

**TruFocus LIO PremiereTM
Laser Indirect Ophthalmoscope
Operator Manual**



TruFocus LIO Premiere Operator Manual
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1 Introduction	1
Clinical Uses for the LIO	1
Indications For Use	1
Contraindications	3
Factors Affecting Spot Size	4
Warnings and Cautions	4
IRIDEX Corporation Contact Information	5
2 Operation	6
Special Considerations	6
Packing and Unpacking the LIO	7
About the Components	7
Installing the Rechargeable Battery on the Headband	8
Setting Up and Operating the Headband-Mounted Rechargeable Battery and Wall-Mounted Cradle	8
Pre-Procedure Set-Up	9
Instructions to Treat a Patient	11
Instructions For BIO Mode	12
3 Troubleshooting	13
General Problems	13
4 Maintenance	14
Inspecting the LIO	14
Cleaning the Fiber-Optic Connector	14
Cleaning the External Surfaces	14
Cleaning the Optical Components	14
Changing and Cleaning the Headband-Mounted Rechargeable Battery	15
Charging the Headband-Mounted Rechargeable Battery	15
Changing the LED or Halogen Illumination Lamp	16
5 Service	17
6 Safety and Compliance	18
Protection for the Physician	18
Protection for All Treatment Room Personnel	18
Safety Compliance	19
Labels	20
Symbols (As Applicable)	21
TruFocus LIO Premiere Specifications	23
EMC Safety Information	24

1 Introduction

The IRIDEX TruFocus LIO Premiere™ Laser Indirect Ophthalmoscope when connected to the family of IRIDEX lasers adds the therapeutic capability of transpupillary retinal photocoagulation to the wide angle diagnostic capabilities of a binocular indirect ophthalmoscope. It enables you to deliver laser energy to the far periphery of the retina and to treat supine patients. Integrated eye safety filters protect your eyes while providing a clear view of the target area. Fully enclosed optics prevent misalignment and contamination.

The TruFocus LIO Premiere is sold to medical doctors and intended to be used by trained medical professionals familiar with the device and the procedures performed by the device.

The LIO is suitable for use on patients of all ages.

Clinical Uses for the LIO

The LIO is widely used to treat proliferative diabetic retinopathy, retinopathy of prematurity, retinal detachments and tears, and intraocular tumors, such as retinoblastoma.

Indications For Use

The IRIDEX TruFocus LIO Premiere Laser Indirect Ophthalmoscope with the Family of IRIDEX® IQ Laser Systems (IQ 532 [532nm], IQ 577 [577nm], IQ 630-670 [630nm-670nm], IQ 810 [810nm]), hand pieces, delivery devices & accessories that are used with them to deliver laser energy in either CW-pulse, MicroPulse® or LongPulse™ mode. Intended for soft and fibrous tissue, including osseous tissue incision, excision, coagulation, vaporization, ablation and vessel hemostasis in the medical specialties of, dermatology, ear, nose and throat (ENT)/ otolaryngology, and ophthalmology as follows:

532nm:

Dermatology:

- Pigmented Skin Lesions
- Vascular Lesions

Ear, Nose, and Throat (ENT)/ Otolaryngology Otosclerotic:

Hearing loss and/or diseases of the inner ear:

- Stapedectomy
- Stapedotomy
- Myringotomies
- Lysis of Adhesions
- Control of Bleeding
- Removal of Acoustic Neuromas
- Soft tissue Adhesion in Micro/Macro Otologic Procedures

Ophthalmology:

Indicated for retinal photocoagulation, laser trabeculoplasty, iridotomy, iridoplasty including:

- Retinal photocoagulation (RPC) for the treatment of
 - Diabetic retinopathy, including:
 - Nonproliferative retinopathy
 - Macular edema
 - Proliferative retinopathy
- Retinal tears and detachments
 - Lattice degeneration
 - Age-related macular degeneration (AMD)
 - Retinopathy of prematurity
 - Sub-retinal (choroidal) neovascularization
 - Central and branch retinal vein occlusion
- Laser trabeculoplasty, iridotomy, iridoplasty for the treatment of glaucoma, including
 - Primary open angle/Closed angle

577nm

Dermatology:

- Treatment of Vascular and pigmented lesions

Ophthalmology:

Indicated for use in photocoagulation of both anterior and posterior segments including:

- Retinal photocoagulation, panretinal photocoagulation and intravitreal endophotocoagulation of vascular and structural abnormalities of the retina and choroid including:
 - Proliferative and nonproliferative diabetic retinopathy
 - Choroidal neovascularization
 - Branch retinal vein occlusion
 - Age-related macular degeneration
 - Retinal tears and detachments
 - Retinopathy of prematurity
- Iridotomy, iridectomy and trabeculoplasty in angle closure glaucoma and open angle glaucoma

630 - 670nm

Ophthalmology:

Indicated for use in photocoagulation of both anterior and posterior segments including:

- Retinal photocoagulation, panretinal photocoagulation and intravitreal endophotocoagulation of vascular and structural abnormalities of the retina and choroid including:
 - Proliferative and non-proliferative diabetic retinopathy
 - Choroidal neovascularization
 - Branch retinal vein occlusion
 - Age-related macular degeneration
 - Retinal tears and detachments
 - Retinopathy of prematurity
- Iridotomy, iridectomy and trabeculoplasty in angle glaucoma and open angle glaucoma

810nm

Ophthalmology:

Indicated for retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation, iridotomy, including the following examples:

- Retinal photocoagulation for the treatment of:
 - Diabetic retinopathy, including:
 - Nonproliferative retinopathy
 - Macular edema
 - Proliferative retinopathy
 - Retinal Tears, Detachments and Holes
 - Lattice degeneration
 - Age-related macular degeneration (AMD) with choroidal neovascularization (CNV)
 - Retinopathy of prematurity
 - Sub-retinal (choroidal) neovascularization
 - Central and Branch Retinal Vein Occlusion
 - Laser trabeculoplasty, Iridotomy, Transscleral Cyclophotocoagulation (TSCPC) for the treatment of glaucoma, including:
 - Primary open angle
 - Closed angle
 - Refractory Glaucoma (recalcitrant/uncontrolled)

Contraindications

The TruFocus LIO Premiere 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 smaller in a myopic eye and larger 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): $1100 \mu\text{m} \times (20\text{D}/60\text{D}) = 360 \mu\text{m}$ spot size on retina
- Myopic eye (70D): $1100 \mu\text{m} \times (20\text{D}/70\text{D}) = 315 \mu\text{m}$ spot size on retina
- Hyperopic eye (50D): $1100 \mu\text{m} \times (20\text{D}/50\text{D}) = 440 \mu\text{m}$ spot size on retina

*Example only, power may vary by patient.

Positioning the 20D 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.

Carefully select your treatment room and location. Treatment locations should be free of uncovered windows and reflective surfaces that could inadvertently reflect the treatment beam.

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 a compatible 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 kink, bend or coil the cable into a diameter less than 15 cm (6 in).

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

IRIDEX Corporation Contact Information



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Warranty and Service. 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.

Dispose of equipment and accessories in compliance with local and regional regulations.
Contact IRIDEX or your distributor for disposal information.

2 Operation

Special Considerations

The TruFocus Premiere Laser Indirect Ophthalmoscope (LIO) is a modified Heine 500 Binocular Indirect Ophthalmoscope (BIO) with the addition of laser delivery optics. In this system there are two mirrors positioned off-axis with respect to the viewing optics (see *Figure 1* below).

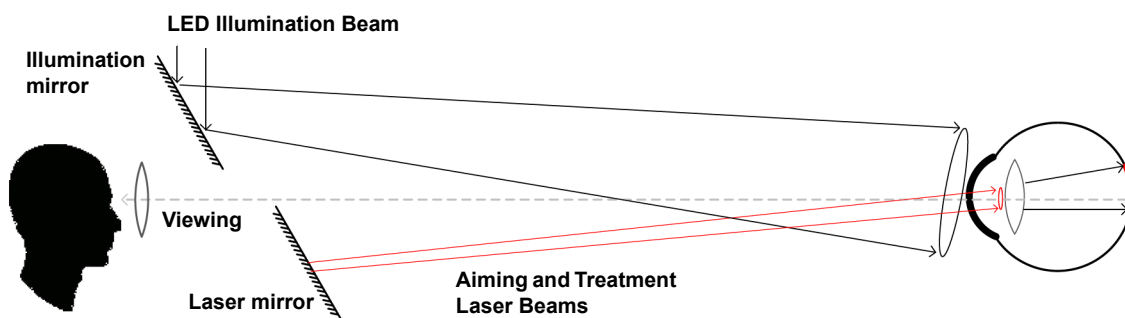


Figure 1. TruFocus LIO Premiere Optics

The illumination mirror is positioned above the viewing plane while the aiming beam and laser treatment beam mirror is positioned below the viewing axis. Unlike single mirror LIO optical systems where the illumination beam and aiming/treatment beams are coaxial, parfocal and are positioned together with a single vertical adjustment and manipulated as a single element, the TruFocus LIO Premiere has two independent mirror controls (see *Figure 2* below), one for illumination the other for the aiming and treatment laser beams.

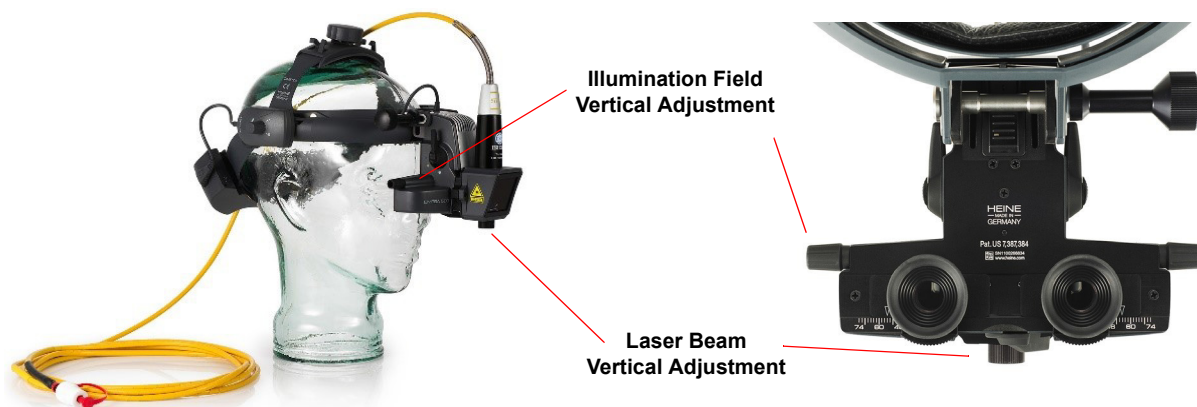


Figure 2. Adjustment Controls

With the use of a condenser lens the illumination field and aim/treatment laser beams will tend to separate at points distal to the lens, but can be adjusted to be concentric with the use of the vertical laser beam control mechanism described above.

NOTE: Reflections of the red aiming beam by various interfaces in the optical path are normal. However, it is good practice to minimize condenser lens tilt in order to minimize aiming beam reflections from the various optical surfaces by maintaining the condenser lens parallel to the pupil plane, making sure all optical surface are clean and free of finger marks and assuring the most convex surface of the condenser lens is facing the clinician.

Packing and Unpacking the LIO

Refer to the Heine 500 IFU included in the LIO carry case for instructions on correct packing and unpacking the LIO from the carry case.

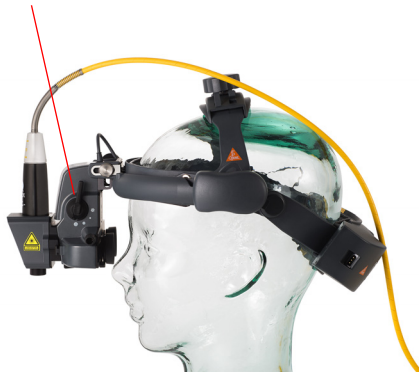
About the Components

Verify that you have received all of the components in the TruFocus LIO Premiere 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 Premiere, zero-diopter lenses, and either a wall-mounted charging cradle and battery or a plug-in transformer and battery. 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.

Illuminated field size adjustment with lock



Headband size adjustment knob

Battery



Cover for LED or halogen bulb

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

Installing the Rechargeable Battery on the Headband

For information on installing the rechargeable headband-mounted battery, see Heine instructions provided with the unit.

NOTE: Ensure battery is fully charged prior to operation.

Setting Up and Operating the Headband-Mounted Rechargeable Battery and Wall-Mounted Cradle

The number of LEDs illuminated on the battery indicates the level of charge. The full operating period is achieved when at least 4 LEDs are lit. If LED is flashing, change or recharge the battery. If all the LEDs are unlit, the battery is fully discharged.

For additional information, reference instructions provided with the rechargeable battery and cradle, being sure to comply with all cautionary guidelines.

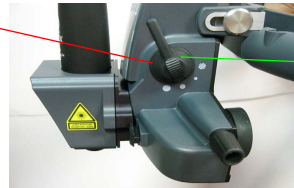
Pre-Procedure Set-Up

NOTE: Start with all adjustments toward a central or middle position, away from extremes of their adjustment range. Consult the Heine Omega-500 manual for additional details.

1. Set Dynamic Range lever on the bottom of the optics unit to its middle position



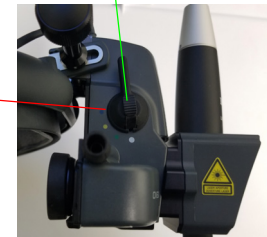
2. Select intermediate illumination spot using the Aperture Control Lever



Each control can be locked to prevent unintentional operation by moving the finger slide

3. Select desired filter setting using the Filter Control Lever

Available settings include no filter, interference red-free filter, a blue or yellow filter which can be introduced into the illumination beam



4. Place the headset on head; adjust the top and rear Headset knobs for a comfortable fit



5. Adjust up/down and forward/back-ward location of the slots of LIO viewing assembly using thumbscrew and secure position with the thumbscrew.



Thumbscrew

6. Adjust pupillary distance (PD) between the oculars for image fusion. While observing through both oculars, the user should be able to comfortably read printed material held at or near the retinal image plane (approximately 370 - 430 mm or 14.6 - 16.9 inches from the headset)

Adjust and fine-tune the PD by closing first one then the other eye and observing an object in the middle of the illumination spot while adjusting the appropriate eyepiece. Repeat until object is in the middle of the field of view, and a single image is obtained. Take off the instrument and check that the PD is symmetrically adjusted. If not, repeat the selection procedure. Correct adjustment of PD is particularly important when examining through a small pupil



- Adjust for patient's pupil size by moving the Dynamic Range lever on the bottom of the unit

Rotate to adjust for large (normal) or small patient pupil size



- Turn on illumination and adjust to an adequate viewing intensity

Adjust illumination brightness to provide sufficient illumination at the treatment site by turning the illumination brightness control knob located on the LIO headband. Do not use more illumination brightness than necessary to provide adequate visualization of the treatment site



- Connect the LIO fiber cable to compatible laser console of correct treatment wavelength. Turn on "aiming beam" and adjust the intensity at the laser control panel



Fiber-optic cable connection to family of OcuLight laser consoles



Fiber-optic cable connection to family of IQ laser consoles. Connect to either Port 1 or Port 2

Instructions to Treat a Patient

BEFORE TREATING A PATIENT:

- Inspect the LIO before use to confirm it is in good operating order. Verify aiming beam is present, uniform, round and not distorted prior to treatment.
- Ensure that the laser components and delivery device(s) are properly connected.
- Post the laser warning sign outside the treatment room door.
- Ensure that all ancillary personnel in the treatment room are wearing the appropriate laser safety eyewear.

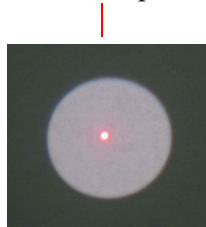
NOTE: Refer to Chapter 6, "Safety and Compliance," and your delivery device manual(s) for important information about laser safety eyewear and eye safety filters.

TO TREAT A PATIENT:

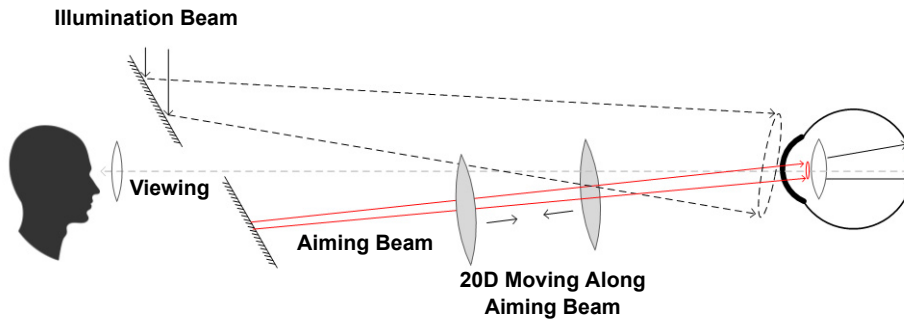
1. Reset the counter.
2. Set the treatment parameters.
3. Position the patient.
4. If required, select an appropriate contact or examination lens for the treatment.
5. Select **Treat** mode.
6. Project the round illumination beam on the patient's forehead and adjust the illumination beam position with the vertical illumination control rotary knobs.



7. Using the condenser lens and vertical aiming beam knob located beneath the dust cover assembly, focus and position the aiming beam in the center of the illumination field already projected on the patient's forehead.



8. Re-position the illumination and aiming beams through the condenser lens and through the patient's dilated pupil. Move the condenser lens along the aiming beam path until the aiming beam is sharp and of the desired diameter. Be sure not to clip the edge of the pupil. For an emmetropic eye with a 20 D condensing lens the laser spot size diameter should be approximately 4mm at the pupil plane and approximately 350 μ m at the retinal plane for a standard spot size LIO or 1.4 mm for a large spot size LIO. Fine tune the vertical aiming beam and illumination beam positions as necessary for treatment.



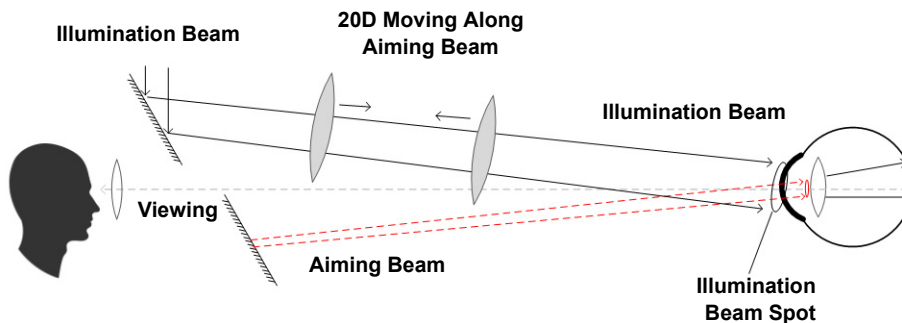
9. Press the footswitch to deliver the treatment beam. Release the footswitch to terminate the laser emission.

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. 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).
8. If a contact lens was used, handle the lens according to the manufacturer's instructions.
9. Keep the protective cap over the fiber-optic connector when the delivery device is not in use.

Instructions For BIO Mode

1. To operate the TruFocus LIO Premiere in a binocular indirect ophthalmoscope (BIO) mode, move the 20 D condenser lens along the illumination beam path until the desired focus is achieved at the intended area of visualization while disregarding the aiming beam or turning off the aiming beam.



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)	Reference instructions provided with the rechargeable battery and cradle.
Illumination light is too dim (LIO only)	Reference instructions provided with the rechargeable battery and cradle.
The aiming beam is large or out of focus on the patient's retina (LIO only)	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.
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 endpoint appearance. Increase the laser power and/or exposure duration, or select a different lens.

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

Inspect the LIO for dirt, debris, and damage prior to each use.

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 and Cleaning the Headband-Mounted Rechargeable Battery

Reference instructions provided with the rechargeable battery.



Headband-mounted rechargeable battery

Charging the Headband-Mounted Rechargeable Battery

Two battery chargers are available for use with the LIO:

1. Wall-Mounted Charging Cradle with plug in transformer:



2. Plug-in transformer:



The LIO battery can be charged with either battery charger. Refer to the Heine instructions provided with each battery charger for safe use and operation of the battery charger.

Wall-Mounted Battery Charging Cradle:

The wall-mounted battery charging cradle is installed on a wall at the user site using hardware and instructions included with the charging cradle. It provides a safe place to store the LIO and accommodates a spare battery. The batteries are automatically charged when placed in a functioning charging cradle. The wall-mounted battery charging cradle offers the following features:

- The battery can be charged in either charging cradle.
- The LIO illumination is automatically switched off as soon as the battery is parked in a functioning charging cradle.
- During charging, the LEDs blink sequentially; during use they remain lit.
- All 5 LEDs will light when the battery is fully charged. As the charge level falls, the LEDs go out in turn. When all LEDs are unlit, the battery is fully discharged.
- If the orange LED starts to flash, recharge the battery.

Plug-In Transformer:

The plug-in transformer allows the battery to be charged by connecting it directly to the plug-in transformer and plugging the transformer into an appropriate AC source.

For additional information, reference Heine instructions provided with the unit.

Changing the LED or Halogen Illumination Lamp

Reference Heine instructions to install or replace the LED or Halogen Illumination Lamp. Replacement lamps are available from IRIDEX, your IRIDEX distributor, or directly from Heine.

5

Service

The LIO contains no user serviceable items. LIO service must be performed by IRIDEX trained service personnel. Contact IRIDEX or your distributor for service information.

6

Safety and Compliance

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

- Always review and observe the safety precautions outlined in the operator manuals before using the device to prevent exposure to laser energy, except as a therapeutic application from either direct or diffusely reflected laser beams.
- This device is intended for use only by a qualified physician or other medical professional. The suitability of the equipment and treatment techniques selected for clinical use 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. These parameters are tabulated for each compatible IRIDEX laser console in the appropriate laser console User Manual for additional information, refer to ANSI Z136.1, ANSI Z136.3, or 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.

The TruFocus Premiere LIO is compliant with EC directive 93/42/EEC and subsequent amendments.

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.

Illumination Phototoxicity

Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged, and the brightness setting should not exceed what is needed to provide clear visualization of the target structures. This device should be used with filters that eliminate UV radiation (< 400 nm) and, whenever possible, filters that eliminate short-wavelength blue light (< 420 nm). The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. If the value of radiance were reduced in half, twice the time would be needed to reach the maximum exposure limit. While no acute optical radiation hazards have been identified for direct or indirect ophthalmoscopes, it is recommended that the intensity of light directed into the patient's eye be limited to the minimum level which is necessary for diagnosis. Infants, aphakes and persons with diseased eyes will be at greater risk. The risk may also be increased if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography.

The IRIDEX LIO based on the OMEGA® 500 Ophthalmoscope is classified as a Group 2 instrument according to EN ISO 15004-2:2007. The classification was performed together with HEINE A.R. 16D/Ø54mm Ophthalmoscopy loupe.

Caution - The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity should not exceed 21 minutes with the LED light and 15 minutes with the 5Watt XHL light.

Labels



















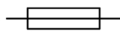

























Laser Aperture Label



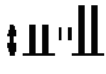
















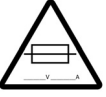





Product Labels



Symbols (As Applicable)

	Aiming beam		Angle		Aspirating probe
	Caution		Audible signal		CE Marking
	Connector type		Do not use if package is damaged		Duration
	Duration with MicroPulse		Emergency stop		ETL mark
	Sterilized using ethylene oxide		Authorized representative in the European Community		Use-by 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		Batch code		Manufacturer
	Date of manufacture		Off		On
	Catalogue number		Power		Pulse count
	Pulse count reset		Non-ionizing electromagnetic radiation		Consult instructions for use
	Remote control		Remote interlock		Serial number
	Do not re-use		Standby		Treat
	Type B Applied Part		Waste Electrical and Electronic Equipment (WEEE)		Pattern is activated

	Temperature limit	IPX4	Protected against splashing water	IPX8	Protected against the effects of continuous immersion in water
	Refer to instruction manual/booklet		Initial power (PowerStep)		Interval between groups
	Number of pulses (group)		Number of steps (PowerStep)		Power (MicroPulse)
	Power increment		Power increment (PowerStep)		Parameter is locked
	Universal serial bus (USB)		Port indicators		Laser firing
	Laser preparing		Speaker		Screen
	System brightness		Not made with natural rubber latex		By prescription only
	Warning, Replace with fuses as indicated		Item or surface can be hot and should not be touched without taking care		CSA Group Mark Health Canada
	Warning of Optical Radiation				

TruFocus LIO Premiere Specifications

Specification	Standard-Spot	Large-Spot
IRIDEX Laser compatibility	OcuLight GL OcuLight GLx OcuLight TX OcuLight SLx OcuLight OR OcuLight SL IQ 532 IQ 577 IQ 810	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	350 μm^*	1400 μm^*
Eye filter	532 nm and 810 nm 532 nm 810 nm 577 nm	810 nm
*May vary with refractive power.		

Operational and Storage Environmental Conditions	
Operational Environment	
Temperature Limits:	10° C (50° F) to 35° C (95° F)
Humidity Limits	20-80% Relative Humidity, Non-condensing
Storage Environment	
Temperature Limits:	-20° C (-4° F) to 60° C (140° F)
Humidity Limits	20 - 80% Relative Humidity, Non-condensing

EMC Safety Information

The laser system (console and accessories) needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this section. Portable and mobile RF communications equipment can affect this system.

This laser system has been tested and found to comply with the limits for medical devices in IEC 60601-1-2 according to the tables in this section. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

CAUTION: *Changes or modifications to this laser system not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment and may result in increased emissions or decreased immunity of the laser system.*

EMC Requirements for Console and Accessories

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
This laser system (console and accessories) is intended for use in the electromagnetic environment specified below. The customer or the user of the laser system should assure that it is used in such an environment.		
Emissions Test	Compliance	
RF emissions CISPR 11	Group 1	The laser system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions	Complies	
The laser system is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.		

Guidance and Manufacturer's Declaration - Immunity			
This laser system (console and accessories) is intended for use in the electromagnetic environment specified below. The customer or the user of the laser system should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment — Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 cycles	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user or the laser system requires continued operation during power mains interruptions, it is recommended that the laser system be powered from an uninterruptible power supply or a battery.
(50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = 1.2 * \text{SQRT} (P)$	80 MHz to 800 MHz $d = 1.2 * \text{SQRT} (P)$	800 MHz to 2.5 GHz $d = 2.3 * \text{SQRT} (P)$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	2.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption from structures, objects, and people.