IRIDEX IQ 577™

Operator Manual

IRIDEX IQ 577™ Operator Manual
15510-EN Rev A

1
Introduction

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 laser systems:

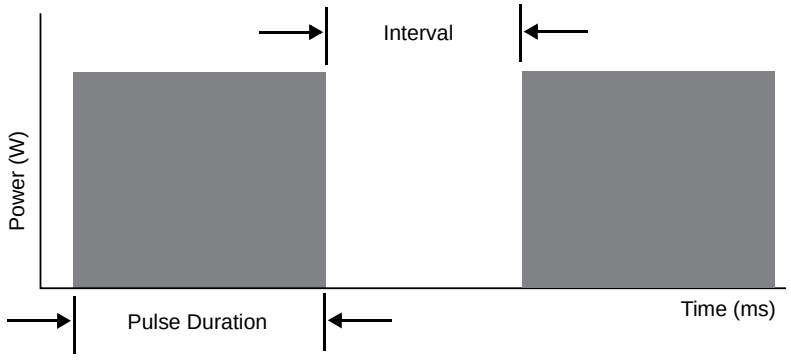
- EndoProbe®
- Slit Lamp Adapters (SLA)
- Laser Indirect Ophthalmoscopes (LIO)

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™.

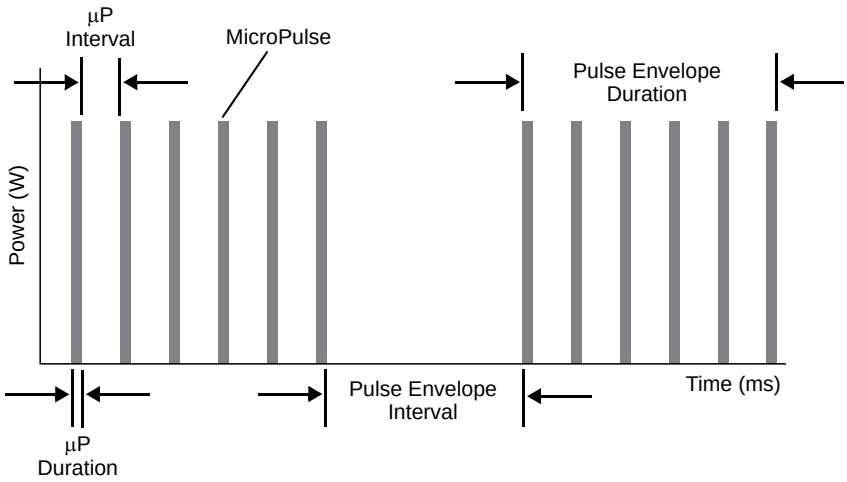
CW-Pulse



MicroPulse

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

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



Indications for Use

This section provides information on the use of the IQ 577 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 IQ 577 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 IQ 577 and the handpieces, delivery devices, and accessories that are used with it to deliver laser energy in either CW-Pulse™ or MicroPulse™ mode are intended for soft and fibrous tissue, including osseous tissue incision, excision, coagulation, vaporization, ablation and vessel hemostasis in Ophthalmology.

Ophthalmology

Indicated for use in photocoagulation of both interior 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
- Iridotomy, iridectomy, and trabeculoplasty in angle closure glaucoma and open angle glaucoma

Procedural Recommendations

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

Technique

The laser energy is recommended to be administered via the EndoProbe optical fiber delivery handpiece which is utilized intra-ocularly.

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 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.

Ophthalmic Treatment Parameters						
Treatment	**Delivery Devices**	**Power (W)**	**MicroPulse Length (ms)**	**MicroPulse Interval (ms)**	**Exposure Duration (ms)**	**Spot Size (µm)**
Trabeculoplasty	SLA	1.5–2.0	0.05–0.5	1–10	100–500	100–500
Retina Grid/Focal	SLA, LIO, EndoProbe, OMA	1.0–2.0	0.05–0.5	1–10	100–1000	50–100
Trabeculoplasty	SLA	0.5–2.0	N/A	N/A	100–500	50–200
Iridotomy	SLA, LIO	0.2–2.0	N/A	N/A	100–300	50–200
Retina Grid/Focal	SLA, LIO, EndoProbe, OMA	0.1–2.0	N/A	N/A	100–1000	100–1000

Specific Warnings and Precautions

It is essential that the surgeon and attending staff be trained in all aspects of this procedure. 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.

Specific Complications and Risks

None known specific to ophthalmology use at this time.

Specific Contraindications

None known specific to ophthalmology use at this time.

M.B. Parodi, S .Spasse, P. Iacono, G. DiStefano, T. Canziani; Subthreshold Grid Laser Treatment of Macular Edema Secondary to Branch Retinal Vein Occlusion With Micropulse Infrared (810 Nm) Diode Laser; *Ophthalmology* Volume 113, Number 12, December 2006.

T J Desmettre, S R Mordo, D M Buzawa and M A Mainster; Micropulse and continuous wave diode retinal photocoagulation: visible and subvisible lesion parameters; *British Journal of Ophthalmology* 2006;90;709-712; originally published online 10 Mar 2006.

JK Luttrull, DC Musch and CA Spink; Subthreshold diode micropulse panretinal and photocoagulation for proliferative diabetic retinopathy., *Eye* online publication, February 2007.

AM Fea, A Bosone, et. al. Micropulse diode laser trabeculoplasty (MDLT): A phase II clinical study with 12 months follow-up. *Clinical Ophthalmology* advance online publication, 9 Apr 2008.

Brancato R, Carassa R, Trabucchi G.; Diode Laser Compared With Argon Laser for Trabeculoplasty *American Journal of Ophthalmology* 112:50-55, 1991.

Moriarty A, McHugh J, ffytche T, Marshall J, Spalton D, Moriarty B.; Diode Laser Trabeculoplasty (DLT) versus Argon Laser Trabeculoplasty (ALT) in Primary Open-Angle Glaucoma *Scientific Poster #52. AAO*. San Francisco, CA. October, 1994.

Wong JS, Chew P, Chee C; Comparison of Corneal Transmissibility of 810 nm Diode Laser With 448 nm Argon Laser; Diode Laser Peripheral Iridoplasty/Iridotomy in Acute Angle Closure Glaucoma; [ARVO Abstract]. *Invest Ophthalmology Vis Sci*. 39(4): S472. Abstract nr2162, 1998

Akduman L, Olk RJ. "Diode Laser (810 nm) versus Argon Green (514 nm) Modified Grid Photocoagulation for Diffuse Diabetic Macular Edema", *Ophthalmology* 104:1433-1441, 1997.

Warnings and Cautions

WARNINGS:

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

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

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

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

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.

Laser plume may contain viable tissue particulates.

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

IRIDEX Corporation Contact Information

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EC REP Medical Devices Consultants International Limited
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CE 0086 Worthing, West Sussex BN11 1SL
United Kingdom

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 U.S., 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

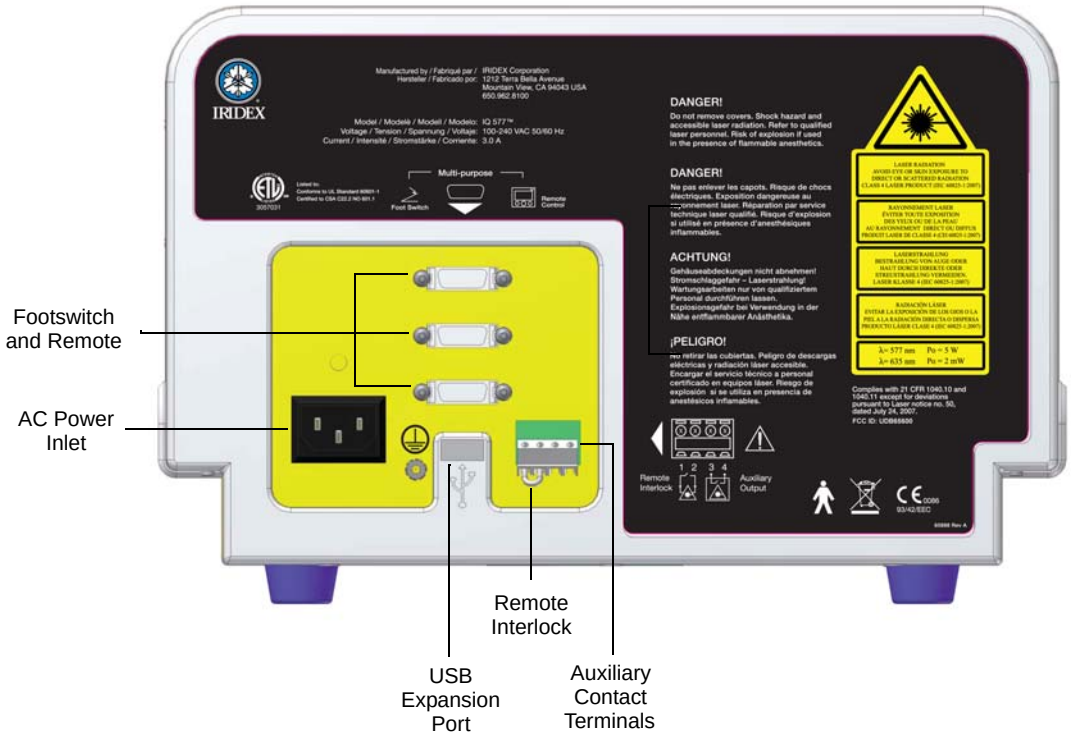
CAUTION: *Do not connect two footswitches to the laser console.*

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 five amps and 24 volts AC or DC. Ensure that all wiring conforms to local electrical codes.

IQ 577 Rear Panel Connectors



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:

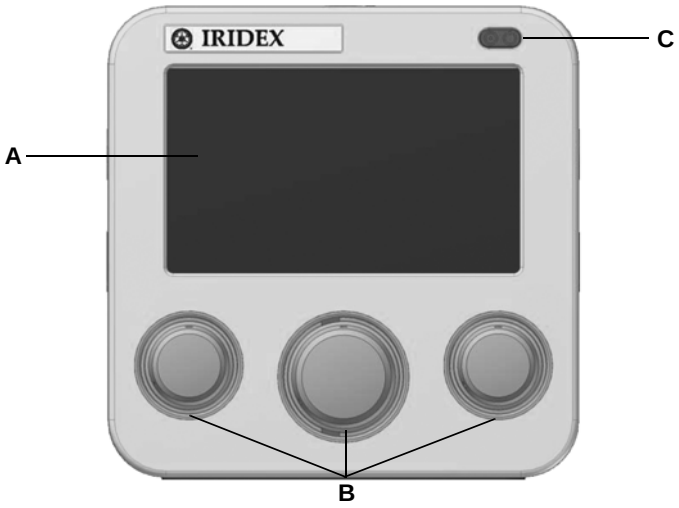
1. Turn on the laser.
2. Reset the counter.
3. Set the treatment parameters.
4. Position the patient.
5. If required, select an appropriate contact lens for the treatment.
6. Ensure that all ancillary personnel in the treatment room are wearing the appropriate laser safety eyewear.
7. Select Treat mode.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

TO CONCLUDE PATIENT TREATMENT:

1. Select Standby mode.
2. Record the number of exposures and any other treatment parameters.
3. Turn off the laser and remove the key.
4. Collect the safety eyewear.
5. Remove the warning sign from the treatment room door.
6. Disconnect the delivery device(s).
7. Disconnect the SmartKey, if used.
8. If the delivery device is single-use, dispose of it properly. Otherwise, inspect and clean the delivery device(s) as instructed in your delivery device manual(s).
9. If a contact lens was used, handle the lens according to the manufacturer's instructions.

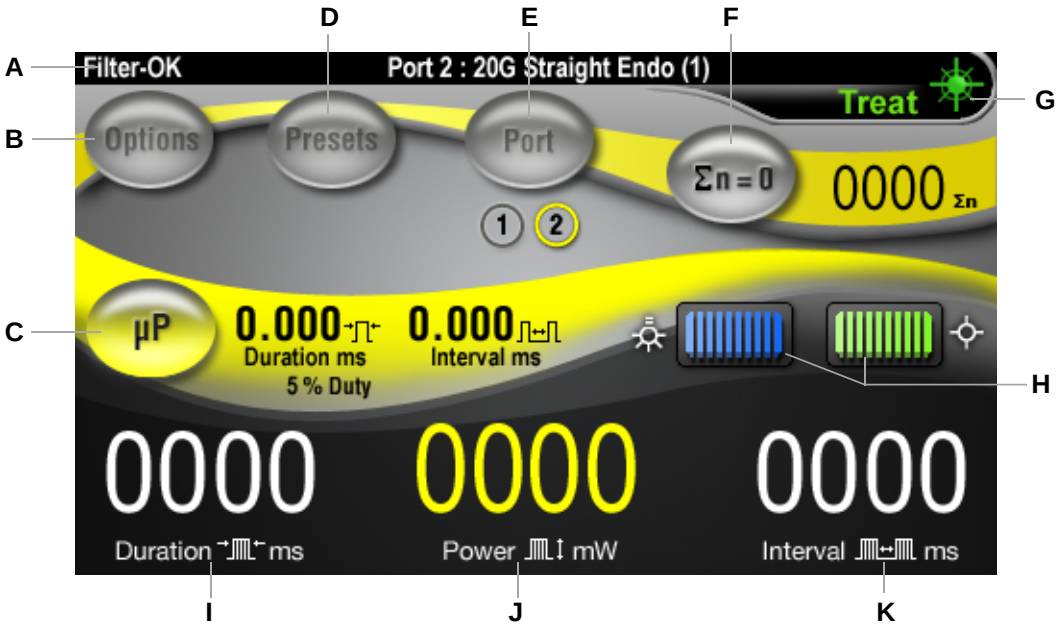
Using the IQ 577

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.

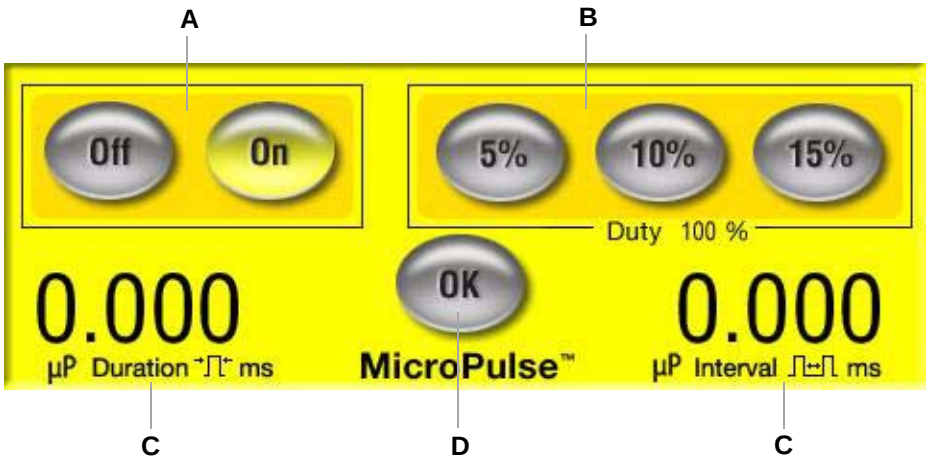
Treat Screen



A	Displays eye safety filter status and delivery device.
B	Go to Options screen.
C	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, are maintained.
K	Displays pulse interval. Adjust with control knob.

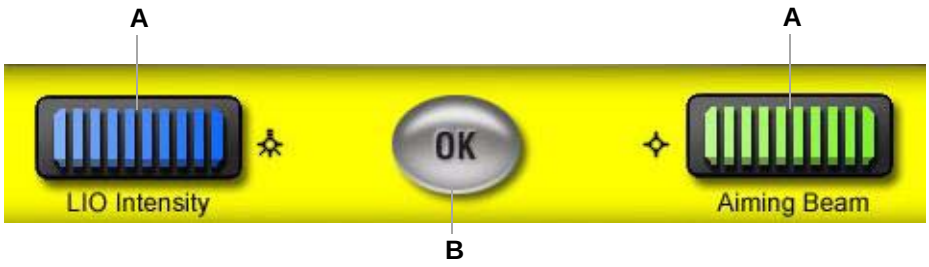
WARNING: *Except during actual treatment, the laser must always be in Standby mode. Maintaining the laser in Standby mode prevents accidental laser exposure if the footswitch is inadvertently pressed.*

MICROPULSE SETTINGS



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.

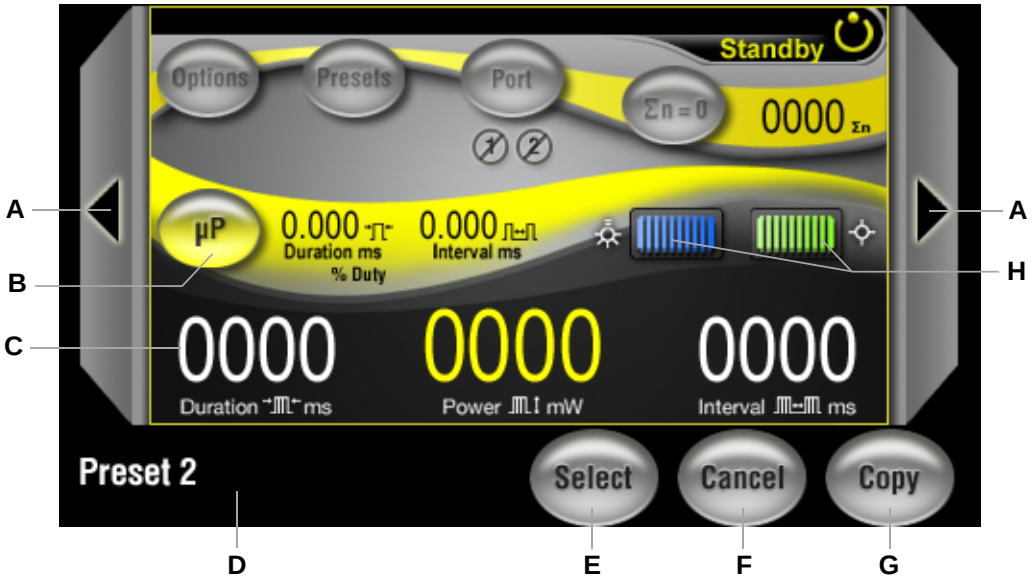
LIO INTENSITY/AIMING BEAM SETTINGS



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

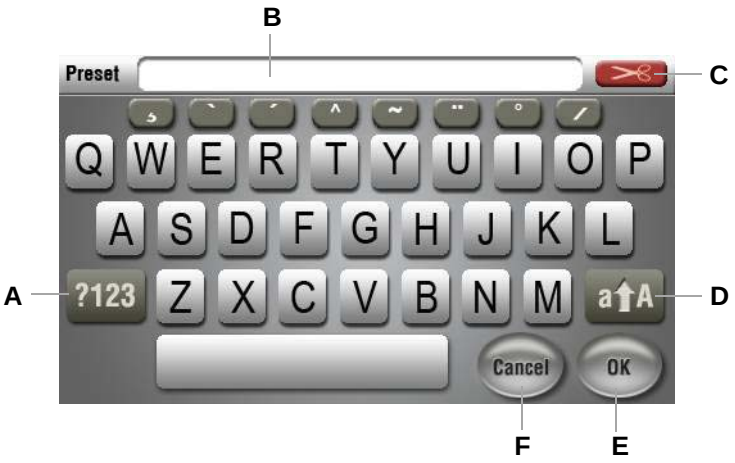
Presets Screen

To access the Presets screen, touch PRESETS.



A	Go to Previous/Next Preset.
B	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 go to Treat screen.
F	Discard changes and go to Treat screen with default parameters.
G	Import information from Treat screen into selected Preset.
H	Aiming Beam and LIO adjustments.

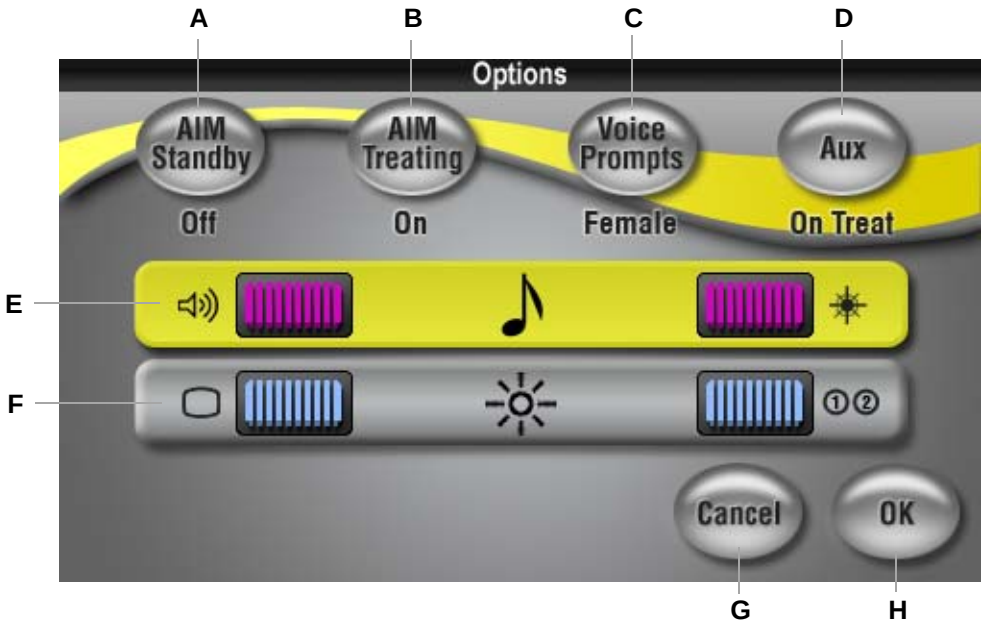
KEYBOARD MODE



A	Select: letters, numbers, or symbols.
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.

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 (yellow=active bar). Use control knobs to set volume.
F	Press bar to select it (yellow=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.

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.

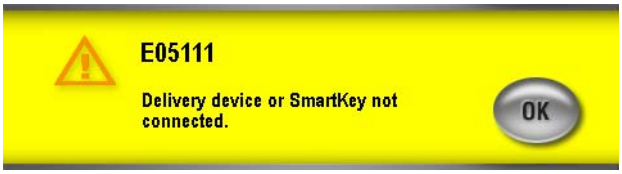
User Action: Turn the keyswitch Off and then On. The system will attempt to correct itself. If the error persists, write down the error code (example: E05002) and contact IRIDEX Service.

Error Code	Error Message
E05002	Emergency STOP pressed. Turn key off 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 Errors

User-correctable 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.



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.
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.
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.

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.*

CAUTIONS:

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

IRIDEX footswitch labeled IPX8 is submersible (per IEC 60529).

TO DECONTAMINATE AND DISINFECT THE FOOTSWITCH:

1. Disconnect the footswitch from the laser (if applicable).
2. Using water, isopropyl alcohol, or enzymatic detergents with mild pH, such as ENZOL®, remove all traces of blood and other body fluids from all exposed surfaces of the footswitch assembly, including the cable (if applicable).
3. Stand the footswitch on end to drain all fluids.
4. Immerse the footswitch in a CIDEX® (2.4% glutaraldehyde) solution:
   - 45 minutes at 25º C to achieve a high level of disinfection
   - 10 minutes at 20º C to 25º C to achieve an intermediate level of disinfection
5. Remove the footswitch from the CIDEX solution.
6. Stand the footswitch on end to drain all fluids.
7. Rinse by completely immersing the footswitch in clean water for one minute. Repeat two more times using clean water for each rinse.
8. Stand the footswitch on end again to drain all fluids.
9. Allow the footswitch to air-dry completely before reusing.
10. Reconnect the footswitch to the laser.

NOTE: *The connector 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, you should measure the actual power being delivered through your IRIDEX delivery device(s) 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 European EN 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.
3. Set the power to 200 mW.
4. Set the duration to 2000 ms and the interval to one pulse.
5. Center the aiming beam at the middle of the power meter sensor.

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

6. Place the laser in Treat mode.
7. Aim the output beam from the IRIDEX delivery device into the power meter, following the power meter instructions for sampling the laser power.
8. Press the footswitch to deliver the treatment beam. Record the power meter reading in the table below.
9. Set the power to 500 mW.
10. Press the footswitch to deliver the treatment beam, and record the reading.
11. Set the power to 1000 mW.
12. Press the footswitch to deliver the treatment beam, and record the reading.
13. Set the power to 2000 mW.
14. Press the footswitch to deliver the treatment beam, and record the reading.

Calibration date for power meter and sensor: _____

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

Date: _____ Calibrated by: _____

Of: _____

15. 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.
16. If the readings are still outside the acceptable levels, contact your local IRIDEX Technical Support Representative.
17. Place a signed copy of the table in your device records to refer to during use and service.

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 the Slit Lamp Adapter, LIO, EasyFit Adapter, IRIDEX Integrated Slit Lamp Workstation, and SL130 Integrated Slit Lamp Workstation. For endophotocoagulation, 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. When using the dermatology handpieces, always wear the appropriate laser safety eyewear.

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 worst case NOHD:

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

where:

NOHD = the distance 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/cm^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.*

NOHD Range				
Delivery Device	**MPE (W/cm^2)**	**Numerical Aperture (NA)**	**Maximum Power (W)**	**NOHD (m)**
Slit Lamp Adapter	2.55×10^{-3}	0.012	2.0	22.38
Laser Indirect Ophthalmoscope (LIO)	2.55×10^{-3}	0.03	2.0	8.95
EndoProbe	2.55×10^{-3}	0.10	2.0	2.69

Safety Compliance

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

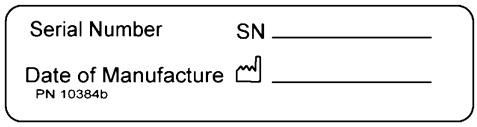
CE-labeled devices comply with all requirements of the European Medical Device Directive MDD 93/42/EE.

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.*

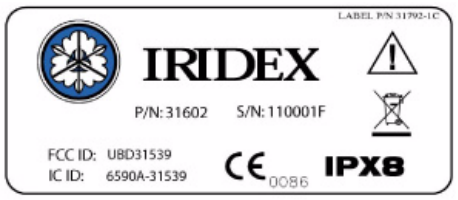
Serial Number (bottom of laser)



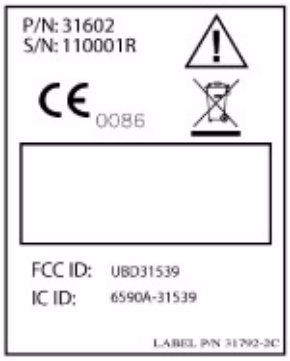
Ground (bottom of laser)

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

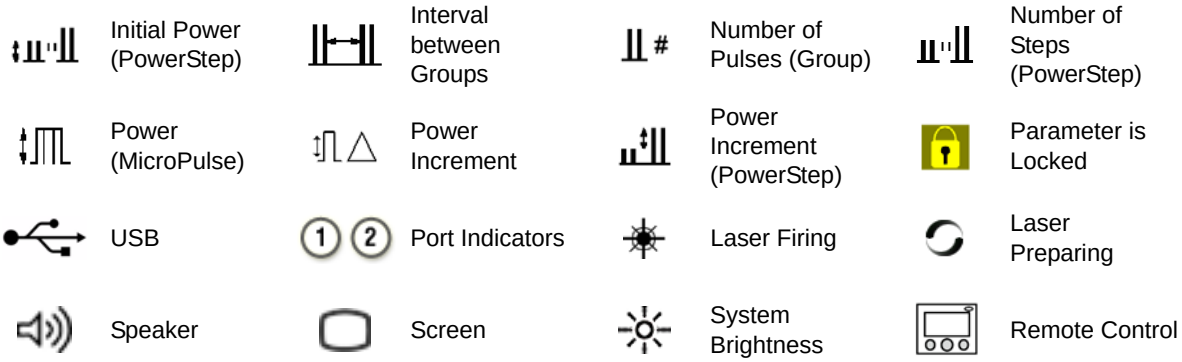


Remote Control

Laser Warning

Symbols (As Applicable)

 Aiming Beam	 Angle	 Aspirating Probe
 Attention! Read Manual	 Audible Signal	 CE Mark
 Connector Type	 Damaged Package	 Duration
 Duration with MicroPulse	 Emergency Stop	 ETL Mark
 EtO Sterile	 European Representative	 Expiration Date
 Footswitch	 Footswitch In	 Footswitch Out
 Fuse	 Gauge	 Ground
 Illuminating Probe	 Increase/Decrease	 Interval
 Interval with MicroPulse	 Laser Aperture at End of Fiber	 Laser Warning
 Illumination	 LOT	 Manufacturer
 Manufacture Date	 Off	On
 Part Number	 Power	 Pulse Count
 Pulse Count Reset	 Radio Antenna	 Read Information
 Remote Control	Remote Interlock	Serial Number
Single Use	Standby	Treat
Type B Equipment	WEEE Guidance. Contact IRIDEX or your distributor for disposal information.	



Specifications

Specification	Description
Treatment wavelength	577 nm
Treatment power	50 – 2000 mW (delivered), depending on delivery device. **Note:** Power setting for CW-Pulse is saved until MicroPulse is selected, and vice-versa.
Duration	**CW-Pulse**: 10 ms – 3000 ms or CW to 60 seconds **MicroPulse**: 0.05 ms – 10.0 ms
Repeat interval	50 – 3000 or single pulse
Aiming beam	Red laser diode. User-adjustable intensity; 1 mW maximum
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 (-40° F to 140° F)
Relative humidity	20% to 80% (non-condensing)
Dimensions	30.5 cm x 35.6 cm x 21.4 cm (12 in. W x 14 in. D x 8.5 in. H)
Weight	8.5 kg (18.7 #)

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 of the laser.*

Testing the Batteries

NOTE: *When batteries need to be replaced, contact your sales representative or IRIDEX Customer Service. The Wireless Power Adjust 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 V/m	$d = 1.2\sqrt{P}$ 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	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 and reflection from structures, objects, and people.