LIO Plus

Operator Manual

LIO Plus Operator Manual
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1
Introduction

The LIO Plus Laser Indirect Ophthalmoscope when connected to an Iridex laser, adds the therapeutic capability of transpupillary retinal photocoagulation to the wide angle diagnostic capabilities of a binocular indirect ophthalmoscope. It enables delivery of laser energy to the far periphery of the retina and to treat supine patients. Integrated eye safety filters protect user's eyes while providing a clear view of the target area. Fully enclosed optics prevent misalignment and contamination.

The LIO Plus is sold to medical doctors and intended to be used by trained medical professionals.

Indications for Use

The LIO Plus is indicated for transpupillary retinal photocoagulation.

Contraindications

The LIO Plus 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 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*:

- Emmetropic eye (60D):1100 μm x (20D/60D) = 360 μm spot size on retina
- Myopic eye (70D):1100 μm x (20D/70D) = 315 μm spot size on retina
- Hyperopic eye (50D):1100 μm x (20D/50D) = 440 μm 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 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

Iridex Corporation
1212 Terra Bella Avenue
Mountain View, California 94043-1824 U.S.A.

Telephone:	(650) 940-4700 (800) 388-4747 (U.S.A. only)
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Technical Support:	(650) 962-8100 techsupport@Iridex.com
Website:	Iridex.com/lio

EC REP Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

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.*

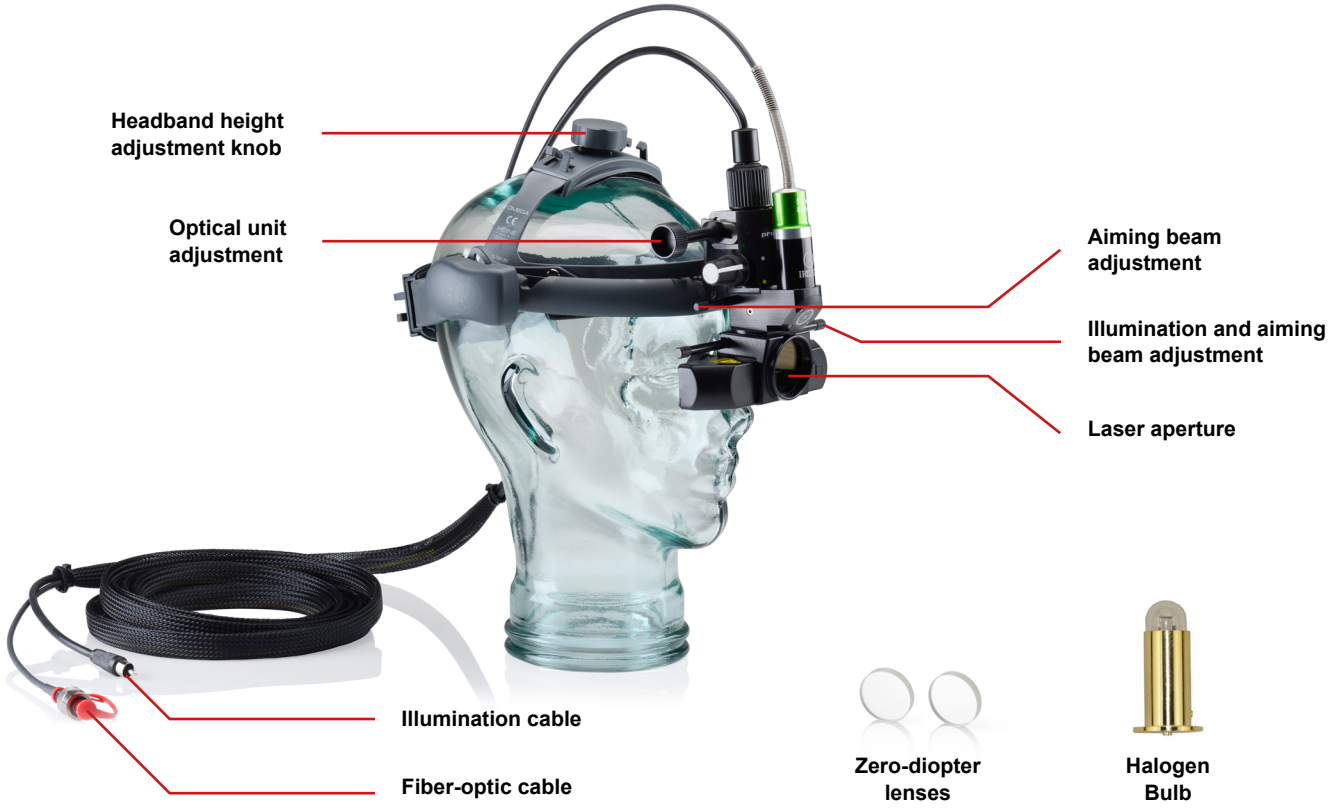
Should you require assistance, please contact your local Iridex Technical Support representative or our corporate headquarters.

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

2
Operation

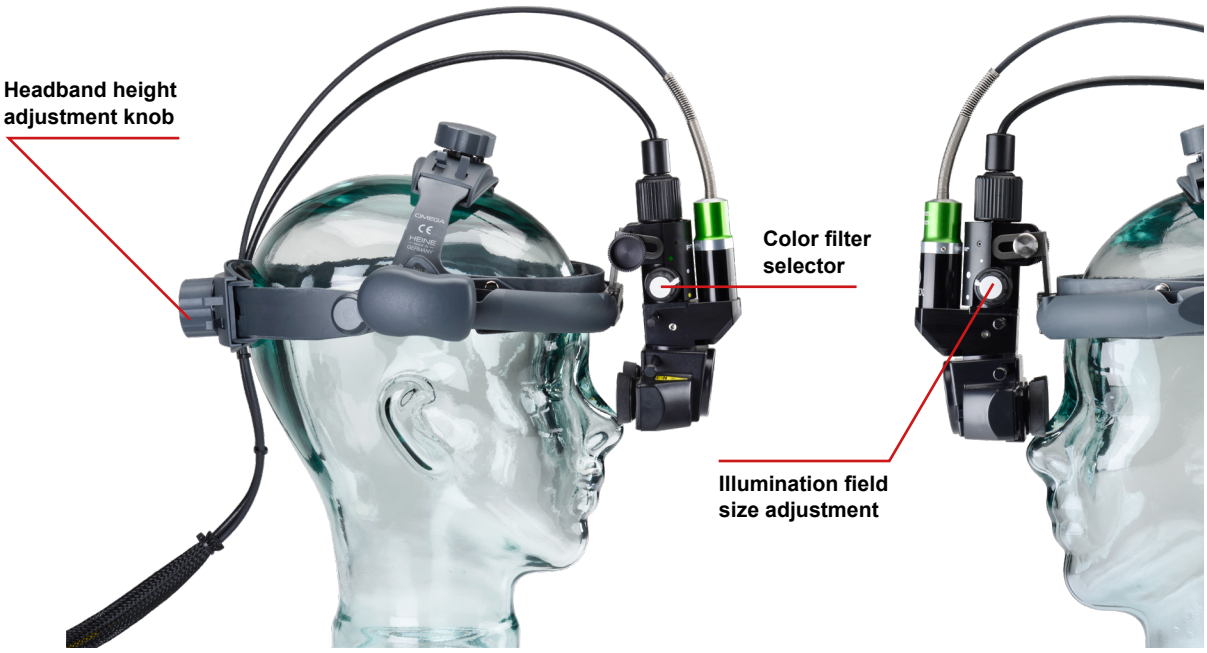
About the Components

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

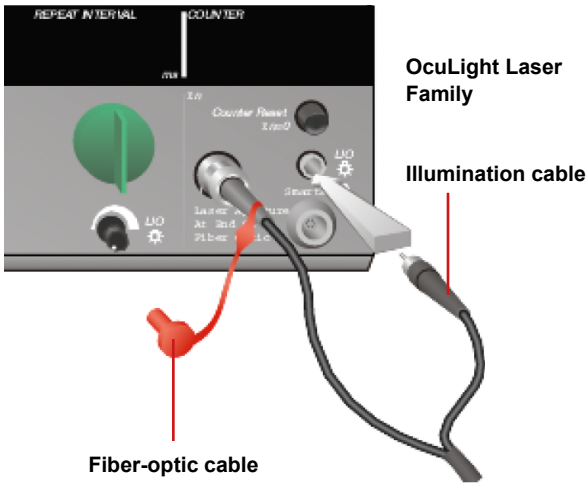


Appearance and type of components may vary based on the delivery device ordered.

One pair of zero-diopter lenses is included with the LIO Plus. 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 Iridex Lasers



Adjusting for Pupillary Distance

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 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. Select an appropriate ophthalmoscopic examination lens.
6. Select Treat mode.
7. Position the aiming beam on the treatment site.
8. Focus or adjust the delivery device as applicable.
9. 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. Inspect and clean the LIO as instructed in section 4 Maintenance, below.
8. If an examination 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.

3
Troubleshooting

General Problems

Problem	User Action(s)
No display	• Verify that the keyswitch is on. • Verify that the components are properly connected. • Verify that the electrical service is on. If there is still no display, contact your local Iridex Technical Support representative.
Inadequate or no aiming beam	• 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. If the aiming beam is still not visible, contact your local Iridex Technical Support representative.
No treatment beam	• 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. If there is still no treatment beam, contact your local Iridex Technical Support representative.
No illumination light	• 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	• 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	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	• 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.

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 the Illumination Lamp

1. Unscrew the retaining cap.
2. Remove the burned-out illumination lamp.
3. Insert an identical replacement lamp, aligning the key on the lamp base with the slot in the LIO Plus so that it points to the observer's right.
4. Screw on the retaining cap.

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Service and Technical Support

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.

Technical Support:

(650) 962-8100
techsupport@Iridex.com

NOTICE TO THE USER AND/OR PATIENT:

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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. Refer to laser console Operator Manual for laser safety eye wear minimum OD; it is specific per each laser console wavelength and maximum power output.

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. Eyewear safety parameters are tabulated for each compatible Iridex laser console in the appropriate laser console operator 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.

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.

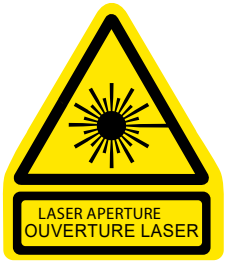
The LIO Plus is classified as a Group 1 instrument according to EN ISO 15004-2:2007. This classification was determined using a 20D ophthalmoscopy lens.

The LIO Plus is classified as a Group 1 instrument according to ANSI Z80.36-2016. This classification was determined using a 20D ophthalmoscopy lens.

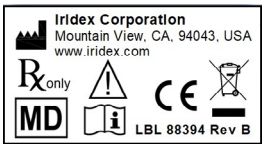
Labels

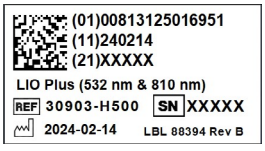
CE Labels

Laser Aperture Label



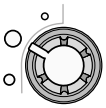
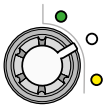
Product Labels





Symbols

These symbols apply to the LIO Plus. Refer to the operator manual of your Iridex laser console for additional symbols.

	Caution		CE Mark		Authorized Representative in the European Community
	Serial Number		Manufacturer		Part Number
	Waste Electrical and Electronic Equipment (WEEE)		CSA Group Mark Health Canada		Laser Aperture
	Illumination Field Size Selector		Filter Selector		ELT Mark

LIO Plus 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 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*	1400 µm
LIO Plus models	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 * SQRT (P)	**80 MHz to 800 MHz** d = 1.2 * SQRT (P)	**800 MHz to 2.5 GHz** d = 2.3 * 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	23
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.			