IRIDEX IQ 577®/IQ 532®
Laser Systems
Operator Manual

IRIDEX IQ 577®/IQ 532® Laser Systems Operator Manual
15510-EN Rev G 2019 01

© 2019 by IRIDEX Corporation. All rights reserved.

IRIDEX, the IRIDEX logo, IRIS Medical, OcuLight, EndoProbe and SmartKey are registered trademarks; BriteLight, CW-Pulse, DioPexy, EasyFit, EasyView, FiberCheck, FlexFiber, G-Probe, IQ 532, IQ 577, IQ 810, LongPulse, MicroPulse, MilliPulse, OtoProbe, PowerStep, SmartKey, Symphony, Tri-Mode, TruFocus, and TruView are trademarks of IRIDEX Corporation. All other trademarks are the property of their respective holders.

1
Introduction

IQ 577® (577 nm, true-yellow) and IQ 532® (532, green) laser systems are solid state lasers that are capable of delivering continuous wave and MicroPulse™ for ophthalmic applications. Improper use of the laser system can result in adverse effects. Follow the instructions for use described in this operator manual.

Compatible Delivery Devices

These IRIDEX delivery devices are compatible with the IQ 577 and IQ 532 laser systems:

- TxCell® Scanning Laser Delivery System
- EndoProbe® handpiece
- Slit Lamp Adapters (SLA)
- Laser Indirect Ophthalmoscopes (LIO)
- ENT Delivery Devices (IQ 532 models only)

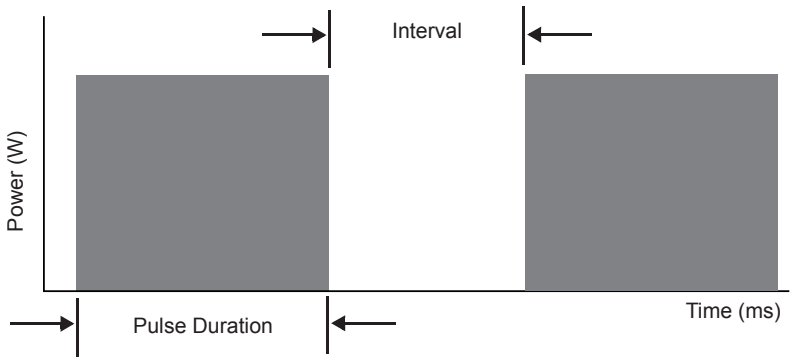
NOTE: *Refer to the appropriate delivery device manual for indications for use, contraindications, precautions, and adverse effects information.*

Pulse Types

The IQ Laser System is capable of delivering a continuous-wave laser pulse in 2 modes: CW-Pulse™ and MicroPulse®.

CW-Pulse

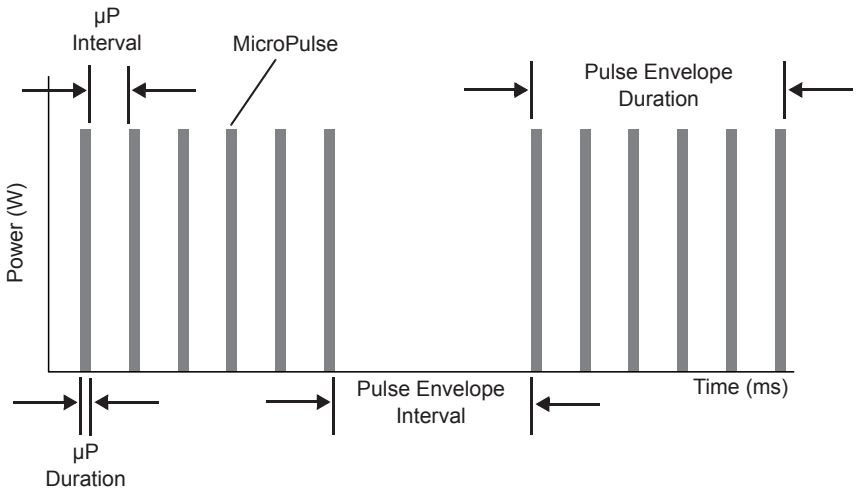
Laser emission is continuous during the entire timed exposure



MicroPulse (Optional)

MicroPulse (µP) is a laser delivery consisting of a group of microsecond bursts.

$$\text{Duty Cycle\%} = \frac{\mu\text{P Duration}}{\mu\text{P Duration} + \mu\text{P Interval}} \times 100$$



MicroPulse is typically used to administer subvisible threshold laser treatments to macular and perimacular targets. When used here, the terms “subvisible”, “subvisible threshold” or “subthreshold” denote that the desired endpoint is one in which treated tissue offers no ophthalmoscopically observable laser effects. Nevertheless, 577 nm and 810 nm studies have confirmed that subvisible laser treatment strategies can be clinically effective while inducing no changes discernible by slit lamp observation, fluorescein angiography (FA), fundus autofluorescence (FAF), or at any time postoperatively.[1,2]

Tissues receiving subvisible MicroPulse laser treatment show no such changes because:

- MicroPulse laser delivery is being used instead of CW, and
- The total laser energy of such doses is only a percentage (often chosen by clinicians to be 20-70%) of that energy needed to produce a visible endpoint.

Energy (J) is equal to [Laser Power (W)] [Exposure Duration(s)] [Duty Factor (%/100)]. Duty Factor is often 5% to 15% when using MicroPulse mode, and is 100% when using CW mode. Clinicians have reported various strategies to adjust these parameters relative to suprathreshold burns in order to achieve clinically effective subvisible endpoints.[1-4]

Additional parameters to consider in any laser treatment protocol, and particularly during MicroPulse, is spacing between laser treatment spots, and the total number of treatment spots administered. Due to the limited thermal spread of MicroPulse exposures, subvisible treatments often call for the administration of a greater number of treatment spots with denser spacing than that used for threshold laser grid treatments.[4]

References

[1] Vujosevic S, Bottega E, Casciano M, Pilotto E, Convento E, Midena E. Microperimetry and fundus autofluorescence in diabetic macular edema: Subthreshold micropulse diode laser versus modified early treatment diabetic retinopathy study laser photocoagulation. Retina 2010;30(6):908-916.

[2] Vujosevic S, Martini F, Convento E, Longhin E, Kotsafti O, Parrozzani R, Midena E: Subthreshold Laser Therapy for Diabetic Macular Edema: Metabolic and Safety Issues. *Curr Med Chem* 2013.

[3] Figueira J, Khan J, Nunes S, Sivaprasad S, Rosa A, de Abreu JF, Cunha-Vaz JG, Chong NV. Prospective randomised controlled trial comparing sub-threshold micropulse diode laser photocoagulation and conventional green laser for clinically significant diabetic macular oedema. Br J Ophthalmol 2009;93(10):1341-4.

[4] Lavinsky D, Cardillo JA, Melo LA, Jr., Dare A, Farah ME, Belfort R, Jr. Randomized clinical trial evaluating mETDRS versus normal or high-density micropulse photocoagulation for diabetic macular edema. Invest Ophthalmol Vis Sci 52(7):4314-23.

Indications for Use - IQ 577 Models

This section provides information on the use of the laser in clinical specialties. Information is provided by specialty and includes procedural recommendations along with specific indications and contraindications. This information is not intended to be all-inclusive and is not intended to replace surgeon training or experience. The regulatory information provided is applicable only in the United States. If you use the laser for indications not included herein, you will be subject to 21 CFR Part 812, the Food and Drug Administration's Investigational Device Exemption (IDE) regulations. For information regarding the regulatory status of indications other than those listed in this manual, contact IRIDEX Regulatory Affairs.

IRIDEX does not make recommendations regarding the practice of medicine. References in literature are provided as a guide. Individual treatment should be based on clinical training, clinical observation of laser tissue interaction, and appropriate clinical endpoints.

The IRIDEX laser and the handpieces, delivery devices, and accessories that are used with it to deliver laser energy in CW-Pulse™ or MicroPulse™ mode in the medical specialty of Ophthalmology.

Ophthalmology

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

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

Procedural Recommendations

The user is directed to review the operating instructions for the compatible delivery devices prior to treatment.

Contraindications

- Any situation where the target tissue cannot be adequately visualized or stabilized.
- Do not treat albino patients who have no pigmentation.

Potential Side Effects or Complications

- Specific to retinal photocoagulation: inadvertent foveal burns; choroidal neovascularization; paracentral scotomata; transient increased edema/decreased vision; subretinal fibrosis; photocoagulation scar expansion; Bruch's membrane rupture; choroidal detachment; exudative retinal detachment; pupillary abnormalities from damage to the ciliary nerves; and, optic neuritis from treatment directly or adjacent to the disc.
- Specific to laser iridotomy or iridoplasty: inadvertent corneal or lens burns/opacities; iritis; iris atrophy; bleeding; visual symptoms; IOP spike; and, rarely, retinal detachment.
- Specific to laser trabeculoplasty: IOP spike, and, disruption of the corneal epithelium.

Specific Warnings and Precautions

It is essential that the surgeon and attending staff be trained in all aspects of these procedures. No surgeon should use these laser products for ophthalmic surgical procedures without first obtaining detailed instructions in laser use. Refer to "Warnings and Cautions" for more information. Proper eye protection for 577 nm light must be utilized. Follow the Eye Protection Policy at your facility.

Laser Settings

Beginning at low power with short duration exposures, the surgeon should note the surgical effect and increase power, power density, or exposure duration until the desired surgical effect is obtained. The information in the following table is intended to provide guidance only for treatment settings, which are not prescriptive for any condition. The operative needs of each patient should be individually evaluated based on the indication, treatment location, and on the patient's medical and wound healing history. If uncertain of expected clinical response, always start with a conservative setting and increase the setting in small steps.

577 nm Typical Laser Treatment Parameters for Ocular Photocoagulation

577 nm Continuous-Wave				
Application	**Delivery Device**	**Spot Size at Target* (µm)**	**Power (mW)**	**Exposure Duration (ms)**
Central Retina Focal/Grid	SLA	50–100	50–250	30–100
Peripheral Retina/PRP/Tears	SLA, LIO, EndoProbe	100–500	50–500	30–200
Trabeculoplasty	SLA	50	385–640	100
Iridotomy	SLA	50	320–640	100–200
Nylon Suture Lysis	SLA	50	200–750	100–200
*Spot size at target is dependent on many parameters, including spot size selection, physician's choice of laser delivery lens, and patient's refractive power.				

577 nm MicroPulse					
Application	**Delivery Device**	**Spot Size at Target* (µm)**	**Power (mW)**	**Duty Cycle (500 Hz)**	**Exposure Duration (ms)**
Central Retina Focal/Grid	SLA	50–200	100–400	5%, 10%, 15%	100–300
Peripheral Retina/PRP	SLA	500–1000	500–1000	5%, 10%, 15%	100–300
Trabeculoplasty	SLA	200–300	400–1200	5%, 10%, 15%	100–300
*Spot size at target is dependent on many parameters, including spot size selection, physician's choice of laser delivery lens, and patient's refractive power.					

Indications for Use - IQ 532 Models

This section provides information on the use of the laser in clinical specialties. Information is provided by specialty and includes procedural recommendations along with specific indications and contraindications. This information is not intended to be all-inclusive and is not intended to replace surgeon training or experience. The regulatory information provided is applicable only in the United States. If you use the laser for indications not included herein, you will be subject to 21 CFR Part 812, the Food and Drug Administration's Investigational Device Exemption (IDE) regulations. For information regarding the regulatory status of indications other than those listed in this manual, contact IRIDEX Regulatory Affairs.

IRIDEX does not make recommendations regarding the practice of medicine. References in literature are provided as a guide. Individual treatment should be based on clinical training, clinical observation of laser tissue interaction, and appropriate clinical endpoints.

The IRIDEX laser and the handpieces, delivery devices, and accessories that are used with it to deliver laser energy in CW-Pulse™ mode or MicroPulse™ mode in the medical specialties of Ear, Nose and Throat (ENT), and Ophthalmology.

Ear, Nose and Throat (ENT)/Otolaryngology

Intended for soft and fibrous tissue, including osseous tissue incision, excision, coagulation, vaporization, ablation and vessel hemostasis.

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 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 choroids, including:
  - Proliferative and nonproliferative diabetic retinopathy
  - Choroidal neovascularization
  - Branch retinal vein occlusion
  - Age-related macular degeneration
  - Retinal tears and detachments
  - Retinopathy of prematurity
  - Macular edema
  - Lattice degeneration
  - Central retinal vein occlusion
- Iridotomy, iridoplasty in angle closure glaucoma, and trabeculoplasty in open angle glaucoma

Procedural Recommendations

The user is directed to review the operating instructions for the compatible delivery devices prior to treatment.

Contraindications

- Any situation where the target tissue cannot be adequately visualized or stabilized.
- Do not treat albino patients who have no pigmentation.

Potential Side Effects or Complications

Ophthalmic:

- Specific to retinal photocoagulation: inadvertent foveal burns; choroidal neovascularization; paracentral scotomata; transient increased edema/decreased vision; subretinal fibrosis; photocoagulation scar expansion; Bruch's membrane rupture; choroidal detachment; exudative retinal detachment; pupillary abnormalities from damage to the ciliary nerves; and, optic neuritis from treatment directly or adjacent to the disc.
- Specific to laser iridotomy or iridoplasty: inadvertent corneal or lens burns/opacities; iritis; iris atrophy; bleeding; visual symptoms; IOP spike; and, rarely, retinal detachment.
- Specific to laser trabeculoplasty: IOP spike, and, disruption of the corneal epithelium.

ENT:

Excessive treatment may cause swelling (edema) in the area treated by the laser.

Anesthesia Considerations:

One of the main concerns during otolaryngeal and bronchial procedures is the substantial risk of endotracheal fires. The following sections provide information and safety guidelines, which can greatly decrease the risks associated with these procedures. Information is also provided on what to do if such a fire does occur.

IRIDEX Corp. recommends the safety guidelines of American National Standards ANSI Z136.3-2007 as follows:

- Care must be taken to protect endotracheal tubes from laser radiation. Ignition or perforation of endotracheal tubes by the laser beam could result in serious or fatal patient complications.
- Use the lowest possible oxygen concentration to support the patient.
- Use the venturi ventilation technique when possible.
- Use intravenous anesthetic agents rather than inhalation techniques.
- Use non-flammable laser-safe endotracheal tubes.
- Protect the endotracheal tube cuff with wet cottonoids.

Reference material and additional information regarding laser safety and the prevention of endotracheal fires may be obtained from the following U.S. sources:

- **ANSI Z136.3, The Safe Use of Lasers in Health Care Facilities**, American National Standards 2007.
- **Recommended Practices: Laser Safety in the Practice Setting**. *AORN Journal*, March 1993, Vol. 57 No. 3, Pg. 720-727.
- **Safety Considerations for the Use of Medical Lasers, The Nursing Spectrum of Lasers**, Pfister, Kneedler, Purcell, *Education Design*, 1988, Pg. 70-72.
- **Prevention of Fires and Protection of Non-Target Tissues, Airway Precautions**, *Plan for Success: A Practical Guide for Your Carbon Dioxide Laser Surgery Program*, Lewis, Coherent 1989, Pg. 16-17.
- **Laser Resistant Stainless Steel Endotracheal Tube: Experimental and Clinical Evaluation**, *Lasers in Surgery and Medicine*, Fried, Marvin P., MD, 11:301-306 (1991).
- **Evaluation & Discussion: Issues in Using and Selecting Laser Resistant Endotracheal Tubes (LRETTs) and Wraps**, *ECRI, Health Devices*, July-August 1991, Vol. 20 Nos. 7-8.
- **Diffuse Reflections, Endoscopic Surgery: Is Laser Safety Eyewear Really Needed?**, *Radiant Resources Newsletter*, Winter 1992, Rockwell Laser Industries.

Specific Warnings and Precautions

It is essential that the surgeon and attending staff be trained in all aspects of these procedures. No surgeon should use these laser products for ophthalmic and ENT surgical procedures without first obtaining detailed instructions in laser use. Refer to "Warnings and Cautions" for more information. Proper eye protection for 532 nm light must be utilized. Follow the Eye Protection Policy at your facility.

Laser Settings

Beginning at low power with short duration exposures, the surgeon should note the surgical effect and increase power, power density, or exposure duration until the desired surgical effect is obtained. The information in the following tables is intended to provide guidance only for treatment settings, which are not prescriptive for any condition. The operative needs of each patient should be individually evaluated based on the indication, treatment location, and on the patient's medical and wound healing history. If uncertain of expected clinical response, always start with a conservative setting and increase the setting in small steps.

532 nm Typical Laser Treatment Parameters for Ocular Photocoagulation

532 nm Continuous-Wave				
Application	**Delivery Device**	**Spot Size at Target* (µm)**	**Power (mW)**	**Exposure Duration (ms)**
Central Retina Focal/Grid	SLA	50–100	100–300	30–100
Peripheral Retina/PRP/Tears	SLA, LIO, EndoProbe	125–500	100–600	30–200
Trabeculoplasty	SLA	50	600–1000	100
Iridotomy	SLA	50	500–1000	100–200
Nylon Suture Lysis	SLA	50	200–750	100–200
*Spot size at target is dependent on many parameters, including spot size selection, physician's choice of laser delivery lens, and patient's refractive power.				

532 nm MicroPulse					
Application	**Delivery Device**	**Spot Size at Target* (µm)**	**Power (mW)**	**Duty Cycle (500 Hz)**	**Exposure Duration (ms)**
Central Retina Focal/Grid	SLA	50–200	100–400	5%, 10%, 15%	100–300
Peripheral Retina/PRP	SLA	500–1000	500–1000	5%, 10%, 15%	100–300
Trabeculoplasty	SLA	200–300	400–1200	5%, 10%, 15%	100–300
*Spot size at target is dependent on many parameters, including spot size selection, physician's choice of laser delivery lens, and patient's refractive power.					

532 nm Typical Laser Treatment Parameters for ENT Photocoagulation

Otology				
Treatment	**Delivery Device**	**Spot Size at Target (µm)****	**Power (mW)**	**Exposure Duration (ms)**
Stapedectomy	Otoprobe	N/A	800–2500	100–2500
Stapedotomy				
Myringotomies				
Removal of Acoustic Neuromas		N/A	200–2500	20–100
Soft Tissue Adhesion in Micro/Macro Otologic Procedures				
Lysis of Adhesions		N/A	1000–2500	20–100
Control of Bleeding		N/A	200–2500	20–100
**Spot size at target is dependent on many parameters, including fiber core diameter and working distance.				

Laryngology						
Treatment	**Delivery Device**	**Spot Size at Target (µm)****	**Power (mW)**		**Exposure Duration (ms)**	**Interval (ms)**
			IQ 532	**IQ 532 XP^**		
Lysis of Adhesions	FlexFiber	200–600	1500–2500	1500–6000	50–200	400–500
Soft Tissue/Vascular Lesions of the Airway and Larynx						
**Spot size at target is dependent on many parameters, including fiber core diameter and working distance. ^ The IQ 532 XP is FDA cleared for laser power deliver of up to 5000 mW (+/- 20%).						

⚠ Warnings and Cautions

DANGER:

Do not remove covers. Shock hazard and accessible laser radiation. Refer servicing to qualified laser personnel. Risk of explosion if used in the presence of flammable anesthetics.

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.

To avoid the risk of electric shock, this equipment must be connected to a supply mains with protective earth.

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.

Laser plume may contain viable tissue particulates.

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

IRIDEX Corporation Contact Information

IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View, California 94043-1824 USA

Telephone:	(650) 940-4700 (800) 388-4747 (US only)
Fax:	(650) 962-0486
Technical Support:	(650) 962-8100 techsupport@iridex.com

EC REP Emergo Europe
Prinsessegracht 20
2514 AP The Hague
CE 2797 The Netherlands

Warranty and Service. Each laser system carries a standard factory warranty. The warranty covers all parts and labor required to correct problems with materials or workmanship. This warranty is void if service is attempted by anyone other than certified IRIDEX service personnel.

WARNING: *Use only IRIDEX delivery devices with the IRIDEX laser system. Use of a non-IRIDEX delivery device may result in unreliable operation or inaccurate delivery of laser power. This Warranty and Service agreement does not cover any damage or defect caused by the use of non-IRIDEX devices.*

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.*

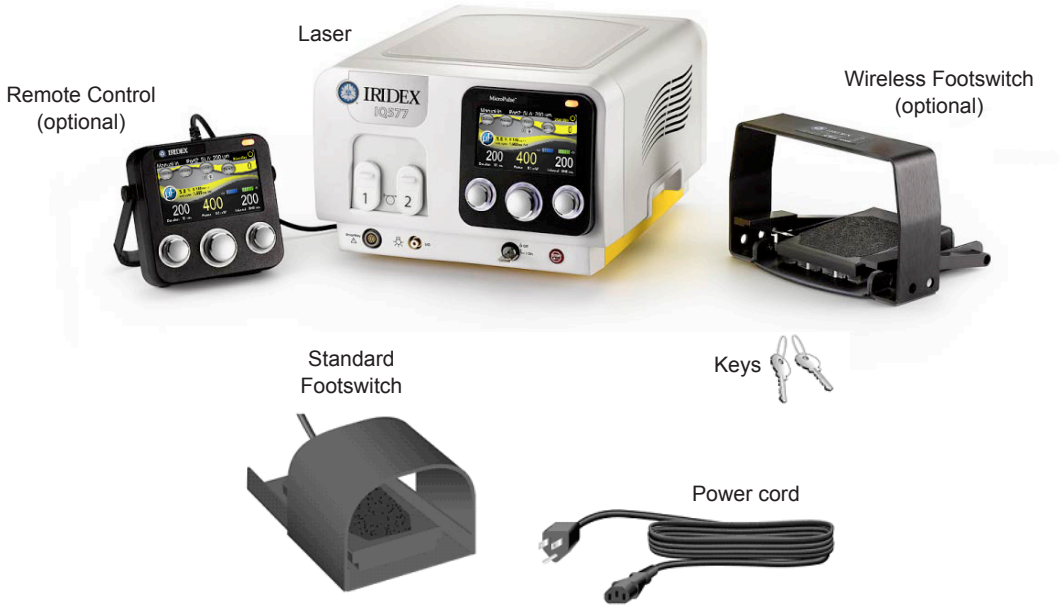
WEEE Guidance. Contact IRIDEX or your distributor for disposal information.

2
Setup

Unpacking the System

Make sure you have all components that were ordered. Check components for damage before use.

NOTE: *Contact your local IRIDEX Customer Service Representative if there are problems with your order.*



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

- Laser (also “Console”)
- Power cord (U.S. configuration shown)
- Keys
- Standard footswitch
- Operator Manual (not shown)
- Laser warning sign (not shown)
- Optional accessories (not all shown)

Choosing a Location

Choose a well-ventilated location within the specified operating range of the console.

Place the laser system on a table or on existing operating room equipment. Allow at least 5 cm (2 in.) of clearance on each side.

In the US, this equipment must be connected to an electrical supply source at 120V or 240V with a center tap.

To ensure that all local electrical requirements can be met, the system is equipped with a hospital-grade (green dot) three-wire grounding plug. When choosing the location, ensure that a grounding-type AC outlet is available; it is required for safe operation.

The power cord included in the packaging is appropriate for your location. Always use an approved three-wire grounding cord set. Do not alter the power inlet. To ensure proper grounding, follow local electrical codes before installing the system.

CAUTIONS:

Do not defeat the purpose of the grounding pin. This equipment is intended to be electrically grounded. Contact a licensed electrician if your outlet prevents you from inserting the plug.

Do not position or use the system near open flames.

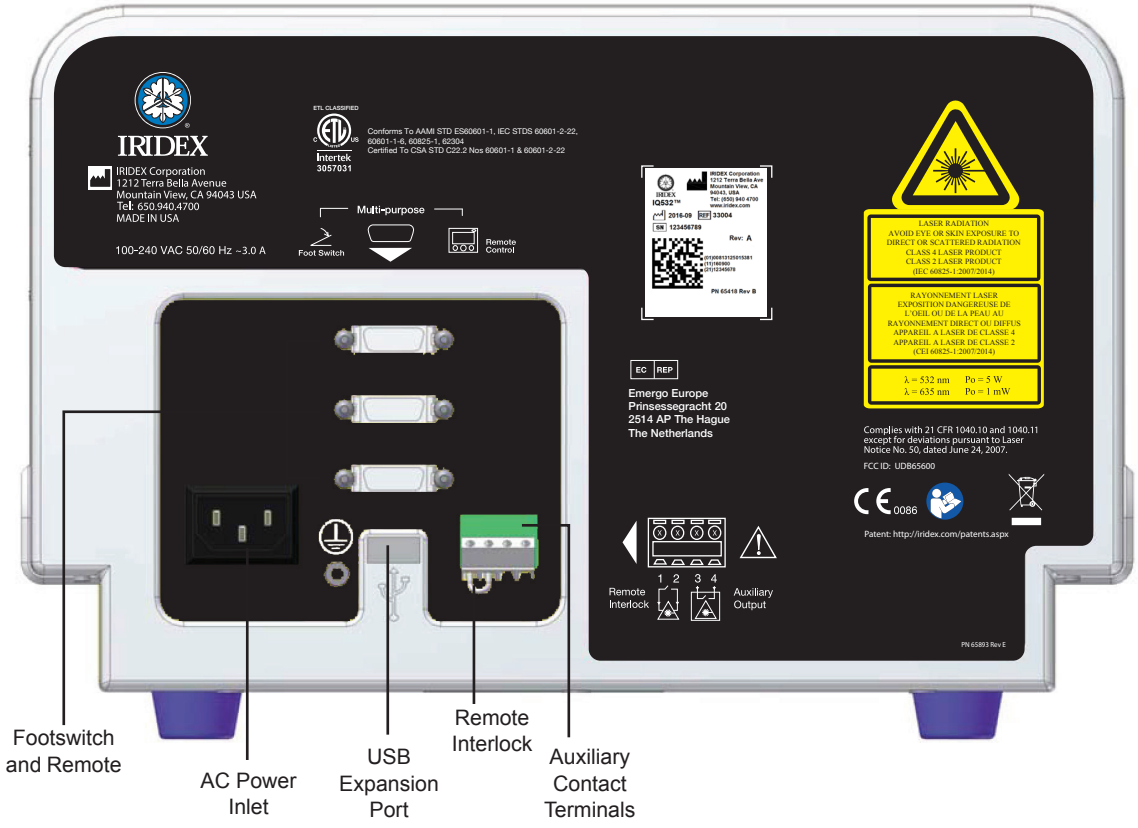
Connecting the Components

CAUTION: *Do not connect two footswitches to the laser console.*

NOTES: *Refer to the appropriate delivery device manual for specific connection instructions.*

The Auxiliary Output contact supports low voltage electrical signaling circuits of up to 5 amps and 24V AC or DC. Ensure that all wiring conforms to local electrical codes.

Rear Panel Connectors - IQ 532/IQ 577



3
Operation

Front Panel Controls

CAUTION: *When no delivery device is attached to the system, ensure that the fiber ports are closed.*

Powering the Laser On and Off

- To turn the laser on, turn the key to the On position.
- To turn the laser off, turn the key to the Off position. Remove and store the key to prevent unauthorized use.

  NOTE: *The key can be removed in the Off position only.*

- In an emergency, press the red EMERGENCY STOP button. This immediately disables the console and all laser related circuits.

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 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:

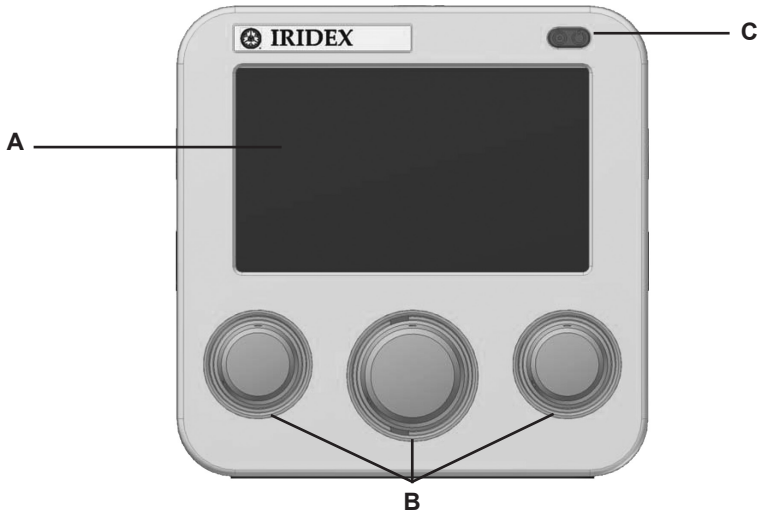
1. Turn on the laser.
2. Reset the counter.
3. Set the treatment parameters.
4. Position the patient.
5. If required, select an appropriate contact lens for the treatment.
6. Ensure that all ancillary personnel in the treatment room are wearing the appropriate laser safety eyewear.
7. Select Treat mode.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

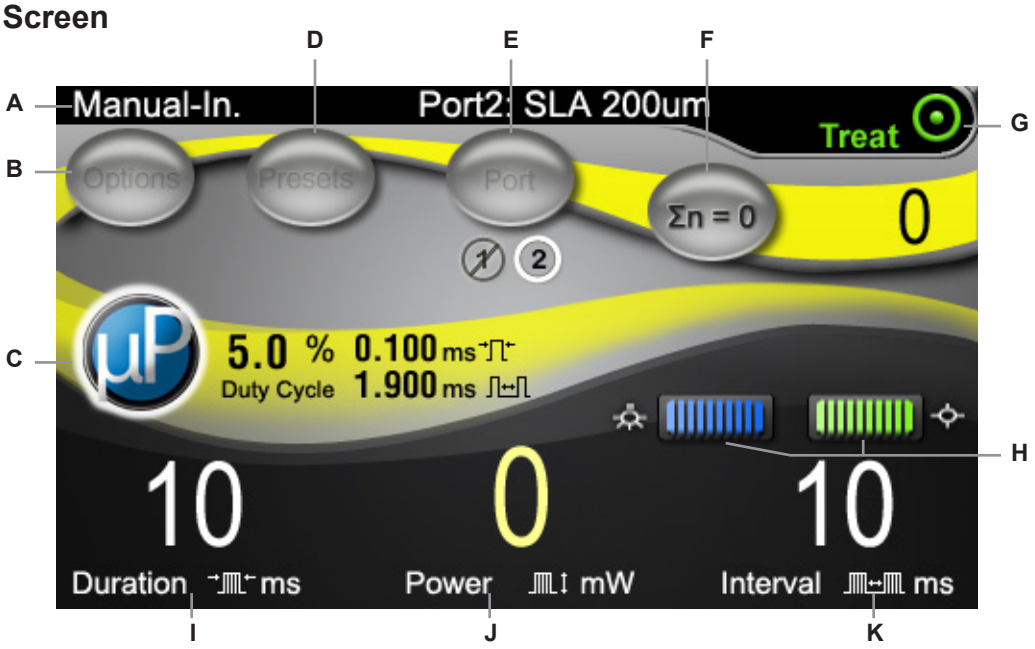
Using the Laser System

System Interface



A	**Touchscreen Interface**	Displays current parameter and functions, and acts as the interface to select screens or parameters.
B	**Control knobs**	Used to adjust parameters on the screen.
C	**Laser button**	Toggles between laser Ready and Standby modes.

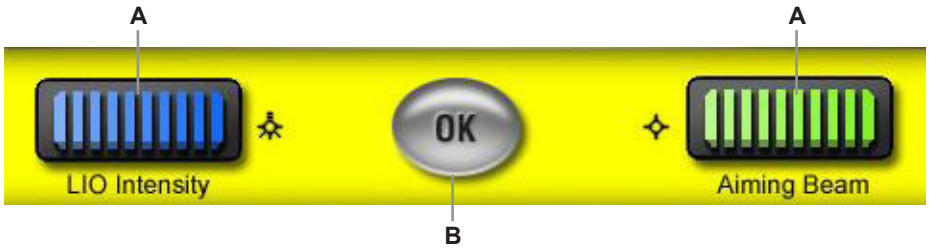
Treat Screen



A	Displays eye safety filter status and delivery device.
B	Go to Options screen.
C	(Optional) Adjust MicroPulse settings. When MicroPulse is activated, parameters are displayed to the right of the button (as shown).
D	Go to Presets screen.
E	Switch port.
F	Reset pulse counter.
G	Indicates laser mode: • Ready: Laser is ready; will fire when footswitch is pressed. • Standby: Laser is disengaged. • Treat: Laser is firing (footswitch pressed).
H	Aiming Beam and LIO adjustments.
I	Displays pulse duration. Adjust with control knob.
J	Displays pulse power. Adjust with control knob. Two power parameters, one for CW-Pulse and one for MicroPulse (if applicable), are maintained.
K	Displays pulse interval. Adjust with control knob.

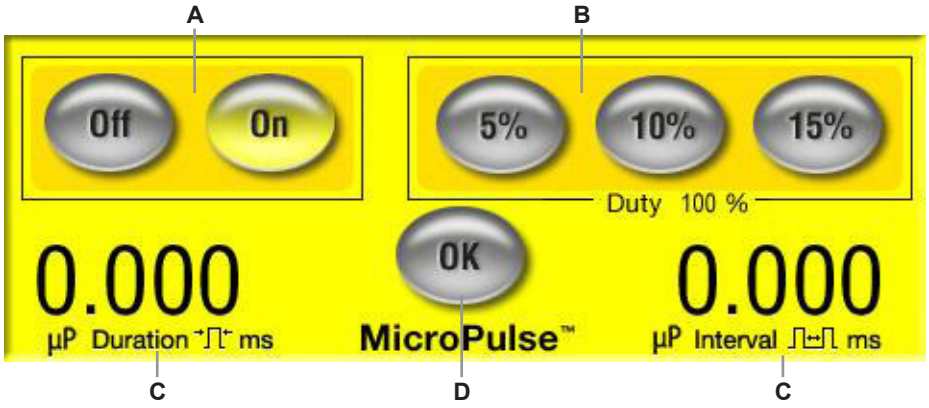
WARNING: *Except during actual treatment, the laser must always be in Standby mode. Maintaining the laser in Standby mode prevents accidental laser exposure if the footswitch is inadvertently pressed.*

LIO Intensity/Aiming Beam Settings



A	Displays LIO and Aiming Beam intensity. Use control knobs to adjust.
B	Save changes and return to previous screen.

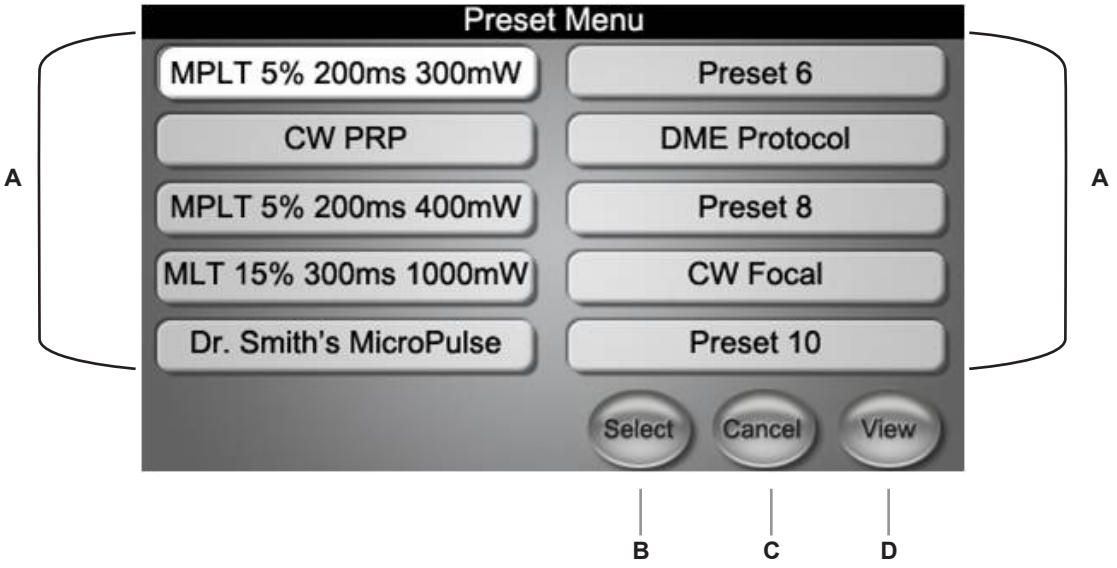
MicroPulse Settings (Optional)



A	Turn MicroPulse ON or OFF.
B	Select preset values for Duty Cycle. MicroPulse duration and Interval parameters update automatically.
C	Displays MicroPulse duration and interval. Use control knobs to adjust and set custom parameters. Duty Cycle value will update automatically.
D	Save changes and return to Treat or Standby screen.

Preset Menu

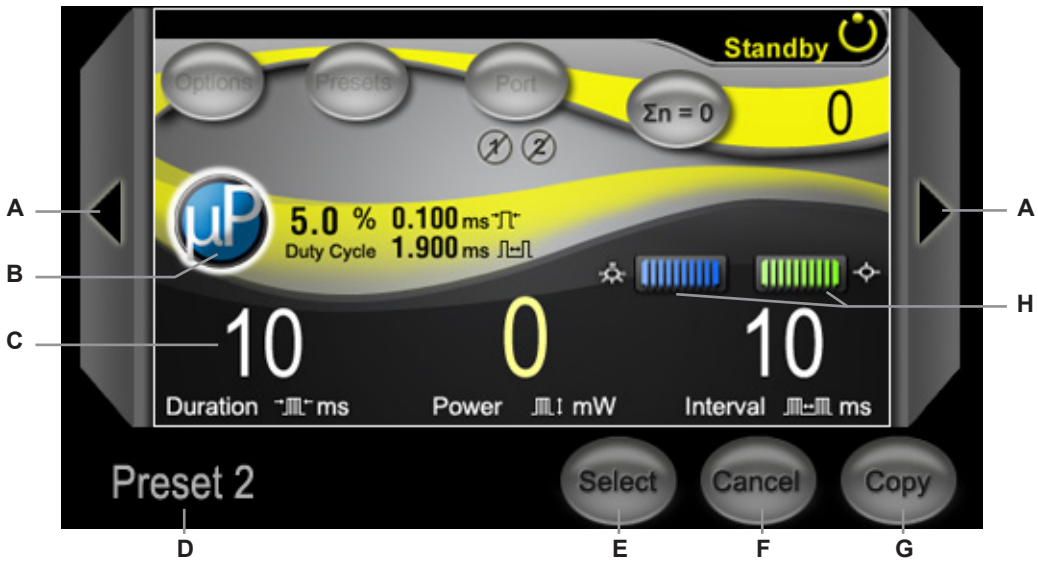
To access the Preset Menu, at the Standby screen, touch PRESETS.



A	Programmable presets.
B	Selection button to load highlighted preset and go to Standby screen.
C	Cancel loading preset selection and return to Standby screen.
D	Go to Presets Screen to view, update and/or select preset parameters.

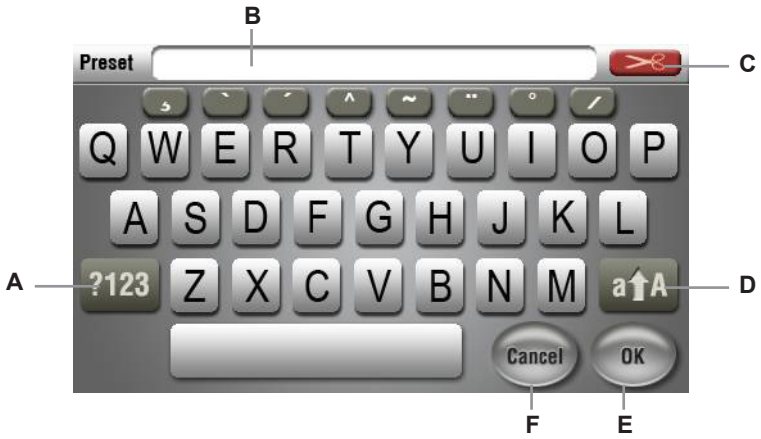
Presets Screen

To access the Presets screen, at the Preset Menu, touch VIEW.



A	Go to Previous/Next Preset.
B	(Optional) Adjust MicroPulse settings.
C	Use control knobs to select pulse duration, power, and interval.
D	Displays Preset name. Press to enter Keyboard mode.
E	Save changes and return to Treat screen.
F	Discard changes and return to Treat screen with default parameters.
G	Import information from Treat screen into selected Preset.
H	Aiming Beam and LIO adjustments.

KEYBOARD MODE



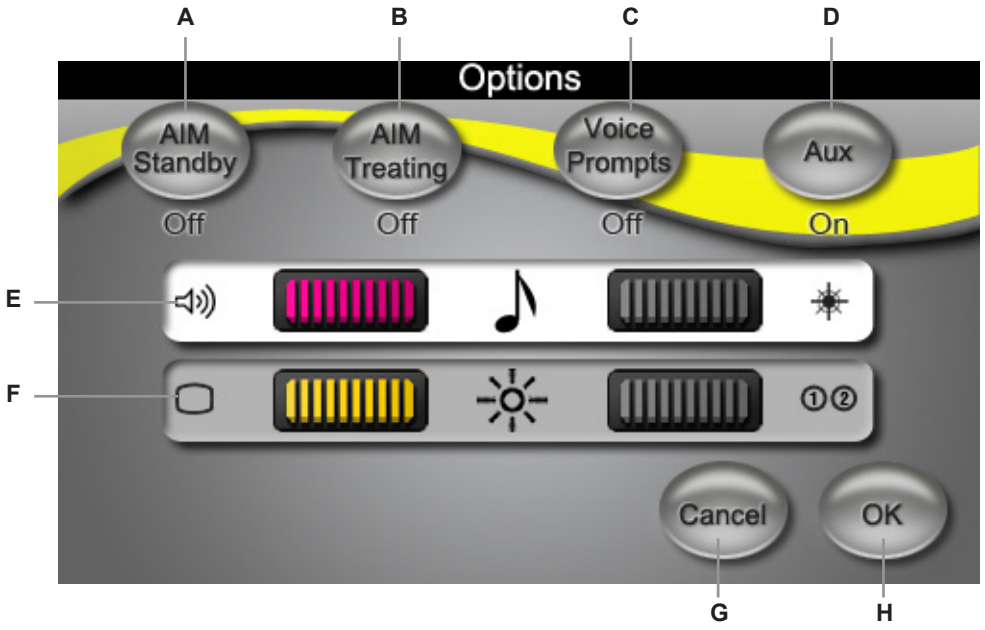
A	Select: letters or numbers
B	Displays Preset name.
C	Deletes characters in Preset Name field.
D	Switch between uppercase and lowercase.
E	Save changes.
F	Cancel changes and return to Presets screen.

NOTE: *When programming a Preset name, use only letters (upper and lower case) and numbers (0 to 9). Do NOT use any symbols. Symbols may generate a warning message, "Aux Device Required" when a TxCell Scanning Laser Delivery System is subsequently connected to the laser console. If this error occurs, laser delivery with the TxCell Scanning Slit Lamp Adapter will be disabled. To correct this:*

1. Delete symbols that were entered into the Preset Name
2. Turn off the laser console
3. Allow the unit to power down, approximately 15 seconds
4. Turn on the laser console
5. If the problem persists, contact your local IRIDEX Technical Support representative.

Options Screen

To access the Options screen, touch OPTIONS.



A	Set aiming beam in Standby: ON or OFF.
B	Set aiming beam in Treat: • OFF: Aiming beam OFF while footswitch is depressed. • ON: ON at all times. • Blink: Blink at fixed rate (not synchronized with laser settings).
C	Set voice prompt: Female, Male, OFF. Use only when adjusting power with footswitch.
D	Set Auxiliary: ON in Standby or ON in Treat. Operate a warning light or auditory signal outside the treatment room.
E	Press bar to select it (white=active bar). Use control knobs to set volume.
F	Press bar to select it (white=active bar). Use control knobs to set brightness.
G	Discard changes and return to Treat screen.
H	Save changes and return to Treat screen.

4
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. • Inspect the fuses. 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 (LIO only)	• 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)	• 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)	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.

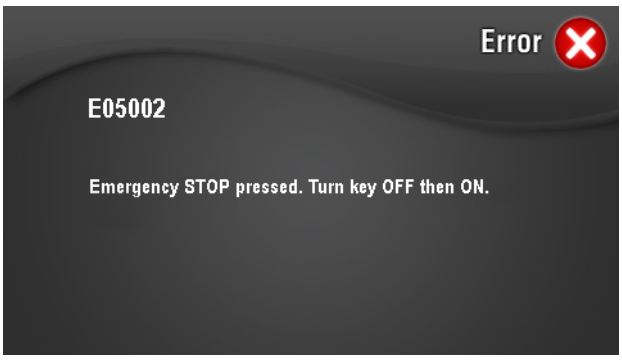
Problem	User Action(s)
The treatment lesions are variable or intermittent (LIO only)	• The LIO may be slightly out of focus. This decreases power density. Readjust your working distance to obtain the smallest spot size. • A poorly centered laser beam may be clipping on the examination lens or on the 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.
Does not fit on the mounting plate (OMA only)	• 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)	• 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.
* Operating microscope adapter compatible with IRIDEX IQ 810 and SLx Systems.	

Error Messages

System Errors

System errors display a message window (example below). When this screen is displayed, the system has detected an interruption in one or more of the sub-systems.

User Action: Turn the keyswitch Off and then On. The system will attempt to correct itself. If the error persists, write down the error code (example: E05002) and contact IRIDEX Service.



Error Code	Error Message
E05002	Emergency STOP pressed. Turn key off for 5 seconds then on.
E00701	System controller watchdog failure.
E01003, E01009	System needs calibration.
E03002, E03003	Invalid sensor reading.
E03010, E03020, E03040	Laser temperature invalid.
E03050	Heat sink reading invalid.
E04018, E04033, E04040, E04050, E04051, E04052, E04120, E04121, E04950, E04951	Voltage supply out of range.
E04099	Laser watchdog failure.
E06001, E06010	Laser power output out of range.
E06006, E06007	Photocell detector readings do not match.
E06030, E06102	Invalid laser output detected.
E06100	Photocell detector not responding.
E06101	Laser output detected in wrong port.
E06200, E06201	Invalid current detected at LCM shunt.
E08000	Software load failure in UIM.

User-Correctable Events and Errors

User-correctable events and errors display a pop-up screen (example below). The pop-up may be cleared, but the laser will not fire until all systems report "OK". An example message is E05111, "Delivery device or SmartKey not connected." You can clear the message; however, you cannot fire the laser until a delivery device or SmartKey is connected.

Refer to the table below for corrective actions. If a user action does not correct the problem, contact IRIDEX Service.

Event / Error Code	Error Message	Cause	User Action(s)
E03012, E03013, E03022, E03023, E03024, E03051	System temperature out of range.	System may have overheated.	System will adjust and attempt to continue.
E03016, E03017, E03018, E03019	Fan signal error. System will attempt to continue.	System unable to detect cooling mechanisms.	System will attempt to continue. If problem persists, call Service.
E05004	Remote interlock not engaged.	System detected an open circuit while auxiliary interlock was in use.	If installed on a room door, close door to proceed.
E05035	Laser safety eye filter not in position.	System detected out-of-position filter while attempting to treat.	Verify that SmartKey is connected. If using a 2-position filter, engage to closed position.
E05092	Footswitch not detected.	System unable to detect footswitch connection.	Check footswitch connection.
E05096	Footswitch depressed.	Footswitch engaged while changing from Standby to Treat mode.	Release footswitch.
E05106	Incompatible eye safety filter wavelength. Attach a compatible filter.	System unable to detect eye safety filter due to wavelength incompatibility.	Check eye safety filter and attach a compatible filter.
E05108	Invalid spot size.	Spot size on delivery device not in correct position.	Turn SLA to select desired spot size.
E05110	Simultaneous connection of 2 SLA devices not permitted.	System detected 2 connected SLA devices.	Disconnect one device.
E05111	Delivery device or SmartKey not connected.	System unable to detect delivery device and/or SmartKey.	Check connections or attach cables.
E06002	Laser power output out of range.	System unable to deliver specified power.	Laser will attempt to operate at a lower setting. Decrease power setting.

Event / Error Code	Error Message	Cause	User Action(s)
E06003	Missing Pulse error.	System unable to deliver laser pulse when it was expected.	Check connections and turn laser key OFF for 5 seconds then back ON.
W0001	Verify a 577 nm eye safety filter is in place.	Confirmation of eye safety filter is required before laser enters Treat mode.	If using a 2-position filter, connect SmartKey.

5
Maintenance

Inspecting and Cleaning the Laser

Clean the outside console covers with soft cloth moistened with a mild detergent. Avoid abrasive or ammonia-based cleaners.

Periodically inspect the laser, power cords, footswitch, cables, etc., for wear. Do not use if there are any exposed or broken wires, and/or broken connectors.

1. The equipment covers should be intact; not loose.
2. All knobs and dials should be in proper working order.
3. The switch cap on the Emergency Stop should be intact; not broken.
4. All eye safety filters are properly installed. No cracks or damage that may cause unintended stray laser light to transmit.
5. All eye safety glasses should be the correct type (wavelength and OD). No cracks or damage that may cause unintended stray laser light to transmit.

WARNING: *Do not remove covers! Removing covers and shields may result in exposure to dangerous optical radiation levels and electrical voltages. Only IRIDEX-trained personnel may access the interior of the laser. The laser has no user serviceable parts.*

CAUTION: *Turn off the laser before inspecting any delivery device components. Keep the protective cap over the laser port when the laser is not in use. Always handle fiber-optic cables with extreme care. Do not coil the cable in a diameter less than 15 cm (6 in.).*

Inspecting and Cleaning the Footswitch

To clean the footswitch

1. Disconnect the footswitch from the laser (if applicable).
2. Using water, isopropyl alcohol, or a mild detergent, wipe down the surfaces of the footswitch. Avoid abrasive or ammonia-based cleaners.
3. Allow the footswitch to air-dry completely before reusing.
4. Reconnect the footswitch to the laser.

NOTE: *The cable is not sealed and should not be immersed into any cleansing agent.*

Verifying the Power Calibration

To ensure that calibration meets the requirements of the National Institute of Standards and Technology (NIST), the laser treatment power is calibrated at the IRIDEX factory with a power meter and an IRIDEX delivery device with previously measured transmission.

Periodically, and at least annually, the actual power being delivered through IRIDEX delivery device(s) should be measured to verify that the laser system is still operating within factory calibration parameters.

Regulatory agencies require that manufacturers of US FDA CDRH Class III and IV and IEC 60825 Class 3 and 4 medical lasers supply their customers with power calibration procedures. Only IRIDEX trained factory or service personnel may adjust the power monitors.

To verify the power calibration:

1. Make sure all persons in the room are wearing the appropriate laser safety eyewear.
2. Connect a properly functioning IRIDEX delivery device or test fiber.
3. Center the aiming beam on the power meter sensor. Measurement equipment must be capable of measuring several watts of continuous optical power.

CAUTION: *A spot size of less than 3 mm diameter can damage the power meter sensor.*

4. Set the laser Duration to 3000 ms and the Interval to Single Pulse, when a CW delivery device is connected. Set the Duration to 3000 ms, MicroPulse Duration to 1.0 ms and MicroPulse Interval to 1.0 ms (50% Duty Factor) when a MicroPulse delivery device is connected.
5. Set the laser Power to 200 mW
6. Place the laser in Treat mode.
7. Direct the aiming beam from the IRIDEX delivery device onto the power meter, following the power meter instructions for sampling the laser power.
8. Actuate the footswitch to deliver the treatment beam. Record the stabilized power meter reading in the table below. This value represents the average power delivered by the device.
9. Set the power to 500 mW, actuate the footswitch to deliver the treatment beam, and record the reading.
10. Set the power to 1000 mW, actuate the footswitch to deliver the treatment beam, and record the reading.
11. Set the power to 2000 mW, actuate the footswitch to deliver the treatment beam, and record the reading.
12. If the readings fall outside the acceptable levels, check the power meter, ensure that you have accurately placed the beam on the power meter, and check the readings again with another IRIDEX delivery device.
13. If the readings are still outside the acceptable levels, contact your local IRIDEX Technical Support Representative.
14. Place a signed copy of the table in your device records to refer to during use and service.

Power Measurements using a CW Delivery Device

Power (mW)	Exposure Duration (ms)	Meter Reading (mW)	Acceptable Range (mW)
200	1000–3000		160–240
500	1000–3000		400-600
1000	1000–3000		800-1200
2000	1000–3000		1600-2400

Data for power measurement equipment: _____ Calibration date: _____

Meter Model and Serial Number: _____ Calibrated by: _____

Power Measurements using a MicroPulse® Delivery Device

Exposure Duration (ms)	MicroPulse® Duration (ms)	MicroPulse® Interval (ms)	Indicated Power (mW)	Measured Power (mW)	Acceptable Range (mW)
1000–3000	1.0	1.0	200		80-120
1000–3000	1.0	1.0	500		200-300
1000–3000	1.0	1.0	1000		400-600
1000–3000	1.0	1.0	2000		800-1200

Data for power measurement equipment: _____ Calibration date: _____

Meter Model and Serial Number: _____ Calibrated by: _____

6
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.

The following formula was used to calculate the most conservative NOHD values:

$NOHD = (1.7/NA)(\Phi/\pi MPE)^{0.5}$

where:

NOHD = the distance, in meters, at which the beam irradiance equals the appropriate corneal MPE

NA = the numerical aperture of the beam emerging from the optical fiber

Φ = the maximum possible laser power, in watts

MPE = the level of laser radiation, in W/m^2, to which a person may be exposed without suffering adverse events

Numerical aperture is equal to the sine of the half-angle of the emerging laser beam. Maximum available laser power and associated NA vary with each delivery device, resulting in unique NOHD values for each delivery device.

NOTE: *Not all delivery devices are available for all laser models.*

IQ 577/IQ 532 NOHD Values for Various Delivery Devices

Delivery Device	MPE (W/m^2)	Numerical Aperture (NA)	Maximum Power Φ (W)	NOHD (m)
EndoProbe	10	0.100	2.000	4.3
Oto/ENT Probes (IQ 532)	10	0.100	2.500	4.8
Oto/ENT Probes (IQ 532 with XP option)	10	0.100	6.000	7.4
Laser Indirect Ophthalmoscope (LIO)	10	0.013	2.000	33.0
Slit Lamp Adapter (SLA)	10	0.012	1.800	33.9

Optical density of laser safety glasses used with IQ 577 (maximum output power of 2 W) should have an OD $\geq$ 4 at 577 nm.

Optical density of laser safety glasses used with IQ 532 (maximum output power of 2.5 W) should have an OD $\geq$ 4 at 532 nm.

Optical density of laser safety glasses used with IQ 532 (maximum output power of 6 W) should have an OD $\geq$ 4.2 at 532 nm.

Safety Compliance

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

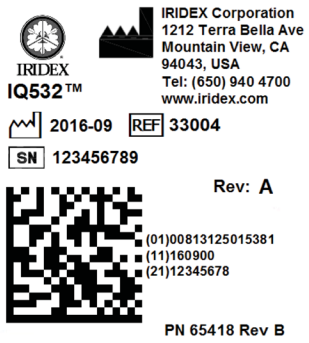
CE-marked devices comply with all requirements of the European Medical Device Directive MDD 93/42/EEC.

Feature	Function
EMERGENCY STOP	Immediately disables the laser.
Protective housing	The external housing prevents unintended access to laser radiation above Class I limits.
Safety interlock	An electronic interlock at the fiber port prevents laser emission if a delivery device is not properly connected.
Remote interlock	An external door interlock outlet is provided to disable the laser if the treatment room doors are opened during treatment. An interlock jumper wire is also provided.
Keyswitch	The system operates only with the proper key. The key cannot be removed while in the On position.
Laser emission indicator	The yellow Standby light provides a visible warning that laser radiation is accessible. When Treat mode is selected, a three-second delay prevents unintentional laser exposure. The console delivers laser energy only when the footswitch is depressed while in Treat mode. An audible tone indicates that the console is delivering laser energy. The audible indicator volume can be adjusted but not turned off.
Beam attenuator	An electronic beam attenuator prevents any laser radiation from exiting the console until all requirements for emission are met.
Viewing optics	Eye safety filters are required when using the laser system.
Manual restart	If laser emission is interrupted, the system goes into Standby mode, the power drops to zero, and the console must be manually restarted.
Internal power monitor	Two monitors independently measure the laser power before emission. If the measurements differ significantly, the system enters Call Service mode.
Footswitch	The laser cannot be placed in Treat mode if the footswitch is damaged or improperly connected. The footswitch can be immersed and cleaned (IPX8 per IEC60529) and is shrouded for safety (ANSI Standard Z136.3, 4.3.1).

Labels

NOTE: The actual label may vary with laser model.

Serial Number (rear panel)



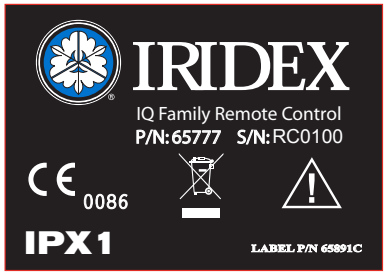
Ground (bottom of laser)

The reliability of the ground connection can only be assured when this device is connected to an approved mating receptacle marked for hospital use and installed in accordance with the appropriate Electrical Codes for medical occupancy.

Footswitch

Wireless Receiver

Remote Control



Laser Warning
Rear panel of console
(IQ 577)

Laser Warning
Rear panel of console
(IQ 532)

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
	Date of manufacture		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		Waste Electrical and Electronic Equipment (WEEE)		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				

Specifications

Specification	Description
Treatment wavelength	**IQ 577**: 577 nm **IQ 532**: 532 nm
Treatment power	**IQ 577**: 50 – 2000 mW (delivered), depending on delivery device. **IQ 532**: 50 – 2500 mW (delivered), depending on delivery device. **IQ 532 with XP Option**: 50 - 5000 mW (delivered), depending on delivery device.
Duration	**CW-Pulse**: 10 ms – 3000 ms or CW to 60 seconds **MicroPulse (Optional)**: 0.05 ms – 1.0 ms
Repeat interval	10 ms – 3000 ms or single pulse **MicroPulse**: 1.0 ms – 10.0 ms
Aiming beam	635 nm laser diode. User-adjustable intensity; <1 mW maximum

Specification	Description
Electrical	100 – 240 VAC, 50/60 Hz, <3 A
Cooling	Air cooled
Operating temperature range	10° C to 35° C (50° F to 95° F)
Storage temperature range	-20° C to 60° C (-4° F to 140° F)
Relative humidity	20% to 80% non-condensing
Dimensions	30.5 cm × 35.6 cm × 21.4 cm (12 in. W × 14 in. D × 8.5 in. H)
Weight	9 kg (19.2 lb)

7
Wireless Footswitch and EMC

Setting Up the Wireless Footswitch

The wireless footswitch comprises:

- Battery-powered footswitch (with or without power adjust)
- Laser console-powered receiver

Connect the wireless receiver to the footswitch receptacle on the rear of the laser. Three pedals (as applicable) on the footswitch control the following:

- Left pedal = decrease power (hold down to ramp the parameter)
- Center pedal = activate laser
- Right pedal = increase power (hold down to ramp the parameter)

CAUTION: *Each footswitch/receiver pair is uniquely linked and will not work with other IRIDEX footswitches or similar components. Clearly identify each pair to prevent separation of the linked components.*

NOTE: *The footswitch is designed to operate within 15 feet (5 meters) of the laser.*

Testing the Batteries

NOTE: *When batteries need to be replaced, contact your sales representative or IRIDEX Customer Service. The wireless footswitch was designed with a battery life expectancy of 3 – 5 years of normal operation and use.*

LEDs on the footswitch assist in troubleshooting and indicate battery conditions as follows:

Footswitch LED Display	Status
Green flash following pedal depression	Footswitch OK Batteries OK
Amber flash following pedal depression	Footswitch OK Batteries low
Blinking red LED for 10 seconds following pedal depression	No RF communication

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.*

The wireless footswitch transmits and receives in the frequency range of 2.41GHz to 2.46GHz with a limited effective radiated power as described below. The transmissions are continuous transmissions at discrete frequencies within the transmission frequency range.

The wireless footswitch has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If the wireless footswitch does cause harmful interference to radio or television reception, which can be determined by turning the laser system off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the laser console into an outlet on a circuit different from that to which the receiver is connected.
- Consult IRIDEX Customer Service for help.

This Class B digital apparatus meets all requirements of the Canadian Interference-Causing Equipment Regulations.

Cet appareil numérique de la classe B respecte toutes les exigences du Réglement sur le matériel brouilleur du Canada.

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 sec	<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 sec	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.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The wireless footswitch is intended for use in the electromagnetic environment specified below. The customer or the user of the wireless footswitch should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the laser system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF IEC-61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$ 80MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[a] Fields strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE 2**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the laser system is used exceeds the applicable RF compliance level above, the laser system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the laser system. **b**: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Wireless Footswitch.

The wireless footswitch is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the wireless footswitch can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the wireless footswitch 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 and reflection from structures, objects, and people.