

# OcuLight<sup>®</sup> SL/SLx

## Operator Manual



OcuLight® SL/SLx Operator Manual  
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# 1 Introduction

## Product Description

The OcuLight SL/SLx<sup>®</sup> are semiconductor diode lasers that deliver true continuous wave infrared laser (810 nm) light for ophthalmic 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 OcuLight SL/SLx is indicated for retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation, and other diode laser treatments. The following are examples of applications for the OcuLight SL/SLx laser systems.

Condition	Treatment
Diabetic Retinopathy <ul style="list-style-type: none"><li>• Nonproliferative Retinopathy</li><li>• Macular Edema</li><li>• Proliferative Retinopathy</li></ul>	Panretinal Photocoagulation (PRP); Focal and Grid Laser Treatments
Glaucoma <ul style="list-style-type: none"><li>• Primary Open Angle</li><li>• Closed Angle</li><li>• Refractory Glaucoma (recalcitrant/uncontrolled)</li></ul>	Laser Trabeculoplasty; Iridotomy; Transscleral Cyclophotocoagulation (TSCPC)
Retinal Tears, Detachments, and Holes	Transscleral Retinal Photocoagulation (TSRPC); Focal and Grid Laser Treatments
Lattice Degeneration	PRP; Focal and Grid Laser Treatments
Age-Related Macular Degeneration (AMD)	Focal and Grid Laser Treatments

Condition	Treatment
Intra-Ocular Tumors <ul style="list-style-type: none"> <li>• Choroidal Hemangioma</li> <li>• Choroidal Melanoma</li> <li>• Retinoblastoma</li> </ul>	Focal and Grid Laser Treatments
Retinopathy of Prematurity	PRP; TSRPC; Focal and Grid Laser Treatments
Sub-Retinal (choroidal) Neovascularization	Focal and Grid Laser Treatments
Central and Branch Retinal Vein Occlusion	PRP; Focal and Grid Laser Treatments

## References

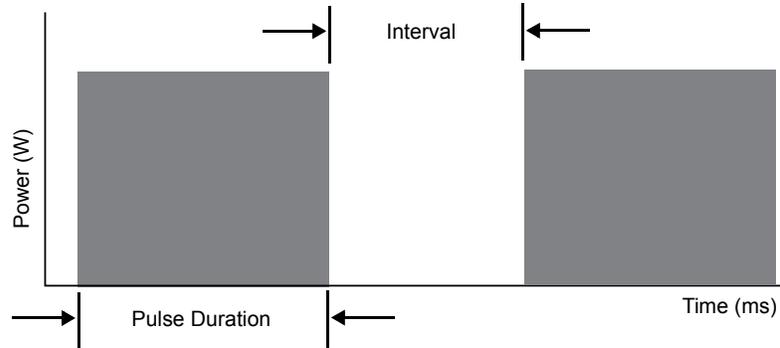
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- Laser Photocoagulation for Threshold Retinopathy of Prematurity, Iversion D, Trese M, Orgel I, Williams G, *Archives Ophthalmology* 109:1342-1343, 1991.
- Photocoagulation of Choroidal Neovascular Membranes with a Diode Laser, Ulbig M, McHugh D, Hamilton P., *British Journal of Ophthalmology* 77:218-221, 1993.
- The Treatment of Macular Disease Using a Micropulsed and Continuous Wave 810-nm Diode Laser, Friberg TR, Karatza EC., *Ophthalmology* 104:2030-2038, 1997.

## Pulse Types

Three pulse types are available: CW-Pulse™, MicroPulse™ (SLx only), and LongPulse™ (optional on SL).

## CW-Pulse

CW-Pulse allows you to select either a single, continuous-wave pulse or repetitive pulses. CW-Pulse is active after each key start.

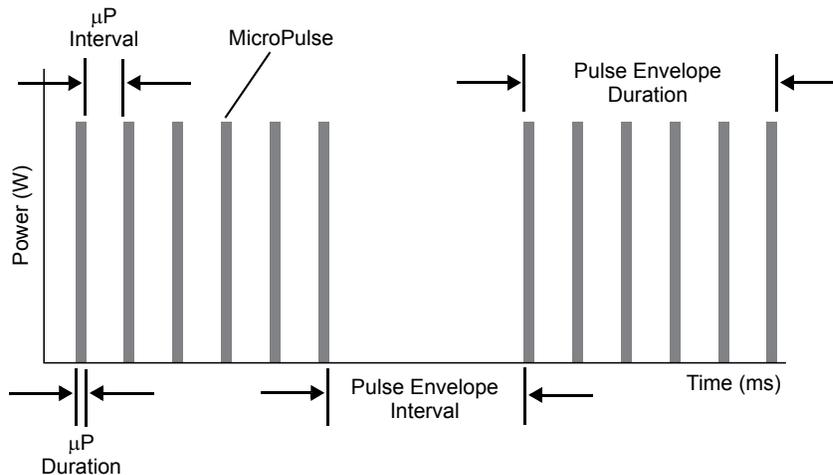


## MicroPulse (SLx Only)

MicroPulse ( $\mu$ P) delivers laser energy in a burst of very short pulses and separating intervals. You may adjust MicroPulse duration and MicroPulse interval or select from three preset duty cycle values.

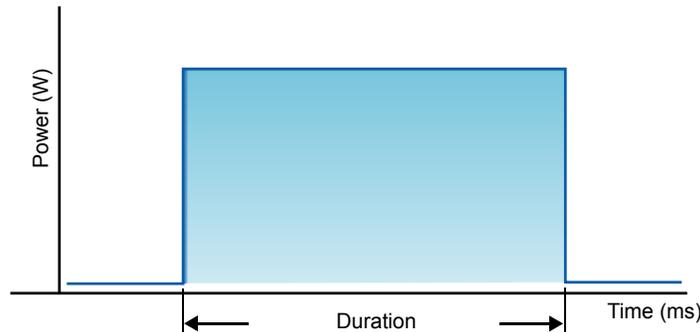
Duty cycle refers to the percentage of time the treatment laser is activated during each pulse; duty cycle is calculated according to this formula:

$$\text{Duty Cycle} = \frac{\mu\text{P Duration}}{\mu\text{P Duration} + \mu\text{P Interval}} \times 100$$



## LongPulse (Optional on SL)

LongPulse involves exposure durations in excess of 9 seconds using a large spot delivery device.



## Compatible Delivery Devices

Compatible Delivery Devices	SLx			SL	
	CW-Pulse™	MicroPulse™	LongPulse™	CW-Pulse	Long Pulse
IR LIO+ (13152-X)	Yes	No	No	Yes	No
LS-LIO+ (13153-X)	Yes	No	Yes	Option	Option
Dual LIO+ (30903-X)	Yes	No	No	Yes	No
EndoProbe* Family	Yes	Yes	No	Yes	No
DioPexy™ Probe	Yes	No	No	Yes	No
G-Probe™/TS-600	Yes	No	No	Yes	No
SLA	Yes	Yes	No	Yes	No
LS-SLA	Yes	No	Yes	Option	Option
Symphony	Yes	Yes	Yes	No	No
Symphony 2	Yes	Yes	No	No	No
OMA	Yes	No	Yes	Option	Option

\* ENT and OTO delivery devices are only compatible with 532 nm laser consoles having cleared ENT indications.

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

## Contraindications

- Any situation where the target tissue cannot be adequately visualized or stabilized.
- Do not treat albino patients who have no pigmentation.

## Potential Side Effects or Complications

- Specific to retinal photocoagulation: inadvertent foveal burns; choroidal neovascularization; paracentral scotomata; transient increased endema/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.

## Specific Warnings and Precautions

It is essential that the surgeon and attending staff be trained in all aspects of the use of this equipment. Surgeons should obtain detailed instructions for proper use of this laser system before using it to perform any surgical procedures. For additional Warnings and Cautions, see "Warnings and Cautions" in this chapter. For clinical information, see "References" in this chapter. Proper eye protection must be utilized for the specific treatment laser wavelength in use (810 nm).

## 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



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**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.

# 2 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 (Wireless Footswitch - Optional Accessory)
- Footswitch jumper cable (optional for SLx, not shown)
- Spare Fuses
- Remote Interlock plug
- Operator Manual (not shown)
- Laser warning sign (not 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:

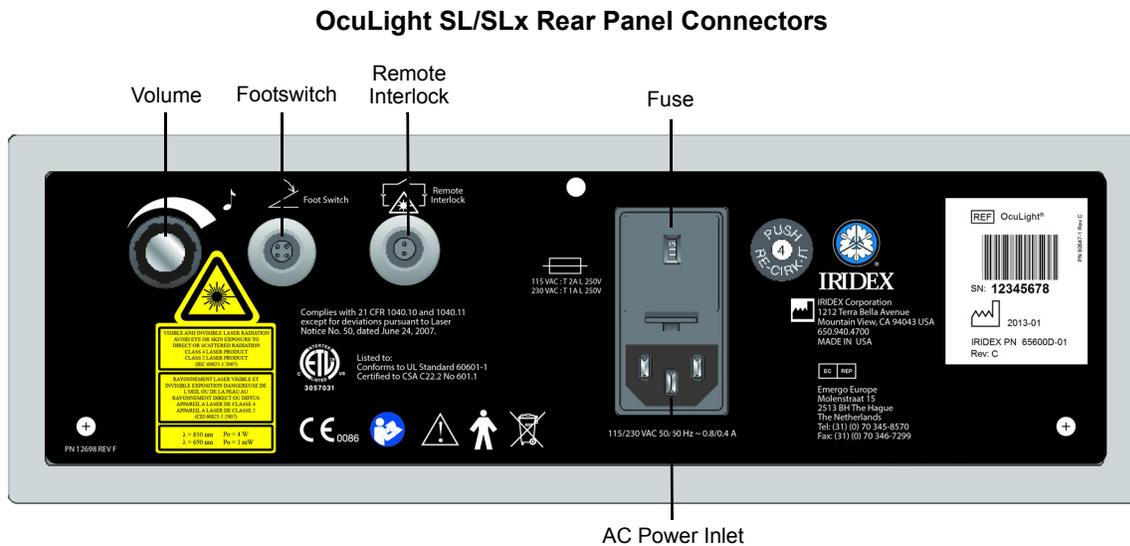
*Do not defeat the purpose of the grounding pin. This equipment is intended to be electrically grounded. Contact a licensed electrician if your outlet prevents you from inserting the plug.*

*Do not position or use the system near open flames.*

# Connecting the Components

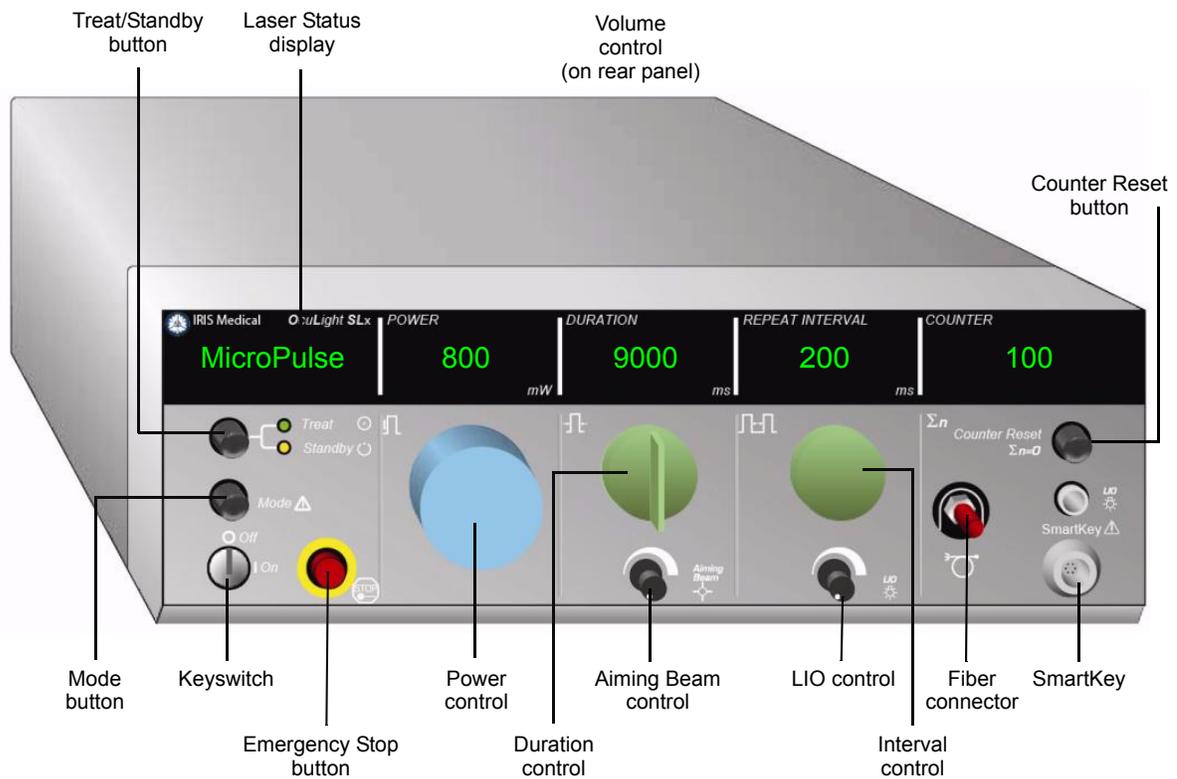
**NOTE:** Refer to the appropriate delivery device manual for specific connection instructions.

**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.



# 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 STOP button. This immediately disables the console and all laser-related circuits.

## Activating the Pulse Type

To activate this pulse type:	From this laser state or mode:	Do this:
CW-Pulse	After key-start or self-test	No action. CW-Pulse is the default type.
	MicroPulse	Press and hold MODE until "NormalPulse" appears in the laser status display, then press MODE again to activate CW-Pulse.
	LongPulse	Turn the Duration control counter-clockwise until "CW-Pulse units" appears in the Duration display.
MicroPulse	Any state or mode	Press and hold MODE until "MicroPulse" appears in the laser status display, then press MODE again.
LongPulse	Any state or mode	Turn the Duration control clockwise until "LP" appears in the laser status display. <b>Note:</b> A large-spot delivery device must be attached to the laser.

## Setting Treatment Parameters

*NOTE: Adjustments cannot be made while pressing the footswitch.*

Power	Set the treatment pulse power.
Duration	Set the treatment pulse duration (CW-Pulse and LongPulse) or the pulse envelope duration (MicroPulse).
Interval (CW-Pulse and MicroPulse only)	Interval between treatment pulses (CW-Pulse) or pulse envelopes (MicroPulse). <b>CW-Pulse:</b> To select a single, fixed-treatment pulse, turn the control counter-clockwise until the Interval display is blank. To select multiple treatment pulses, turn the control clockwise. <b>MicroPulse:</b> To select the intervals between pulse envelopes, turn the control clockwise or counter-clockwise as necessary.
Counter	Press the COUNTER RESET button to reset to zero.
Aiming Beam	Adjust the aiming beam intensity.
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.

### 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 Treatment Settings (MicroPulse)

Duty cycles are available from three presets (5%, 10%, 15%) or a user-definable setting.

### TO SELECT A PRESET DUTY CYCLE:

1. Select MicroPulse.
2. Press the TREAT/STANDBY button to scroll to the desired preset option.
3. Press MODE. The Duration and Interval values associated with the selected preset option appear in the laser displays.

### TO SELECT A USER-DEFINED DUTY CYCLE:

1. Select MicroPulse.
2. Press the TREAT/STANDBY button to scroll to "User?"
3. Use the Duration control to set the duration of the pulse.
4. Use the Interval control to set the interval between pulses.
5. Press MODE.

## Selecting User Preferences (SL)

### TO VIEW OR CHANGE USER PREFERENCE SETTINGS:

1. Place the laser in Standby mode.
2. Press and hold the MODE button until “User Preferences” appears in the laser status display.
3. Press MODE to activate the first menu option, Aiming Beam.
4. Press COUNTER RESET to toggle Aiming Beam on or off in Standby mode.
5. Press TREAT/STANDBY to access Languages, then press COUNTER RESET to scroll through the languages (English, Spanish, French, German, Italian, or Portuguese).
6. Press TREAT/STANDBY twice to access Message Review (view only), then press COUNTER RESET to review.
7. To activate your selection(s) and exit User Preferences mode, press MODE.

## Selecting User Preferences (SLx)

### TO VIEW OR CHANGE USER PREFERENCE SETTINGS:

1. Place the laser in Standby mode.
2. Press and hold the MODE button until “User Preference” appears in the laser status display. “MicroPulse” will appear in the laser status display if a MicroPulse-capable device is connected. If so, press the TREAT/STANDBY (signifies “NO”) button to access user preferences.
3. Press the MODE (signifies “YES”) button to accept.
4. Press the TREAT/STANDBY button to scroll through the User Preferences menu; the current setting for each menu item appears in the laser status display.
5. To change a menu setting, press COUNTER RESET until the desired setting appears in the laser status display.
6. To exit User Preferences mode, press MODE.

The User Preference settings are:

- Aiming Beam On or Off in Standby mode
- Aiming Beam On or Off with Treatment Pulse
- Display Language: English, Spanish, French, German, Italian, or Portuguese
- Message Review (view only)

## Treating Patients

### BEFORE TREATING A PATIENT:

- Ensure that the eye safety filter (as appropriate) is properly installed and that the SmartKey<sup>®</sup>, 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.

# 4

## Troubleshooting

### General Problems

Problem	User Action(s)
No display	<ul style="list-style-type: none"> <li>• Verify that the keyswitch is on.</li> <li>• Verify that the components are properly connected.</li> <li>• Verify that the electrical service is on.</li> <li>• Inspect the fuses.</li> </ul> <p>If there is still no display, contact your local IRIDEX Technical Support representative.</p>
Inadequate or no aiming beam	<ul style="list-style-type: none"> <li>• Verify that the delivery device is properly connected.</li> <li>• Verify that the console is in Treat mode.</li> <li>• Turn the aiming beam control fully clockwise.</li> <li>• Verify that the fiber-optic connector is not damaged.</li> <li>• If possible, connect another IRIDEX delivery device and place the console in Treat mode.</li> </ul> <p>If the aiming beam is still not visible, contact your local IRIDEX Technical Support representative.</p>
No treatment beam	<ul style="list-style-type: none"> <li>• Verify that the remote interlock has not been activated.</li> <li>• Verify that the aiming beam is visible.</li> <li>• Verify that the fiber switch is in the correct position for the laser system and wavelength you are using.</li> <li>• Verify that the eye safety filter is in the closed position.</li> </ul> <p>If there is still no treatment beam, contact your local IRIDEX Technical Support representative.</p>
No illumination light (LIO only)	<ul style="list-style-type: none"> <li>• Verify that the illumination connector is connected to the console.</li> <li>• Verify that the special function control is not between detents.</li> <li>• Check the bulb and replace it (if necessary).</li> </ul>
Illumination light is too dim (LIO only)	<ul style="list-style-type: none"> <li>• Verify that the special function control is not between detents.</li> <li>• Adjust the console illumination intensity control.</li> </ul>
The aiming beam is large or out of focus on the patients' retina (LIO only)	<p>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.</p>

Problem	User Action(s)
The treatment lesions are variable or intermittent (LIO only)	<ul style="list-style-type: none"> <li>• The LIO may be slightly out of focus. This decreases power density. Readjust your working distance to obtain the smallest spot size.</li> <li>• 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.</li> <li>• 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.</li> </ul>
Does not fit on the mounting plate (OMA only)	<ul style="list-style-type: none"> <li>• Inspect and clean the mounting plate.</li> <li>• Verify that the mounting plate corresponds to your microscope.</li> </ul>
Laser and viewing systems are not focussed at the same point (OMA only)	<ul style="list-style-type: none"> <li>• Verify installation of a 175 mm microscope objective lens on the microscope.</li> <li>• Turn on the aiming beam to determine focus position and adjust as necessary.</li> </ul>
View is blocked or partially blocked by OMA (OMA only)	Set magnification to 10X or more.

## Status Panel Messages

Status Panel Message	User Action(s)
<b>Calibration Required</b>	Contact your local IRIDEX Technical Support representative.
<b>Call Service</b>	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.
<b>Connect Fiber</b>	Connect an appropriate delivery device.
<b>Connect Footswitch</b>	<ul style="list-style-type: none"> <li>• Verify that the footswitch or receiver is properly connected.</li> <li>• Verify that two footswitches are not connected.</li> </ul>
<b>Connect SmartKey</b> OR <b>No SmartKey</b>	Verify that the SmartKey is properly installed.
<b>Emergency Stop</b>	<ul style="list-style-type: none"> <li>• Turn the system off (using the key) and wait several seconds.</li> <li>• Turn the system on.</li> </ul>
<b>Eye Safety Filter?</b> OR <b>810 nm Safety Filter?</b>	Verify that the eye safety filter is properly installed, and press MODE to continue.
<b>Footswitch Stuck / Release Footswitch</b>	Remove foot or other object from footswitch.
<b>No Remote Interlock</b>	<ul style="list-style-type: none"> <li>• Verify that the remote interlock plug is properly inserted.</li> <li>• Verify that the door switches or other circuits are closed.</li> </ul>
<b>Remove Fiber</b>	Disconnect the fiber optic from the fiber port.
<b>Slit Lamp Spot Size?</b> OR <b>Spot Size?</b>	Verify that the spot size selector is not between positions.
<b>Unknown Fiber Type</b>	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<sup>®</sup>, 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<sup>®</sup> (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.*

## Changing the AC Line Fuses

Each leg of the AC line is independently fused. The fuse holder is integral to the power inlet on the laser console.

### **TO CHECK AND CHANGE FUSES:**

1. Remove the power cord from the inlet receptacle.
2. Unlatch and open the fuse carrier.
3. Remove and inspect both fuses.
4. Replace any blown fuses.
5. If newly replaced fuses also blow, contact your local IRIDEX Technical Support representative.

## Resetting the Circuit Breaker

The circuit breaker, located next to the power outlet, protects the power-supply transformer from extended overload. When conditions such as high internal operating temperatures or low line voltages threaten the reliability of the laser, the circuit-breaker button pops out.

### **TO RESET THE CIRCUIT BREAKER:**

1. Correct any power input conditions or allow the laser to cool down.
2. Press the circuit-breaker reset button.
3. If the button pops out after you have pressed it, contact your local IRIDEX Technical Support representative.

## 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 2000 ms and the interval to one pulse.
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.
9. Set the power to 500 mW.
10. Press the footswitch to deliver the treatment beam, and record the reading.
11. Set the power to 1000 mW.
12. Press the footswitch to deliver the treatment beam, and record the reading.
13. Set the power to 2000 mW.
14. Press the footswitch to deliver the treatment beam, and record the reading.

Calibration date for power meter and sensor: \_\_\_\_\_

Power (mW)	Exposure Duration (ms)	Meter Reading (mW)	Acceptable Range (mW)
200	2000–5000		160–240
500	2000–5000		400–600
1000	2000–5000		800–1200
2000	2000–5000		1600–2400

Date: \_\_\_\_\_

Calibrated by: \_\_\_\_\_

Of: \_\_\_\_\_

15. 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.
16. If the readings are still outside the acceptable levels, contact your local IRIDEX Technical Support Representative.
17. 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:

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

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

$\Phi$  = the maximum possible laser power, in watts

MPE = the level of laser radiation, in  $\text{W}/\text{m}^2$ , 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.

<b>SLx NOHD Values for Various Delivery Devices</b>				
<b>Delivery Device</b>	<b>MPE (<math>\text{W}/\text{m}^2</math>)</b>	<b>Numerical Aperture (NA)</b>	<b>Maximum Power <math>\Phi</math> (W)</b>	<b>NOHD (m)</b>
EndoProbe	16	0.10	2.0	3.4
G-Probe	16	0.25	3.0	1.7
DioPexy Probe	16	0.03	2.0	11
Slit Lamp Adapter (SLA)	16	0.04	2.0	8.5
Large Spot Slit Lamp Adapter (LS-SLA)	16	0.01	2.0	34
Laser Indirect Ophthalmoscope (LIO)	16	0.02	2.0	17
Large Spot Laser Indirect Ophthalmoscope (LS-LIO)	16	0.02	2.0	17
Symphony Slit Lamp Adapter (810 nm)	16	0.01	1.5	29
Operating Microscope Adapter (OMA)	16	0.01	2.0	34

<b>SL NOHD Values for Various Delivery Devices</b>				
<b>Delivery Device</b>	<b>MPE (<math>\text{W}/\text{m}^2</math>)</b>	<b>Numerical Aperture (NA)</b>	<b>Maximum Power <math>\Phi</math> (W)</b>	<b>NOHD (m)</b>
EndoProbe	16	0.10	1.5	2.9
G-Probe	16	0.25	2.0	1.4
DioPexy Probe	16	0.03	1.8	11
Slit Lamp Adapter (SLA)	16	0.04	1.3	6.8
Large Spot Slit Lamp Adapter (LS-SLA)	16	0.01	1.3	27
Laser Indirect Ophthalmoscope (LIO)	16	0.02	1.5	15
Large Spot Laser Indirect Ophthalmoscope (LS-LIO)	16	0.02	1.5	15
Operating Microscope Adapter (OMA)	16	0.01	1.3	27

## 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.

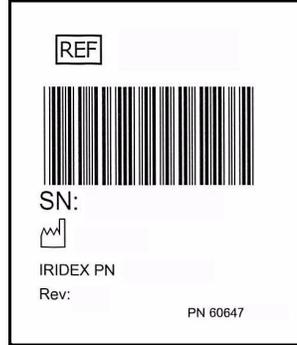
The OcuLight SL and SLx use a solid-state electronic switching power supply that meets strict EN60601-1 performance and safety standards. A dedicated microprocessor continuously monitors the safe function of all subsystems within the laser console.

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.*

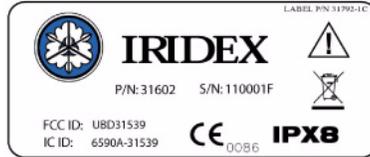
**Serial Number  
(rear panel)**



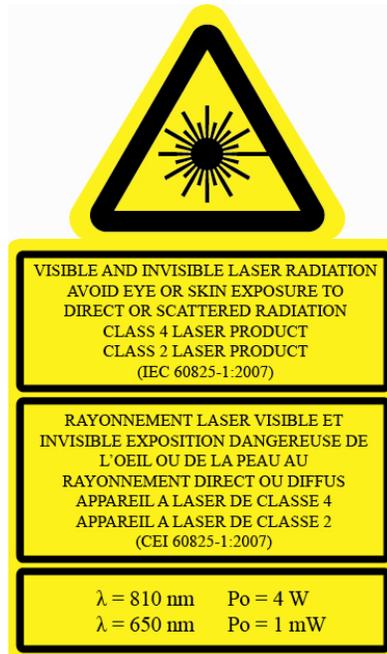
**Ground  
(bottom of laser)**

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**

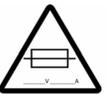


**Laser Warning**



# 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		Pulse Count
	Pulse Count Reset		No-ionizing Electromagnetic Radiation		Read Information
	Remote Control		Remote Interlock		Serial Number
	Single Use		Standby		Treat
	Type B Equipment		WEEE Guidance. Contact IRIDEX or your distributor for disposal information.		Pattern is Activated

	Temperature Limitations	<b>IPX4</b>	Protections Against Splash Water Coming from all Directions	<b>IPX8</b>	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 SL and SLx.

Specification	Description
Treatment wavelength	810 nm
Treatment power	Varies by type of delivery device. The laser system displays the power delivered to the tissue. <b>SL:</b> 0-2000 mW <b>SLx:</b> 0-3000 mW
Duration	<b>CW-Pulse:</b> 10, 20, 30, 40, 50, 75, 100, 150, 200, 300, 400, 500, 600, 700, 800, 900, 1000, 1500, 2000, 2500, 3000, 3500, 4000, 4500, 5000, 6000, 7000, 8000, 9000 ms <b>MicroPulse (SLx only):</b> 0.10-1.00 ms (on time), increments of 0.05 ms 1.0-10.0 ms (off time or interval time), increments of 0.10 ms <b>LongPulse (option available for SL):</b> 10-60 seconds (increments of 5 seconds) 1-2 minutes (increments of 10 seconds) 2-5 minutes (increments of 30 seconds) 5-30 minutes (increments of 1 minute)
Interval	None, 50, 100, 200, 300, 400, 500, 600, 700, 800, 900, and 1000 ms
Aiming beam	Red laser diode. User-adjustable intensity; 1 mW maximum; coaxial with treatment beam; 650 nm
Electrical	115 VAC, 50/60 Hz, 0.8 A 230 VAC, 50/60 Hz, 0.4 A
Operating temperature range	10° C to 40° C (50° F to 104° F)
Storage temperature range	-20° C to 60° C (-4° F to 140° F) If stored at temperatures below 10° C (50° F), allow to rise to room temperature for 4 hours prior to operation.
Relative humidity	20% to 80%
Dimensions	30 cm x 30 cm x 10 cm (12 in. W x 12 in. D x 4 in. H)
Weight	6.3 kg (14 lbs.)
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 Power Adjust 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 Règlement sur le matériel brouilleur du Canada.

## EMC Requirements for Console and Accessories

<b>Guidance and Manufacturer's Declaration - Electromagnetic Emissions</b>		
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.		
<b>Emissions Test</b>	<b>Compliance</b>	
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.		

<b>Guidance and Manufacturer's Declaration - Immunity</b>			
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.			
<b>Immunity Test</b>	<b>IEC 60601 Test Level</b>	<b>Compliance Level</b>	<b>Electromagnetic Environment - Guidance</b>
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.
<b>NOTE:</b> $U_T$ 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 V/m	$d = 1.2 \sqrt{P}$ 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). <sup>a</sup> Fields strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. <sup>b</sup> 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.