8.7 Safety Features of the Laser System
The GreenLight XPS™ Laser System incorporates the following safety features:
• The laser will stop firing when the pressure is removed from either footswitch pedal.
• An automatic circuit breaker shuts the console off in the event of an electrical overload.
• The laser provides an operating room door interlock connection, which must be set up by the biomedical personnel.
• The key can only be removed when the key-switch is in the OFF position.
• An onboard microprocessor continuously monitors the status of the console and displays messages on the screen along with appropriate user prompts.
• Laser energy cannot be emitted from the console unless a fiber has been connected.
• Console will go into ready mode when the Ready button is touched on the touchscreen, or when the button on top of the footswitch is pressed.
• A fiber pole lifts and positions the fiber in a safe and unobtrusive position.
• A continuous audible tone is heard when the surgical beam is activated (that is, foot pedal is pressed). A higher frequency tone is heard for vaporization and a lower tone for coagulation.
• When the laser is fired for the first time after entering Ready mode, and whenever switching between vaporization mode and coagulation mode, a voice will announce the current mode.
• A 2-second delay occurs before laser energy is emitted after the laser is placed in Ready mode.
• An Emergency Laser Stop switch is available to disable the console immediately, in the case of an emergency.
• When switching between Ready and Standby mode, a voice will announce the current mode.

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

Note: The laser system should be protected against unauthorized use. When the console is not in use, remove the key from the key switch and place in a secure location.

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.

WARNING: No modification of this equipment is allowed.

Tipping Hazard:

During transportation, pull or push the console carefully using the intended handle to prevent tipping.

WARNING: Console may tip if inclined at an angle of greater than 5 degrees.

Rolling Hazard: Secure the console with the wheel locks to prevent the unit from inadvertently rolling.
9 CONSOLE DESCRIPTION

1. Screen/Touchscreen — Displays user information:
   • Console status (Standby, Ready)
   • Laser output (in watts), separate display for vaporization and coagulation
   • Aiming beam brightness level
   • Energy meter (displays total number of Joules delivered)
   • Exposure time (displays total time light is emitted)
   • Buttons on the screen, when pressed, place the laser in either Ready or Standby mode
   • Error codes and screen prompts

2. Card Reader — Reads fiber card
3. Storage Compartment
4. Fiber Shield — Protects the fiber hub from inadvertent damage
5. Fiber Pole — Secures and protects the fiber (retractable)
6. Fiber Port Cover — Connection for fiber
7. Emergency Laser Stop — Turns console off and terminates laser light emission in case of emergency
8. On/Off Key Switch — Switches the console on and off
9. Footswitch — For control of laser emission

Figure 2. Front View of Console
1. Back Handle
2. Upper Power Cord Storage Hook — 2 upper hooks for coiling footswitch cord
3. Footswitch Storage Hook — 2 hooks for footswitch storage
4. Footswitch Cord Storage Hook — 2 hooks for coiling footswitch cord
5. Footswitch Connection
6. Service Port — USB ports for factory service only
7. Remote Interlock Socket — Can be connected to the room door so the footswitch will be disabled in the event of entry
8. Coolant Reservoir — For refilling the internal cooling liquid (see Coolant Refill Instructions)
9. Coolant Drain — For draining the internal cooling liquid (see Coolant Refill Instructions)
10. AC Power Cord
11. Lower Power Cord Storage Hook — 2 lower hooks for coiling power cord
12. Circuit Breaker — Automatically trips in the event of a power overload, shutting off power to the console
13. Wheel Lock — For locking and unlocking back wheels

Figure 3. Back View of Console
10 ACCESSORIES

The operator must use accessories/tools that were cleared by BSC for use with the laser system. BSC assumes no liability and warranty for damage and consequential damage when using the laser system with non-qualified accessories/tools. Contact BSC for an up-to-date list of accessories/tools for the GreenLight XPS™ Laser System.

10.1 Video Camera Insert

A video camera insert must be inserted between the telescope and the camera (unless a comparable camera insert is built into the telescope). The video camera inserts have an optical density (OD) of 5 at a wavelength of 532 nm. This blocks most of the laser light, preventing saturation of the video camera sensor. The optimum transmission at wavelengths other than 532 nm and the video camera insert diameter depends on the video camera and telescope model.

10.2 Laser Protective Eyewear

Eyewear has been designed to protect operating room personnel from the 532 nm laser energy. The eyewear has a minimum optical density (OD) of 6.0 at 532 nm. The eyewear requirements for EU are 532 D L6.

- Physician protective eyewear — The essentially clear lens material has high visible light transmission and minimal color distortion.
- Spectator protective eyewear — Although it has good visible light transmission, the orange color of the plastic lens causes some color distortion.

11 INSTALLATION

This section provides general guidelines for the installation of the laser system. This laser system has specific installation requirements. It is the user’s responsibility to fulfill these requirements before the installation of the laser system. Improper installation can result in intermittent operation and even damage to the laser system. Please read the below information carefully.

11.1 Responsibility of BSC

A BSC service representative will install the laser system. Upon arrival at the installation site, the representative will perform the following:

1. Verify appropriate electrical power is available.
2. Remove the console from the crate and inspect for damage.
3. Perform all optical, electronic, and system checks necessary to bring the laser into operation.
4. Inventory all shipped accessories.

11.2 Responsibility of Customer

Provisions for proper power must be made before the receipt and installation of the laser system. Return visits by service personnel for installation will not be covered under warranty. The customer should complete the Installation Checklist and return it to BSC or distributor. Upon completion of the pre-installation site preparation, contact BSC or the distributor to check shipment date and schedule installation of the system.

The laser system uses standard electrical service and has built-in cooling systems; therefore, installation requires minimal site preparation.

11.3 Positioning of the Console

The console must be positioned not more than 5 ft (1.5 m) from the centerline of the treatment table to ensure proper handling of the fiber. Position the console at least 1 ft (0.3 m) from the wall for proper ventilation during use.

11.4 Power Requirements

The power source for the GreenLight XPS Laser System must be a single-phase service with voltage between 200 to 240 VAC, 50/60 Hz, current ≤ 20 Amp*. 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 %.

For BSC to provide the correct electrical plug, the customer must provide information about the installed receptacle in the facility to BSC before installation. Any 250 VAC, current ≤ 20 Amp*, two poles, three wire receptacle can be used if it meets the system’s electrical requirements; meets facility, city, county, state, and country ordinances; and complies with EN 60601 for leakage current.

It is recommended the GreenLight XPS Laser System use a dedicated circuit breaker with a minimum rating of 16 Amp or higher to ensure normal operation.

* The 20 Amp rating indicates the current rating that the power source is expected to be capable of supplying to operate the laser at the maximum rated power output of 180 W. The 20 A rating is neither the minimum nor maximum operational main current requirement; it is a current in which internal circuitry protects the GreenLight XPS Laser System in an over-current condition.
12 INSTRUCTIONS FOR USE

12.1 Touchscreen and Footswitch

The touchscreen and footswitch are used to control the console. Laser parameters are selected and the console status is changed by using a touchscreen. Use the button on top of the footswitch to go between Ready and Standby laser status. The aiming beam is activated when the console is in the Ready mode or the surgical beam is activated. The surgical beam is activated by pressing a foot pedal. Press the yellow pedal for VAPOR and the blue pedal for COAG.

Power is set by touching the ▼ or ▲ buttons on the touchscreen. An audible tone will be heard when the buttons are pressed.

![Figure 4. Touchscreen](image)

12.2 Preparation

1. Ensure protective eyewear is worn by all personnel including the patient.
2. Ensure the circuit breaker on the back of the console is OFF and connect the power cord to an appropriate electrical outlet.
3. Turn the circuit breaker to ON. On the front of the console, turn the key switch to ON.
4. The console’s self-check mechanism detects most problems. A message will appear on the touchscreen to alert the user of problems. Courtesy messages alert the user of problems that the user can correct. Service prompts alert the user of a problem that requires a service call.

![Figure 5. Footswitch](image)
**Note:** It may take time (typically 5 to 15 minutes, but can be up to 40 minutes in rare cases such as extremely cold conditions) for the console to reach the proper operating temperature and pass all internal self-check tests before it is ready for operation.

5. The console will perform self-tests. When the tests are completed, a screen is displayed prompting to insert fiber card.

![Insert Fiber Card Screen](image)

6. Prepare the patient for the procedure.

7. If the telescope does not include a built-in video camera insert, place a small or large video camera insert between the telescope and the camera. The video camera insert protects the camera from the high-intensity light.
   A. To insert the large video camera insert, hold the camera head pointing up. Place the video camera insert (labeled side facing towards camera) onto the camera head and depress the coupler. Attach the telescope to the camera.
   B. To insert the small video camera insert, hold the telescope portion of the cystoscope with the eyepiece pointing up. Place the video camera insert (writing side facing outward) into the eyepiece. Attach the camera to the telescope.

**Note:** Some telescopes have a built-in video camera insert to prevent the transmission of green light. In this case, do not insert an additional video camera insert between the telescope and the camera.

**CAUTION:** Do not touch multiple areas on the touchscreen at one time. Contact in multiple areas of the screen will result in no response from the command buttons. Only touch the desired command button when making adjustments to parameters.
8. Open the laser fiber box. Locate the fiber card attached to the outside of the pouch. Insert the fiber card into the card reader with the chip side facing operator. The touchscreen then prompts for fiber attachment.

**CAUTION:** Do not remove the fiber card until procedure is complete.

9. Open the fiber pouch and remove the sterile fiber using aseptic technique.

**Note:** To protect the laser-fiber interface, the fiber connector must be kept free of lubricant, cleaners, and other contaminants.

10. Connect the fiber to the fiber port of the console by pushing the connector into the fiber port (arrow on connector facing up) and turning it ¼-turn clockwise until it locks.

11. Follow additional instructions from the fiber package insert.

12. On the console, select the desired vaporization and coagulation setting by pressing the arrow keys.
13. To change the aiming beam intensity, display intensity, or audio volume, touch Press for Set-up at the bottom of the main screen.

14. Adjust the desired setting by touching the arrow keys.
15. To return to the main screen, touch Press for Main Menu at the bottom of the screen.
16. Press the Ready button to activate the aiming beam. When the Ready button turns orange, the laser system is ready for use in a procedure.

17. Advance the assembled cystoscope with the visual obturator through the urethra into the bladder using standard technique.
18. Advance the fiber through the fiber port and into the visual field of view. A suction tube can be connected to the outflow port of the cystoscope to direct outflow irrigation.
19. Rotate the control knob of the fiber to examine the fiber markings. The triangle is contralateral to where the laser beams fires. The triangle must be visible at all times while firing the beam. The red octagonal stop sign is aligned with the aiming beam of the fiber. Do not activate the working beam if the stop sign is centered in the field of view.
20. Advance the fiber to the treatment site. The tip of the fiber should be in clear view and extended beyond the tip of the cystoscope. The output beam of the fiber is aligned with index of the knob on the distal portion of the fiber.
21. Place the console in Ready mode to enable the footswitch.
22. Observe that the aiming beam is on the tissue targeted for treatment before activating the laser.

12.3 Procedure

17. Advance the assembled cystoscope with the visual obturator through the urethra into the bladder using standard technique.
18. Advance the fiber through the fiber port and into the visual field of view. A suction tube can be connected to the outflow port of the cystoscope to direct outflow irrigation.
19. Rotate the control knob of the fiber to examine the fiber markings. The triangle is contralateral to where the laser beams fires. The triangle must be visible at all times while firing the beam. The red octagonal stop sign is aligned with the aiming beam of the fiber. Do not activate the working beam if the stop sign is centered in the field of view.
20. Advance the fiber to the treatment site. The tip of the fiber should be in clear view and extended beyond the tip of the cystoscope. The output beam of the fiber is aligned with index of the knob on the distal portion of the fiber.
21. Place the console in Ready mode to enable the footswitch.
22. Observe that the aiming beam is on the tissue targeted for treatment before activating the laser.
23. Laser energy will be emitted when a footswitch is pressed. The Active mode (Vaporization Active or Coagulation Active) is displayed at the top of the screen, depending on the footswitch pressed. Audio tone sounds during emission. The first time a given footswitch is pressed, the word Vapor or Coag will be vocalized, depending on which footswitch is pressed.

24. To go back to Standby, press Standby or step on the black Ready/Standby footswitch.

25. The laser emission can be disabled and the aiming beam can be turned off by pressing the Standby button on the touchscreen or by stepping on the black Ready/Standby footswitch.

26. Begin the procedure. Treatment times may vary based on tissue, power settings, and other factors.

27. Steadily rotate (sweep) the laser beam across a 30° to 40° arc over the targeted tissue, continually moving the laser beam while maintaining a working distance (fiber-to-tissue distance) between 1 mm and 3 mm. Adjust the sweep speed to achieve the desired tissue effect. Adjusting the power level will affect the rate of tissue removal.

28. Bleeding can often be controlled by sweeping the working beam around (not directly at) the bleeder while pressing the Coag footswitch. In Coag mode the beam is modulated to increase coagulation effectiveness. This causes the beam to pulse (blink on and off). Adjust the sweep speed and Coag power to achieve the most effective coagulation. Do not fire the laser directly at the center of the source of the bleeding.

29. Once the desired tissue has been treated, turn off the inflow and outflow valves of the cystoscope, and check for bleeding. If bleeding is occurring, it may be necessary to treat the bleeding.

30. Once the laser treatment has ended, fill the bladder with saline, and remove the cystoscope. Slowly drain the bladder and check the flow and color of the outgoing fluid. The placement of a Foley catheter may be necessary at physician discretion.

31. Prescribe post-procedure medication at physician discretion.

12.4 After the Procedure

32. When the procedure has ended, place the console in Standby mode.

33. Document the total lasing time and energy appropriately.

34. Remove the fiber from the cystoscope and discard per hospital procedures. Remove the cystoscope from the patient.

35. Remove the fiber card and discard.

36. Turn the key switch to the OFF position.

37. On the back panel, switch the circuit breaker to the OFF position and disconnect the AC power cable from the electric outlet.

38. To protect against unauthorized use, remove the key from the key switch and store in a secure location.

39. The footswitch can be stored on the back of the console.

40. Store the laser system per recommendations in Handling and Storage.
13 TECHNICAL DATA

Table 1. Console Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Specification Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laser Type</td>
<td>Solid-state, frequency doubled</td>
</tr>
<tr>
<td>Wavelength</td>
<td>532 nm</td>
</tr>
<tr>
<td>Maximum Power Output at 532 nm</td>
<td>Limited by fiber delivery device, up to 180 W</td>
</tr>
<tr>
<td>Nominal Ocular Hazard Distance (NOHD)</td>
<td>67.1 meters (MPE = 10 W/m²)</td>
</tr>
<tr>
<td>Repetition Rate</td>
<td>Quasi-CW (23.6 kHz) Coagulation: Modulated at ~12.5 Hz, ~25 % duty cycle</td>
</tr>
<tr>
<td>Maximum Aiming Beam Power</td>
<td>5 mW</td>
</tr>
<tr>
<td>Output Beam Divergence</td>
<td>≥ 0.078 Radians</td>
</tr>
<tr>
<td>Electrical Requirements</td>
<td>200 to 240 VAC, 50/60 Hz, ≤ 20 Amp, single-phase</td>
</tr>
<tr>
<td>Operating Temperature</td>
<td>50 °F to 86 °F (10 °C to 30 °C)</td>
</tr>
<tr>
<td>Operating Humidity</td>
<td>10 % to 90 %, non-condensing</td>
</tr>
<tr>
<td>Dimensions</td>
<td>Width: Approximately 22 in (56 cm)</td>
</tr>
<tr>
<td></td>
<td>Depth: Approximately 36 in (91 cm)</td>
</tr>
<tr>
<td></td>
<td>Height (screen down): Approximately 48 in (122 cm)</td>
</tr>
<tr>
<td></td>
<td>Height (screen up): Approximately 55 in (140 cm)</td>
</tr>
<tr>
<td>Weight</td>
<td>Approximately 475 lb (215 kg)</td>
</tr>
<tr>
<td>AC Power Cable</td>
<td>15 ft (457 cm) maximum length, model 321203</td>
</tr>
<tr>
<td></td>
<td>AC power cable is a trademark of OLFLEX.</td>
</tr>
<tr>
<td>Footswitch Cable</td>
<td>13 ft (396 cm) maximum length, Cordset #997-G27-1</td>
</tr>
<tr>
<td></td>
<td>Footswitch cable is a trademark of LINEMASTER Switch Corporation.</td>
</tr>
<tr>
<td>Standards and Regulations</td>
<td>• Safety Regulations conforms with EN/IEC 60825</td>
</tr>
<tr>
<td></td>
<td>• EMF output conforms with IEC 60601-1 General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests</td>
</tr>
</tbody>
</table>

13.1 Safety Classifications and Electromagnetic Compatibility

Classification: Type of protection against electric shock: Class I equipment

Table 2. Electromagnetic Emissions

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment — Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions CISPR 11</td>
<td>Group 1</td>
<td>The GreenLight XPS™ Laser System uses RF energy only for its internal function. Therefore, its RF emissions are low and are not likely to cause interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF Emissions CISPR 11</td>
<td>Class A</td>
<td>The GreenLight XPS™ Laser System is suitable for use in all establishments other than domestic and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Harmonic Emissions IEC 61000-3-2</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage Fluctuations/Flicker Emissions IEC 61000-3-3</td>
<td>Section 5 of Standard</td>
<td></td>
</tr>
</tbody>
</table>

WARNING: This equipment/system are intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the GreenLight XPS™ Laser System or shielding the location.
## Table 3. Electromagnetic Interference Resistance

| Guidance and Manufacturer’s Declaration — Electromagnetic Immunity |
|---|---|---|
| The GreenLight XPS™ Laser System is intended for use in the electromagnetic environment specified below. The customer or user of the GreenLight XPS Laser System should assure that it is used in such an environment. |

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment — Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic Discharge (ESD) IEC 61000-4-2</td>
<td>± 6 kV contact ± 8 kV air</td>
<td>± 6 kV contact ± 8 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.</td>
</tr>
<tr>
<td>Electrical Fast Transient/Burst IEC 61000-4-4</td>
<td>± 2 kV for power supply lines</td>
<td>± 2 kV for power supply lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>± 1 kV line to line ±2 kV line(s) to ground</td>
<td>± 1 kV line(s) to line(s) ±2 kV line(s) to ground</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</td>
<td>&lt; 5 % (U_1) (&gt; 95 % dip in (U_1) for 0.5 cycle)</td>
<td>&lt; 5 % (U_1) (&gt; 95 % dip in (U_1) for 0.5 cycle)</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the GreenLight XPS Laser System requires continued operation during power mains interruptions, it is recommended that the GreenLight XPS Laser System be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td>Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8</td>
<td>N/A</td>
<td>N/A</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

**Note:** \(U_1\) is the AC mains voltage prior to application of the test level.
# Guidance and Manufacturer’s Declaration — Electromagnetic Immunity

The GreenLight XPS™ Laser System is intended for use in the electromagnetic environment specified below. The customer or user of the GreenLight XPS Laser System should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment — Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>IEC 61000-4-6</td>
<td>3 Vrms</td>
<td>d = 1.7 * P ½ 80 MHz to 800 MHz</td>
</tr>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
<td>3 Vrms</td>
<td></td>
</tr>
<tr>
<td>Radiated RF</td>
<td>IEC 61000-4-3</td>
<td>3 V/m</td>
<td>d = 2.3 * P ½ 800 MHz to 2.5 GHz</td>
</tr>
<tr>
<td></td>
<td>80 MHz to 2.5 GHz</td>
<td>3 V/m</td>
<td></td>
</tr>
</tbody>
</table>

- Portable and mobile RF communications equipment should be used no closer to any part of the GreenLight XPS Laser System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
- Recommended separation distance $d = 1.7 \times P^{\frac{1}{2}}$ for 80 MHz to 800 MHz
- $d = 2.3 \times P^{\frac{1}{2}}$ for 800 MHz to 2.5 GHz

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

---

**Note 1:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

* Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the GreenLight XPS Laser System is used exceeds the applicable RF compliance level above, the GreenLight XPS Laser System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the GreenLight XPS Laser System.

* Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
Table 4. Recommended Protective Distances

Recommended separation distances between portable and mobile RF communications equipment and the equipment or system — for equipment and systems that are not life-supporting.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter W</th>
<th>Separation distance according to frequency of transmitter m</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 kHz to 80 MHz d = [3.5 / V1] * P (1/2)</td>
<td>80 MHz to 800 MHz d = [3.5 / E1] * P (1/2)</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.37</td>
</tr>
<tr>
<td>1</td>
<td>1.17</td>
</tr>
<tr>
<td>10</td>
<td>3.69</td>
</tr>
<tr>
<td>100</td>
<td>11.67</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

14 MAINTENANCE

The console has been designed to provide trouble-free operation with minimal maintenance. This section provides information on the routine maintenance and care required for the console.

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

14.1 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, do not use harsh or abrasive cleansers, especially on the LCD screen panel, and do not pour water or other liquid over the console. If liquid is spilled on the console and it is thought that some may have gone inside, turn the unit off and call BSC technical support.

14.2 Preventative Maintenance

Regular, routine preventative maintenance should be performed by an authorized BSC service representative. Preventive maintenance consists of replacing consumable components such as video camera inserts, adjusting the calibration, and other tasks designed to keep the laser operating reliably and within specification. Preventive maintenance should be scheduled every 6 months unless otherwise determined by the BSC Service organization.

14.3 Coolant Refill Instructions

The console uses a vented internal cooling system that uses distilled or deionized water. Over time, some evaporation can occur resulting in a ‘Please fill chiller reservoir with deionized water’ courtesy message. The below instructions describe the water filling process for restoring the proper coolant level.

14.4 Instructions How to Refill Coolant

Note: The console holds approximately 1,700 ml of distilled or deionized water.

The below procedure is to be used to top off the water level for the console only if a low water fault occurs.

1. Turn the circuit breaker off and unplug the console.
2. Remove the reservoir cap in the back of the console.
3. Pour water into the filler reservoir until its level stops falling. Fill the reservoir to just above the halfway 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. Do not over-fill the reservoir.
6. Replace the cap.
7. Continue with console startup. If a ‘Please fill chiller reservoir with deionized water’ message is still present, call BSC technical support or the local GreenLight XPS Laser System distributor.
The console’s self-check mechanism will detect most problems with the console and alert the operating room staff. A message will appear on the screen at the time of system malfunction. Depending on the severity of the problem, the console will either maintain status or require a solution before reactivating. See Troubleshooting for the types of messages.

14.5 End of Useful Life
When the laser system reaches the end of its useful life, dispose of all products, accessories, tools, and packaging materials in accordance with hospital, administrative, and/or local government policy. Used products should be collected separately and not disposed of as unsorted municipal waste.

15 TROUBLESHOOTING
The console’s self-check mechanism will detect most problems with the console and alert the operating room staff. A message will appear on the screen at the time of system malfunction. Depending on the severity of the problem, the console will either maintain status or require a solution before reactivating.

Two types of messages are displayed:
- Courtesy Messages alert the user of problem conditions that the user can correct.
- Service Prompts alert the user of problem conditions that may require a service call.

15.1 Courtesy Messages
When a condition requiring user action is detected, a blue box containing a message describing the condition is displayed on the screen. The messages require that corrective action is taken.

Courtesy messages may display numerical information that may vary depending on the circumstances. In the below table, examples of such additional information are shown in bold.

Table 5. Courtesy Messages

<table>
<thead>
<tr>
<th>Message</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attach a Fiber</td>
<td>Attach a fiber.</td>
</tr>
<tr>
<td>Insert Fiber Card</td>
<td>A fiber card should be inserted.</td>
</tr>
<tr>
<td>Please fill chiller reservoir with deionized water</td>
<td>Restore coolant level (see Coolant Refill Instructions). Turn system off and add distilled or deionized water.</td>
</tr>
<tr>
<td>Fiber Approaching Joule Limit</td>
<td>The number of Joules remaining on the fiber is displayed. If the procedure requires treatment beyond the limit, use a new fiber.</td>
</tr>
<tr>
<td>Less than 50,000 joules remaining</td>
<td></td>
</tr>
<tr>
<td>Fiber Expired</td>
<td>The fiber has exceeded its rated Joule limit. The actual number of Joules used is displayed. If the procedure requires treatment beyond the limit, use a new fiber.</td>
</tr>
<tr>
<td>400,000 Joules used</td>
<td></td>
</tr>
<tr>
<td>Attach a Footswitch</td>
<td>Plug the footswitch into the appropriate socket on the back of the unit. If this fails to resolve the problem, contact BSC technical support.</td>
</tr>
<tr>
<td>Release Footswitch</td>
<td>User should reposition his or her foot, to contact only one footswitch.</td>
</tr>
<tr>
<td>Only one footswitch may be pressed at a time</td>
<td></td>
</tr>
<tr>
<td>Vapor footswitch disabled when in Standby</td>
<td>Press the Ready/Standby button on the screen or on the footswitch.</td>
</tr>
<tr>
<td>Coag footswitch disabled when in Standby</td>
<td>Press the Ready/Standby button on the screen or on the footswitch.</td>
</tr>
<tr>
<td>Fiber Port Overheated, try another fiber.</td>
<td>Wait for device port to cool off. If problem repeats, replace the fiber. Contact BSC technical support if problem persists.</td>
</tr>
<tr>
<td>If problem persists, contact Customer Care Center</td>
<td></td>
</tr>
<tr>
<td>Check Fiber Card Insertion</td>
<td>Remove and reinsert fiber card. If problem persists, contact BSC technical support.</td>
</tr>
<tr>
<td>Remove and then re-insert card</td>
<td></td>
</tr>
<tr>
<td>Invalid Fiber Card 10-2079 not valid for this system</td>
<td>The fiber attached is not a valid GreenLight XPS™ Laser System device. The part number of the invalid fiber is displayed. Replace the fiber with one approved for use with GreenLight XPS Laser System.</td>
</tr>
<tr>
<td>Card Read Error</td>
<td>Remove and reinsert fiber card. If problem persists, contact BSC technical support.</td>
</tr>
<tr>
<td>Remove and then re-insert card</td>
<td></td>
</tr>
<tr>
<td>Fiber type does not match card type</td>
<td>Fiber ID does not match Fiber ID on fiber card. Make sure that the fiber card being used is the one that was packaged with the fiber.</td>
</tr>
<tr>
<td>Try another fiber or card</td>
<td></td>
</tr>
<tr>
<td>Fiber Type Error</td>
<td>Usually this is caused by a bad fiber connector. If a second fiber gives the same message, the fiber coupler or its cabling may be damaged. If problem persists, contact BSC technical support.</td>
</tr>
<tr>
<td>Check fiber connection or try another fiber</td>
<td></td>
</tr>
<tr>
<td>Remote Interlock Opened</td>
<td>If the remote interlock has been connected to the operating room door, make sure the door is closed. Otherwise, make sure the remote interlock bypass connector is inserted into the socket on the back panel of the system.</td>
</tr>
<tr>
<td>Excessive FiberLife Activity</td>
<td>FiberLife can detect if the fiber tip is overheating. Usually this is due to a dirty or damaged fiber. If the problem persists after cleaning or if the fiber is damaged, replace the fiber with a new one.</td>
</tr>
<tr>
<td>Please clean and inspect fiber tip</td>
<td></td>
</tr>
</tbody>
</table>
Message | Corrective Action
--- | ---
Fiber Approaching Time Limit  Less than 5:00 minutes remaining | The amount of time remaining on the fiber is displayed. If the procedure requires treatment beyond the limit, use a new fiber.
Fiber Expired  Time-out limit reached | The fiber has exceeded one of the time-out limits: Maximum Fiber Time Limit Reached (150 minutes). Inactivity Time-out Surpassed (30 minutes). If the procedure requires treatment beyond the limit, use a new fiber.
Check Footswitch Connection | Double check the footswitch connector: reattach and/or tighten connection. If problem persists, contact BSC technical support.

15.2 Service Prompts

An error code will appear in a yellow box on the screen. When these error codes appear, the user should accurately record the complete problem number and contact BSC technical support or call the local GreenLight XPS™ Laser System distributor.

Error codes are three or four digit numbers. The right two digits identify a specific problem. The remaining digit(s) on the left indicate the error group. These groups are described in the below table.

**Table 6. Service Prompts**

<table>
<thead>
<tr>
<th>Error Group</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>Resonator</td>
</tr>
<tr>
<td>200</td>
<td>Laser Power Supply</td>
</tr>
<tr>
<td>300</td>
<td>Master Control Board</td>
</tr>
<tr>
<td>400</td>
<td>Data Log</td>
</tr>
<tr>
<td>500</td>
<td>Display Assembly</td>
</tr>
<tr>
<td>600</td>
<td>Chiller</td>
</tr>
<tr>
<td>700</td>
<td>Q-Switch Driver</td>
</tr>
<tr>
<td>800</td>
<td>System</td>
</tr>
<tr>
<td>900</td>
<td>Peripherals</td>
</tr>
<tr>
<td>1000</td>
<td>Software</td>
</tr>
</tbody>
</table>

Note: Courtesy Messages: Correct the problem as indicated in the Courtesy Message table above and continue the procedure.

Note: Service Prompts: The system can be reset when the message ‘Press Here to Continue’ is displayed. If the system cannot reset itself, then it will require servicing before it can be used again.
16 WARRANTY
Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC’s control directly affect the instrument and the results obtained from its use. BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.

If BSC receives timely notice of matters covered under warranty, BSC shall, at its option, either repair or replace instruments or parts that prove to be defective. Instruments or parts shipped under this warranty or used as replacements under this warranty may be either refurbished or new, at BSC option. BSC neither assumes nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with a BSC instrument.

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

Warranty service is performed either on-site or at a BSC facility at BSC 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 work is performed at the Buyer’s 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 for the incremental cost of such work. Where warranty service is provided at BSC, instruments must be returned to a BSC service facility designated by BSC. Parts and labor provided under this Warranty are warranted for 90 days from completion of the service repair or shipment of the replacement instruments/part(s). Instruments may only be returned with the prior approval of BSC. A valid Return Goods Authorization (RGA) number must evidence such approval. Buyer shall prepay shipping charges (and shall pay all duties and taxes) for instruments returned to BSC. BSC shall pay for return of the instrument to Buyer.

Note: 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 depending on the instrument. Every BSC instrument and component is assigned a warranty code that defines the nature and duration of the warranty provided for the particular instrument. Contact BSC for a copy of the Warranty Policy, which defines the warranty codes in detail and assigns a code to each instrument/component.

16.1 Limitation of Warranty
The foregoing warranty shall be voided where in BSC’s sole judgment there has been:
1. Improper or inadequate maintenance by Buyer, or service performed by anyone other than BSC or a party authorized by BSC 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 GreenLight XPS™ Laser System.
4. Improper site preparation and maintenance, including but not limited to improper electrical utilities.
5. Use of delivery devices or accessories not manufactured by BSC or approved by BSC for use with the GreenLight XPS Laser System.

16.2 Additional Terms of Warranty for Mobile Systems
Due to the special situations surrounding GreenLight XPS Laser System that are moved to numerous sites of service, the following terms and conditions also apply to mobile systems:
1. Every mobile provider must have a clinical trainer on staff. This person must be certified by BSC to provide clinical support to physicians for their first cases and beyond.
2. Every mobile provider must have qualified technicians (as certified by BSC) on staff to transport, setup, and operate the GreenLight XPS Laser System in all cases. Annual recertification is required.

16.3 Transport of the System
1. Every mobile provider must have suitable transportation for moving the GreenLight XPS Laser System 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 GreenLight XPS Laser System.
3. Transport the laser system in the original shipping crate or other suitable method designed to absorb road shock (vertical and horizontal loads), to protect the GreenLight XPS Laser 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. The GreenLight XPS Laser System must be protected from temperatures below 32 °F (0 °C). Freezing temperatures can damage the laser system.