

IRIS Medical[®] OcuLight[®] SL/SLx Operator Manual



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The OcuLight SL and SLx are manufactured using one or more of the following patents: 5,085,492; 5,088,803; 6,540,391; 6,733,490.

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About IRIDEX

Overview

IRIDEX Corporation, headquartered in Mountain View, California, is a leading worldwide manufacturer of solid-state medical laser systems. The Company develops, manufactures and markets laser systems, delivery instrumentation and related accessories for the ophthalmology, dermatology and veterinary markets.

The ophthalmic solid-state laser systems, marketed under the brand name IRIS Medical, are used to treat a variety of ocular diseases, including the three leading causes of irreversible blindness: macular degeneration, diabetic retinopathy and glaucoma.

IRIDEX is an FDA registered medical device manufacturer and complies with current QSR, ISO 13485 and MDD regulations and guidelines.

Contact Information

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About the OcuLight SL and SLx

Introduction

The IRIS Medical OcuLight SL and OcuLight SLx (SL/SLx) are advanced laser systems. The laser source, power supply, and control panel are combined in a single unit making it portable and easy to stack on a cart, counter or other treatment room instruments.

The laser console uses modern semiconductor diode laser technology to produce a visible treatment beam at a nominal wavelength of 810 nm. Diode lasers are efficient and consume very little electrical power, thus the console may be operated from a standard power outlet (115/230V) and does not require water cooling or tube replacements. The laser console uses a solid-state electronic switching power supply that meets strict U.S. and international performance and safety standards. The laser is controlled by a dedicated microprocessor that continuously monitors the safe function of all subsystems.

This manual contains important information on how to unpack, setup, operate, troubleshoot and maintain this system. Keep it available for reference.

Potential Adverse Effects

Improper use of the SL/SLx can result in adverse effects. Follow the instructions for use described in this operator manual.

CAUTION: *Federal (U.S.) law restricts this device to sale by or on the order of a physician.*

CAUTION: *Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.*

CAUTION: *Laser plume may contain viable tissue particulates.*

Indications for Use

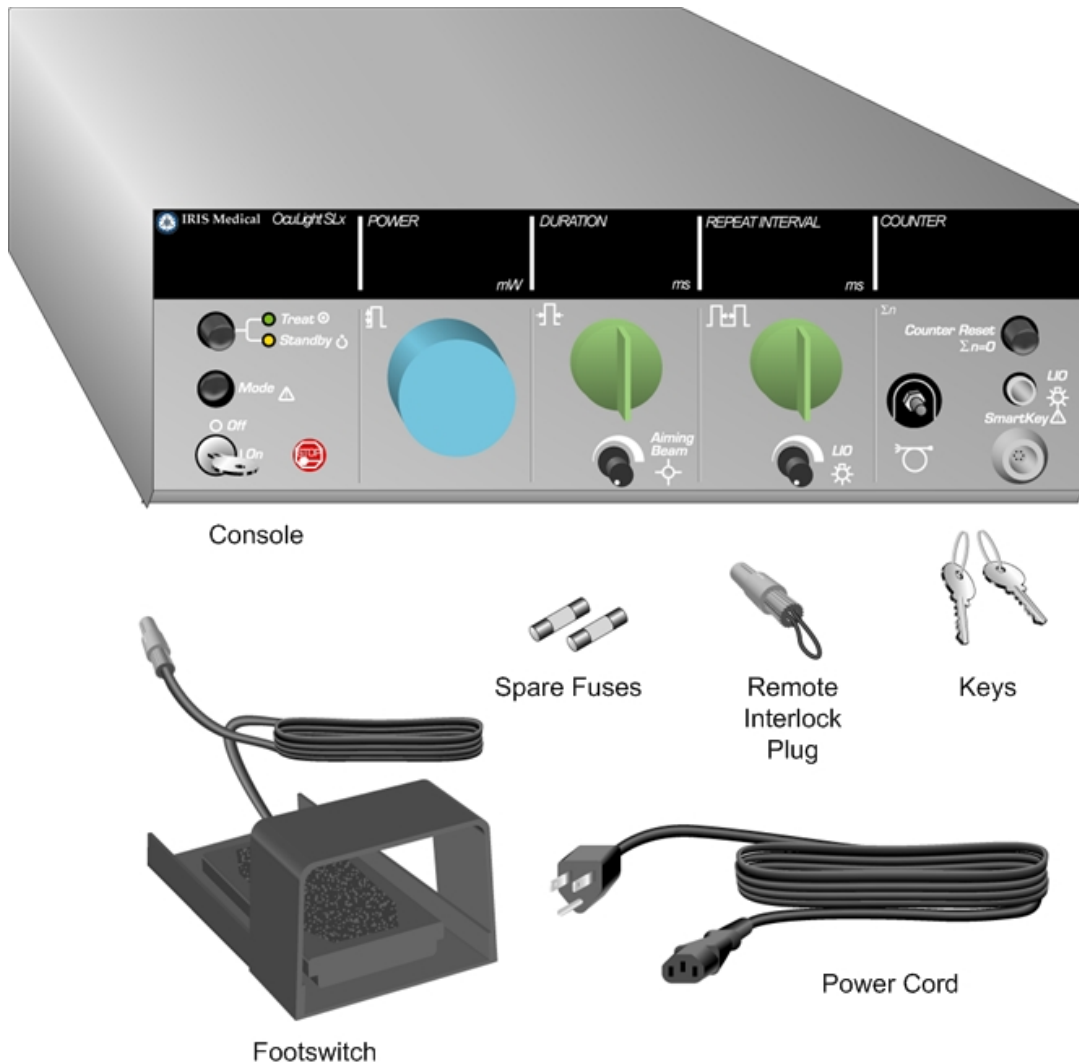
The SL/SLx is indicated for retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation and iridotomy.

About the Components

Packing List

Before assembling the SL/SLx, make sure the package contains all ordered components. Check the components carefully before use to ensure no damage occurred during transit.

All standard shipments include a laser console, footswitch, medical grade power cord, keys, spare fuses remote interlock plug, laser warning sign, this operator manual and any other accessories that you may have ordered.



If there are any items missing from the shipment, please contact IRIDEX customer service immediately.

Component Descriptions

Console

The console contains the laser head, electronics, microprocessor and display panels. The console is the source of laser emission and is the central unit to which all delivery devices attach.

Operator Manual

The operator manual contains installation, operation, troubleshooting and safety instructions. Keep the manual readily available for reference.

Footswitch

The footswitch activates the treatment beam when depressed.

AC Power Cord

The power cord connects the console to an electrical outlet. The plug is medical grade (hospital grade). Unplugging the power cord is the only way to eliminate the flow of all electrical current to the SL/SLx.

Key

The key fits into the switch on the front panel and is used to turn the console on and off.

Spare Fuses

AC line fuses protect the SL/SLx from over-current conditions. Two spare fuses are provided.

Positioning the SL/SLx

Temperature and Humidity Considerations

The SL/SLx should be operated in a well-ventilated location with a temperature between 10°C (50°F) and 32°C (90°F) with relative humidity between 20 and 80%, non-condensing.

Electrical Requirements

North American Installation

The SL/SLx is equipped with a hospital grade (green dot) three-wire grounding plug. When choosing a location, ensure that a grounding-type AC receptacle is available, as it is required for safe operation.

Installation Outside of North America

When the SL/SLx is shipped, IRIDEX customer support will ensure that the power cord included in the packaging is appropriate for local operation.

Replacement cords may be ordered to match the IEC320 power inlet with local electrical standards. Always use a three-wire grounding cord set. Do not alter the power inlet, as it contains protective fusing. Follow local electrical codes before installing the SL/SLx to ensure proper grounding.

Physical Location Considerations

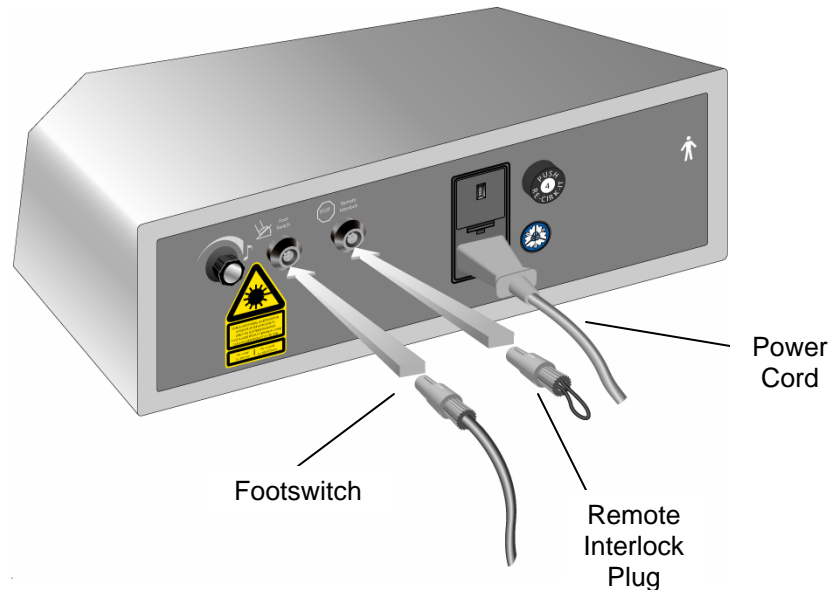
Place the SL/SLx on a flat table, existing operating room equipment or cart.

WARNING: *Do not defeat the purpose of the grounding pin. This equipment is intended to be electrically grounded. Contact a licensed electrician if the desired outlet prevents insertion of the grounding pin.*

CAUTION: *Do not position or use the SL/SLx near open flames, compressed oxygen or other flammables.*

CAUTION: *Allow enough space between the console and the electrical outlet to permit access to the plug at all times.*

Rear Panel Connections



Required Connections

Power Cord

Plug the female end of the power cord into the AC Power Inlet. Insert the opposite end into a properly grounded electrical outlet.

Footswitch

Insert the footswitch connector into the connector labeled "Footswitch". Ensure the connection is secure.

Remote Interlock

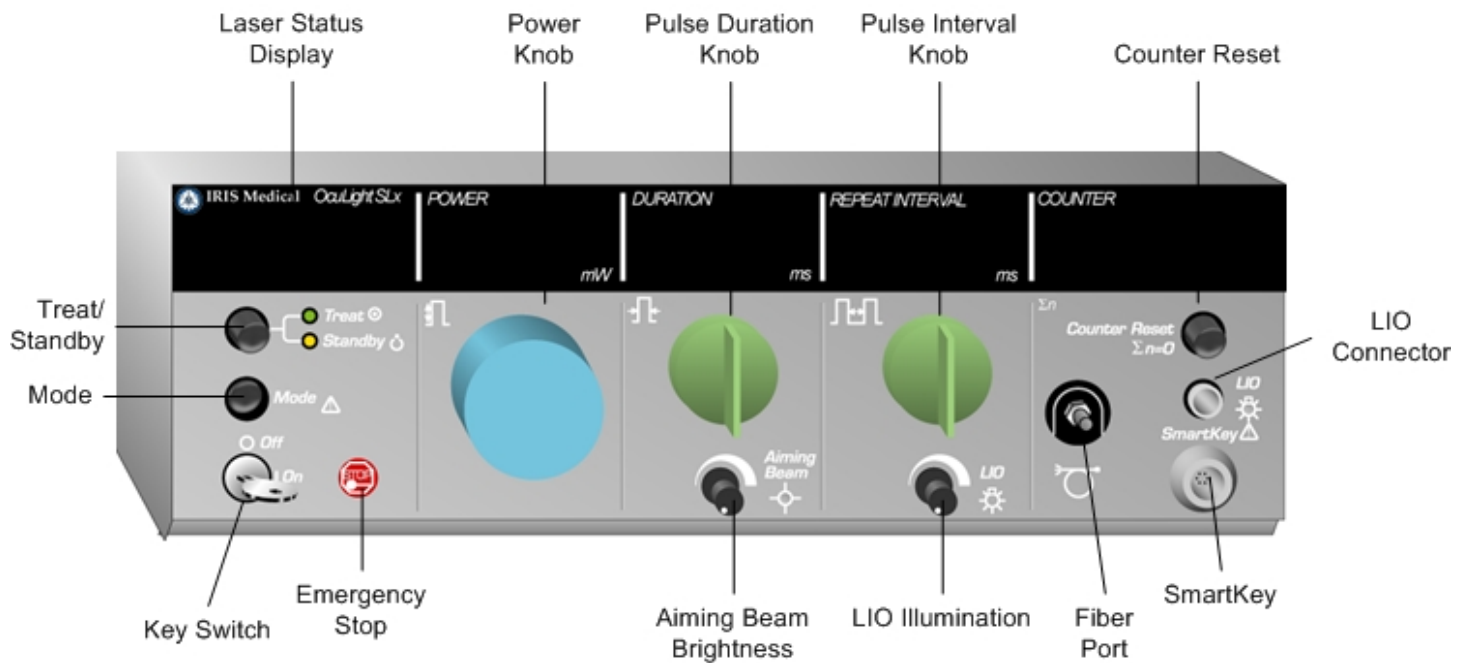
Insert the remote interlock plug into the remote interlock connector. If desired, this circuit can be used to disable the console if the door to the treatment room is opened. To use the remote interlock, attach the door switch to the screw terminals in place of the shorting wire. If the remote interlock is not properly connected, the message, "No Remote Interlock" will be displayed when the console is turned on.

Fuses

The SL/SLx is shipped with two independent line fuses installed behind the panel. This panel should be opened only in the event of a blown fuse. Review the Maintenance section of this manual for replacement instructions.

NOTE: *If you have an OcuLight GL or OcuLight GLx, see your operator manual for instructions on how to control both laser systems with a single footswitch.*

Front Panel Controls and Connections



Feature Descriptions

Laser Status Display

Displays spot size, pulse duration, status and error messages

Treat/Standby

Toggles the laser status between Treat and Standby. The treatment laser is enabled only when Treat is selected.

Mode

Multi-function button. Used to display, activate, confirm and clear messages and settings.

Key Switch

The key is used to turn the system on and off. Store the key between uses in a secured location to prevent unauthorized use.

Emergency Stop

Disables the laser and electronic circuits in an emergency.

Power Knob

Rotate knob to select the desired level of energy to be delivered to the tissue through the selected delivery device. Power level is displayed in milliwatts (mW).

Pulse Duration Knob

Rotate knob to select the desired pulse duration. Duration is displayed in milliseconds (ms).

Pulse Interval Knob

Rotate knob to select the desired pulse interval. Repeat interval is displayed in milliseconds (ms).

Counter Reset

Press button to clear the pulse counter.

Fiber Port

All delivery devices are connected to the console at the fiber port. Cover the end of the port with the cap between uses to protect it from damage, dirt and debris.

LIO Connector

Insert the illumination fiber from the LIO to this connector.

SmartKey

Transmits electrical signals from selected delivery devices to the console.

Aiming Beam Brightness

Rotate the knob clockwise to increase aiming beam intensity.

LIO Illumination

Rotate the knob clockwise to increase aiming beam intensity.

Operating Basics

Connecting a Delivery Device

After choosing a delivery device for treatment, insert the fiber-optic into the fiber port. Make sure the connection is secure; however, do not over-tighten the nut. If a Slit Lamp Adapter (SLA) or Operating Microscope Adapter (OMA) is used, connect the SmartKey from the device into the receptacle on the front panel of the SL/SLx. Refer to the delivery device operator manual for additional instructions.

NOTE: *Always check the integrity of the attached delivery device by looking for the presence of the aiming beam. If the aiming beam is not present while the SL/SLx is set to Treat, this may indicate a problem with the fiber optic. If you are in doubt as to the integrity of the fiber optic, measure the treatment laser with a power meter.*

CAUTION: *Do not twist, bend or tightly coil the delivery device fiber optic. Do not bend the fiber optic in loops smaller than 6 inches in diameter. Loosely drape or coil excess length on a flat surface. Keep the fiber-optic cable away from locations where it may be stepped on. Do not touch the end of the fiber optic as dirt or contaminants on these surfaces may affect optical transmission. Always cap the end of the delivery device when not attached to the SL/SLx.*

Turning On the SL/SLx

Place the key into the key switch and turn clockwise to the on position. The SL/SLx will perform a self-test and warm-up for several seconds. During the self-test, the SL/SLx checks for proper component connections and any inconsistencies with the internal safety system. Following a successful startup sequence, the yellow Standby light will illuminate and the system will enter the CW-Pulse operating mode. The attached delivery device and spot size, if applicable, are also displayed.



Turning Off the SL/SLx

After use, turn the key to the off position. Remove and store the key to prevent unauthorized use. The key can only be removed in the off position. After disconnecting a delivery device, insert and secure the fiber port cap to the fiber port.

Emergency Stop

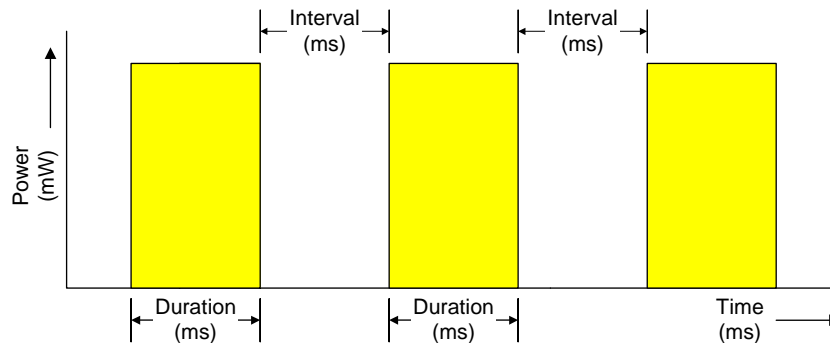
In the event of an emergency, push the red **Emergency Stop** button on the front panel. This will immediately disable the laser and all related electronic circuits. The display will read "Emergency Stop!".

To recover following an emergency stop, turn the key to the off position. After a minimum of three seconds, turn the key back to the on position. After restarting, the SL/SLx will be in Standby mode with the power set to 0 mW.

CW-Pulse Mode

Overview

CW-Pulse is the default operating mode on the SL/SLx and is active after each key start. In this mode, can be programmed to deliver a single pulse, a series of regularly spaced, intermittent pulses or a continuous pulse. The pulse duration and interval between pulses can be changed over a range of millisecond (10^{-3}) values (duration: 10-9000 ms, interval: 50-1000 ms). The CW-Pulse waveform is shown below:



Selecting Treatment Settings

Setting the Power

At startup, the displayed power is set to 0 mW. Rotate the **Power** control to select the desired value. Maximum power varies depending on the attached delivery device.



NOTE: The power cannot be adjusted while the footswitch is depressed.

Selecting the Pulse Duration

Rotate the **Duration** control to set the treatment pulse duration. The display will show the selected duration for each treatment pulse.



Selecting the Repeat Interval

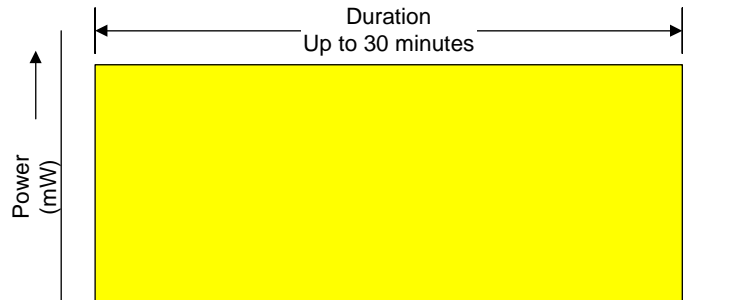
Rotate the **Repeat Interval** control to select a single pulse or repeating pulses. To select a single pulse, rotate the knob counterclockwise until the display is blank. With this setting, the SL/SLx will deliver a single timed pulse every time the footswitch is depressed. To select repeating pulses, rotate the control clockwise to the desired value. The pulses will repeat as long as the footswitch is depressed.



LongPulse Mode

Overview

In LongPulse, the SL/SLx generates a continuous wave exposure for up to 30 minutes when a large spot delivery device is connected to the laser (Large Spot SLA, Large Spot LIO or Operating Microscope Adapter). The power is constant throughout the duration of each pulse. LongPulse is illustrated in the following diagram:



Using LongPulse Mode

Entering LongPulse Mode

To access the LongPulse operating mode, attach a large spot delivery device to the SL/SLx. Rotate the **Duration** control until "LP" displays in the Duration display.



Selecting Parameters

Continue rotating the **Duration** control clockwise to select the desired treatment time. The treatment duration period is shown in the top right hand portion of the status display. The lower right hand portion of the status display indicates the

amount of time the treatment beam has been activated during the current treatment. Rotate the **Power** control to the desired level.

Initiating Treatment

After selecting all desired pulse parameters, press **Treat/Standby** to select Treat. Direct the aiming beam onto the treatment site. Continuously depress the footswitch throughout the treatment cycle. The console will emit an intermittent audible tone when the treatment laser is activated. The SL/SLx will beep multiple times upon completion of the treatment exposure. In the counter display the shows the amount of energy, in Joules (J), delivered during the treatment. Press **Counter Reset** to clear the display and initiate another timed treatment cycle.

NOTE: *If the footswitch is released prior to the completion of a programmed LongPulse treatment, laser emission will stop immediately.*

NOTE: *The repeat interval display will is blank when the SL/SLx is operated in LongPulse mode.*

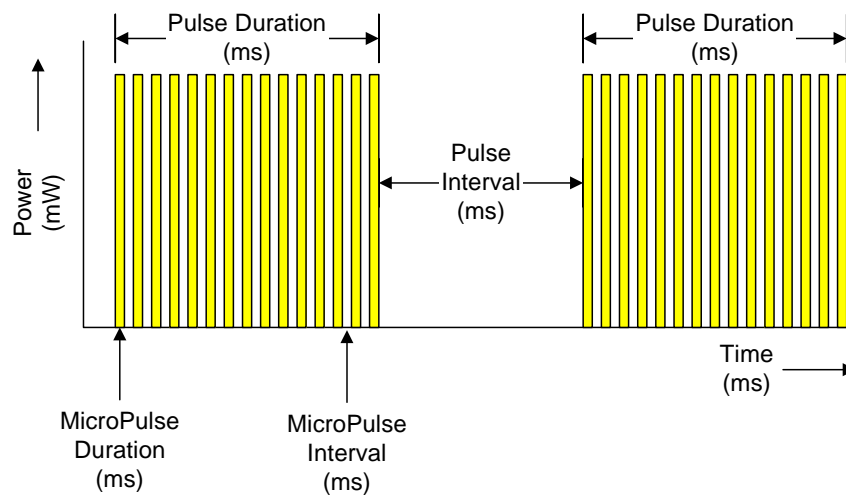
Energy Display

In LongPulse mode the Counter display shows the total energy (Joules) delivered to the tissue during the treatment session. Press **Counter Reset** to clear this display.

MicroPulse Mode (OcuLight SLx Only)

Overview

MicroPulse is a special operating mode available on the OcuLight SLx. In MicroPulse, the SLx can be programmed to deliver a single pulse or a series of regularly spaced, intermittent pulses. In MicroPulse mode each pulse is subdivided into shorter, regularly spaced microsecond pulses. Consequently the amount of energy delivered to the tissue is much less than with equivalently timed pulses in CW-Pulse mode. MicroPulse mode may only be used with a slit lamp adapter (SLA). The MicroPulse waveform is illustrated in the following diagram:



The percentage of time the treatment laser is activated during each pulse is referred to as the duty factor. The duty factor is calculated according to the following formula:

$$\frac{\text{MicroPulse Duration}}{\text{MicroPulse Duration} + \text{MicroPulse Interval}} \times 100\% = \text{Duty Factor}$$

Using MicroPulse Mode

To enter MicroPulse mode, press and hold the Mode button for approximately two seconds or until the status display flashes "MicroPulse". Press **Mode** again to activate the MicroPulse menu options. The display shows the first menu option.



Selecting a Preset Duty Factor

There are three preset duty factor settings in MicroPulse mode: 5%, 10% and 15%. After entering MicroPulse mode any of these settings can be selected by pressing the **Treat/Standby** button to scroll through the selections. Press **Mode** to select and confirm the desired selection.



NOTE: MicroPulse mode can only be accessed if the Status Display reads "Tri-Mode Activated" during the startup sequence.

NOTE: MicroPulse mode cannot be used with a Large Spot Slit Lamp Adapter.

Selecting a Custom Duty Factor

Once in MicroPulse mode, to create a custom duty factor, press **Treat/Standby** until "User?" is displayed on the status display. Rotate the **Duration** control to select the MicroPulse duration. Rotate the **Repeat Interval** control to select the MicroPulse interval. Press **Mode** to confirm and save the settings.



Selecting Power, Pulse Duration and Interval

After selecting the desired duty factor, the power, pulse duration (envelope) and pulse interval can be selected by rotating the corresponding controls.

Initiating Treatment

After selecting all desired pulse parameters, press **Treat/Standby** to select Treat. Direct the aiming beam onto the treatment site. Press the footswitch to activate the laser. The console will emit an audible tone when the treatment laser is emitted. Press **Treat/Standby** when not treating patients.

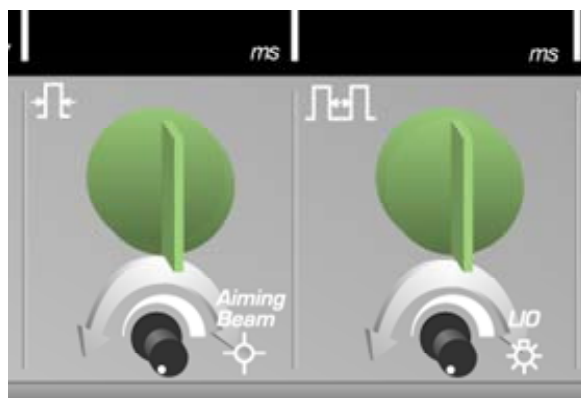
Customizing the SL/SLx

Adjusting Aiming Beam Intensity

Rotate the **Aiming Beam Brightness** control to adjust the intensity of the red aiming beam when the laser status is set to Treat. To turn the aiming beam off, turn the control fully counter-clockwise.

Adjusting LIO Illumination

Rotate the **LIO Illumination** control to adjust the intensity of the white illumination lamp. This adjustment is active only when an LIO is attached to the fiber port.



Adjusting the Volume

The SL/SLx emits an audible tone whenever the treatment laser is emitted. Rotate the **Volume** control to adjust the loudness. For safety reasons, the tone cannot be completely turned off.



User Preferences Menu

Entering the User Preferences Menu

To access the User Preferences Menu hold the **Mode** button until the Status Display flashes “*User Preferences*”. Press **Mode** again to activate the menu options. The first menu option is the Aiming Laser setting.

Changing the Aiming Laser Preference Setting

The aiming beam can be programmed to turn on or off while in Standby mode. After entering the User Preferences screen, press **Counter Reset** to toggle between the two selections. Press **Mode** to activate the desired selection and exit the User Preferences Menu.

Changing the Display Language

After entering the User Preferences Menu, press **Treat/Standby** to access the language preferences screen. Press **Counter Reset** to cycle through the display language selections. Press **Mode** to activate the selection and exit the User Preferences Menu.

Reviewing the List of Onscreen Messages

After entering the User Preferences Menu, press **Treat/Standby** twice to access the onscreen messages screen. Press **Counter Reset** to review all available system prompts. There are no user adjustable selections on this screen. Press **Mode** to exit the User Preferences Menu.

Troubleshooting

This section provides troubleshooting information for commonly encountered problems. If the problem cannot be mitigated with any of the guidelines below, contact IRIDEX Technical Support. Take note of any message displayed on the screen, the product name, serial number and delivery device used prior to contacting Technical Support.

<u>Problem</u>	<u>Action</u>
No display	Ensure that the key switch is on Ensure that all required attachments are connected properly Ensure that electrical service is on Inspect the fuses to ensure they are not blown If after checking the above items, there is still no display, contact IRIDEX Technical Support
Poorly illuminated or absent aiming beam	Ensure that the IRIS Medical delivery device is connected properly to the SL/SLx Ensure the console is set to Treat Rotate the aiming beam control fully clockwise Ensure the fiber-optic connector or fiber face is not damaged If possible, connect another IRIS Medical delivery device and set the console to Treat. If the aiming beam is still not visible, contact IRIDEX Technical Support

Absent treatment beam	<p>Ensure that the remote interlock has not been activated; if so a message indicating the remote interlock is open will be displayed.</p> <p>Ensure that the aiming beam is present and bright. If not, this is a possible indication of a damaged delivery device. Contact IRIDEX Technical Support for assistance.</p>
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<u>Onscreen Message</u>	<u>Action</u>
Connect Footswitch	Ensure that the footswitch is properly connected.
Connect Fiber	Connect an appropriate IRIS Medical delivery device, ensure the connection is secure.
No Remote Interlock	Ensure that the remote interlock is properly connected or jumpered. Ensure that door switches or other circuits are closed, if applicable.
Calibration Required	Contact IRIDEX Technical Support
Emergency Stop	To recover following an emergency stop, turn the key to the off position. After several seconds, turn the key back to the on position
Call Service	Press the Mode button. A description of the fault briefly displays. The console restarts and performs a self-test, checking for proper component connections and any inconsistencies with the internal safety system. If the message is displayed again, contact IRIDEX Technical Support.
Footswitch Stuck	Release foot or other object from footswitch

Maintenance

Cleaning the Console

Keep the SL/SLx enclosure clean by applying soap, mild detergent or isopropyl alcohol (non-reagent grade) with a soft, moist cloth. Avoid using abrasive or ammonia-based cleansers. Frequency of cleaning is up to the user and may be dependent upon use and/or environmental conditions. Turn the SL/SLx off prior to initiating any cleaning procedure.

CAUTION: *Do not open the enclosure. Removing the enclosure and electrical shields may result in exposure to dangerous optical radiation and lethal electrical voltages. There are no user-serviceable parts or functions inside the protective covers.*

NOTE: *The SL/SLx enclosure should not be placed within the sterile field of the operating room.*

Cleaning the Footswitch

The footswitch is submersible (IPX8 per IEC 60529). To decontaminate and disinfect the footswitch:

1. Disconnect the footswitch from the laser console.
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 and the attached cable.
3. Stand the footswitch on the end opposite the cord to drain all fluids.
4. Submerge the footswitch in a CIDEX[®] (2.4% glutaraldehyde) solution for 45 minutes minimum at 25°C to achieve a high level of disinfection.
5. Remove the footswitch from the CIDEX solution.
6. Stand the footswitch on the end opposite the cord to drain all fluids.
7. Completely submerge the footswitch in water for a minimum of 1 minute. Repeat this step two more times using clean water for each rinse.
8. Stand the footswitch on the end opposite the cord to drain all fluids.
9. Allow the footswitch to air-dry completely before reusing.

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

Changing the AC Line Fuses

The AC line connection has two independent fuses. The fuse holder is integral to the power inlet on the rear panel of the SL/SLx.

To check or change fuses:

1. Remove the power cord from the inlet receptacle.
2. Using a small screwdriver, unlatch and open the fuse panel.
3. Remove and inspect both fuses.
4. If one or both are open, replace them with new fuses, as indicated on the rear panel label. Replacement fuses are IEC 127 2A, 250V, medium time delay, 5 mm x 20 mm.
5. If newly replaced fuses fail, contact IRIDEX Technical Support.

Resetting the Circuit Breaker

Next to the power inlet is a circuit breaker protecting the power supply transformer from extended overload. The circuit breaker senses high internal operating temperatures, often caused by high ambient temperatures or by greatly exceeding typical clinical usage parameters and overcurrent conditions such as low line voltage. When any of these conditions threaten reliability of the SL/SLx, the circuit breaker button pops out.

If the circuit breaker pops:

- 1) Correct any power input conditions or allow the SL/SLx to cool.
- 2) Press the circuit breaker reset button.
- 3) If the circuit breaker is tripped after manually resetting, contact IRIDEX Technical Support.

Verifying the Power Calibration

Laser power is calibrated at the factory. IRIDEX calibrates the power with the aid of a power meter and a delivery device with known transmission characteristics. The factory calibration procedure meets the requirements established by the National Institute of Standards and Technology (NIST).

On an annual basis, SL/SLx owners should compare the delivered power to the power setting to verify that the console is still operating within the factory calibration parameters. IRIDEX recommends using the following power meters to perform the verification procedure:

Ophir Optronics
200 Corporate Pl. #7,
Peabody, MA 01960
978-535-5777
www.ophiropt.com
Model: AN/2

Coherent Auburn Group
2303 Lindbergh Street
Auburn, CA 95602
530-888-5107
www.cohr.com
Model: FieldMax-TO

To verify the power calibration:

1. Ensure that all persons in the room where the power calibration procedure will be conducted are wearing laser safety eyewear.
2. Connect a properly functioning IRIDEX delivery device.
3. Turn on the SL/SLx
4. Set the **Power** to 200 mW.
5. Set the **Duration** to a value greater than 5000 ms.
6. Set the **Interval** to One Pulse
7. Select an intermediate spot size setting on the delivery device (if applicable).
Using very small spot sizes may damage the power meter sensor.
8. Position the power meter in front of the delivery device
9. Center the aiming beam at the middle of the power meter sensor.
10. Adjust the distance between the delivery device and the power meter to produce a 3 to 5 mm diameter spot on the sensor.
11. Place the console in Treat mode.
12. Aim output beam from the delivery device into the power meter, following the power meter instructions for sampling the laser power.
13. Press the footswitch to deliver the treatment beam.

14. If the console is calibrated properly, the power meter reading should be between 160 and 240 mW.
15. Adjust the **Power** to 500 mW.
16. Repeat steps 4 through 13 and record the power value. If the console is calibrated properly, the power meter reading should be between 400 and 600 mW.
17. Adjust the **Power** to 1000 mW.
18. Repeat steps 4 through 13 and record the power value. If the console is calibrated properly, the power meter reading should be between 800 and 1200 mW
19. Adjust the **Power** to 2000 mW.
20. Repeat steps 4 through 13 and record the power value. If the console is calibrated properly, the power meter reading should be between 1600 and 2400 mW

Record the values in the following table and keep with other device records

Power (mW)	Meter Reading (mW)	Acceptable Range (mW)	Pass/Fail
200		160-240	
500		400-600	
1000		800-1200	
2000		1600-2400	

Model:_____

S/N:_____

Date:_____

Verification By:_____

If any of the readings fall outside the minimum/maximum levels:

- 1) Check to see if the power meter is operating properly
- 2) Ensure the beam is directed onto the power meter
- 3) Repeat the above procedure with a different IRIS Medical delivery device (if possible)

If the delivered power is still not within the acceptable minimum/maximum levels, the SL/SLx requires repair. Contact a local IRIDEX Technical Support Representative for service instructions. **Any recalibration of the SL/SLx must be performed by authorized IRIDEX personnel.**

Warranty and Service

Warranty

The SL/SLx console carries a standard factory warranty. The warranty covers all parts and labor required to correct problems with materials or workmanship; however the warranty is voided if the enclosure is removed by anyone other than certified IRIDEX service personnel.

Product Registration

Please complete and forward the product registration card to IRIDEX. Prompt reply will ensure the console is tracked by customer service. The registered owner will be kept informed on any product notices and/or upgrades.

Service and Technical Support

IRIDEX is committed to supporting installations worldwide. Contact IRIDEX Technical Support if you require assistance with the SL/SLx.

Safety Information

General Measures

This section addresses the safe use and operation of the SL/SLx. Failure to comply with this safety information may result in harm to the physician, patient, or bystanders. This device is intended for use by qualified physicians only. The applicability of the equipment and treatment technique is the sole responsibility of the physician. Do not use this device if it is believed to not be functioning properly. Before operating the laser, carefully observe the following protective measures:

- ❑ Never look directly into the laser aperture or at laser energy scattered from specular surfaces. Avoid directing the treatment beam at highly reflective surfaces or unintended objects.
- ❑ Ensure that all persons in the treatment room are wearing laser safety eyewear. Never substitute prescription eyewear for laser safety eyewear.
- ❑ Do not use the laser in the presence of explosives, compressed oxygen, volatile anesthetics or other flammable materials.
- ❑ Always keep the laser in the Standby mode when not treating patients.
- ❑ Turn the console off and remove the key between procedures to prevent unauthorized use.
- ❑ Do not open the SL/SLx enclosure. Only factory-trained personnel are qualified to examine and repair the interior of the SL/SLx.

CAUTION: *Removal and/or opening of the enclosure and electrical shields may result in exposure to dangerous optical radiation and lethal electrical voltages. There are no user-serviceable parts or functions inside the enclosure.*

Eye Safety Filters

Eye safety filters provide protection from backscattered laser emissions. IRIS Medical slit lamp adapters (SLA) and laser indirect ophthalmoscopes (LIO), have integral eye safety filters permanently installed in the viewing path. When using the SL/SLx for intraocular procedures, a separate discrete eye safety filter assembly must be installed into all viewing paths of the operating microscope. All IRIS Medical eye safety filters have an optical density (O.D.) sufficient to permit long-term viewing of diffuse 810 nanometer light at Class I levels, per ANSI Z136.1:2000.

Laser Safety Eyewear

In order to adequately protect the eyes of all persons in the treatment room, all occupants must wear safety glasses with a minimum O.D. of 4.0 at 800-840 nm. Verify that the safety glasses chosen for use with the SL/SLx are appropriate for use by checking the O.D. and wavelength rating on the frames. Additional glasses may be purchased through IRIDEX.

Determining When Safety Eyewear is Required

Safety eyewear is required when the laser is in use and individuals are physically located inside the Nominal Ocular Hazard Distance (NOHD). The NOHD is the maximum distance from the laser at which damage to the eye can occur. Any individuals within this distance from the laser must wear protective eyewear or risk unintended eye damage.

The NOHD varies depending upon the type of delivery device attached to the SL/SLx. The formula to calculate worst case NOHD is given by the following:

$$\text{NOHD(m)} = \left(\frac{1.7}{N.A.} \right) \cdot \sqrt{\left(\frac{\Phi}{\pi \cdot MPE} \right)}$$

Where:

N.A.= equals the Numerical Aperture of the delivery device

MPE: equals the Maximum Permissible Exposure (level of laser radiation to which a person may be exposed without suffering adverse effects), expressed in watts per square meter (W/m²)

Φ: equals the maximum power available for each delivery device, expressed in watts (W)

The range of worst case NOHD values calculated for all IRIS Medical delivery devices is included in the following table:

Delivery Device	MPE (W/m²)	Numerical Aperture (N.A.)	Maximum Power (W)	NOHD (m)
G-Probe	16.8	0.25	3.0	1.6
EndoProbe	16.8	0.10	2.0	3.3
SLA (500 micron spot)	16.8	0.04	2.0	8.3
DioPexy Probe	16.8	0.03	2.0	11.0
Large Spot SLA	16.8	0.03	2.0	11.0
LIO	16.8	0.02	2.0	16.6
Large Spot LIO Large Spot Symphony	16.8	0.02	2.0	16.6
Symphony 810 Fiber	16.8	0.01	2.0	33.1
Operating Microscope Adapter (OMA) (2.0 mm spot)	16.8	0.01	2.0	33.1

Safety Features

The SL/SLx complies with FDA Laser Safety Requirements 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated 7/26/01.

CE-labeled devices comply with appropriate performance standards as specified in Annex II of the Medical Device Directive MDD 93/42/EEC.

Emergency Off

Pushing the emergency off button immediately disables the laser and electronic circuits.

Protective Housing

The external enclosure prevents unintended access to laser radiation above CDRH Class I limits.

Safety Interlock

An electronic interlock at the fiber port prevents the SL/SLx from emitting laser energy if a delivery device is not properly connected.

Remote Interlock

An external interlock circuit is located on the back panel. The circuit can be used to disable the console if the treatment room door is opened during treatment. For locations that do not require an external interlock, an interlock jumper is provided.

Key Switch

The SL/SLx operates only when the proper key is in place. The key cannot be removed while the key switch is turned to the On position.

Laser Emission Indicator

When the footswitch is depressed, an audible tone indicates that the console is delivering laser energy. The audible indicator volume may be adjusted but not turned off.

Time Delay When Activating Laser

The console delivers laser energy only when Treat is selected and the footswitch is depressed. When the status of the console is changed from Standby to Treat, the footswitch is disabled for 3 seconds to help prevent unintentional delivery of energy.

Beam Attenuator

The SL/SLx includes an electronic attenuator that prevents the treatment beam from exiting the console until all requirements for emission are met and the footswitch is depressed.

Viewing Optics

Operating microscopes used with the SL/SLx must be equipped with a fixed safety filter assembly, which is installed in the viewing path of the microscope. When properly installed, the IRIS Medical eye safety filters will protect anyone viewing through the microscope from laser radiation in excess of CDRH Class I levels. The IRIS Medical Laser Indirect Ophthalmoscope (LIO) and Slit Lamp Adapters (SLA) include a fixed filter, which ensures any laser radiation returned to the physician's eyes during clinical use is below the Class I limit.

Location of the Controls

The laser controls for the SL/SLx are located on the front of the console and positioned at a safe distance from the laser aperture.

Manual Restart

The SL/SLx immediately disables all laser circuits upon interruption of the Remote Interlock circuit or loss of line power. In this event, the SL/SLx must be manually reset by cycling the keyswitch off and on.

Internal Power Monitor

The power emitted from the delivery device is indicated on the display. Two internal power monitors independently measure the laser power before energy is emitted through the delivery device. If the measurements from the two monitors differ significantly, the console will display a warning message instructing the user to call IRIDEX Technical Support.

Footswitch

Depressing the footswitch, while in Treat, delivers the treatment beam. If the footswitch is damaged or improperly connected, Treat cannot be selected and the Connect Footswitch message will be displayed. The footswitch can be safely immersed and cleaned (in compliance with IPX8 per IEC 60529), and is shrouded for maximum safety (in compliance with ANSI Standard Z136.3, 4.3.1).

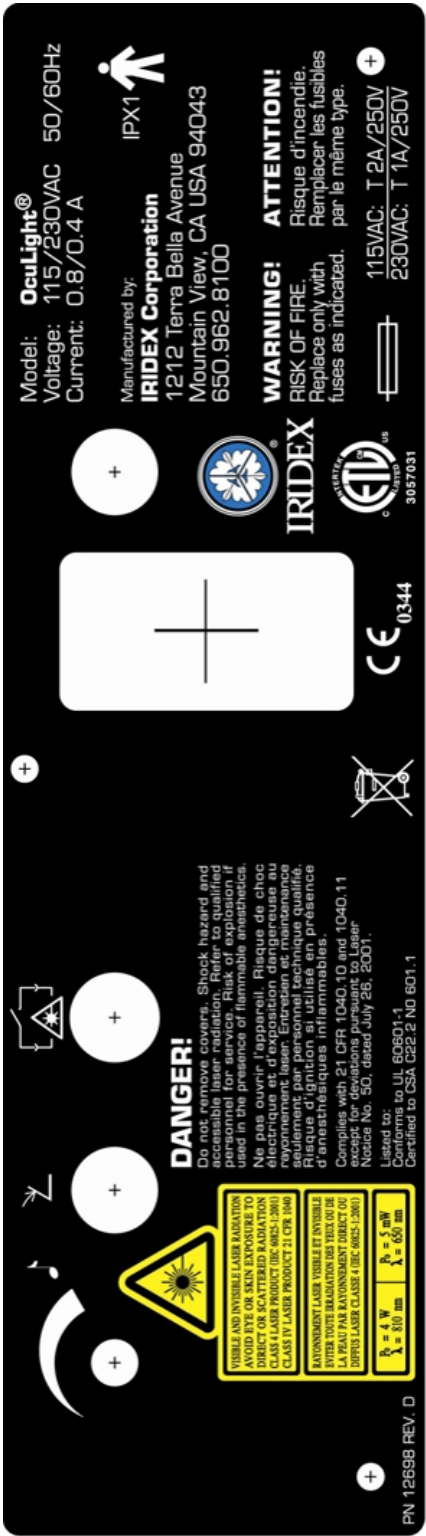
Long Term Reliability

A crystal oscillator controls the timing of the Pulse Duration. Initial uncertainty in the measurement is less than 1 ms. The level of uncertainty is not expected to increase or decrease over the life of the product.

Power is automatically controlled by optical sampling circuits. Initial uncertainty in the measurement is less than 5% of the requested power, including laser power meter uncertainties. This uncertainty is not expected to increase or decrease by more than 1% of the requested power over the life of the product. Laser delivery is affected by many parameters, just one of which is the accurate control of optical energy. Other factors include cleanliness and condition of delivery devices as well as alignment accuracy.

Labeling

Back Panel



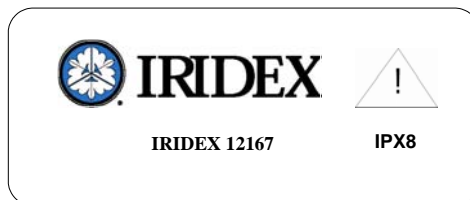
Manufacturing Date and Serial Number Label

S/N: _____
MANUFACTURED: _____





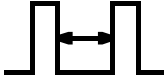








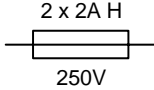







Grounding Label

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 Label



Guide to Symbols

	Pulse Power		Attention!
	Pulse Duration		Volume
	Pulse Interval		Footswitch
	Aiming Beam		LIO Illumination
	On		Treat
	Off		Standby
	ETL Mark		Fuse
	CE Mark		Emergency Stop
	Remote Interlock		Dispose Properly
	Laser Aperture at End of Fiber		Pulse Count
	Type B Equipment		

Product Specifications

Treatment Beam

Wavelength:	810 nm (nominal)
Laser Class:	Class IV, per CFR 1040.10 Class4 per IEC 60825-1
Source:	Solid-state diode
Output Power:	50–3000 mW (SLx), dependent upon attached delivery device 50-2000 mW (SL), dependent upon attached delivery device
Duration	CW-Pulse Mode- 10 ms-9000 ms in 29 increments and continuous pulse up to 60 s MicroPulse Mode (SLx only)- 0.10-1.0 ms in 0.05 ms increments LongPulse Mode- 10 seconds to 30 minutes in 26 increments
Repeat Interval:	50-1000 ms in 11 increments and Single Pulse

Aiming Beam

Wavelength:	650 nm (nominal), coaxial with treatment beam
Source:	Solid-state diode
Output Power:	<1 mW maximum

General

Dimensions:	30 cm W x 30 cm D x 10 cm H (12 in x 12 in x 4 in)
Mass:	6.3 kg (14 lbs)
Operating Conditions:	10 to 35°C (50 to 95°F), 10-90% relative humidity (non-condensing)
Shipping/Storage Conditions:	-20 to 60°C (-4 to 140°F), 10-90% relative humidity (non-condensing), 0 to 10,000 ft.
Electrical:	115/230 VAC, 50/60 Hz, 0.8/0.4 A
Cooling:	Ambient air cooled, no external air/water cooling systems are required

Onscreen Languages: English, Dutch, French, German, Greek, Italian, Portuguese, Spanish

Compatible Delivery Devices: Compatible with the following IRIS Medical Devices: Infrared Slit Lamp Adapters (SLA), Laser Indirect Ophthalmoscopes (LIO), EndoProbe Handpieces, DioPexy Probe, G-Probe, Symphony (SLx only) and Operating Microscope Adapters (OMA).

Contact IRIDEX Customer Service for complete information regarding delivery device compatibility with the SL/SLx

Operating Mode Compatibility:

Delivery Device	CW-Pulse	MicroPulse	LongPulse
Slit Lamp Adapter (SLA)	●	●	
Large Spot SLA	●		●
LIO	●	●	
Large Spot LIO	●		●
EndoProbe	●	●	
DioPexy Probe	●		●
G-Probe	●		
Operating Microscope Adapter	●		●

WARNING: Each IRIS Medical delivery device contains a proprietary connector that identifies the proper transmission characteristics for each device. Substitution of a non-IRIS Medical delivery device may result in unreliable operation or inaccurate delivery of laser power. Any attempt to use fiber-optic devices from another manufacturer will void the warranty on the SL/SLx.

Appendix A- Table 201 per IEC 60601-1-2

Guidance and manufacturer's declaration-electromagnetic emissions		
The SL/SLx is intended for use in the electromagnetic environment specified below. The customer or the user of the SL/SLx should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The SL/SLx uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The SL/SLx is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Appendix B- Table 202 per IEC 60601-1-2

Guidance and manufacturer's declaration-electromagnetic immunity			
The SL/SLx is intended for use in the electromagnetic environment specified below. The customer or the user of the SL/SLx 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 ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode	±1 kV differential 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 25 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 25 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 of SL/SLx requires continued operation during power mains interruptions, it is recommended that the SL/SLx be powered from an uninterruptible power supply or a battery.
Power frequency (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.			

Appendix C- Decontamination Certificate

Under the provision of Postal Law, Title 18, United States Code, Section 1716 and the Department of Transportation regulations contained in CFR 49, Part 173.386 and 173.387, "etiologic agents, diagnostic specimens and biological products ... are nonmailable..."

The undersigned therefore certifies that the IRIS Medical SL/SLx is being returned by

Individual/Institution

City, State, Country

and has undergone decontamination with a commercially available germicide cleared for use as a "hospital disinfectant" and is clean and free from biohazards, including, but not limited to, human or animal blood, tissue or tissue fluids or components thereof.

The undersigned also agrees to reimburse IRIDEX for any costs incurred in cleaning the enclosed equipment, in the event that said item(s) is/are received by IRIDEX in a contaminated condition.

Model _____

Model _____

Serial # _____

Serial # _____

IRIDEX RMA # _____

IRIDEX RMA# _____

Typed/Printed Name _____

Typed/Printed Name _____

Signature _____

Signature _____