

TruFocus™ LIO+

Operator Manual



TruFocus™ LIO+ Operator Manual
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1 Introduction

The TruFocus™ LIO+ (Laser Indirect Ophthalmoscope), when connected to an IRIDEX laser, adds the therapeutic capability of transpupillary retinal photocoagulation. It enables you to deliver laser energy to the far periphery of the retina and to treat supine patients. The eye safety filter protects your eyes while providing a clear view of the target area. Fully enclosed optics prevent misalignment and contamination.

Indications for Use

The TruFocus LIO+ is indicated for transpupillary retinal photocoagulation. Qualified physicians should review the available literature presented in clinical papers before using the TruFocus LIO+ delivery device.

Contraindications

The TruFocus LIO+ is not indicated for cases involving laser photocoagulation within the arcades. Do not treat albino patients who have no pigmentation.

Factors Affecting Spot Size

- The refractive index of media in the eye.
- Working distance. The smallest spot is obtained when the laser spot is at its focus point on the image plane.
- Refractive status of the eye. The laser spot size on the retina is smallest in a myopic eye and largest in a hyperopic eye.

$A \times (B/C) = \text{spot size on the retina where:}$

- A = aerial spot size
- B = diopter power of handheld aspheric lens
- C = power of eye

Using this formula*:

- Emmetropic eye (60D): $1100 \times (20D/60D) = 360 \text{ mm spot size on retina}$
- Myopic eye (70D): $1100 \times (20D/70D) = 315 \text{ mm spot size on retina}$
- Hyperopic eye (50D): $1100 \times (20D/50D) = 440 \text{ mm spot size on retina}$

*Example only, power may vary by patient.

Positioning the aspheric lens 55 mm from an emmetropic eye should produce a magnified aerial image of the fundus.

Warnings and Cautions

WARNINGS:

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

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

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

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

Always inspect the fiber-optic cable before connecting it to the laser 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.

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

Do not use the delivery device with any laser system other than an IRIDEX laser. Such use may void product warranties and threaten the safety of the patient, yourself, and others in the treatment room.

CAUTIONS:

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

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

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

Turn off the laser before inspecting any delivery device components.

Always handle the fiber-optic cables with extreme care. Do not coil the cable into a diameter less than 15 cm (6 in).

Do not use the cable retainers on the headset for fiber-optic cables.

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

Do not touch the bulb. Remove any fingerprints from the bulb with a cotton-tipped swab moistened with methanol.

IRIDEX Corporation Contact Information



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Warranty and Service. This device carries a standard factory warranty. This warranty is void if service is attempted by anyone other than certified IRIDEX service personnel.

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

Should you require assistance, please contact your local IRIDEX Technical Support representative or our corporate headquarters.

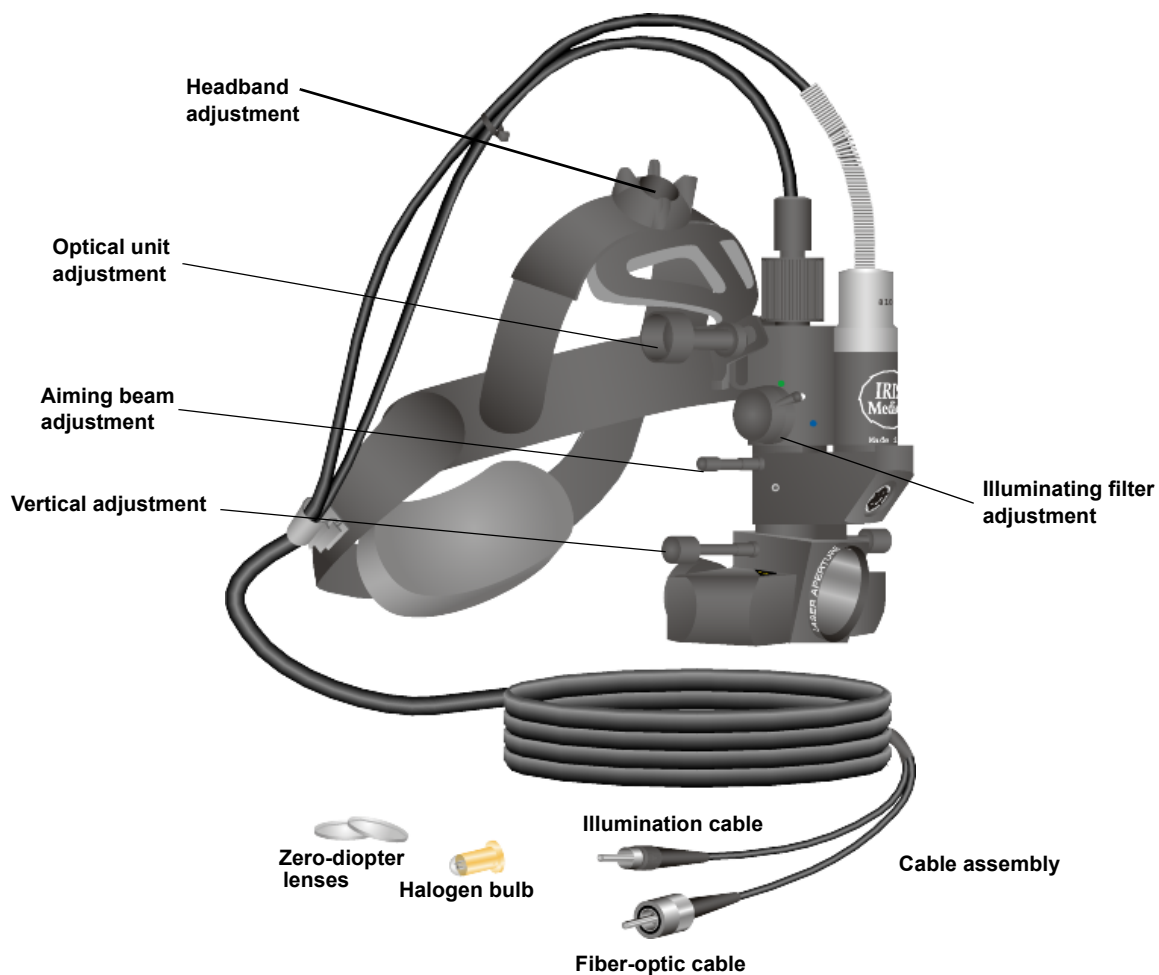


WEEE Guidance. Contact IRIDEX or your distributor for disposal information.

2 Operation

About the Components

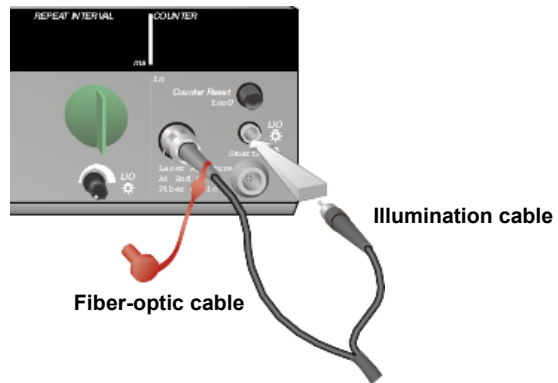
Verify that you have received all of the components in the TruFocus LIO+ package, and check the components carefully before use to ensure that no damage occurred during transit. Along with this manual, you should have the TruFocus LIO+, zero-diopter lenses, and a spare halogen bulb. If there is a problem, contact your local IRIDEX Technical Support representative.



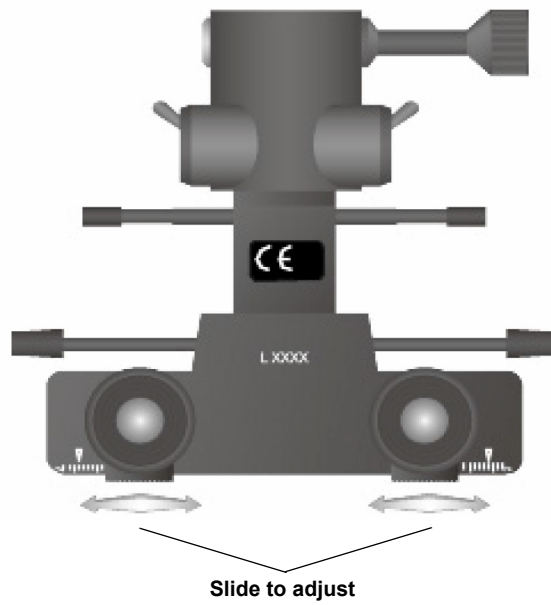
Appearance and type of components may vary based on the delivery device ordered.

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 Cables to the Laser



Adjusting for Pupillary Distance



Treating Patients

BEFORE TREATING A PATIENT:

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

NOTE: Refer to Chapter 5, "Safety and Compliance," and your delivery device manual(s) for important information about laser safety eyewear and eye safety filters.

TO TREAT A PATIENT:

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

TO CONCLUDE PATIENT TREATMENT:

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

3 Troubleshooting

General Problems

Problem	User Action(s)
No display	<ul style="list-style-type: none"> • Verify that the keyswitch is on. • Verify that the components are properly connected. • Verify that the electrical service is on. <p>If there is still no display, contact your local IRIDEX Technical Support representative.</p>
Inadequate or no aiming beam	<ul style="list-style-type: none"> • Verify that the delivery device is properly connected. • Verify that the console is in Treat mode. • Turn the aiming beam control fully clockwise. • Verify that the fiber-optic connector is not damaged. • If possible, connect another IRIDEX delivery device and place the console in Treat mode. <p>If the aiming beam is still not visible, contact your local IRIDEX Technical Support representative.</p>
No treatment beam	<ul style="list-style-type: none"> • Verify that the remote interlock has not been activated. • Verify that the aiming beam is visible. • Verify that the fiber switch is in the correct position for the laser system and wavelength you are using. • Verify that the eye safety filter is in the closed position. <p>If there is still no treatment beam, contact your local IRIDEX Technical Support representative.</p>
No illumination light (LIO only)	<ul style="list-style-type: none"> • Verify that the illumination connector is connected to the console. • Verify that the special function control is not between detents. • Check the bulb and replace it (if necessary).
Illumination light is too dim (LIO only)	<ul style="list-style-type: none"> • Verify that the special function control is not between detents. • Adjust the console illumination intensity control.
The aiming beam is large or out of focus on the patients' retina (LIO only)	<p>Readjust your working distance between the LIO headset and the examination lens. The aiming beam should be sharply defined and at its smallest diameter when in focus.</p>
The treatment lesions are variable or intermittent (LIO only)	<ul style="list-style-type: none"> • The LIO may be slightly out of focus. This decreases power density. Readjust your working distance to obtain the smallest spot size. • A poorly centered laser beam may be clipping on the examination lens or on the patient's iris. Adjust the laser beam in the illumination field. • The laser treatment parameters may be too close to the tissue response threshold for consistent response. Increase the laser power and/or exposure duration, or select a different lens.

Problem	User Action(s)
Does not fit on the mounting plate (OMA only)	<ul style="list-style-type: none"> • Inspect and clean the mounting plate. • Verify that the mounting plate corresponds to your microscope.
Laser and viewing systems are not focussed at the same point (OMA only)	<ul style="list-style-type: none"> • Verify installation of a 175 mm microscope objective lens on the microscope. • Turn on the aiming beam to determine focus position and adjust as necessary.
View is blocked or partially blocked by OMA (OMA only)	Set magnification to 10X or more.

4

Maintenance

TO PROVIDE ROUTINE CARE:

- Do not kink or bend the fiber-optic cable.
- When the fiber-optic cable is connected to the console, ensure that the cable is located away from high traffic areas.
- Do not strike the fiber-optic connector against hard surfaces.
- Keep the optical components free of fingerprints.
- When not in use, cover the LIO+ to keep it free of dust, and store all accessories in suitable storage boxes.

Inspecting the LIO+

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

Cleaning the Fiber-Optic Connector

Always inspect the fiber-optic connector for cleanliness prior to use; if needed, clean the connector using a cotton swab moistened with acetone. Inspect the fiber-optic connector using a minimum of 100X magnification to verify cleanliness. Inspect the lanyard for contamination before re-installing it onto the fiber-optic connector.

Cleaning the External Surfaces

Wipe the external surfaces of the LIO+ (except the optics) with a soft lint-free cloth dampened with a 70/30 Isopropyl Alcohol (IPA) solution.

Cleaning the Optical Components

TO CLEAN THE OPTICAL COMPONENTS:

1. Place 2-3 drops of high-grade acetone onto a cotton swab.
2. Wipe the optics gently in one direction with the swab to remove all dust and debris.
3. Repeat as needed with a fresh swab until all dust and debris have been removed from the optical surfaces.

Changing the Illumination Lamp

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.

5

Safety and Compliance

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

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

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

Protection for the Physician

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

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

Protection for All Treatment Room Personnel

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

Safety Compliance

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

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

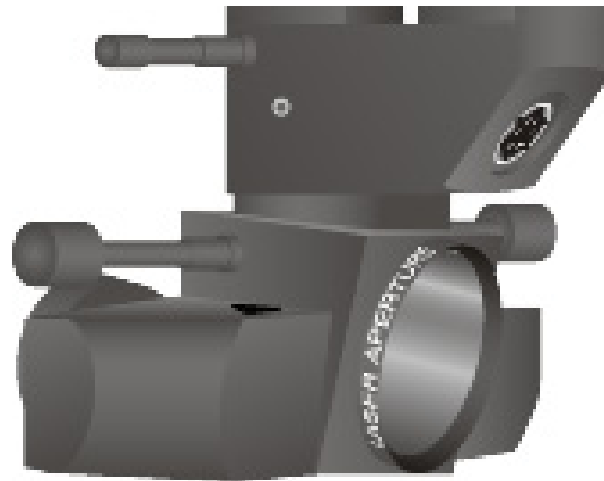
Feature	Function
Eye safety filter	The eye safety filter ensures that all laser radiation returned to the physician and any co-observers is below Class I limits.
Laser emission indicator	Illumination of the green Treat light on the laser provides a visible warning that laser radiation may be emitted.
Safety interlock	The delivery device's protective housing and the laser fiber connector cannot be opened without the use of special tools. The delivery device is also safety-interlocked at the fiber-optic port on the laser.

Labels

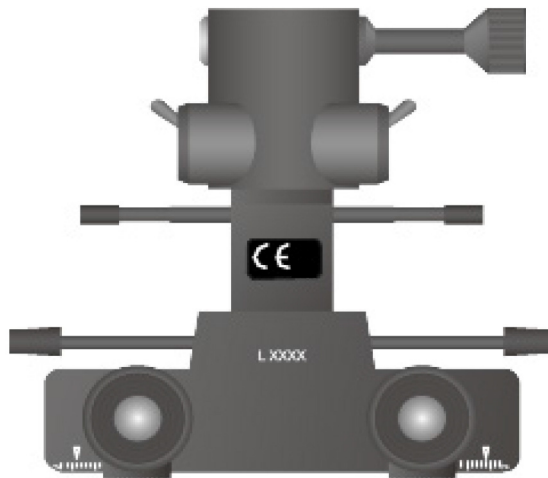
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













































Laser Aperture Label























CE Label



Symbols (As Applicable)

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

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

TruFocus LIO+ Specifications

Specification	Standard-Spot	Large-Spot
Laser compatibility	OcuLight GL OcuLight GLx OcuLight TX OcuLight SLx OcuLight OR OcuLight SL IQ 532 IQ 577 IQ 810	OcuLight SL (with upgrade) OcuLight SLx IQ 810
Laser firmware compatibility (if applicable)	OcuLight GL version 3.2 and above OcuLight GLx version 3.3 and above OcuLight SLx version 4.1 and above	
Laser spot size on retina with 20D lens	360 μm*	1.3 mm*
Eye filter	532 nm and 810 nm 810 nm 577 nm	810 nm
*May vary with refractive power.		