TruFocus™ LIO+
Operator Manual

IRIDEX®

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Revision C

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Contents

Introduction

About the TruFocus LIO+

The TruFocus™ LIO+, when connected to the OcuLight® console, adds the therapeutic capability of transpupillary retinal photocoagulation to the diagnostic indirect ophthalmoscope. It enables you to deliver laser energy to pathologies in the far periphery of the retina and to treat supine patients.

The TruFocus LIO+ is ideal for patients who are best examined and treated in a supine position, including infants in neonatal units, small children, and disabled patients. The non-moving eye safety filter protects your eyes while providing a clear view of the developing lesion. The exclusive TruFocus optical system provides consistent treatment results by offering the capability of changing working distance and lens position without changing laser focus adjustments. Its unique controls allow you to move the laser and the illumination field separately or both together. Fully enclosed optics prevent misalignment and contamination.

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 console and the TruFocus LIO+ in accordance with the procedures described in your console manual and this manual. Failure to do so may harm yourself, your patient, or others.

TruFocus LIO+ Specifications

Standard-Spot Dual Wavelength TruFocus LIO+

Console compatibility

OcuLight GL

OcuLight GLx

OcuLight TX

OcuLight SLx

OcuLight OR

IQ 810™

Console firmware compatibility

OcuLight GL version 3.2 and above

OcuLight GLx version 3.3 and above

OcuLight TX version 4.0 and above

OcuLight SLx version 4.1 and above

OcuLight OR version 2.0 and above

IQ 810 version 1.0 and above

Treatment wavelength

Diode-Pumped, Frequency-Doubled Solid State, 532 nm

Laser Diode, 810 nm

Laser spot size

360 µm spot at the retina using a 20 D lens

Headset styles

Cap, strap

Standard-Spot 810 nm Wavelength TruFocus LIO+

Console compatibility

OcuLight SL

OcuLight SLx

IQ 810

Treatment wavelength

Laser Diode, 810 nm

Laser spot size

360 µm spot at the retina using a 20 D lens

Headset styles

Cap, strap

Large-Spot 810 nm Wavelength TruFocus LIO+

Console compatibility

OcuLight SL (with optional large-spot upgrade)

OcuLight SLx

IQ 810

Treatment wavelength

Laser Diode, 810 nm

Laser spot size

1.3 mm spot at the retina using a 20 D lens

Headset styles

Cap, strap

Warranty and Service

NOTE

Your console may not be configured for Large-Spot delivery device compatibility.

Warranty

The TruFocus LIO+ carries a standard factory warranty.

Product registration

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

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.

Operation

About the Components

After unpacking the contents of the TruFocus LIO+ package, ensure that you have received all of the components ordered. Check the components carefully before use to ensure that no damage occurred during transit.

Along with this manual, you should have the TruFocus LIO+, zero-diopter lenses, and a spare halogen bulb.

NOTE

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

TruFocus LIO+

The TruFocus LIO+ delivers the treatment and aiming beam from the console to the patient's eye. It consists of:

- Optical assembly
- Controls for adjusting the headpiece
- Controls for adjusting the position of the optical assembly
- Controls for adjusting the eyepieces
- Controls for selecting the illumination light filter
- Controls for adjusting the aperture size of the white illumination beam
- Controls for moving the treatment and aiming beams vertically
- Controls for moving the entire illuminated field and treatment/aiming beam simultaneously
- Identification of wavelength engraved on fiber adapter cap

Cable assembly

Fiber-optic cable

The fiber-optic cable and connector is part of the cable assembly attached to the TruFocus LIO+. The fiber-optic cable transmits the laser light from the console to the TruFocus LIO+ optics.

Illumination cable

The illumination cable and connector is also part of the cable assembly. The illumination power supply is built into the console. The connection of the illumination connector to the console allows you to adjust the intensity of the illuminated field using the console controls.

Zero-diopter lenses

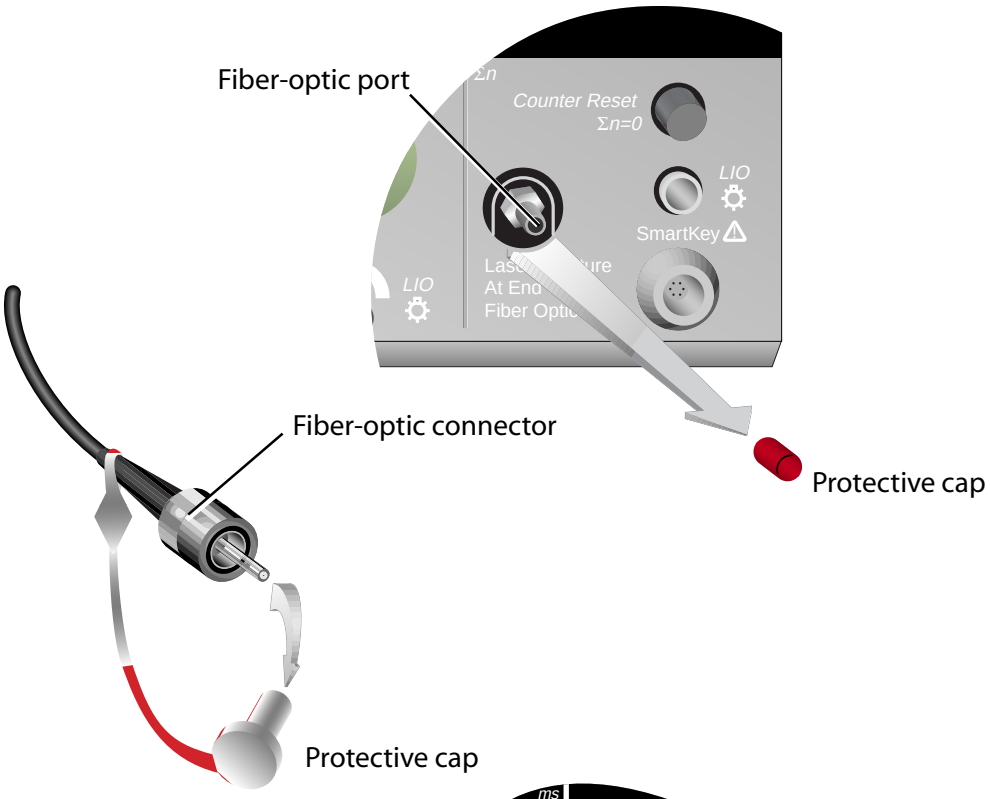
One pair of zero-diopter lenses is included with the TruFocus LIO+. If desired, you may interchange these lenses with the two-diopter lenses that are factory-mounted in the binocular eye pieces.

Connecting the Components

Using the TruFocus LIO+ as a therapeutic device

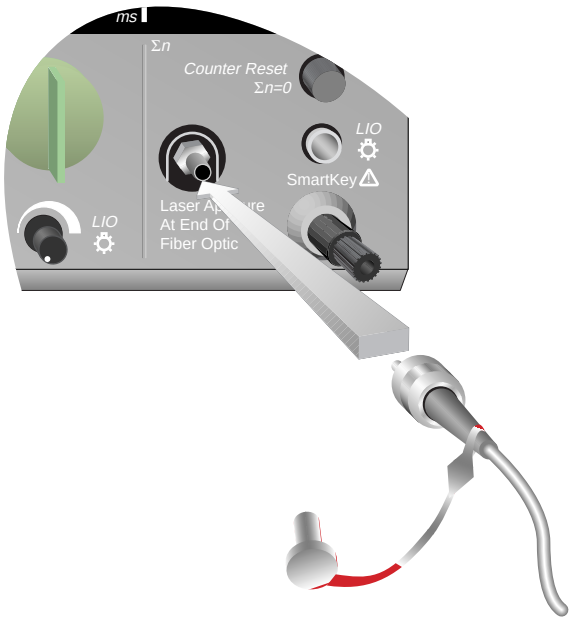
Connect the fiber-optic to the console

Remove the protective caps from the console fiber-optic port and from the TruFocus LIO+ fiber-optic connector.



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

If the TruFocus LIO+ is properly connected, when you turn on the console, LIO+ or LS-LIO+ displays on the console status panel.



WARNING

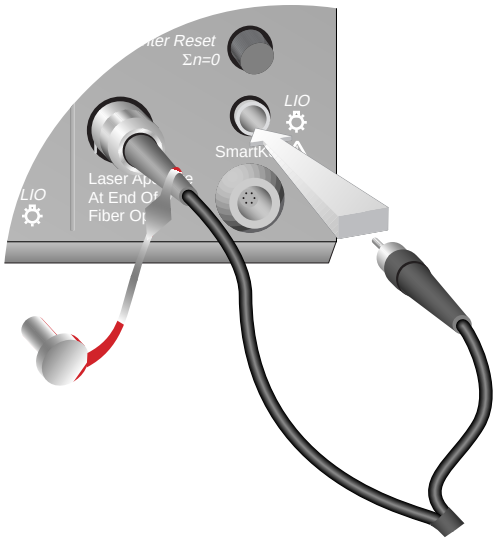
Always inspect the fiber-optic cable before connecting it to the console to ensure that it has not been damaged. A damaged fiber-optic cable could cause accidental laser exposure or injury to yourself, your patient, or others in the treatment room.

WARNING

Do not use the TruFocus LIO+ with any laser system other than an IRIDEX console. Such use may void any product warranties and jeopardize the safety of the patient, yourself, and others in the treatment room.

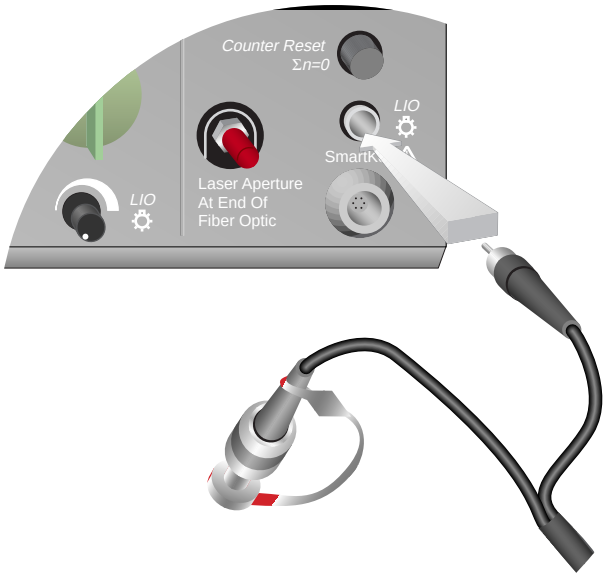
Connect the illumination connector to the console

Insert the illumination connector into the console TruFocus LIO+ receptacle. Press firmly to seat the connector.



Using the TruFocus LIO+ as a diagnostic device

Connect the illumination connector to the console.



Adjusting the Fit

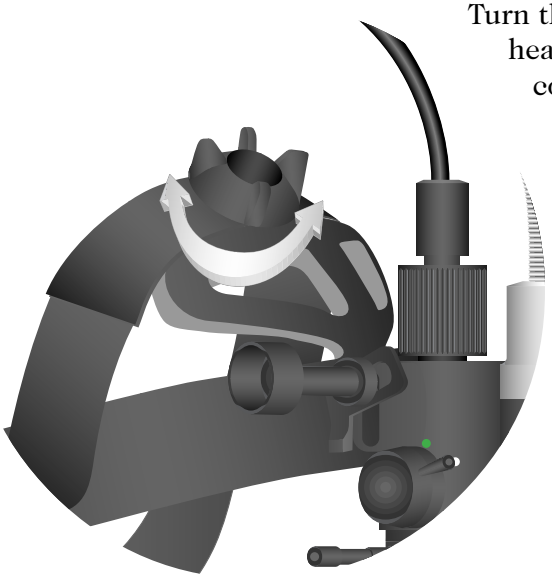
Fitting the headpiece

Adjusting the head size

Turn the knob on the strap at the back of the headpiece counter-clockwise to enlarge the circumference of the strap enough to easily fit over your head. Place the TruFocus LIO+ on your head. Turn the knob clockwise until the TruFocus LIO+ fits securely.

Adjusting the height

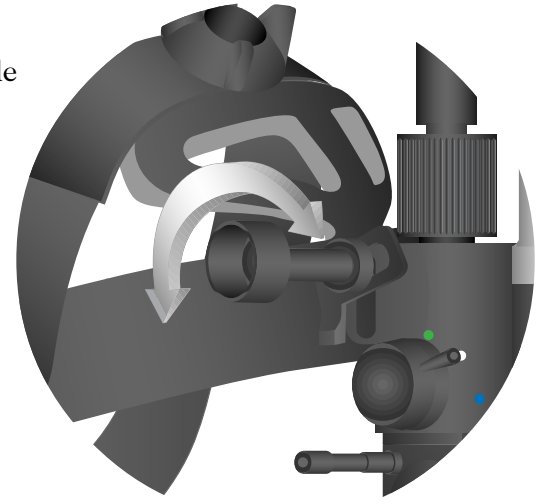
Turn the knob at the top of the headpiece until the headband is comfortably positioned.



Example of cap style headpiece

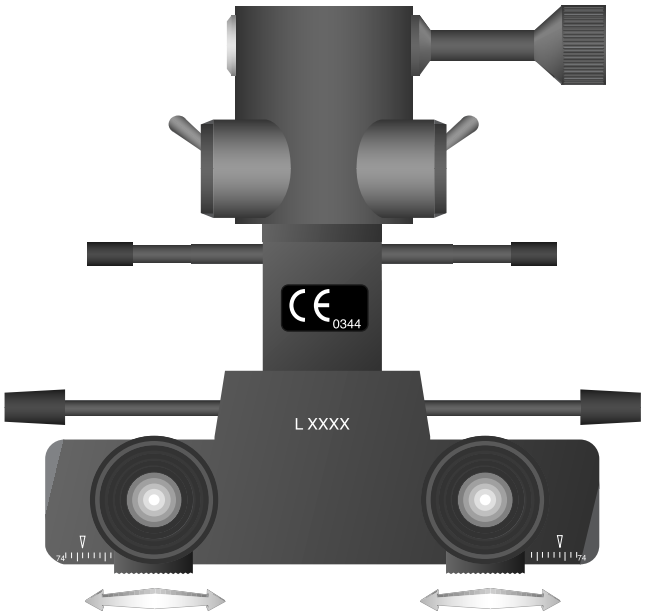
Adjusting the optical unit

While holding the optical unit, loosen the adjustment knob. This enables you to move the optical unit up and down, in and out, and tilt it forward and backward. Make the necessary adjustments to obtain a comfortable view and tighten the knob to secure the optical unit.



Adjusting the eyepieces

Slide each eye piece to the correct position by pushing the finger tabs under each eyepiece (interpupillary distance adjustment). Place a viewing target 36 cm (14 inches) away for the TruFocus LIO+. Close one eye. Adjust the separation until you see the entire target. Do the same with the other eye. The eyepieces are properly adjusted when each eye sees the entire target.

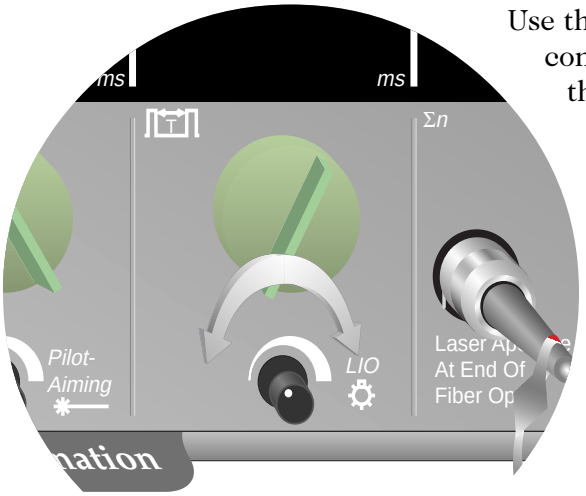


Adjusting the Illumination Light and Aiming Beam

Using the TruFocus LIO+ as a therapeutic device

Adjusting the illumination light and aiming beam ensures that the treatment beam will be in the field of view when the TruFocus LIO+ is used for therapeutic laser treatment.

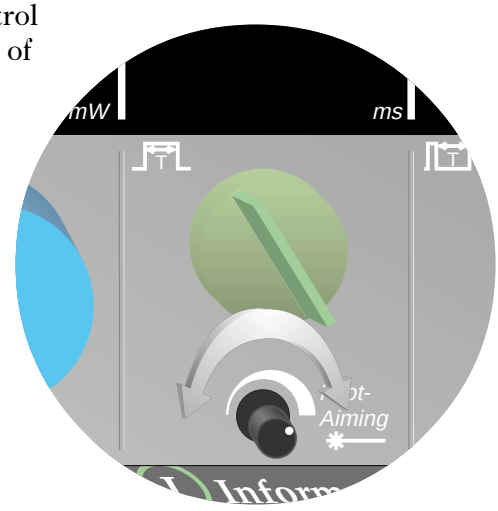
Adjusting the white illumination beam intensity



Use the illumination brightness control on the console to adjust the intensity of the white illumination beam.

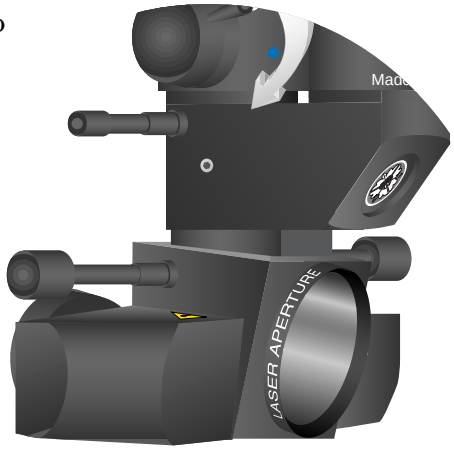
Adjusting the aiming beam intensity

Use the Pilot-Aiming adjustment control on the console to adjust the intensity of the red aiming beam. Use the lowest setting that still allows you to clearly see the aiming spot on the patient's retina.

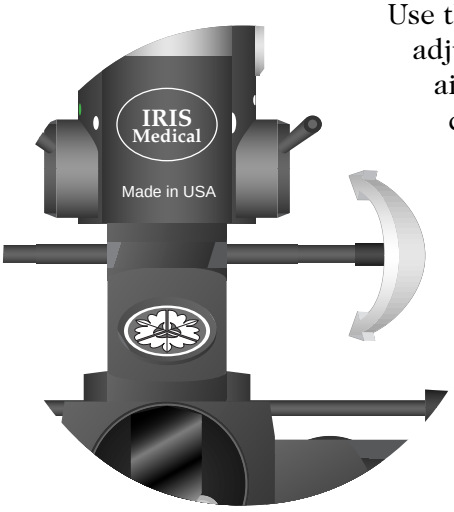


Positioning the white illumination beam

Use the vertical adjustment control to center the white light within the field of view. If the illumination beam appears to be displaced to one side, move both interpupillary distance adjustment finger tabs in the same direction until the light is centered.



Positioning the red aiming beam



Use the aiming beam/treatment beam adjustment control to position the red aiming beam within the field of view. The console delivers the treatment beam to the site illuminated.

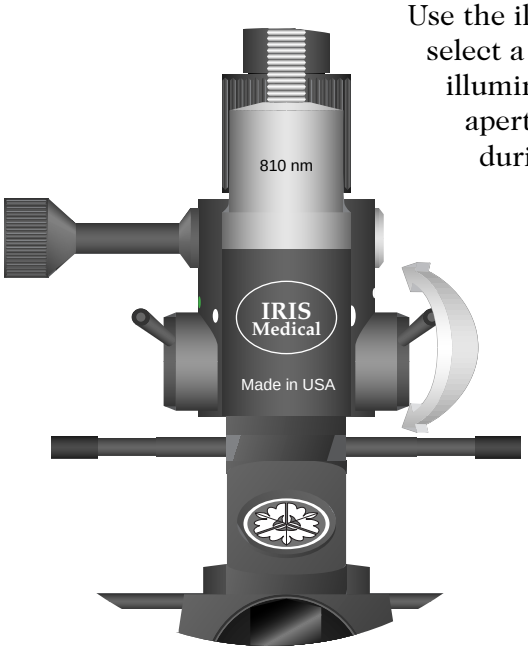
Using the Special Function Controls

Selecting the illumination filter

Use the illumination filter controls to select red-free, cobalt or white light illumination. White light is most frequently used during laser treatment.

Selecting the illumination aperture size

Use the illumination aperture control to select a small, medium, or large illumination aperture. The large aperture is most frequently used during laser treatment.



Before Treating Patients

REFERENCE

Read the **Clinical and Safety** sections of your console manual and this manual before using the TruFocus LIO+.

REFERENCE

See the **Connecting the Components** sections of your console manual and this manual for connection instructions.

1. Ensure that the console and TruFocus LIO+ are properly connected and set up.
2. Post the laser warning sign outside the treatment room door.

Treating a Patient

1. Turn on the console.
2. Ensure that the TruFocus LIO+ fits properly.
3. Make the necessary illumination light and aiming beam adjustments.
4. Select the illumination filter.
5. Set the treatment parameters.
6. Position the patient.
7. Place a patch over the eye not being treated.
8. Ensure that all ancillary personnel in the treatment room are wearing the appropriate laser safety eyewear.
9. Select Treat mode.
10. If desired, adjust the intensity of the red aiming beam.
11. Position the laser-coated aspheric lens on the eye to be treated.
12. Locate the retinal pathology to be treated.
13. Press the footswitch to activate the treatment beam.
14. When you do not require the treatment beam, remove your foot from the footswitch and place the console in Standby mode.

REFERENCE

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

REFERENCE

See the **Adjusting the Fit of the TruFocus LIO+** and **Adjusting the Illumination Light and Aiming Beam** sections of this manual for adjustment instructions.

REFERENCE

See the **Selecting the Illumination Filter** section of this manual for selection instructions.

REFERENCE

See the **Clinical and Safety** sections of your console manual and this manual for important laser safety eyewear information.

WARNING

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

Concluding Patient Treatment

REFERENCE

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

1. Place the console in Standby mode.
2. If desired, record the number of exposures and any other treatment parameters.
3. Turn off the console and remove the key to prevent unauthorized use.
4. Disconnect the TruFocus LIO+ input connector from the console fiber-optic port. Cover the fiber-optic port and the connector with the protective caps.
5. Disconnect the illumination light input connector from the console.
6. If desired, inspect, clean, and store the aspheric lens in accordance with your manufacturer's instructions.
7. If desired, inspect, clean, and store the TruFocus LIO+.
8. If desired, inspect, clean, and store the console.
9. If desired, remove the laser warning sign from the treatment room door.

Troubleshooting

Reporting problems

Should you experience problems with yourTruFocus LIO+, 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 console and the TruFocus LIO+ before contacting your local IRIDEXTechnical Support representative.

REFERENCE

See the **Operation** sections of your console manual and this manual for more information.

Problem	Action
Inadequate or no aiming beam	• Ensure that the TruFocus LIO+ is properly connected to the console. • Ensure that the console is in Treat mode. • Turn the Aiming Beam control fully clockwise. • Ensure that the fiber-optic connector is not damaged. • If possible, connect another IRIS Medical delivery device and place the console in Treat mode. If the aiming beam is still not visible, contact your local IRIDEX Technical Support representative.
No treatment beam	• Ensure that the remote interlock has not been activated. • Ensure that the aiming beam is present and bright. • If you still have no treatment beam, contact your local IRIDEX Technical Support representative.

Problem	Action
No illumination light	• Ensure that the illumination connector is connected to the console. • Ensure that the special function control is not between detents. • Check the bulb and replace, if necessary.
Illumination light is too dim	• Ensure that the special function control is not between detents and that the large aperture is selected. • Adjust the console illumination intensity control.
The aiming beam is large or out of focus on the patient's retina	• Readjust your working distance between the TruFocus LIO+ headset and the examination lens. The aiming beam should be sharply defined and at its smallest diameter when in focus.

Problem	Action
The treatment lesions are variable or intermittent	• The TruFocus LIO+ may be slightly out of focus. This decreases power density . Readjust your working distance to obtain the smallest spot size. • A poorly centered laser beam may be clipping on the examination lens or on the patient's iris. Adjust the laser beam in the illuminated field. • The laser treatment parameters may be too close to the tissue response threshold for consistent response. • Increase the laser Power and/or exposure Duration. Alternatively laser power density may be increased by selecting a lower diopter examination lens to reduce the laser spot size on the retina. This will also alter your field of view
Status panel reads: Connect Fiber	• Ensure that the delivery device is properly connected.

Maintenance

Inspecting and Cleaning

Routine care

- Do not tightly kink or bend the fiber-optic.
- When connected to the console, ensure that the fiber-optic is located away from high traffic areas.
- Keep the dust window and the hand held aspheric lens free of fingerprints.

Inspect the TruFocus LIO+

Frequently inspect the TruFocus LIO+ for dirt, debris, and damage.

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. Place the protective cap on the fiber-optic connector.

Clean the external surfaces

Wipe headpiece surfaces with a soft cloth dampened with a mild detergent.

Clean the hand held aspheric lens

Follow the manufacturer's instructions for cleaning the handheld aspheric lens.

Clean the binocular eyepieces

Moisten a lens tissue with lens cleaner and gently wipe the eyepieces to remove fingerprints or debris.

Clean the dust window

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.

CAUTION

Turn off the console before inspecting any delivery device components.

CAUTION

Always handle the fiber-optic 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 connector when the TruFocus LIO+ is not in use.

Changing the Illumination Lamp

CAUTION

Do not touch the lamp's glass envelope. Remove any fingerprints from the lamp envelope with a cotton-tipped swab moistened with methanol.

1. Unscrew the retaining cap.
2. Remove the burned-out illumination lamp.
3. Insert an identical type of lamp, aligning the key on the lamp base with the slot in the TruFocus LIO+.
4. Screw on the retaining cap.

Clinical Applications

Indications for clinical use

The TruFocus LIO+ is indicated for retinal photocoagulation and is typically used for treating outside of the arcades.

Contraindication

The TruFocus LIO+ is not indicated for cases involving laser photocoagulation within the arcades.

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 theTruFocus LIO+ delivery device. A Reference Catalog of clinical papers and presentations is available through IRIDEX Marketing.

Panretinal photocoagulation (outpatient)

- Slit lamp delivery is typically used to treat the posterior 80% of the retina with the use of mirrored contact lenses. The most peripheral 20% of the retina can more easily be seen and treated with scleral depression and the TruFocus LIO+.
- The prismatic effect of the hand held aspheric lens allows for easier treatment around cataracts (cortical spokes), and hemorrhage and vitreous debris. The hand held lens is rocked from side-to-side in addition to utilizing scleral depression to push ‘untreated’ retina into the view of the TruFocus LIO+.

Panretinal photocoagulation (operating room)

The TruFocus LIO+:

- Is particularly useful for diabetic patients undergoing pars plana vitrectomy
- Allows for better treatment of the superior quadrant than does the endolaser.
- Allows better visibility through phakic gas-filled eyes since there are fewer reflections than present with biconcave lenses.
- Minimizes the risk of lens damage by the endolaser probe when treating in the far periphery
- Allows for complete inspection and treatment of the peripheral edges of a giant tear.

Sealing treatment

- The TruFocus LIO+ allows easier treatment of the anterior retina than is possible with either 'panfundus' or mirrored-styled contact lenses used at the slit lamp.
- Concurrent scleral depression is often helpful to flatten pockets of subretinal fluid near the retinal tear or detachment using sealing treatment.

Treating patients who have a gas-filled eye

Postoperatively, patients whose eyes harbor gas bubbles can be quite difficult to treat because of troublesome reflections at the slit lamp. The TruFocus LIO+ allows positioning of the eye and the patient's head to minimize these reflections.

Treating patients with recent ocular surgery

Postoperative patients often have corneal striae, vitreous and anterior chamber haze, etc. The TruFocus LIO+ provides better visibility through these media opacities. As a non-contact procedure, laser indirect ophthalmoscopy:

- Avoids discomfort induced by pressure from a contact lens in the postoperative patient.
- Reduces stress to recently sutured wounds.
- Minimizes the risk of infection.

Treating patients with a localized vitreous hemorrhage

The prismatic effect of the lens and use of scleral depression may assist in moving vitreous hemorrhage out of the way or pushing untreated retina into the view of the laser beam. The 810 nm (infrared) wavelength penetrates vitreous hemorrhage better than the 514-532 nm (green) wavelengths.

Treating patients with a scleral buckle

The thickness of the scleral buckle allows conventional transconjunctival cryotherapy. The peripheral buckle may also be difficult to reach with slit lamp delivery.

Treating patients with small pupils

Patients with small pupils and particularly those with media opacities are difficult to treat with a slit lamp. Better visualization through a small pupil may be obtained with the TruFocus LIO+ and an appropriate choice of auxiliary lens.

Treatment considerations

Positioning

Place the patient in a supine position. Position your head (TruFocus LIO+) approximately 37 to 50 cm (15 to 20 in) from the patient's eye. Direct the white illumination light and the red aiming beam into the patient's eye. Hold the aspheric lens (laser coated) with the white ring side toward the patient so that the patient's pupil is centered in the lens. Adjust the position of the lens until a clear image of the retina fills the area of the lens. A 20-diopter (20D) aspheric lens is most commonly used for laser indirect ophthalmoscopy. This provides an aperture of 51 mm and 45° retinal field of view

Using the scleral depressor

The use of the scleral depressor is extremely helpful when treating with the TruFocus LIO+:

- The scleral depressor helps stabilize the eye, acting as a 'splint' to inhibit voluntary and involuntary eye movement.
- The depressor helps to manipulate the eye in various fixations and helps to flatten residual subretinal fluid.
- The depressor decreases the thickness of the ocular media by bringing the retina closer to the front of the eye.
- The depressor can stretch and 'thin out' the choroid to reduce its cooling effect, contributing to a hotter burn.
- Since the eye has a curved surface, the depressor can flatten the retina and manipulate it into a position more perpendicular to the laser beam. This helps to create a round spot with a more evenly distributed power density.

Moving the spot

To minimize neck fatigue, move the eye with the depressor while holding the TruFocus LIO+ steady to move the spot, or shift the handheld condensing lens. Because the plus (+) lens has a large amount of 'base-in' prism, you can move the laser spot with the motion of the handheld lens. To achieve the largest spot movement, move your head to the desired position.

Positioning the condensing lens

- Treat within the central two-thirds of the lens to minimize peripheral aberrations.
- There are two specular reflections on the lens corresponding to the front and back surfaces. To improve visibility within the center of the lens, tilt the lens to move the two white reflections apart.
- When treating in the peripherythe laser spot develops astigmatism (the spot becomes oval and elongated). To achieve a more round spot, tilt one edge of the lens toward the patient.Tilting the lens toward the patient induces compensating astigmatism in the opposite direction.
- To help guide the laser beam around media opacities and hemorrhage, move the lens from side-to-side.

Power density and spot size

Tissue response to laser light is primarily determined by power density Power density (Watts/cm^2) is laser power (Watts) divided by the area (cm^2) of the illuminated spot; therefore, you can increase power density either by increasing the laser power or by decreasing the spot size.

It is important to remember that changing the aspheric lens affects spot size, power density, and the field of view.

Choosing anesthesia

Topical anesthesia is most commonly used and has advantages over general anesthesia. Topical anesthesia decreases the blink reflex. The patient is not sedated and maintains the ability to change positions if necessary during treatment.

Retrobulbar anesthesia may be desirable when treating the anterior half of the eye. It is often more painful treating anteriorly compared to treating the posterior retina.The disadvantage; however , is the removal of the patient's ability to move the eye is various directions. Scleral depression is vital in manipulating the eye duringTruFocus LIO+ treatment with retrobulbar anesthesia.

NOTE

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 a console and the TruFocus LIO+.

Other factors that can affect spot size include:

- The refractive index of media in the eye, as shown.

Medium	*Spot Size*
Air	Smaller
Fluid	Standard
Silicone	Larger

- Working distance. The smallest spot is obtained when the laser spot is at its focus point on the image plane. Focusing on either side of that point creates a larger spot.
- Refractive status of the eye. The laser spot size on the retina in a myopic eye is smaller than in an emmetropic eye. The converse occurs for the hyperopic eye.

  A x (B/C) = spot size on the retina

  where, A = aerial spot size

  B = diopter power of handheld aspheric lens

  C = power of eye

  Using this formula we arrive the following values

  Emmetropic eye (60D):1100 x (20D/60D) = 360µm spot size on retina

  Myopic eye* (70D):1100 x (20D/70D) = 315µm spot size on retina

  Hyperopic eye* (50D):1100 x (20D/50D) = 440µm spot size on retina

  *This is only an example. The power of myopic or hyperopic eyes vary by patient.

  Positioning the aspheric lens 55 mm from an emmetropic eye should produce a magnified aerial image of the fundus. A myopic eye requires the examination lens to be slightly closer (the hyperopic eye slightly farther) to obtain the desired fundus image.

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. Longer pulse durations may be safer to use with the TruFocus LIO+, but it may be more difficult for you to keep your head steady in an effort to create a round spot.

Repeat interval

Placing multiple treatment spots on the fundus is more easily accomplished utilizing the console's repeat mode. This eliminates constant foot pedal action that is very awkward, especially in a standing position while the surgeon attempts to avoid head motion.

Use of the repeat interval may be less desirable in the air-filled phakic eye where there is a tendency toward smaller, potentially more dangerous spot sizes. Patients who have undergone retinal reattachment with an intraoperative air-fluid exchange may still have trapped pockets of subretinal fluid that can affect size and shape of the burns and can cause additional problems.

The time required between pulses should allow enough time for the surgeon to move the laser beam to another location. Laser spot placement that is done too rapidly can lead to inaccuracies in placement of the lesions. A repeat interval of 300 ms to 500 ms seems ideal.

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.

REFERENCE

See the **Adjusting the Illuminating Light and Aiming Beam** section of this manual for proper focusing and set up procedures.

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 TruFocus LIO+ is properly connected to the 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.

WARNING

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

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 console operator manual before using the TruFocus LIO+.

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 console and TruFocus LIO+ unattended, turn off the console and remove the key to prevent unauthorized use.

Ensuring safe operation

Do not use the TruFocus LIO+ if you suspect it is not functioning properly.

Connect the 810 nm TruFocus LIO+ only to an OcuLight SL, OcuLight SLx, or IQ 810 console. Connect the dual wavelength TruFocus LIO+ to either an OcuLight SL, OcuLight SLx, OcuLight GL, OcuLight GLx, OcuLight TX or OcuLight OR console. Do not connect the TruFocus LIO+ to any other console. If you operate the TruFocus LIO+ with any other laser, you could jeopardize your patient's safety, as well as your own, and void product warranty

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 console and TruFocus LIO+ in the presence of flammables or explosives such as volatile anesthetics, alcohol, and surgical preparation solutions.

Ensuring ocular protection

Protection for the physician

An integral eye safety filter on theTruFocus LIO+ ensures that any laser radiation returned to your eyes during clinical use is below Class 1 limit.

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

When using the console with the TruFocus LIO+, 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 theTruFocus LIO+ and the console used and the configuration of the treatment room.

Regulatory compliance safety features

The TruFocus LIO+ 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 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 I limits.

Laser emission indicator

Illumination of the greenTreat light on the console provides a visible warning that laser radiation may be emitted from theTruFocus LIO+.

Safety interlock

The TruFocus LIO+'s protective housing and the laser fiber connector attached to the TruFocus LIO+ cannot be opened without the use of special tools. The TruFocus LIO+ is also safety interlocked at the fiber-optic port on the console.

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

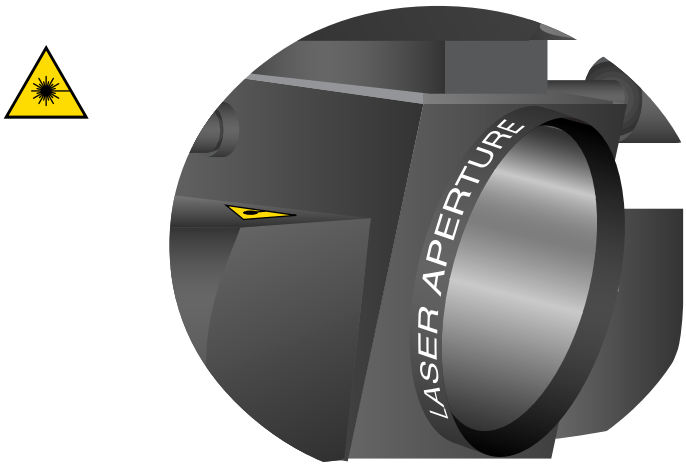
See your console manual for more information about the formula used to calculate the worst case NOHD for the TruFocus LIO+ and the console in use.

REFERENCE

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

Laser aperture labels

LASER APERTURE LASER APERTURE LASER APERTURE



CE label