OcuLight[®] Symphony[™] Operator Manual



IRIDEX CORPORATION

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About the OcuLight Symphony System

The OcuLight Symphony system combines the capabilities of both the 810 nm and 532 nm wavelengths with a diagnostic and therapeutic slit lamp workstation. The system is designed for different models of slit lamps: the IRIDEX Workstation, the Zeiss 30 SL, or the Zeiss 30 SL/M. The OcuLight Symphony System includes the OcuLight SLx with Tri-Mode console, the OcuLight GLx/TX console, the OcuLight Symphony Adapter, and a components cart. The IRIDEX slit lamp also comes with a workstation table featuring a motorized height control, and conveniently located illumination and viewing controls.

The OcuLight Symphony Adapter features parfocal adjustment of all spot sizes for precise focus and consistent burns, superior viewing through a dual wavelengh eye safety filter featuring UltraView $^{\text{\tiny M}}$ optics which protects from both infrared and green wavelengths, and a switch that enables you to quickly and easily change from one wavelength to another. Additionally, the OcuLight Symphony Adapter has a self-centering micromanipulator for easy positioning of the treatment spot.

CAUTION

Federal law restricts this device to sale by or on the order of a physician.

WARNING

Surgical lasers generate a highly concentrated beam of light which may cause injury if improperly used. Be sure to operate the OcuLight SLx console, the OcuLight GLx/TX console, and the OcuLight Symphony Adapter in accordance with the procedures described in the OcuLight console Manuals and this manual. Failure to do so may harm yourself, your patient, or others.

REFERENCE

See the OcuLight console manuals for console features.

OcuLight Symphony Adapter Specifications

REFERENCE

See the OcuLight console manuals for console specifications.

Console compatibility

OcuLight SLx console

OcuLight GLx console

OcuLight TX console

Slit lamp compatibility

IRIDEX Slit Lamp Workstation

Zeiss 30 SL

Zeiss 30 SL/M

Standard-spot 810 nm for the OcuLight SLx console

Treatment wavelength

Laser diode, 810 nm (infrared)

Spot size

125, 200, 350, 600, 1000 µm (all parfocal)

Large-spot 810 nm-LS for the OcuLight SLx console

Treatment wavelength

Laser diode, 810 nm (infrared)

Spot size

600, 1000, 1800, 3000, 5000 µm (all parfocal)

Standard-spot 532 nm for the OcuLight GLx/TX console

Treatment wavelength

Diode-pumped, frequency-doubled solid state, 532 nm (green)

Spot size

50, 100, 200, 300, 500 μm (all parfocal)

IRIDEX Slit Lamp Workstation Specifications

Microscope

Туре

Galilean converging binocular

Magnification

5 position rotating drum (5x, 8x, 12x, 20x, 32x)

Oculars

10.0x

Diopter adjustment

±6 diopter

Field of view

5.2, 8, 14, 24, 37 mm

Interpupillary adjustment

48.5 to 80 mm

Stereoscopic angle

80

Slit illumination

Slit width

0 to 14 mm, continuously variable

Slit length

14 mm (1.8-12 continuously variable)

Light source

6V, 20W, halogen lamp

Aperture diameter

0.3, 5.5, 9, 14 mm

REFERENCE

See the Zeiss model 30 SL and model 30 SL/M slit lamp operating instructions for specification information.

Filters

Cobalt blue, red free, heat absorbing

Slit angle

± 90° continuous

Swivel range of slit prism

0 to 180° with scale

Angle of incidence

0º horizontal

Free working distance

6.9 cm from exit prism to patient's eye

Joystick movement

Z vertical: 35 mm, X axis: 10.8 cm, Y axis: 11.3 cm

Horizontal fine movement

10 mm

Slit lamp table top dimension

38 x 50 cm or 39 x 89 cm

Chin rest vertical movement

7.1 cm

Fixation lamp

Micro lamp, 18V, 26 mA, Red

Power requirement

115 VAC, 60 Hz 230 VAC, 50 Hz

Maximum power consumption

40 W

Warranty and Service

Warranty

The OcuLight Symphony system carries a standard factory warranty.

Product registration

Please complete and forward to us the enclosed product registration cards.

Service and technical support

IRIDEX has established an efficient process to support its installations worldwide. Should you require assistance, please contact your local IRIDEX Technical Support representative or our corporate headquarters.

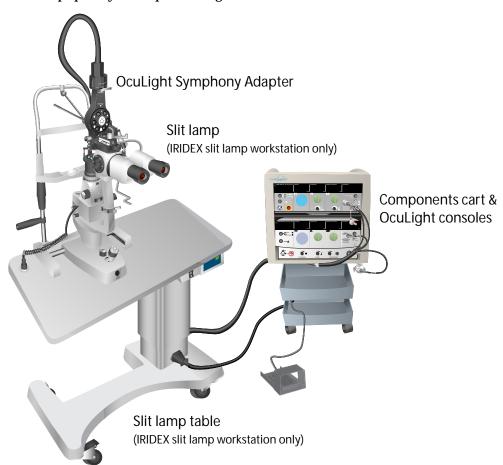


About the Components 1

The OcuLight Symphony system consists of:

- a components cart and other accessories necessary for assembly;
- the console components which include the OcuLight SLx console, the OcuLight GLx or TX console, two power cables, a footswitch and cable, the remote interlock plug, two keys, spare fuses, and the Laser in Use warning sign;
- the slit lamp components, which come only with the IRIDEX slit lamp workstation, include the slit lamp and headrest assembly;
- the OcuLight Symphony Adapter components which include the OcuLight Symphony Adapter, a micromanipulator handle, and a finger rest.
- the slit lamp table components, which come only with the IRIDEX slit lamp workstation, include a table top, pedestal, base, and other accessories necessary for assembly;

Together, the slit lamp, the OcuLight SLx and GLx or TX consoles, and the OcuLight Symphony Adapter provide diagnostic and therapeutic capability of transpupillary laser photocoagulation.



NOTE

Should you notice problems with your order, please contact your local IRIDEX Technical Support representative immediately.

REFERENCE

See your OcuLight console manuals for descriptions of the console components.

NOTE

The OcuLight TX console will require the use of a 2nd footswitch. The footswitch jumper used in the OcuLight SLx/GLx configuration is not compatible with the OcuLight TX console.

Components cart

The factory-assembled components cart provides a convenient location for the OcuLight SLx and OcuLight GLx or TX consoles and their accessories. The cart also has bins for storing delivery devices such as the TruFocus™ LIO+ and the Endoprobe® handpieces. It includes various cable guides to prevent damage to the fiber optic assembly, footswitch, and power cables.



Slit lamp table (for the IRIDEX slit lamp workstation only)

The slit lamp table consists of a tabletop, pedestal, base, casters, cable guides, and the screws necessary for assembly. Once assembled, the electrically-controlled slit lamp table supplies power to the slit lamp. It also includes the table height and slit illumination controls.



IRIDEX slit lamp

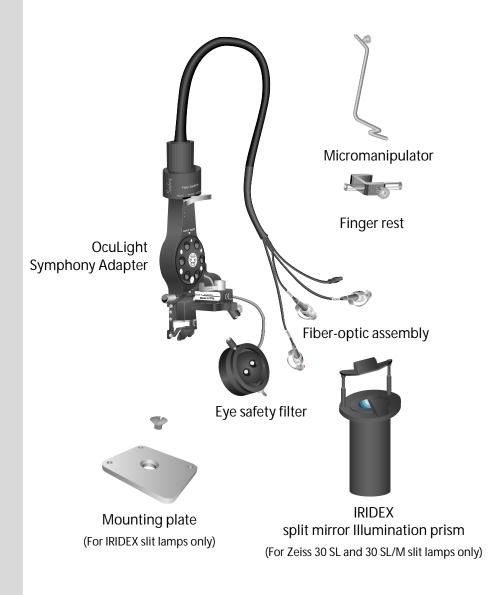
The slit lamp is specially designed to connect to the OcuLight Symphony Adapter. It consists of a patient chinrest and headrest with fixation light, a viewing assembly with oculars, magnification changer and objective lens, an illumination prism, an illumination housing, and a slit lamp base.



OcuLight Symphony Adapter

The OcuLight Symphony Adapter attaches to the slit lamp, enabling the slit lamp to be used as the therapeutic device.

The adapter has an integral fiber-optic assembly which houses up to three fiber-optic cables: the 532 nm wavelength, the large-spot 810 nm wavelength, and the standard-spot 810 nm wavelength. These fiber-optic cables transmit laser light to the slit lamp optics. The fiber-optic assembly also has a SmartKey®. The SmartKey communicates spot size and eye safety filter information from the OcuLight Symphony Adapter to the OcuLight console, depending on which console is in use.



The OcuLight Symphony Adapter includes an eye safety filter. The eye safety filter has optics which protect your eyes from laser reflections during laser treatment while using the OcuLight Symphony Adapter.

Additionally, the OcuLight Symphony Adapter contains the controls for adjusting the laser spot size, a micromanipulator, and a finger rest. The micromanipulator adds precision beam steering capabilities to the OcuLight Symphony Adapter while offering a full range of motion over the treatment area. The finger rest provides a stable, comfortable resting place for your hand or finger when using the micromanipulator and is particularly useful during long treatment sessions.

If you have a Zeiss 30 SL or 30 SL/M slit lamp, the OcuLight Symphony adapter comes with an IRIDEX split-mirror illumination prism and tools for installing it. The IRIDEX split-mirror illumination prism projects light from the slit lamp into the patient's eye.

Connecting the Components

Placing the components onto the cart

Remove the screws from the back panel. Remove the back panel from the cart.

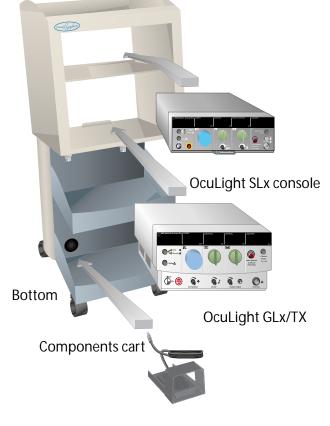


REFERENCE

See your OcuLight console manuals for important information about choosing the location and position for the consoles.

Place the OcuLight SLx console on the top shelf of the components cart. Place the OcuLight GLx or TX console on the bottom shelf of the cart. Place the footswitch in the bottom storage bin.

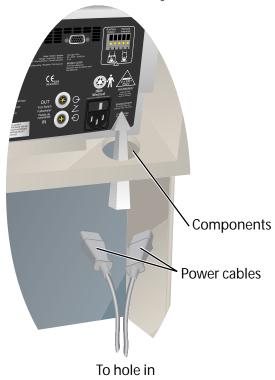
Plug the footswitch into the OcuLight GLx/TX console Footswitch port.



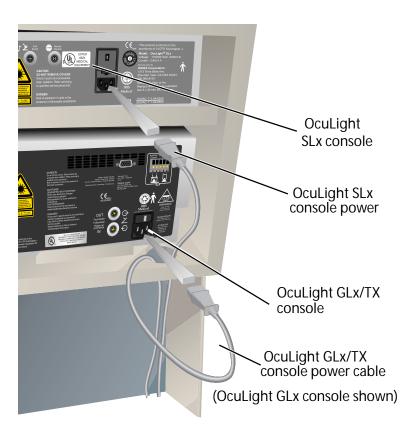
Connecting the console components

Connect the main power cables

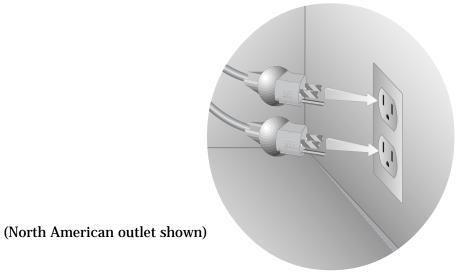
Thread the main power cables through the hole on the back of the shelf and again through the hole on the bottom shelf of the components cart.



Plug one of the power cables into the OcuLight SLx console AC power inlet. Plug the other power cable into the OcuLight GLx console AC power inlet.

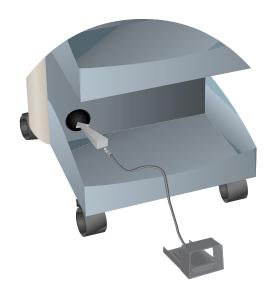


Plug the other ends of the main power cables into a properly grounded electrical outlet.



Connect the footswitch

Thread the end of the footswitch cable through the hole in the bottom bin on the components cart and again through the hole on the bottom shelf of the components cart.



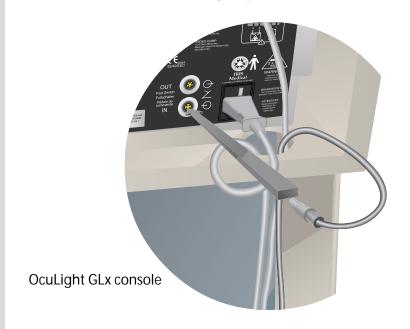


NOTE

The OcuLight TX console will require the use of a 2nd footswitch. The footswitch jumper used in the OcuLight SLx/GLx configuration is not compatible with the OcuLight TX console.

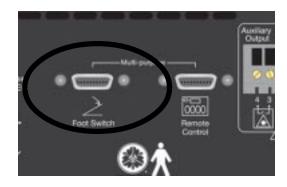
If the footswitch is not properly connected, when you turn on the OcuLight GLx/TX console and enter the Treat mode, Connect Footswitch displays on the console status panel.

Connect the GLx footswitch jumper cable



NOTE

The OcuLight TX console will require the use of a 2nd footswitch. The footswitch jumper used in the OcuLight SLx/GLx configuration is not compatible with the OcuLight TX console.



OcuLight TX console

Plug the five pin end of the footswitch jumper cable into the OcuLight GLx console Footswitch Out port.

Plug the four pin end of the footswitch jumper cable into the OcuLight SLx console Footswitch port.

If the footswitch jumper cable is not properly connected, when you turn on the console and enter the Treat mode, Connect Footswitch displays on the console status panel.



When using an OcuLight TX with an OcuLight SLx, connect a footswitch directly to each console.

NOTE

The OcuLight TX console will require the use of a 2nd footswitch. The footswitch jumper used in the OcuLight SLx/GLx configuration is not compatible with the OcuLight TX console.

If desired, connect a remote interlock switch

As a safety feature, a remote interlock switch may be installed, for example a switch that disables the laser whenever a treatment room door opens while the console is in the Treat mode. If you will be using a remote interlock switch, install a remote interlock switch to each console as described:

Connecting to the OcuLight SLx console

Attach the two wires connecting the door switch to the remote interlock plug in place of the shorting connection.

Insert the remote interlock plug (either by itself or attached to a remote interlock switch) into the remote interlock port.

If the remote interlock plug is not properly connected, when you turn on the OcuLight SLx console, No Remote Interlock displays on the console status panel.



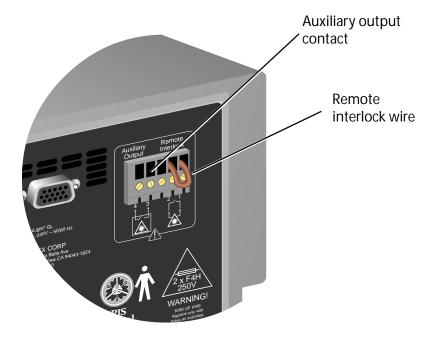
Connecting to the OcuLight GLx/TX console

Remove the factory installed wire and in its place attach the two wires leading to your own switch.

If the remote interlock switch is not properly connected, when you turn on the OcuLight GLx or TX console, No Remote Interlock displays on the console status panel.

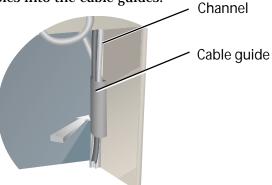
If desired, connect an external warning device

As an additional safety measure you may connect an external warning device such as a warning light or small rotating beacon to the Auxiliary Output contact on the OcuLight GLx or TX console. If an external warning device is used, the system activates the device when you are in the Treat mode. You also have the option of programming the system to activate the warning device when you turn on the key switch or when you press the footswitch.



Secure the power cables to the cart

Snap the cable guide tabs into the channel on the cart leg. Clip the footswitch and power cables into the cable guides.



Attach the back panel to the cart



Cable

Install the cable guides for the fiber-optic assembly

To keep the fiber-optic cables off the ground and prevent damage to the cables, attach the cable guides, where desired, in the holes provided on the underside of the cart.

Assembling the slit lamp table (For IRIDEX slit lamp workstation only)

- 1. Place the pedestal upside down with the switch facing away from you.
- 2. If present, remove and reserve the four pedestal screws.



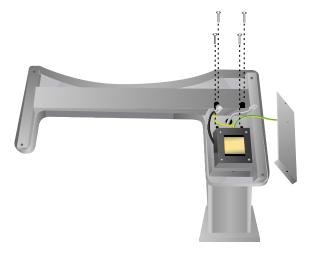
- 4. If a small metal cover is attached to the underside of the base, remove and reserve the screws from each end. The underside of the cover is attached to a grounding wire by a star washer and fixation nut. Leaving the cover attached to the grounding wire, remove the cover to expose the hole in the base; set the cover aside.
- 5. Ensure that the base is upside down and the arc is facing away from you.



- 6. Ensure that the table switch on the pedestal is facing away from you.
- 7. Holding each side of the base, raise the base and place it on top of the pedestal.
- 8. Balancing the opposite end of the base on a chair or table, route the cables from the pedestal through the hole in the base.



9. Secure the pedestal to the base with either the four reserved pedestal screws or the packaged screws that came with the slit lamp table components.



- 10. Connect the transformer cable to the pedestal cable.
- 11. Replace the small metal cover with the two reserved screws.



- 12. Screw the two locking wheels into the holes on the arc side of the base. Screw the other two wheels to the opposite corners of the base.
- 13. Turn the pedestal and base upright.



14. Plug one end of the power cable into the base inlet; plug the other end into a properly grounded electrical outlet.



15. Press the table switch ▲ (up) and ▼ (down) to ensure that the pedestal properly raises and lowers.



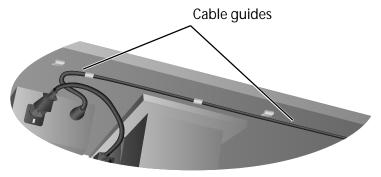
16. Align the four holes on the pedestal to the inserts on the underside of the table top; secure the table top to the pedestal with the four screws.



17. Connect the small electrical cable from the pedestal to the slit lamp power supply.



18. To keep the fiber-optic cables off the ground and prevent damage to the cables, attach the cable guides to the underside of the tabletop.



Installing the OcuLight Symphony Adapter

Prepare the slit lamp for OcuLight Symphony Adapter installation

- 1. Ensure that the slit lamp is properly assembled.
- 2. Loosen the thumbscrew to remove the oculars from the slit lamp.
- 3. Rotate the illumination tower to either side of the centered position, allowing enough clearance for the IRIDEX split-mirror illumination prism, if applicable, and the OcuLight Symphony Adapter.



Install the IRIDEX split-mirror illumination prism

(for Zeiss 30 SL and 30 SL/M slit lamps only)

Replace the original illumination prism with the IRIDEX split-mirror illumination prism:

- 1. Loosen the retaining ring at the base of the original illumination prism by rotating the knurled ring clockwise until it disengages.
- 2. Lift the original prism out of the illumination housing and properly store.
- 3. Lower the IRIDEX split-mirror illumination prism into the housing, aligning the pin at the base of the prism with the slot in the housing.
- 4. Rotate the knurled ring counter-clockwise to secure the IRIDEX splitmirror illumination prism in position.

IRIDEX split-mirror illumination prism

Illumination housing

Zeiss 30 SL model shown

REFERENCE

See your CSO slit lamp manual for instructions on assembling the slit lamp.

WARNING

Do not use the OcuLight Symphony Adapter with any laser system other than an IRIDEX OcuLight SLx/GLx/TX console. Such use may void any product warranties and jeopardize the safety of the patient, yourself, and others in the treatment room.

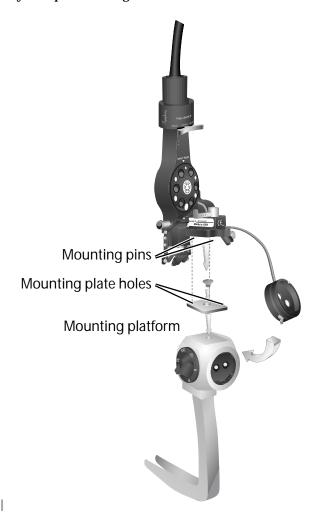
WARNING

If you will be installing observation equipment such as a beamsplitter or co-observation tube, the equipment must be installed between the eye safety filter and the oculars.

Install the OcuLight Symphony Adapter and the eye safety filter

IRIDEX slit lamp workstation instructions

- 1. Attach mounting plate to top of the slit lamp mounting platform. Tighten the screw to secure.
- 2. Align the mounting pins of the OcuLight Symphony Adapter with the holes on the mounting plate.
- 3. Lower the OcuLight Symphony Adapter onto the slit lamp mounting plate until it is fully seated. Tighten the screw to secure.
- 4. Hold the eye safety filter so that the lever is facing downward.
- 5. Tilt the eye safety filter and insert the lower edge into the dovetail mount.
- 6. Tilt the eye safety filter upright and then place the top edge into the dovetail mount. Use the set screw provided with the OcuLight Symphony Adapter and tighten to secure.



Zeiss 30 SL and 30 SL/M slit lamp instructions

- 1. Align the mounting pins of the OcuLight Symphony Adapter with the holes on the slit lamp mounting platform.
- 2. Lower the OcuLight Symphony Adapter onto the slit lamp mounting platform until it is fully seated. Tighten the screw to secure.
- 3. Hold the eye safety filter so that the lever is facing downward.
- 4. Tilt the eye safety filter and insert the lower edge into the dovetail mount.

5. Tilt the eye safety filter upright and then place the top edge into the dovetail mount. Use the set screw provided with the OcuLight Symphony Adapter and tighten to secure.



Replace the oculars

Attach the oculars to the eye safety filter dovetail mount and tighten the thumbscrew to secure.



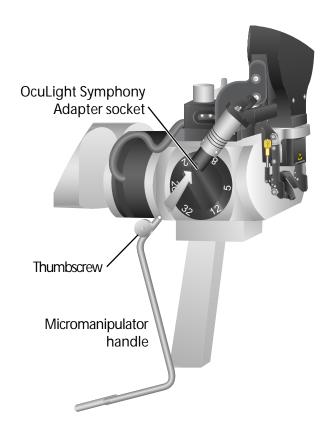
Reposition the illumination housing

Carefully rotate the illumination housing back into its centered position.



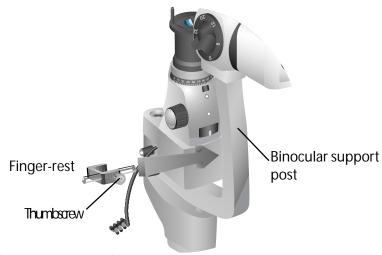
Attach the micromanipulator handle

Insert the micromanipulator handle into the OcuLight Symphony Adapter socket and tighten the thumbscrew to secure.



If desired, attach the finger-rest to the slit lamp

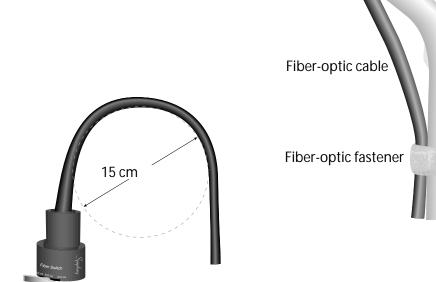
Slide the finger-rest onto the binocular support post and tighten the thumbscrew to secure.



Secure the fiber-optic assembly

Secure the fiber-optic assembly to the slit lamp

Using the fiber-optic fasteners, secure the fiber-optic assembly to the slit lamp headrest by forming a gentle arc with no less than a 15 cm (6 inch) diameter bend.



WARNING

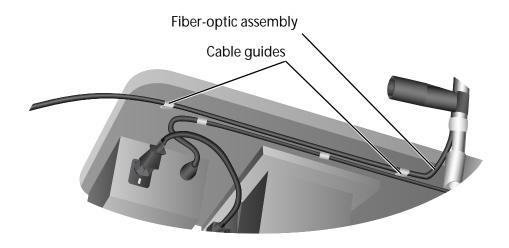
Always inspect the fiber-optic assembly before securing it to the slit lamp headrest to ensure that it has not been damaged. A damaged fiber-optic cable could cause accidental laser exposure or injury to yourself, your patient, or others in the treatment room.

NOTE

Avoid making any sharp bends or kinks in the cable assembly as this can compromise the integrity of the fiber-optic and prevent or reduce laser light transmission.

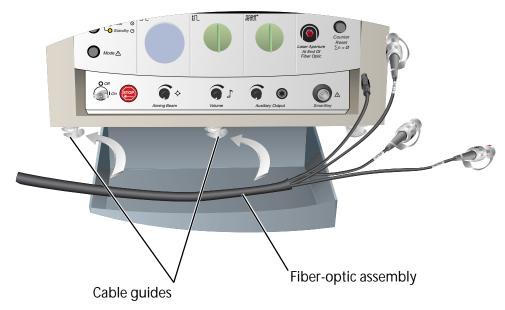
Secure the fiber-optic assembly to the slit lamp table

Using the cable guides installed previously on the slit lamp table, secure the fiber-optic assembly to the slit lamp table.



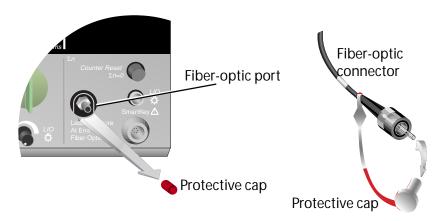
Secure the fiber-optic assembly to the components cart

Using the cable guides installed previously on the components cart, secure the fiber-optic assembly to the slit lamp table.



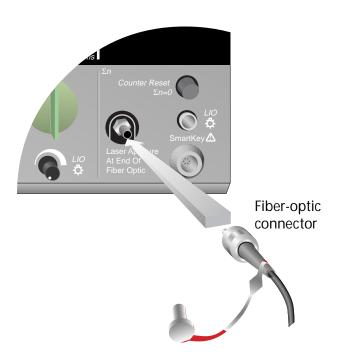
Connect the desired 810 nm fiber-optic to the OcuLight SLx console

Remove the protective caps from the OcuLight SLx console fiber-optic port and from the desired fiber-optic connector (810 nm or 810-LS).



Carefully insert and finger-tighten the connector into the OcuLight SLx console fiber-optic port until secure.

If the fiber-optic is not properly connected, when you turn on the OcuLight SLx console, Connect Fiber displays on the console control panel.



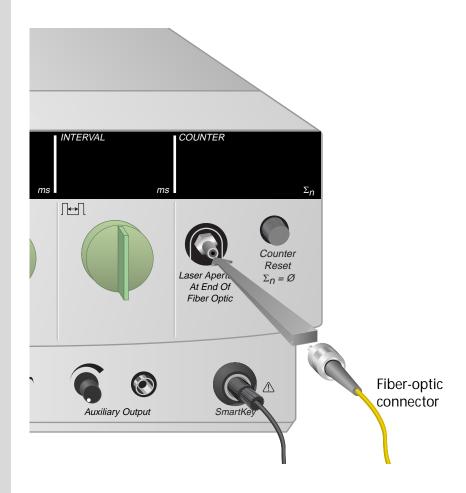
CAUTION

Do not touch the end of the fiber-optic connector, as finger oils can impair light transmission through the fiber-optic and reduce power.

Connect the 532 nm fiber-optic to the OcuLight GLx or TX console

Remove the protective caps from the OcuLight GLx/TX console fiber-optic port and from the fiber-optic connector.

Carefully insert and finger-tighten the connector into the OcuLight GLx/TX console fiber-optic port until secure.



Connect the SmartKey

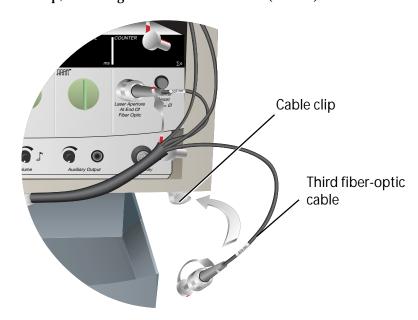
Insert the SmartKey into the desired OcuLight console SmartKey port. For example: if you will be using the OcuLight SLx console for treatment, insert the SmartKey into the OcuLight SLx console SmartKey port.



Insert the SmartKey into the desired OcuLight console SmartKey port. For example: if you will be using the OcuLight SLx console for treatment, insert the SmartKey into the OcuLight SLx console SmartKey port.

If present, store the third unused fiber-optic

If a third fiber-optic cable is present, ensure that the protective cap is over the end of the fiber-optic connector. Store the unused fiber-optic cable on the cable clip, ensuring no less than a 15 cm (6 inch) diameter bend.



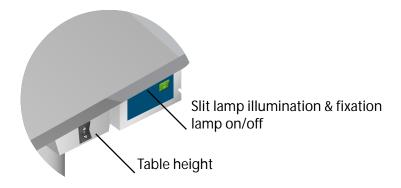
Using the Slit Lamp and Table Controls (IRIDEX workstation only)

Turning the slit lamp illumination & fixation lamp on/off

Use the slit lamp illumination switch to turn the illumination and fixation lamps on or off.

Adjusting the table height

Use the table height control to adjust the table height. Press the up arrow to raise the table and the down arrow to lower it.



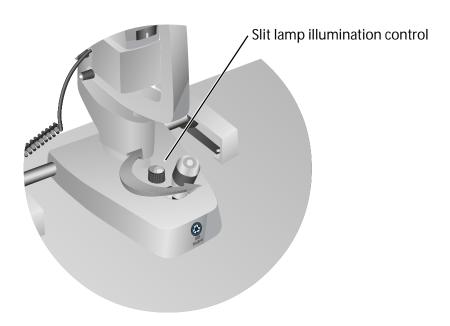
Adjusting the illumination intensity

Use the slit lamp illumination control to increase or decrease the intensity of the illumination lamp.

Turn the control clockwise to increase intensity and counter-clockwise to decrease.

NOTE

Though no damage to the patient's eyes is likely to occur, to reduce discomfort for the patient, always keep the illumination intensity at the minimum required for treatment.

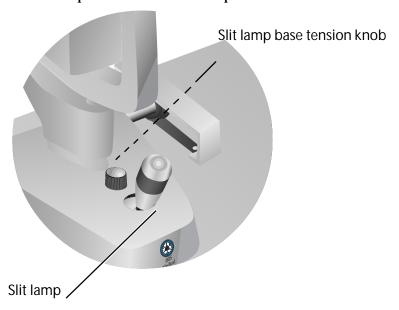


Positioning and securing the slit lamp base

Use the slit lamp base control to move the slit lamp base laterally and vertically.

Pull the control towards you to move the slit lamp closer to you. Push the control away from you to move the slit lamp towards the patient. Turn the control clockwise to raise the slit lamp and counter-clockwise to lower.

When the slit lamp is in the desired position, turn the base tension knob clockwise to secure the position of the slit lamp.



Positioning the chinrest

Use the chinrest height control to raise or lower the chinrest.

Turn the control counter-clockwise to raise the chinrest and clockwise to lower.



Adjust the interpupillary distance

Move the oculars apart or together to adjust the interpupillary distance for your eyes.



Focus the oculars

Rotate the oculars to your approximate prescription. \\



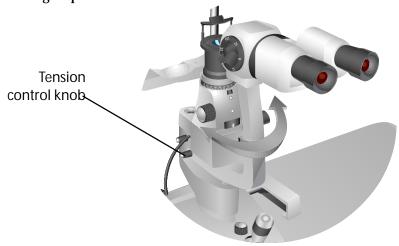
Set the magnification

Rotate the control to the desired magnification.



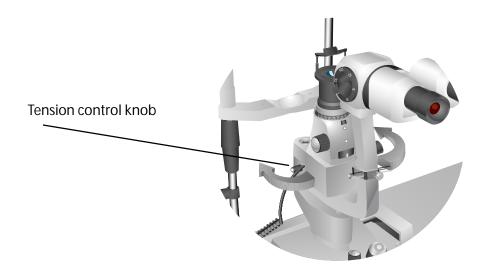
If desired, set the slit lamp for off-axis viewing

Loosen the tension control to unlock the oculars and magnification housing. Carefully swing the oculars to the left or right to view the patient's eye at an angle. Turn the tension control to secure the oculars and magnification housing in place.



If desired, set the slit lamp for off-axis illumination

Loosen the tension control to unlock the illumination housing. Carefully swing the illumination housing to the left or right to illuminate the patient's eye at an angle. Turn the tension control to secure the illumination housing in place.

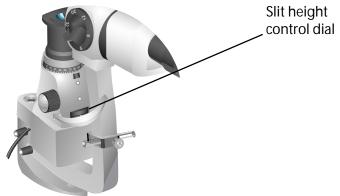


NOTE

To avoid discomfort and protect the patient's eyes from excessive optical radiation, reduce the size of the illuminated area (slit height and width).

Adjust the slit height

Rotate the top dial to adjust the slit height.



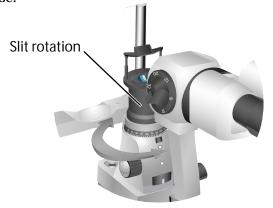
Adjust the slit width

Use the slit width control to adjust the slit width from round to slit.



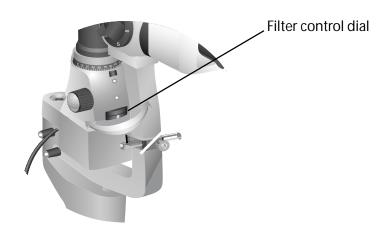
Select the desired rotation of the slit

Use the slit rotation control to rotate the slit. Turn the control to the left to rotate the slit clockwise and to the right to rotate the slit counter-clockwise.



Select the desired filter

Rotate the bottom dial to change the slit lamp filter. The various filters are indicated on the dial by a colored marker: cobalt blue filter = blue marker, red-free filter = green marker, heat-absorbing = red marker, white marker = no filter.



NOTE

To avoid discomfort and protect the patient's eyes from excessive optical radiation, always use the color filter appropriate for treatment.

Using the OcuLight Symphony Adapter

REFERENCE

See the Operations section of your OcuLight console manuals for instructions on using the console controls.

REFERENCE

Read the Clinical & Safety sections of your OcuLight console manuals and this manual before using the OcuLight Symphony Adapter.

Selecting the fiber-optic

Ensure that the 532 nm fiber-optic connector is properly connected to the OcuLight GLx/TX console.

Ensure that the desired 810 nm (standard-spot or large-spot) fiber optic connector is properly connected to the OcuLight SLx console.

Move the Fiber Switch to select the desired fiber-optic. Up to three fibers are available: 532 nm, 810-LS (large-spot, 810 nm), and 810 nm (standard-spot, 810 nm).



Selecting the spot size

Rotate the Spot Size selector to the desired position.

The OcuLight SLx/GLx/TX console status display indicates the selected spot size.



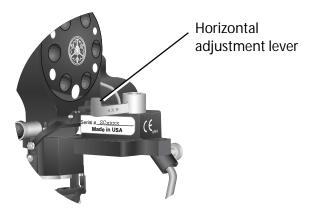


If the spot size selector is between detents, the OcuLight SLx/GLx/TX console status display reads Spot Size?

Positioning and focussing the spot

Before treating patients, ensure that the spot is positioned and focussed properly for the OcuLight Symphony Adapter.

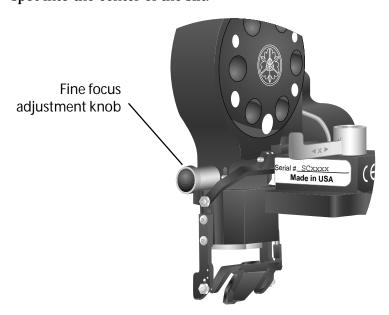
- 1. Insert the focus post, if using the IRIDEX slit lamp or position a paper target on the headrest, if using a Zeiss 30SL or 30 SL/M slit lamp.
- 2. Set the oculars to the physician's approximate prescription.
- 3. Turn on the slit lamp illumination and adjust the intensity to a comfortable level.
- 4. Adjust the position of the slit lamp so that the slit is illuminated on the focus post.
- 5. Focus the vertical edges of the bright slit until its edges are in crisp focus.
- 6. Lock the slit lamp base.
- 7. Readjust the oculars one at a time.



8. Leave the focus post inserted or the paper target attached to the headrest while positioning and focussing the spot.



- 9. Turn on the OcuLight console and place it in Treat mode.
- 10. Use the lever labeled <X> to adjust the horizontal position of the laser spot into the center of the slit.



- 11. Rotate the nut labeled <Y> to adjust the vertical position of the laser spot into the center of the slit.
- 12. Set the spot size selector to the smallest spot size.

- 13. Rotate the fine focus adjustment knob until the spot is at its smallest and sharpest focus.
- 14. Remove the focus post.

Using the eye safety filter

The eye safety filter is specifically designed to protect your eyes from laser radiation above regulatory requirements. Use the lever on the eye safety filter to select the desired position.

Opening the filter while using the OcuLight SLx console

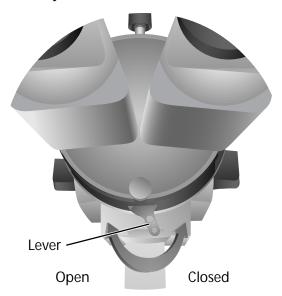
When the filter is open while using the OcuLight SLx console, the 532 nm (green) eye safety filter moves out of your visual path and the 810 nm (infrared) eye safety filter protects you from laser radiation above regulatory requirements.

Opening the filter while using the OcuLight GLx/TX console

When the filter is open while using the OcuLight GLx console, the 532 nm (green) eye safety filter moves out of your visual path, Green Safety Filter? displays on the OcuLight GLx console status panel, and the yellow Standby light flashes.

Closing the filter while using the OcuLight GLx/TX console

Before beginning treatment with the OcuLight GLx/TX console, close the eye safety filter. 532 nm and xxx μ m (spot size) displays on the OcuLight GLx/TX console status panel when the filter is closed.



NOTE

The eye safety filter must be in the closed position to enter the Treat mode when using the OcuLight GLx/TX console.

Before Treating Patients

REFERENCE

Read the Clinical and Safety sections of your OcuLight console manuals and this manual before using the OcuLight Symphony System.

REFERENCE

See the Connecting Components sections of your OcuLight console manuals and this manual for connection instructions

REFERENCE

See the Using the
OcuLight Symphony
Adapter section of this
manual for instructions on
adjusting the slit lamp
oculars and for properly
positioning and focussing
the spot.

- 1. Ensure that the OcuLight consoles, the slit lamp, and the OcuLight Symphony Adapter are properly connected and set up.
- 2. Ensure that your slit lamp oculars are properly adjusted.
- 3. Post the laser warning sign outside the treatment room door.
- 4. Turn on the OcuLight consoles.
- 5. Ensure that the fiber-optic cable labeled 532 nm is connected to the OcuLight GLx.
- 6. Ensure proper connection of the other fiber-optic cable(s) and the SmartKey:
 - If using the OcuLight GLx or TX during treatment, ensure that the SmartKey is connected.
 - If using the OcuLight SLx console for treatments requiring the large-spot fiber-optic, connect the fiber optic labeled 810-LS and the SmartKey to the OcuLight SLx console.
 - If using the OcuLight SLx console for treatments requiring the standard spot fiber-optic, connect the fiber optic labeled 810 nm and the SmartKey to the OcuLight SLx console.
- 7. Select the desired fiber-optic with the Fiber Switch on the Symphony Slit Lamp Adapter.
- 8. Ensure that the spot is properly positioned and focussed.

Treating a Patient

- 1. Select the spot size.
- 2. Set the treatment parameters on the OcuLight console.
- 3. Position the patient.
- 4. Select an appropriate contact lens for the treatment.
- 5. Adjust the slit lamp and table, if necessary.
- 6. Ensure that all ancillary personnel in the treatment room are wearing appropriate laser safety eyewear.
- 7. If using the OcuLight GLx or TX console, close the eye safety filter.
- 8. Select Treat mode.
- 9. Position the aiming beam on the treatment site.
- 10. If desired, adjust the intensity of the red aiming beam.
- 11. Press the footswitch to deliver the treatment beam.
- 12. If you require another wavelength during patient treatment:
 - Remove your foot from the footswitch.
 - Place the OcuLight console in Standby mode.
 - Ensure that the appropriate fiber-optic connector and the SmartKey are connected to the desired laser console, and
 - Select the desired fiber-optic with the Fiber Switch on the Symphony Slit Lamp Adapter.
 - Resume treatment, following steps 7 11 above.
- 13. When you do not require the treatment beam, remove your foot from the footswitch and place the OcuLight SLx/GLx console in Standby mode.

REFERENCE

See the Using the OcuLight Symphony Adapter section of this manual for instructions on selecting the spot size and for instructions on closing the eye safety filter.

REFERENCE

See the Using the Control Panel section of your OcuLight console manuals for instructions on using the treatment controls and displays.

REFERENCE

See Using the Slit Lamp and Table Controls section of this manual for adjustment instructions.

REFERENCE

See the Clinical and Safety sections of your OcuLight console manuals for important laser safety eyewear and eye safety filter information.

WARNING

Always keep the
OcuLight SLx/GLx console
in Standby mode when you
are not treating a patient.
Maintaining the
OcuLight console in
Standby mode prevents
accidental laser exposure if
the footswitch is
inadvertently pressed.

Concluding Patient Treatment

- 1. Ensure that the OcuLight console is in Standby mode.
 - 2. If desired, record the number of exposures and any other treatment parameters.
 - 3. Turn off the OcuLight console and remove the key to prevent unauthorized use.
 - 4. Handle the contact lens according to the manufacturer's instructions.
 - 5. If desired, clean the OcuLight Symphony Adapter fiber-optic connectors and replace the protective caps. If desired, clean the OcuLight Symphony Adapter, Slit Lamp, and OcuLight console.
 - 6. If desired, remove the laser warning sign from the treatment room door.

REFERENCE

See the Inspecting and Cleaning sections of your OcuLight console manuals and this manual for cleaning and storing instructions.

Troubleshooting

Reporting problems

Should you experience problems with your OcuLight Symphony system, refer to the suggestions in this section. If you continue to experience problems, write down the error message, product name, and serial number of the OcuLight SLx/GLx/TX console, the OcuLight Symphony Adapter, and the slit lamp before contacting your local IRIDEX Technical Support representative.

Problem

Inadequate or no aiming beam

Action

- Ensure that the OcuLight Symphony Adapter is properly connected to the console.
- Ensure that the OcuLight SLx/GLx/TX console is in Treat mode.
- Ensure that the Fiber Switch is in the correct position for the console and wavelength you are using.
- Turn the aiming beam control fully clockwise.
- Ensure that the fiber-optic connectors are not damaged.
- If the aiming beam is still not visible, contact your local IRIDEX Technical Support representative.

REFERENCE

See the Troubleshooting section of your OcuLight console manuals for additional information.

Problem

No treatment beam

Action

- Ensure that the Fiber Switch is in the correct position for the console and wavelength you are using.
- Ensure that the remote interlock has not been activated.
- Ensure that the aiming beam is present and bright.
- If using the OcuLight GLx or TX console, ensure that the eye safety filter is in the closed position.
- If you still have no treatment beam, contact your local IRIDEX Technical Support representative.

The Status panel reads:

Connect Fiber

Connect SmartKey

Spot Size?

Green Safety Filter?

0 0 1 1 511 0

SWITCH XXXXX Fiber on SLA

Press Mode to Continue

- Ensure that the OcuLight Symphony Adapter is properly connected.
- Ensure that the SmartKey is properly inserted.
- Ensure that the spot size selector is not between detents.
- Ensure that the eye safety filter is properly connected and, if using the OcuLight GLx or TX console, that it is in the closed position.
- Ensure that the Fiber Switch is in the correct position for the console and wavelength you are using and press the Mode button on the OcuLight SLx/GLx/TX console to continue.

Problem

Action

The Status panel reads:

Unknown Fiber Type

fiber-optic connector to the OcuLight GLx or TX console.

• Connect the 532 nm

Incompatible Device

Use with 810 nm console

• Connect the 810 nm or

810-LS fiber-optic connector to the OcuLight SLx console.



Inspecting and Cleaning Enal Cleaning

OcuLight Symphony Adapter

Routine care

- Do not tightly kink or bend the fiber-optic cable.
- When connected to the console, ensure that the fiber-optic cable is located away from high traffic areas.
- Keep the delivery mirror free of fingerprints.

Inspect the OcuLight Symphony Adapter

Periodically inspect the OcuLight Symphony Adapter for dirt, debris, and damage.

Clean the OcuLight Symphony Adapter

Clean the fiber-optic connector

If needed, clean the fiber-optic connector using a cotton swab moistened with 100% methanol (preferred) or 100% isopropyl alcohol. Replace the protective cap on the end of the fiber-optic connector.

Clean the external surfaces

Wipe the external non-optical surfaces of the OcuLight Symphony Adapter with a soft cloth dampened with a mild detergent. Do not spray or submerge the OcuLight Symphony Adapter in any cleaning agents.

CAUTION

Turn off the OcuLight SLx/GLx/TX before inspecting any delivery device components.

CAUTION

Always handle the fiberoptic cable with extreme care. Do not wrap the cable in a diameter less than 15 cm (6 in).

Damage to the fiber can impair light transmission through the fiber-optic and reduce power.

CAUTION

Keep the protective cap over the fiber-optic when it is not in use.

REFERENCE

See the Maintenance sections of the OcuLight console manuals for console maintenance instructions.

Clean the delivery mirror and eye safety filter

To clean the optical surfaces of the delivery mirror and eye safety filter:

- 1. Wrap a lens tissue around one end of a cotton-tipped swab.
- 2. Place several drops of 100% ethanol, 100% methanol, or high-grade acetone on the tissue.
- 3. Wipe the lens gently with the swab to remove all dust and debris.
- 4. If the surface is still not clean, put a clean lens tissue around the end of the swab and gently wipe it again.



Delivery mirror

Slit lamp and slit lamp table (for IRIDEX slit lamp workstation only)

Routine care

- Keep the optical components free of fingerprints.
- When not in use, cover the slit lamp with the provided cover to keep the slit lamp free of dust and store all accessories in suitable storage boxes.

Inspect the slit lamp

Periodically inspect the slit lamp for dirt, debris, and damage.

Clean the slit lamp

Clean the external surfaces

Remove accumulated dust with a very soft cloth. When necessary, wipe the external non-optical surfaces with a soft cloth dampened with a mild detergent. Do not spray any cleaning agents on the slit lamp.

Clean the optical components

Use a soft brush to remove dust from accessible surfaces. When necessary, clean the front surface of the objective carefully:

- 1. Turn on the slit lamp illumination to ensure proper cleaning.
- 2. Moisten a cotton-tipped swab with 100% ethanol, 100% methanol, or high-grade acetone.
- 3. Gently wipe the surface circularly from the lens center to the edge.
- 4. If the surface is still not clean, use a newly-moistened, cotton-tipped swab and gently wipe the surface again using the same technique.

Clean the slit lamp table

Remove accumulated dust with a soft cloth dampened with a mild detergent.

REFERENCE

For instructions on routine care and cleaning of the Zeiss slit lamp, see the Zeiss model 30 SL and model 30 SL/M slit lamp operating instructions.

Replacing the Slit Lamp Illumination Bulb

(for IRIDEX slit lamp workstation only)

REFERENCE

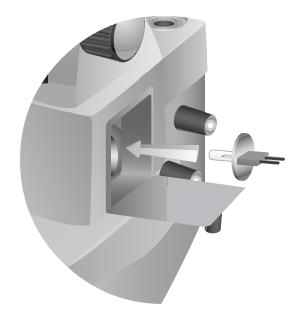
For instructions on replacing the Zeiss slit lamp illumination bulb, see the Zeiss model 30 SL and model 30 SL/M slit lamp operating instructions.

CAUTION

Do not handle illumination lamp by its glass bulb. Skin oils can degrade its performance.

To replace the illumination bulb:

- 1. Unplug the slit lamp main power cable from the electrical outlet.
- 2. Open the illumination bulb hatch by rotating the knob and pulling down the door.
- 3. Ensure that the bulb has cooled.
- 4. Remove the old bulb.
- 5. Hold and properly orient a new bulb by the plastic envelope (not by the bulb); insert the new bulb into the bulb housing.
- 6. Close the illumination bulb door.



Replacing the Slit Lamp Fixation Light Bulb

(for IRIDEX slit lamp workstation only)

To replace the fixation light bulb:

- 1. Unplug the slit lamp main power cable from the electrical outlet.
- 2. Remove the red cap from the fixation point.
- 3. Remove the defective light bulb.
- 4. Insert a new light bulb.
- 5. Replace the red cap on the fixation light.

REFERENCE

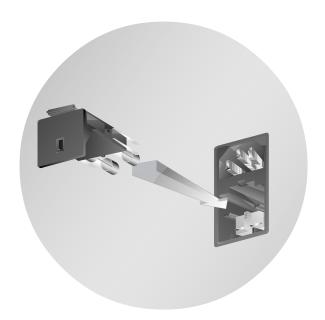
For instructions on replacing the Zeiss slit lamp fixation bulb, see the Zeiss model 30 SL and model 30 SL/M slit lamp operating instructions.

Changing the Slit Lamp Fuse (for IRIDEX slit lamp workstation only)

REFERENCE

For instructions on replacing the Zeiss slit lamp fuse, see the Zeiss model 30 SL and model 30 SL/M slit lamp operating instructions. To check or change fuses:

- 1. Unplug the slit lamp main power cable from the electrical outlet.
- 2. Remove the other end of the slit lamp power cord from the main power port. Beneath the main power port is the fuse cartridge.
- 3. Using a small screwdriver, gently push against the two locking tabs on either side of the fuse cartridge until the cartridge pops up from the port.
- 4. Remove the cartridge.
- 5. Remove and inspect both fuses.
- 6. If one or both are blown, replace them with new fuses.
- 7. Gently push the fuse cartridge back into the port until the locking tabs latch.



Clinical Applications & Safety

Indications for clinical use

The OcuLight Symphony Adapter, when connected to the OcuLight SLx/GLx/TX console, provides diagnostic and therapeutic capability of retinal photocoagulation and for laser trabeculoplasty in the treatment of glaucoma.

Contraindication

Do not treat albino patients.

Recommended procedure for clinical use

This section contains general guidelines and is not intended to suggest treatment techniques. Qualified physicians should review the available literature presented in clinical papers before using the OcuLight Symphony Adapter.

Power density and spot size

Tissue response to laser light is primarily determined by power density. Power density (Watts/cm²) is laser power (Watts) divided by the area (cm²) of the illuminated spot; therefore, you can increase power density either by increasing the laser power or by decreasing the spot size.

Power and duration

If you are uncertain of tissue response, always start with the lower power settings and increase the power until you observe satisfactory clinical lesions.

Shorter pulse durations require higher power densities to create a burn; however, very short pulse durations can be potentially dangerous.

Red aiming and treatment beams

Since the red aiming beam and the treatment beam come to focus at the same optical point, ensure that the aiming beam is always in sharp focus during laser delivery. An out-of-focus spot may not produce a clinically satisfactory lesion.

CAUTION

Take particular care when examining infants or aphakic patients.

NOTE

Avoid dilating the patient's pupils unless necessary for treatment.

WARNING

The relationship between spot size and resultant power density is not linear. Halving the spot size quadruples the power density. The physician must understand the relationship between spot size, laser power, power density, and laser/tissue interaction before using the OcuLight Symphony Adapter.

Safety

CAUTION

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

WARNING

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

WARNING

Always verify that the OcuLight Symphony Adapter is properly connected to the OcuLight console. An improper connection may result in an inadvertent secondary laser beam. Severe eye or tissue damage could occur.

WARNING

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.

Preventing unintended exposure of laser energy

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 this manual and the OcuLight console manuals before using the OcuLight Symphony Adapter.

Preventing unauthorized use of the system

This device is intended for use only by you, the qualified physician. The applicability of the equipment and treatment techniques selected is your sole responsibility. When you leave the OcuLight SLx/GLx/TX console and the

OcuLight Symphony Adapter unattended, turn off the system and remove the key to prevent unauthorized use.

Ensuring safe operation

Do not use the OcuLight Symphony Adapter if you suspect it is not functioning properly.

Connect the OcuLight Symphony Adapter only to the OcuLight SLx/GLx/TX console, not to any other console.

Preventing reflection hazards

Laser beams reflected from specular surfaces can harm your eyes, the patient's eyes, or others' eyes. Any mirror or metal object which reflects the laser beam can constitute a reflection hazard. Make sure to remove all reflection hazards near the laser. Use nonreflecting instruments whenever possible. Be careful not to direct the laser beam at unintended objects.

Preventing fire and explosion hazards

Do not operate the OcuLight SLx/GLx/TX console and OcuLight Symphony Adapter in the presence of flammables or explosives such as volatile anesthetics, alcohol, and surgical preparation solutions.

Ensuring ocular protection

Protection for the physician

An eye safety filter on the OcuLight Symphony Adapter ensures that any laser radiation returned to your eyes during clinical use is below Class 1/I limit.

Protection for all persons in the treatment room — laser safety eyewear requirements

When using the OcuLight SLx/GLx/TX console with the OcuLight Symphony Adapter, a Laser Safety Officer should determine the need for safety eyewear for others in the treatment room based on the MPE, Nominal Ocular Hazard Area (NOHA), and Nominal Ocular Hazard Distance (NOHD) for the OcuLight Symphony Adapter and the OcuLight SLx/GLx console used and the configuration of the treatment room.

Regulatory compliance safety features

The OcuLight Symphony Adapter complies with 21 CFR subchapter J as administered by the Center for Devices and Radiological Health of the Food and Drug Administration (FDA).

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

Eye safety filter

The eye safety filter ensures that all laser radiation returned to the physician and any co-observers is below Class 1/I limits.

Safety interlock

The laser fiber-optic connector attached to the OcuLight Symphony Adapter cannot be opened without the use of special tools. The OcuLight Symphony Adapter is also safety interlocked at the fiber-optic port on the OcuLight SLx/GLx/TX console.

WARNING

Do not operate the OcuLight SLx/GLx console and OcuLight Symphony Adapter in the presence of flammables or explosives such as volatile anesthetics, alcohol, and surgical preparation solutions.

WARNING

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

REFERENCE

See your OcuLight console manuals for more information about the formula used to calculate the worst case NOHD for the OcuLight Symphony Adapter and the OcuLight console.

REFERENCE

For further information, you may refer to: IEC 60825-1 and ANSI Z136.1.

Location of regulatory compliance and other system labels

Serial number label

Serial #_SCxxxx Made in USA

CE label

(E₀₃₄₄

Fiber Switch label





Laser aperture, laser emission labels



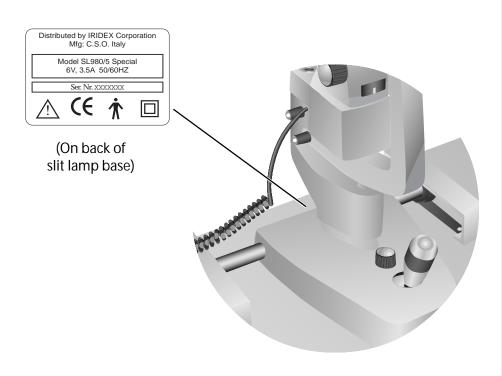


Eye safety filter label

IRIS Medical **810 nm + 532 nm**



810 nm Laser eye safety filter



Slit lamp specifications label

