OcuLight® GL/GLx/TX

Operator Manual

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33003-EN Rev B 2013-05

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Introduction

The OcuLight® GL, GLx, and TX are solid state lasers that deliver true continuous wave green laser (532 nm) light for ophthalmic applications. The OcuLight TX and GLx are also indicated for otolaryngological applications. Improper use of the laser system can result in adverse effects. Follow the instructions for use described in this operator manual.

Indications for Use

This section provides information on the use of the laser in clinical specialties. Information is provided by specialty and includes procedural recommendations along with specific indications and contraindications. This information is not intended to be all-inclusive and is not intended to replace surgeon training or experience. The regulatory information provided is applicable only in the United States. If you use the laser for indications not included herein, you will be subject to 21 CFR Part 812, the Food and Drug Administration's Investigational Device Exemption (IDE) regulations. For information regarding the regulatory status of indications other than those listed in this manual, contact IRIDEX Regulatory Affairs.

IRIDEX does not make recommendations regarding the practice of medicine. References in literature are provided as a guide. Individual treatment should be based on clinical training, clinical observation of laser tissue interaction, and appropriate clinical endpoints. The IRIDEX laser and the handpieces, delivery devices, and accessories that are used with it to deliver laser energy in CW-Pulse™ or MicroPulse™ mode in the medical specialty of Ophthalmology. The OcuLight® GL, GLx, and TX are intended for use in ophthalmic and otolaryngological applications for therapeutic purposes only by trained medical practitioners. IRIDEX does not make recommendations regarding the practice of medicine. References in literature are provided as a guide. Individual treatment should be based on clinical training, clinical observation of laser-tissue interaction, and appropriate clinical endpoints.

	OcuLight GL	OcuLight GLx	OcuLight TX
Ophthalmology			
Retinal photocoagulation	✓	✓	✓
Laser trabeculoplasty	✓	✓	✓
Iridotomy	✓	✓	✓
Iridoplasty	✓	✓	✓
Otolaryngology			
Stapedectomy		✓	✓
Stapedotomy		✓	✓

References

Ophthalmology. Ludwig K, Lasser TH, Sakowski H, Abramowski H, Wörz G. Continuous wave laser photocoagulation at different wavelengths: equivalent power settings in edematous and non-edematous retina. *Lasers and Light in Ophthalmology* 1994 Vol. 6 No. 3 159-167.
Gnanaraj L, Brennan R, Cottrell DG. Retinopathy of Prematurity in Practice. II: Longterm Results Following Treatment for Threshold Disease. *Eye* 2003;(17); 189-193.
HC Agarwal, S Poovali, R Sihota and T Dada. Comparative evaluation of diode laser trabeculoplasty vs. frequency-doubled Nd: YAG laser trabeculoplasty in primary open angle glaucoma. *Eye* (2006) 20, 1352-1356.
Abreu MM, Sierra RA, Netland PA. Diode laser-pumped, frequency-doubled neodymium: YAG laser peripheral iridotomy. *Ophthalmic Surg Lasers* 1997;28:305-310.

Otolaryngology. Poe DS. Laser-assisted endoscopic stapedectomy: a prospective study. *Laryngoscope* 2000 May: 110(5 Pt 2 Suppl 95):1-37.

OcuLight GL/GLx

The OcuLight GL/GLx is indicated for retinal photocoagulation and laser trabeculoplasty. The following are examples of applications for the OcuLight GL/GLx laser systems.

Condition	Treatment
Diabetic Retinopathy • Nonproliferative Retinopathy • Macular Edema • Proliferative Retinopathy	Retinal Photocoagulation (RPC); Focal and Grid Laser Treatments
Glaucoma • Primary Open Angle • Closed Angle	Laser Trabeculoplasty; Iridotomy; Iridoplasty
Retinal Tears and Detachments	RPC; Focal and Grid Laser Treatments
Lattice Degeneration	RPC; Focal and Grid Laser Treatments
Age-Related Macular Degeneration (AMD)	RPC; Focal and Grid Laser Treatments
Intra-Ocular Tumors • Choroidal Hemangioma • Choroidal Melanoma • Retinoblastoma	RPC; Focal and Grid Laser Treatments
Retinopathy of Prematurity	RPC; Focal and Grid Laser Treatments
Sub-Retinal (choroidal) Neovascularization	RPC; Focal and Grid Laser Treatments
Central and Branch Retinal Vein Occlusion	RPC; Focal and Grid Laser Treatments
Ear, Nose and Throat* • Otosclerotic Hearing Loss	Stapedotomy

*GLx only

OcuLight TX

Otolaryngology. The OcuLight TX is intended to be used in ENT surgery for tissue incision, excision, coagulation, vaporization, ablation and vessel hemostasis. Indications for use include, but are not limited to Stapedectomy, Stapedotomy, Myringotomy, Lysis of adhesions, control of bleeding, removal of Acoustic Neuromas, Soft Tissue Adhesion in Micro/Macro Otologic procedures.

Ophthalmology. The OcuLight TX is intended to photocoagulate ocular tissue in ophthalmic procedures. Indications for use include: Retinal Photocoagulation, Laser Trabeculoplasty, Iridotomy, Iridoplasty.

Compatible Delivery Devices

Compatible Delivery Devices	OcuLight GL	Oculight GLx	OcuLight TX
Laser Indirect Ophthalmoscope (LIO)	✓	✓	✓
EndoProbe®	✓	✓	✓
OtoProbe™		✓	✓
Slit Lamp Adapter (SLA)	✓	✓	✓
EasyFit™ Adapter	✓	✓	✓
EasyView™ SLA	✓	✓	✓
IRIDEX Integrated Slit Lamp Workstation	✓	✓	✓
Symphony™ SLA / Symphony 2	✓	✓	✓

NOTE: *Refer to the appropriate delivery device manual for indications for use, contraindications, precautions, and adverse effects information.*

Procedural Recommendations

The user is directed to review the operating instructions for the compatible delivery devices prior to treatment.

Specific Warnings and Precautions

It is essential that the surgeon and attending staff be trained in all aspects of these procedures. No surgeon should use these laser products for ophthalmic and ENT surgical procedures without first obtaining detailed instructions in laser use. Refer to "Warnings and Cautions" for more information. Proper eye protection for 532 nm light must be utilized. Follow the Eye Protection Policy at your facility.

Potential Side Effects or Complications

Ophthalmic

- Specific to retinal photocoagulation: inadvertent foveal burns; choroidal neovascularization; paracentral scotomata; transient increased edema/decreased vision; subretinal fibrosis; photocoagulation scar expansion; Bruch's membrane rupture; choroidal detachment; exudative retinal detachment; pupillary abnormalities from damage to the ciliary nerves; and, optic neuritis from treatment directly or adjacent to the disc.
- Specific to laser iridotomy or iridoplasty: inadvertent corneal or lens burns/opacities; iritis; iris atrophy; bleeding; visual symptoms; IOP spike; and, rarely, retinal detachment.
- Specific to laser trabeculoplasty: IOP spike, and, disruption of the corneal epithelium.

ENT

Excessive treatment may cause swelling (edema) in the area treated by the laser.

Anesthesia Considerations

One of the main concerns during otolaryngeal and bronchial procedures is the substantial risk of endotracheal fires. The following sections provide information and safety guidelines, which can greatly decrease the risks associated with these procedures. Information is also provided on what to do if such a fire does occur.

IRIDEX Corp. recommends the safety guidelines of American National Standards ANSI Z136.3-2007 as follows:

- Care must be taken 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.
- Use the lowest possible oxygen concentration to support the patient.
- Use the venturi ventilation technique when possible.
- Use intravenous anesthetic agents rather than inhalation techniques.
- Use non-flammable laser-safe endotracheal tubes.
- Protect the endotracheal tube cuff with wet cottonoids.

Reference material and additional information regarding laser safety and the prevention of endotracheal fires may be obtained from the following U.S. sources:

- **ANSI Z136.3**, **The Safe Use of Lasers in Health Care Facilities**, American National Standards 2007.
- **Recommended Practices: Laser Safety in the Practice Setting**. *AORN Journal*, March 1993, Vol. 57 No. 3, Pg. 720-727.
- **Safety Considerations for the Use of Medical Lasers, The Nursing Spectrum of Lasers**, Pfister, Kneedler, Purcell, *Education Design*, 1988, Pg. 70-72.
- **Prevention of Fires and Protection of Non-Target Tissues, Airway Precautions**, *Plan for Success: A Practical Guide for Your Carbon Dioxide Laser Surgery Program*, Lewis, Coherent 1989, Pg. 16-17.
- **Laser Resistant Stainless Steel Endotracheal Tube: Experimental and Clinical Evaluation**, *Lasers in Surgery and Medicine*, Fried, Marvin P., MD, 11:301-306 (1991).

- **Evaluation & Discussion: Issues in Using and Selecting Laser Resistant Endotracheal Tubes (LRETTs) and Wraps**, *ECRI, Health Devices*, July-August 1991, Vol. 20 Nos. 7-8.
- **Diffuse Reflections, Endoscopic Surgery: Is Laser Safety Eyewear Really Needed?**, *Radiant Resources Newsletter*, Winter 1992, Rockwell Laser Industries.

Specific Contraindications

- None known specific to ENT use at this time.
- Ophthalmic:
  - Any situation where the target tissue cannot be adequately visualized or stabilized.
  - Do not treat albino patients who have no pigmentation.

Laser Settings

Beginning at low power with short duration exposures, the surgeon should note the surgical effect and increase power, power density, or exposure duration until the desired surgical effect is obtained. The information in the following tables is intended to provide guidance only for treatment settings, which are not prescriptive for any condition. The operative needs of each patient should be individually evaluated based on the indication, treatment location, and on the patient's medical and wound healing history. If uncertain of expected clinical response, always start with a conservative setting and increase the setting in small steps.

Ophthalmic Treatment Parameters				
Treatment	**Delivery Devices**	**Power (W)**	**Exposure Duration (ms)**	**Spot Size (µm)**
Trabeculoplasty	SLA	1.5–2.0	100–500	100–500
Retina Grid/Focal	SLA, LIO, EndoProbe	1.0–2.0	100–1000	50–100
Trabeculoplasty	SLA	0.5–2.0	100–500	50–200
Iridotomy	SLA, LIO	0.2–2.0	100–300	50–200
Retina Grid/Focal	SLA, LIO, EndoProbe	0.1–2.0	100–1000	100–1000

ENT Treatment Parameters				
Treatment	**Delivery Device**	**Power (W)**	**Exposure Duration (ms)**	**Spot Size (µm)**
Stapedectomy	Otoprobe FlexFiber	0.8–2.3	100–1000	N/A
Stapedotomy				
Myringotomies				
Lysis of Adhesions				
Control of Bleeding	Otoprobe FlexFiber	0.2–0.6	800–2000	N/A
Removal of Acoustic Neuromas				
Soft Tissue Adhesion in Micro/Macro Otologic Procedures				

Warnings and Cautions

DANGER:

Do not remove covers. Shock hazard and accessible laser radiation. Refer servicing to qualified laser personnel. Risk of explosion if used in the presence of flammable anesthetics.

WARNINGS:

Lasers generate a highly concentrated beam of light that may cause injury if improperly used. To protect the patient and the operating personnel, the entire laser and the appropriate delivery system operator manuals should be carefully read and comprehended before operation.

Never look directly into the aiming or treatment beam apertures or the fiber-optic cables that deliver the laser beams, with or without laser safety eyewear.

Never look directly into the laser light source or at laser light scattered from bright reflective surfaces. Avoid directing the treatment beam at highly reflective surfaces such as metal instruments.

Ensure that all personnel in the treatment room are wearing the appropriate laser safety eyewear. Never substitute prescription eyewear for laser safety eyewear.

To avoid the risk of electric shock, this equipment must be connected to a supply mains with protective earth.

US federal law restricts this device to sale by or on the order of a healthcare practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

Use of controls or adjustments or performing of procedures other than those specified herein may result in hazardous radiation exposure.

Do not operate the equipment in the presence of flammables or explosives, such as volatile anesthetics, alcohol, and surgical preparation solutions.

Laser plume may contain viable tissue particulates.

Keep the protective cap over the fiber-optic connector when the delivery device is not in use.

IRIDEX Corporation Contact Information

IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View, California 94043-1824 USA

Telephone:	(650) 940-4700 (800) 388-4747 (US only)
Fax:	(650) 962-0486
Technical Support:	(650) 940-4700 (800) 388-4747 (US only) techsupport@iridex.com

EC REP Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands
Tel: (31) (0) 70 345-8570
CE 0086 Fax: (31) (0) 70 346-7299

Warranty and Service. Each laser system carries a standard factory warranty. The warranty covers all parts and labor required to correct problems with materials or workmanship. This warranty is void if service is attempted by anyone other than certified IRIDEX service personnel.

WARNING: *Use only IRIDEX delivery devices with the IRIDEX laser system. Use of a non-IRIDEX delivery device may result in unreliable operation or inaccurate delivery of laser power. This Warranty and Service agreement does not cover any damage or defect caused by the use of non-IRIDEX devices.*

NOTE: *This Warranty and Service statement is subject to the Disclaimer of Warranties, Limitation of Remedy, and Limitation of Liability contained in IRIDEX's Terms and Conditions.*

WEEE Guidance. Contact IRIDEX or your distributor for disposal information.

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Setup

Unpacking the System

Make sure you have all components that were ordered. Check components for damage before use.

NOTE: *Contact your local IRIDEX Customer Service representative if there are problems with your order.*

Appearance and type of components may vary based on the system ordered.

- Laser (also "Console")
- Power cord (U.S. configuration shown)
- Keys
- Standard footswitch
- Operator Manual (not shown)
- Laser warning sign (not shown)
- Optional accessories (not all shown)

Choosing a Location

Choose a well-ventilated location within the specified operating range of the console.

Place the laser system on a table or on existing operating room equipment. Allow at least 5 cm (2 in.) of clearance on each side.

In the US, this equipment must be connected to an electrical supply source at 100-240 VAC with a center tap.

To ensure that all local electrical requirements can be met, the system is equipped with a hospital-grade (green dot) three-wire grounding plug. When choosing the location, ensure that a grounding-type AC outlet is available; it is required for safe operation.

The power cord included in the packaging is appropriate for your location. Always use an approved three-wire grounding cord set. Do not alter the power inlet. To ensure proper grounding, follow local electrical codes before installing the system.

CAUTIONS:

Do not defeat the purpose of the grounding pin. This equipment is intended to be electrically grounded. Contact a licensed electrician if your outlet prevents you from inserting the plug.

Do not position or use the system near open flames.

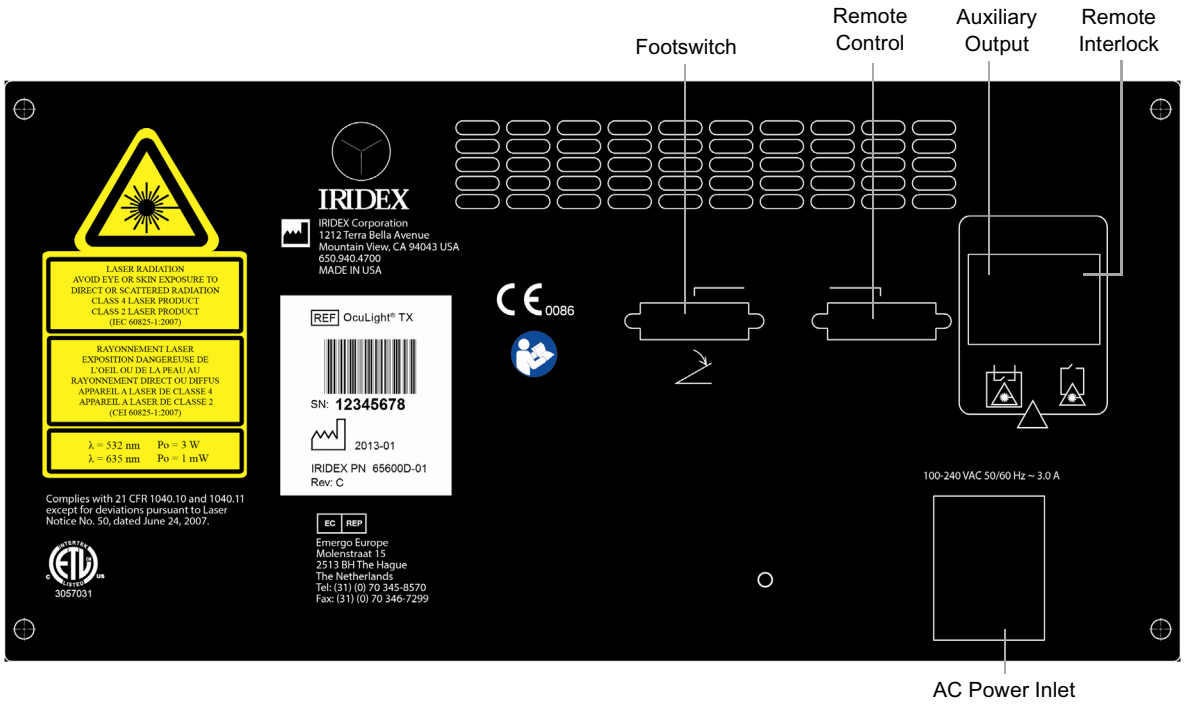
Connecting the Components

CAUTION: *Do not connect two footswitches to the laser console.*

NOTE: *Refer to the appropriate delivery device manual for specific connection instructions.*

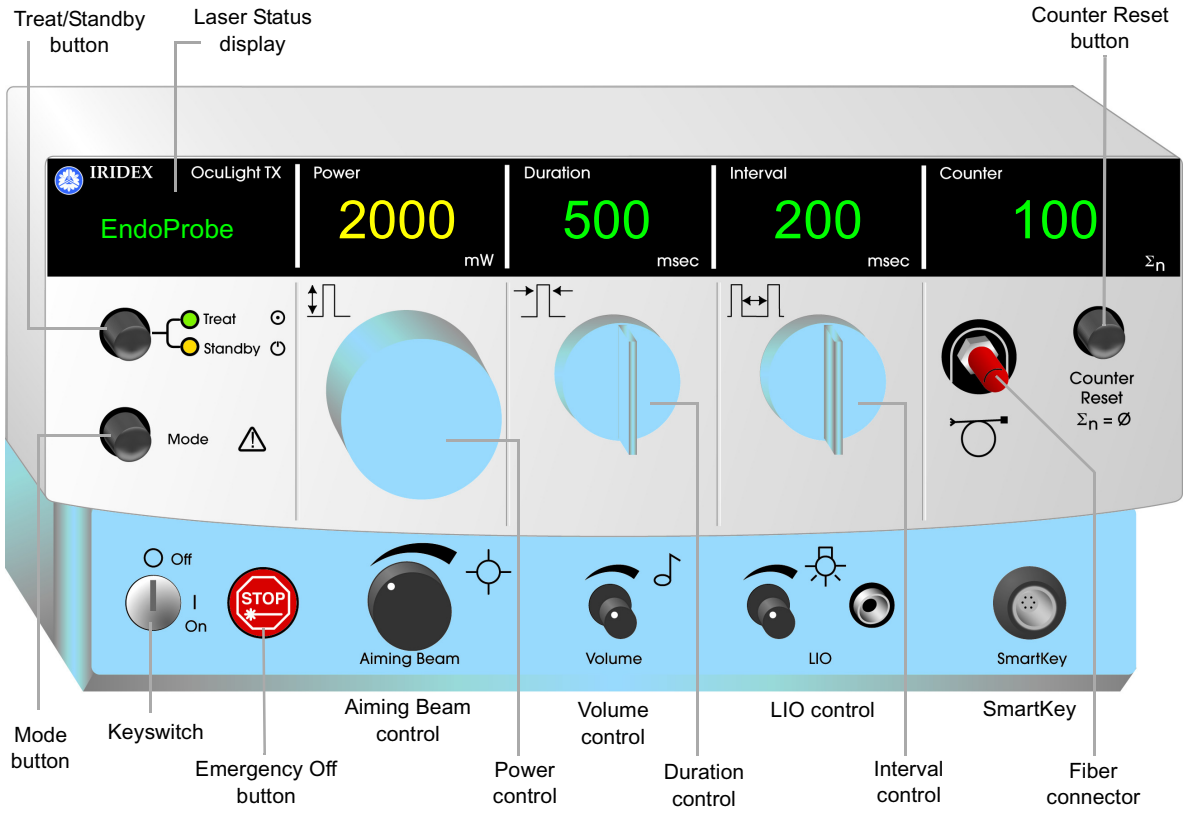
NOTE: *The Auxiliary Output contact supports low-voltage electrical signaling circuits of up to five amperes and 24 volts AC or DC. Ensure all wiring conforms to local electrical codes.*

OcuLight GL/GLx/TX Rear Panel Connectors



3
Operation

Front Panel Controls



Powering the Laser On and Off

- To turn the laser on, turn the key to the On position.
- To turn the laser off, turn the key to the Off position. Remove and store the key to prevent unauthorized use.

  NOTE: *The key can be removed in the Off position only.*

- In an emergency, press the red EMERGENCY OFF button. This immediately disables the console and all laser-related circuits.

Setting Treatment Parameters

Power	Set the treatment pulse power.
Duration	Set the treatment pulse duration. To select continuous duration (available only when using an EndoProbe), turn the control until four dashes appear in the Duration and Interval displays and “EndoProbe CW” appears in the laser status display.
Interval	Interval between treatment pulses. To select single pulse mode, turn the control until the Interval display is blank.
Counter	Press the COUNTER RESET button to reset to zero.
Aiming Beam	Adjust the aiming beam power.
LIO	Adjust the LIO illumination intensity.
Volume	Adjust the volume of audible indicators.

Selecting the Laser Mode

Press the TREAT/STANDBY button to select the laser mode:

- Yellow = Standby mode

  The footswitch and the treatment beam are disabled.

- Green = Treat mode

  The footswitch is enabled. Press the footswitch to deliver the treatment beam.

To adjust the laser mode using the remote control, press TREAT/STANDBY to change the laser state to and from Treat and Standby. Use the other buttons on the remote control to adjust Power, Duration, Interval, and Aiming Beam. The remote display indicates “Power” until you press another button. The light above a parameter button illuminates to indicate the parameter being displayed. To increase or decrease a parameter rapidly, hold down the parameter button.

WARNINGS:

> *Except during actual treatment, the laser must always be in Standby mode. Maintaining the laser in Standby mode prevents accidental laser exposure if the footswitch is inadvertently pressed.*
>
> *Verify that all persons in the treatment room are wearing the appropriate laser safety eyewear before placing the laser in Treat mode. Never substitute prescription eyewear for laser safety eyewear.*

Selecting User Preferences

NOTE: *Menu selections are automatically saved when selecting a new menu item or when exiting User Preferences mode.*

TO VIEW OR CHANGE USER PREFERENCE SETTINGS:

1. Place the laser in Standby mode.
2. Press and hold MODE until the laser status display flashes "User Preferences." The Interval display reads "0".
3. Select the User Preferences menu settings using the Interval control.
4. Select the option for each menu setting using the Duration control.
5. To exit User Preferences mode, press MODE.

The OcuLight TX, GLx, and GL User Preferences menu settings are described in the following table.

Interval Setting	User Preferences Menu	Duration Setting	User Preferences Options
0	Default Menu	N/A	N/A
1	Aiming Beam On/Off in Standby mode	0 1	Aiming Beam Off in Standby mode Aiming Beam On in Standby mode
2	Aiming Beam On/Off with Pulse	0 1	Aiming Beam Off with Pulse Aiming Beam On with Pulse
3	Display Language	0 1 2 3 4 5	English Spanish French German Italian Portuguese
4	External Warning Device	0 1 2	On with Key On in Treat mode On with Footswitch
5	Message Review	1-21	Displays messages
6	Remote Power Min Stepsize	10 20 30 40 50	Sets minimum power adjustment set by remote or footswitch.

Treating Patients

BEFORE TREATING A PATIENT:

- Ensure that the eye safety filter (as appropriate) is properly installed and that the SmartKey®, if used, is selected.
- Ensure that the laser components and delivery device(s) are properly connected.
- Post the laser warning sign outside the treatment room door.

NOTE: *Refer to Chapter 6, "Safety and Compliance," and your delivery device manual(s) for important information about laser safety eyewear and eye safety filters.*

TO TREAT A PATIENT:

1. Turn on the laser.
2. Reset the counter.
3. Set the treatment parameters.
4. Position the patient.
5. If required, select an appropriate contact lens for the treatment.
6. Ensure that all ancillary personnel in the treatment room are wearing the appropriate laser safety eyewear.
7. Select Treat mode.
8. Position the aiming beam on the treatment site.
9. Focus or adjust the delivery device as applicable.
10. Press the footswitch to deliver the treatment beam.

TO CONCLUDE PATIENT TREATMENT:

1. Select Standby mode.
2. Record the number of exposures and any other treatment parameters.
3. Turn off the laser and remove the key.
4. Collect the safety eyewear.
5. Remove the warning sign from the treatment room door.
6. Disconnect the delivery device(s).
7. Disconnect the SmartKey, if used.
8. If the delivery device is single-use, dispose of it properly. Otherwise, inspect and clean the delivery device(s) as instructed in your delivery device manual(s).
9. If a contact lens was used, handle the lens according to the manufacturer's instructions.
10. Keep the protective cap over the fiber-optic connector when the delivery device is not in use.

1.

4
Troubleshooting

General Problems

Problem	User Action(s)
No display	• Verify that the keyswitch is on. • Verify that the components are properly connected. • Verify that the electrical service is on. If there is still no display, contact your local IRIDEX Technical Support representative.
Inadequate or no aiming beam	• Verify that the delivery device is properly connected. • Verify that the console is in Treat mode. • Turn the aiming beam control fully clockwise. • Verify that the fiber-optic connector is not damaged. • If possible, connect another IRIDEX delivery device and place the console in Treat mode. If the aiming beam is still not visible, contact your local IRIDEX Technical Support representative.
No treatment beam	• Verify that the remote interlock has not been activated. • Verify that the aiming beam is visible. • If using Symphony Slit Lamp Adapter, verify that the Wavelength Switch is in the correct position for the desired laser system. • Verify that the eye safety filter is in the closed position. If there is still no treatment beam, contact your local IRIDEX Technical Support representative.
No illumination light (LIO only)	• Verify that the illumination connector is connected to the console. • Verify that the special function control is not between detents. • Check the bulb and replace it (if necessary).
Illumination light is too dim (LIO only)	• Verify that the special function control is not between detents. • Adjust the console illumination intensity control.

Problem	User Action(s)
The aiming beam is large or out of focus on the patients' retina (LIO only)	Readjust your working distance between the LIO headset and the examination lens. The aiming beam should be sharply defined and at its smallest diameter when in focus.
The treatment lesions are variable or intermittent (LIO only)	• The LIO may be slightly out of focus. This decreases power density. Readjust your working distance to obtain the smallest spot size. • A poorly centered laser beam may be clipping on the examination lens or on the patient's iris. Adjust the laser beam in the illumination field. • The laser treatment parameters may be too close to the tissue response threshold for consistent response. Increase the laser power and/or exposure duration, or select a different lens.

Status Panel Messages

Status Panel Message	User Action(s)
`Calibration Required`	Contact your local IRIDEX Technical Support representative.
`Call Service`	Press the MODE button. A description of the fault displays briefly on the status panel. The console restarts and performs a self-test. If the message displays again, contact your local IRIDEX Technical Support representative.
`Connect Fiber`	Connect an appropriate delivery device.
`Connect Footswitch`	• Verify that the footswitch or receiver is properly connected. • Verify that two footswitches are not connected.

`Connect SmartKey`
or
`No SmartKey`
	Verify that the SmartKey is properly installed.

`Emergency Stop`	• Turn the system off (using the key) and wait several seconds. • Turn the system on.

`Eye Safety Filter?`
or
`532nm Safety Filter?`
	Verify that the eye safety filter is properly installed, and press MODE to continue.

`Footswitch Stuck /` `Release Footswitch`	Remove foot or other object from footswitch.
`No Remote Interlock`	• Verify that the remote interlock plug is properly inserted. • Verify that the door switches or other circuits are closed.
`Remove Fiber`	Disconnect the fiber optic from the fiber port.

`Slit Lamp Spot Size?`
or
`Spot Size?`
	Verify that the spot size selector is not between positions.

`Unknown Fiber Type`	Connect the fiber-optic connector.

5
Maintenance

Inspecting and Cleaning the Laser

Clean the outside console covers with soft cloth moistened with a mild detergent. Avoid abrasive or ammonia-based cleaners.

Periodically inspect the laser, power cords, footswitch, cables, etc., for wear. Do not use if there are any exposed or broken wires, and/or broken connectors.

1. The equipment covers should be intact; not loose.
2. All knobs and dials should be in proper working order.
3. The switch cap on the Emergency Stop should be intact; not broken.
4. All eye safety filters are properly installed. No cracks or damage that may cause unintended stray laser light to transmit.
5. All eye safety glasses should be the correct type (wavelength and OD). No cracks or damage that may cause unintended stray laser light to transmit.

WARNING: *Do not remove covers! Removing covers and shields may result in exposure to dangerous optical radiation levels and electrical voltages. Only IRIDEX-trained personnel may access the interior of the laser. The laser has no user serviceable parts.*

CAUTION: *Turn off the laser before inspecting any delivery device components. Keep the protective cap over the laser port when the laser is not in use. Always handle fiber-optic cables with extreme care. Do not coil the cable in a diameter less than 15 cm (6 in.).*

Inspecting and Cleaning the Footswitch

IRIDEX footswitch labeled IPX8 is submersible (per IEC 60529).

TO DECONTAMINATE AND DISINFECT THE FOOTSWITCH:

1. Disconnect the footswitch from the laser (if applicable).
2. Using water, isopropyl alcohol, or enzymatic detergents with mild pH, such as ENZOL®, remove all traces of blood and other body fluids from all exposed surfaces of the footswitch assembly, including the cable (if applicable).
3. Stand the footswitch on end to drain all fluids.
4. Immerse the footswitch in a CIDEX® (2.4% glutaraldehyde) solution:
   - 45 minutes at 25° C to achieve a high level of disinfection
   - 10 minutes at 20° C to 25° C to achieve an intermediate level of disinfection
5. Remove the footswitch from the CIDEX solution.

6. Stand the footswitch on end to drain all fluids.
7. Rinse by completely immersing the footswitch in clean water for one minute. Repeat two more times using clean water for each rinse.
8. Stand the footswitch on end again to drain all fluids.
9. Allow the footswitch to air-dry completely before reusing.
10. Reconnect the footswitch to the laser.

NOTE: *The connector is not sealed and should not be immersed into any cleansing agent.*

Verifying the Power Calibration

To ensure that calibration meets the requirements of the National Institute of Standards and Technology (NIST), the laser treatment power is calibrated at the IRIDEX factory with a power meter and an IRIDEX delivery device with previously measured transmission.

Periodically, and at least annually, you should measure the actual power being delivered through your IRIDEX delivery device(s) to verify that the laser system is still operating within factory calibration parameters.

Regulatory agencies require that manufacturers of US FDA CDRH Class III and IV and European EN 60825 Class 3 and 4 medical lasers supply their customers with power calibration procedures. Only IRIDEX-trained factory or service personnel may adjust the power monitors.

TO VERIFY THE POWER CALIBRATION:

1. Make sure all persons in the room are wearing the appropriate laser safety eyewear.
2. Connect a properly functioning IRIDEX delivery device.
3. Set the power to 200 mW.
4. Set the duration to 100 ms and the interval to 100 ms.
5. Center the aiming beam at the middle of the power meter sensor.

   CAUTION: *A spot size of less than 3 mm diameter can damage the power meter sensor.*
6. Place the laser in Treat mode.
7. Aim the output beam from the IRIDEX delivery device into the power meter, following the power meter instructions for sampling the laser power.
8. Press the footswitch to deliver the treatment beam. Record the power meter reading in the table below. The reading should be a minimum of 80 mW and a maximum of 120 mW.
9. Set the power to 500 mW.
10. Complete steps 4 through 8, and record the reading. It should be a minimum of 200 mW and a maximum of 300 mW.
11. Set the power to 1000 mW.
12. Complete steps 4 through 8, and record the reading. It should be a minimum of 400 mW and a maximum of 600 mW.

Calibration date for power meter and sensor: _____

Power (mW)	Exposure Duration (ms) and Interval (ms)	Meter Reading (mW)	Acceptable Range (mW)
200	100		80-120
500	100		200-300
1000	100		400-600

Date: _____ Calibrated by: _____

Of: _____

13. If the readings fall outside the acceptable levels, check the power meter, ensure that you have accurately placed the beam on the power meter, and check the readings again with another IRIDEX delivery device.
14. If the readings are still outside the acceptable levels, contact your local IRIDEX Technical Support Representative.
15. Place a signed copy of the table in your device records to refer to during use and service.

6
Safety and Compliance

To ensure safe operation and prevent hazards and unintended exposure to the laser beams, read and follow these instructions:

- To prevent exposure to laser energy, except as a therapeutic application from either direct or diffusely reflected laser beams, always review and observe the safety precautions outlined in the operator manuals before using the device.
- This device is intended for use only by a qualified physician. The applicability of the equipment and treatment techniques selected is your sole responsibility.
- Do not use any device if you think it is not functioning properly.
- Laser beams reflected from specular surfaces can harm your eyes, the patient's eyes, or others' eyes. Any mirror or metal object that reflects the laser beam can constitute a reflection hazard. Be sure to remove all reflection hazards near the laser. Use non-reflecting instruments whenever possible. Be careful not to direct the laser beam at unintended objects.

CAUTION: *Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.*

Protection for the Physician

Eye safety filters protect the physician from backscattered treatment laser light. Integral eye safety filters are permanently installed in every compatible Slit Lamp Adapter (SLA) and Laser Indirect Ophthalmoscope (LIO). For endophotocoagulation or for Operating Microscope Adapter (OMA) use, a separate discrete eye safety filter assembly must be installed into each viewing path of the operating microscope. All eye safety filters have an optical density (OD) at the laser wavelength sufficient to permit long-term viewing of diffuse laser light at Class I levels.

Always wear appropriate laser safety eye wear when performing or observing laser treatments with the unaided eye.

Protection for All Treatment Room Personnel

The Laser Safety Officer should determine the need for safety eyewear based on the Maximum Permissible Exposure (MPE), Nominal Ocular Hazard Area (NOHA), and Nominal Ocular Hazard Distance (NOHD) for each of the delivery devices used with the laser system, as well as the configuration of the treatment room. For additional information, refer to ANSI Z136.1, ANSI Z136.3, or European Standard IEC 60825-1.

The following formula was used to calculate the most conservative NOHD values:

$NOHD = (1.7/NA)(\Phi/\pi MPE)^{0.5}$

where:

NOHD = the distance, in meters, at which the beam irradiance equals the appropriate corneal MPE

NA = the numerical aperture of the beam emerging from the optical fiber

Φ = the maximum possible laser power, in watts

MPE = the level of laser radiation, in W/m^2, to which a person may be exposed without suffering adverse events

Numerical aperture is equal to the sine of the half-angle of the emerging laser beam. Maximum available laser power and associated NA vary with each delivery device, resulting in unique NOHD values for each delivery device.

NOTE: *Not all delivery devices are available for all laser models.*

GL NOHD Values for Various Delivery Devices				
Delivery Device	**MPE (W/m^2)**	**Numerical Aperture (NA)**	**Maximum Power Φ (W)**	**NOHD (m)**
EndoProbe	10	0.100	1.500	3.7
Laser Indirect Ophthalmoscope (LIO)	10	0.013	1.500	28.6
Slit Lamp Adapter (SLA)	10	0.012	1.200	27.7

GLx/TX NOHD Values for Various Delivery Devices				
Delivery Device	**MPE (W/m^2)**	**Numerical Aperture (NA)**	**Maximum Power Φ (W)**	**NOHD (m)**
EndoProbe	10	0.100	2.000	4.3
Oto/ENT Probes	10	0.100	2.500	4.8
Laser Indirect Ophthalmoscope (LIO)	10	0.013	2.000	33.0
Slit Lamp Adapter (SLA)	10	0.012	1.800	33.9

Safety Compliance

Complies with FDA performance standards for laser products, except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

CE-labeled devices comply with all requirements of the European Medical Device Directive MDD 93/42/EEC.

The IRIDEX GL, GLx, and TX use solid-state electronic switching power supply that meets strict EN60601-1 and UL 60601-1 performance and safety standards. A dedicated microprocessor continuously monitors the safe function of all subsystems within the laser console.

Feature	Function
Emergency off	Immediately disables the laser.
Protective housing	The external housing prevents unintended access to laser radiation above Class I limits.
Safety interlock	An electronic interlock at the fiber port prevents laser emission if a delivery device is not properly connected.
Remote interlock	An external door interlock outlet is provided to disable the laser if the treatment room doors are opened during treatment. An interlock jumper wire is also provided.
Key switch	The system operates only with the proper key. The key cannot be removed while in the On position.
Laser emission indicator	The yellow Standby light provides a visible warning that laser radiation is accessible. When Treat mode is selected, a three-second delay prevents unintentional laser exposure. The console delivers laser energy only when the footswitch is depressed while in Treat mode. An audible tone indicates that the console is delivering laser energy. The audible indicator volume can be adjusted but not turned off.
Beam attenuator	An electronic beam attenuator prevents any laser radiation from exiting the console until all requirements for emission are met.
Viewing optics	Eye safety filters are required when using the laser system.
Manual restart	If laser emission is interrupted, the system goes into Standby mode, the power drops to zero, and the console must be manually restarted.
Internal power monitor	Two monitors independently measure the laser power before emission. If the measurements differ significantly, the system enters Call Service mode.
Footswitch	The console cannot be placed in Treat mode if the footswitch is damaged or improperly connected. The footswitch can be immersed and cleaned (IPX8 per IEC60529) and is shrouded for safety (ANSI Standard Z136.3, 4.3.1).

Labels

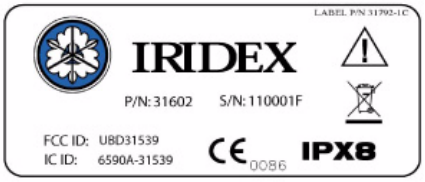
NOTE: *The actual label may vary with laser model.*

Serial Number (rear panel)

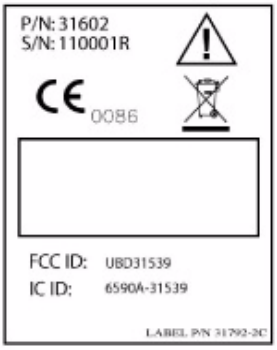
Ground (bottom of laser)

The reliability of the ground connection can only be assured when this device is connected to an approved mating receptacle marked for hospital use and installed in accordance with the appropriate Electrical Codes for medical occupancy.

Footswitch



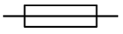
Wireless Receiver

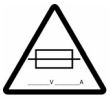


Remote Control

Laser Warning

Symbols (As Applicable)

 Aiming Beam	 Angle	 Aspirating Probe
 Caution	 Audible Signal	 CE Mark
 Connector Type	 Do Not Use if Package is Damaged	 Duration
 Duration with MicroPulse	 Emergency Stop	 ETL Mark
 EtO Sterile	 EU Authorized Representative	 Expiration Date
 Footswitch	 Footswitch In	 Footswitch Out
 Fuse	 Gauge	 Protective Earth (Ground)
 Illuminating Probe	 Decrease/Increase	 Interval
 Interval with MicroPulse	 Laser Aperture at End of Fiber	 Laser Warning
 Illumination	 LOT	 Manufacturer
 Manufacture Date	 Off	On
 Part Number	 Power	Σ_n Pulse Count
$\Sigma_n = 0$ Pulse Count Reset	 No-ionizing Electromagnetic Radiation	 Read Information
 Remote Control	 Remote Interlock	SN Serial Number
 Single Use	Standby	Treat
Type B Equipment	WEEE Guidance. Contact IRIDEX or your distributor for disposal information.	Pattern is Activated

	Temperature Limitations	**IPX4**	Protections Against Splash Water Coming from all Directions	**IPX8**	Protections Against Continuous Immersion
	Refer to Instruction Manual/Booklet (in blue)		Initial Power (PowerStep)		Interval between Groups
	Number of Pulses (Group)		Number of Steps (PowerStep)		Power (MicroPulse)
	Power Increment		Power Increment (PowerStep)		Parameter is Locked
	USB		Port Indicators		Laser Firing
	Laser Preparing		Speaker		Screen
	System Brightness		Latex Free		Prescription
	Warning, Replace with fuses as indicated				

Specifications

NOTE: *Unless otherwise noted, laser console specifications are identical for the OcuLight GL, GLx, and TX.*

Specification	Description
Treatment Wavelength	532 nm
Treatment power	Varies by type of delivery device. The laser system displays the power delivered to the tissue. **GL**: 0 –1500 mW **GLx/TX**: 0 – 2500 mW
Duration	Varies by type of delivery device. One minute duration available with EndoProbe® (Power ≤500 mW). **GL**: 30 - 1000 ms **GLx/TX**: 10 - 3000 ms
Interval	Varies by type of delivery device. Duty cycle up to 100% is available at powers ≤500 mW. **GL**: 30 - 1000 ms **GLx/TX**: 10 - 3000 ms
Aiming Beam	635 nm nominal <1 mW
Electrical	100-240 VAC, 50/60 Hz, 3.0 A
Cooling	Whisper fan with peltier cooling
Operating temperature range	10° C to 35° C (50° F to 95° F) If stored at temperatures below 10° C (50° F), allow to return to room temperature for 4 hours prior to operation.
Storage temperature range	-20° C to 60° C (-4° F to 140° F)
Relative humidity	10% to 90% (non-condensing)
Dimensions	30 cm × 30 cm × 15 cm (12 in. W × 12 in. D × 6 in. H)
Weight	<6.0 kg (13.2 lb)
Equipment Protection	Class 1

7
Wireless Footswitch and EMC

Setting Up the Wireless Footswitch

The wireless footswitch comprises:

- Battery-powered footswitch (with or without power adjust)
- Laser console-powered receiver

Connect the wireless receiver to the footswitch receptacle on the rear of the laser. Three pedals (as applicable) on the footswitch control the following:

- Left pedal = decrease power (hold down to ramp the parameter)
- Center pedal = activate laser
- Right pedal = increase power (hold down to ramp the parameter)

CAUTION: *Each footswitch/receiver pair is uniquely linked and will not work with other IRIDEX footswitches or similar components. Clearly identify each pair to prevent separation of the linked components.*

NOTE: *The footswitch is designed to operate within 15 feet of the laser.*

Testing the Batteries

NOTE: *When batteries need to be replaced, contact your sales representative or IRIDEX Customer Service. The Wireless Footswitch was designed with a battery life expectancy of 3 – 5 years of normal operation and use.*

LEDs on the footswitch assist in troubleshooting and indicate battery conditions as follows:

Footswitch LED Display	Status
Green flash following pedal depression	Footswitch OK Batteries OK
Amber flash following pedal depression	Footswitch OK Batteries low
Blinking red LED for 10 seconds following pedal depression	No RF communication

EMC Safety Information

The laser system (console and accessories) needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this section. Portable and mobile RF communications equipment can affect this system.

This laser system has been tested and found to comply with the limits for medical devices in IEC 60601-1-2 according to the tables in this section. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

CAUTION: *Changes or modifications to this laser system not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment and may result in increased emissions or decreased immunity of the laser system.*

The wireless footswitch transmits and receives in the frequency range of 2.41GHz to 2.46GHz with a limited effective radiated power as described below. The transmissions are continuous transmissions at discrete frequencies within the transmission frequency range.

The wireless footswitch has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential 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 radio communications. However, there is no guarantee that interference will not occur in a particular installation. If the wireless footswitch does cause harmful interference to radio or television reception, which can be determined by turning the laser system 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 laser console into an outlet on a circuit different from that to which the receiver is connected.
- Consult IRIDEX Customer Service for help.

This Class B digital apparatus meets all requirements of the Canadian Interference-Causing Equipment Regulations.

Cet appareil numérique de la classe B respecte toutes les exigences du Réglement sur le matériel brouilleur du Canada.

EMC Requirements for Console and Accessories

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
This laser system (console and accessories) is intended for use in the electromagnetic environment specified below. The customer or the user of the laser system should assure that it is used in such an environment.		
Emissions Test	**Compliance**	
RF emissions CISPR 11	Group 1	The laser system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions	Complies	
The laser system is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.		

Guidance and Manufacturer's Declaration - Immunity			
This laser system (console and accessories) is intended for use in the electromagnetic environment specified below. The customer or the user of the laser system should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user or the laser system requires continued operation during power mains interruptions, it is recommended that the laser system be powered from an uninterruptible power supply or a battery.
(50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The wireless footswitch is intended for use in the electromagnetic environment specified below. The customer or the user of the wireless footswitch should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the laser system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF IEC-61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$ 80MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[a] Fields strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE 2**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
a:Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the laser system is used exceeds the applicable RF compliance level above, the laser system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the laser system. **b**:Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Wireless Footswitch.

The wireless footswitch is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the wireless footswitch can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the wireless footswitch as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	2.3

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.