IRIDEX Cyclo G6™ Laser System

Operator Manual

IRIDEX Cyclo G6™ Laser System Operator Manual
66294-EN Rev D 2018

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Introduction

The IRIDEX Cyclo G6™ Laser System is a semiconductor diode laser that delivers true continuous wave infrared (810 nm) laser light 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 Families of Probe Delivery Devices are compatible with the Cyclo G6 laser system:

- **MicroPulse® Family**
  - MicroPulse P3: A single-use, RFID, fiber-optic handheld delivery device that when used with the Cyclo G6, transmits 810 nm MicroPulse laser energy transsclerally to the ciliary processes for the treatment of glaucoma. The fiber-optic tip of the MicroPulse P3 is 600-µm diameters and protrudes 0.4 mm from the handpiece which allows accurate positioning of the fiber-optic tip at 3 mm posterior to the limbus.
  - The MicroPulse Family may also include additional probes.
- **G-Probe™ Family**
  - G-Probe: A single-use, RFID, fiber-optic handheld delivery device that when used with the Cyclo G6, transmits continuous-wave infrared laser transsclerally to the ciliary processes for the treatment of glaucoma. The fiber-optic tip of the G-Probe is 600-µm diameter and protrudes 0.7 mm from the handpiece which allows accurate positioning of the fiber-optic tip at 1.2mm posterior to the limbus.
  - G-Probe™ Illuminate: Identical to the G-Probe with the addition of transillumination. Transillumination aids the physician in identifying the location of the ciliary processes.
  - The G-Probe Family may also include additional probes.

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

Illumination Control and Light Regulation

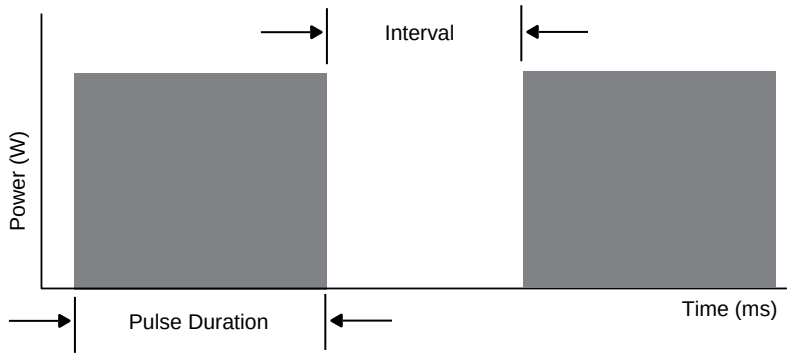
The IRIDEX Cyclo G6 Laser System includes a white light illumination source for augmenting visualization of target tissue during treatment. Compatible delivery devices, such as G-Probe Illuminate, contain illumination fibers for carrying white light from the console to the distal tip of the device. The light source is a white (broad spectrum) LED that is driven from 0 – 5 mW; the power level (and therefore the amount of illumination) is adjustable by the user via the touch screen interface on the console and remote control. Power to the white LED is normally OFF; power ON is managed automatically by the console when a compatible connector is inserted into the light source orifice. An optical microswitch in the light source orifice detects proximity of a compatible connector and triggers the ON/OFF function of the illumination source.

Pulse Types

Two pulse types are available: CW-Pulse™ and MicroPulse® mode.

CW-Pulse™

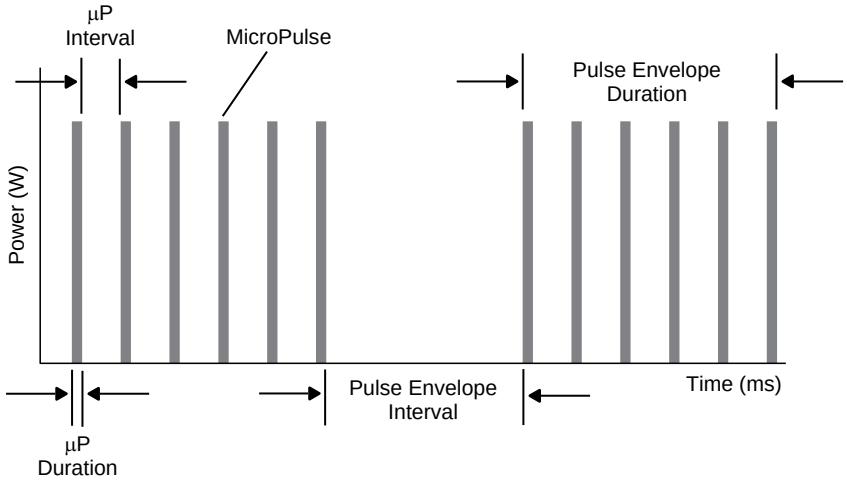
Laser emission is continuous during the entire timed exposure.



MicroPulse®

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

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



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, studies using 810 nm lasers 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

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Indication for Use

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 the laser is used for indications not included herein, the user 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.

Indication for Use

The Family of IRIDEX IQ Laser Systems (IQ 532 [532nm], IQ 577 [577nm], IQ 630-670 [630nm-670nm], IQ 810 [810nm] [IRIDEX Cyclo G6 Laser System]) and the hand pieces, delivery devices & accessories that are used with them to deliver laser energy in either CW-pulse, MicroPulse® or LongPulse™ mode. Intended for soft and fibrous tissue, including osseous tissue incision, excision, coagulation, vaporization, ablation and vessel hemostasis in the medical specialties of, dermatology, ear, nose and throat (ENT)/ otolaryngology, and ophthalmology as follows:

810nm (The IRIDEX Cyclo G6 Laser System)

Ophthalmology:

The IRIDEX Cyclo G6™ Laser System and Probe Delivery Devices (G-Probe, G-Probe Illuminate, & MicroPulse® P3) are used to deliver laser energy in either CW-Pulse (CW) or MicroPulse (μP) treatment mode and indicated for the treatment of Glaucoma:

DELIVERY DEVICE	Condition (Indicated for)	Treatment (Intended Use)	CW/μP
MicroPulse® P3 Device	For the treatment of Glaucoma including: • Primary Open-Angle • Closed-Angle • Refractory	Transscleral cyclophotocoagulation (TSCPC) of the ciliary processes	μP
G-Probe & G-Probe Illuminate	For the treatment of Glaucoma including: • Primary Open-Angle • Closed-Angle • Refractory	Transscleral cyclophotocoagulation (TSCPC) of the ciliary processes	CW

Procedural Recommendations

The user is directed to review the "Instructions For Use" 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

- As with any surgical procedure, there is the potential risk of infection, inflammation, and post-operative pain.

Specific Warnings and Precautions

It is essential that the surgeon and attending staff be trained in all aspects of the use of this equipment. Surgeons should obtain detailed instructions for proper use of this laser system before using it to perform any surgical procedures. For additional Warnings and Cautions, see "Warnings and Cautions" in this chapter. For clinical information, see "References" at the end of this manual. Proper eye protection must be utilized for the specific treatment laser wavelength in use (810 nm).

Laser Settings

CAUTION: *The following treatment parameters are those reported by physicians using IRIDEX products, or like products, either in published literature or reported directly to IRIDEX. These treatment parameters are presented as guidance ultimately it is the physician's responsibility to determine safe treatment parameters that will be used on patients on a case by case basis.*

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

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.

810 nm Typical Laser Treatment Parameters for Ocular Photocoagulation

810 nm Continuous-Wave*					
Application	**Delivery Device**	**Power (mW)**	**Exposure Duration (ms)**	**Treatment Application Sites**	**Total Energy (J)**
Transscleral Cyclophotocoagulation	G-Probe™	1250-1500	3500 – 4000	18-20	79-120
Transscleral Cyclophotocoagulation	G-Probe™ Illuminate	1250-1500	3500 – 4000	18-20	79-120

810 nm MicroPulse®**					
Application	**Delivery Device**	**Power (mW)**	**Duty Cycle (500 Hz)**	**Exposure Duration (ms)**	**Total Energy (J)**
Transscleral Cyclophotocoagulation	MicroPulse® P3	2000-2250	31.3%	50,000-180,000 Superior 50,000-180,000 Inferior	31-126

References

***G-PROBE™**

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***G-PROBE™ ILLUMINATE:** *(includes references for G-Probe as well as the two references below)*

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****MICROPULSE® P3**

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Warnings and Cautions

DANGER:

Do not remove cover as this may expose persons to hazards of electrical shock and laser radiation. Refer servicing to qualified laser personnel. There is a risk of explosion if a laser system is 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.

Before connecting or disconnecting the power cord, make sure that the area is clear of water and any spillage and that hands are dry.

Always disconnect the laser by grasping the plug and not the power cord. Power is shut off by removing the plug from the electrical main.

Instructions provided, indicate not to position the laser to make it difficult to operate the plug of the power cord since the plug is used to provide isolation from electrical shock. Do not place the laser in an area where access to the plug of the power cord is obstructed or prevented.

To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth. EN 60601-1:2006/AC:2010

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.

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2514 AP The Hague
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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.*

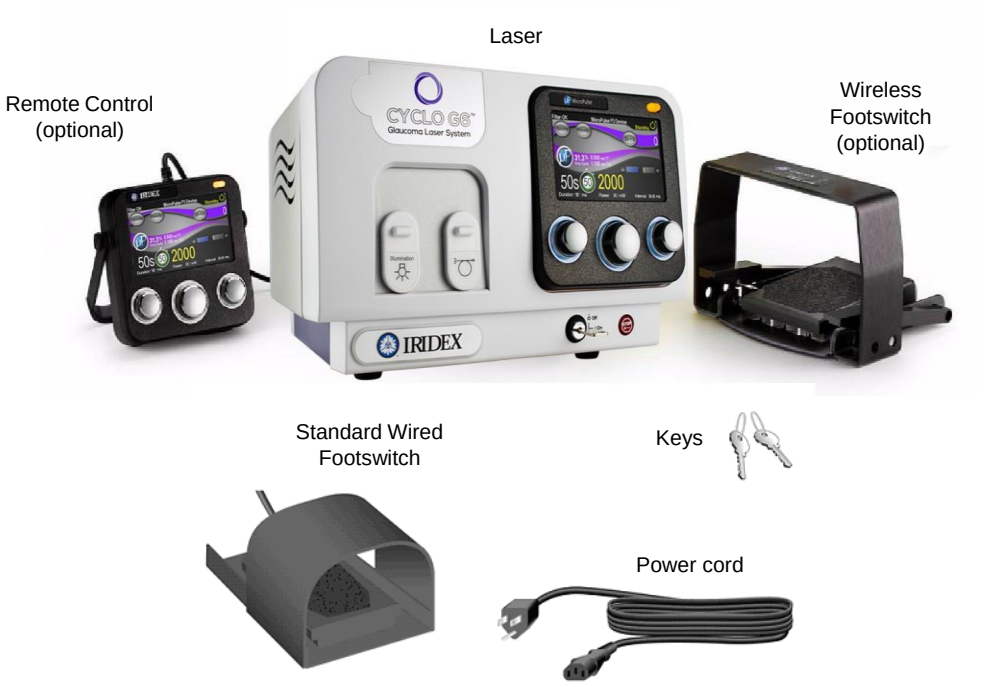
WEEE Guidance. Contact IRIDEX or your distributor for disposal information.

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
- Power cord (U.S. configuration shown)
- Keys
- Standard wired footswitch
- Operator Manual (not shown)
- Laser warning sign (not shown)
- Optional accessories (not 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 medical grade universal input power supply 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.

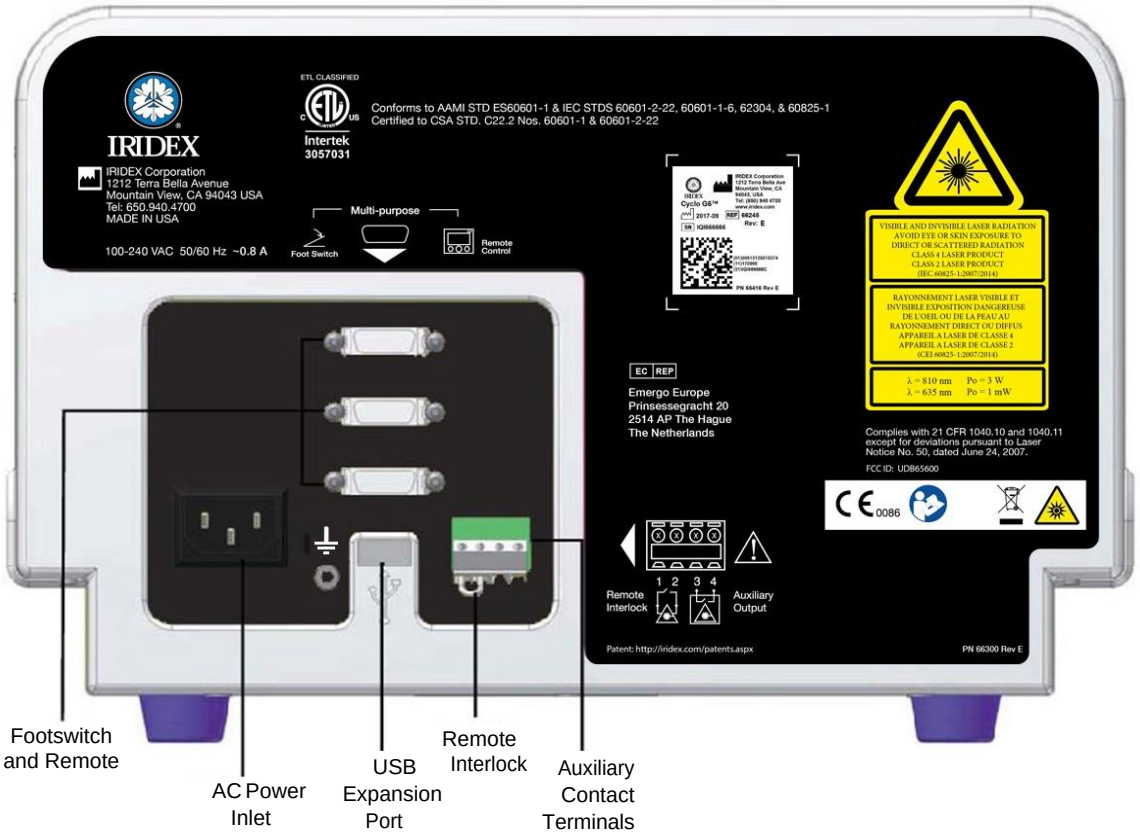
Do not position or use the system near open flames.

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.*

Cyclo G6™ Rear Panel



3
Operation

Front Panel Controls

CAUTION: *When no delivery device is attached to the system, ensure that the illumination and 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.
- 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:

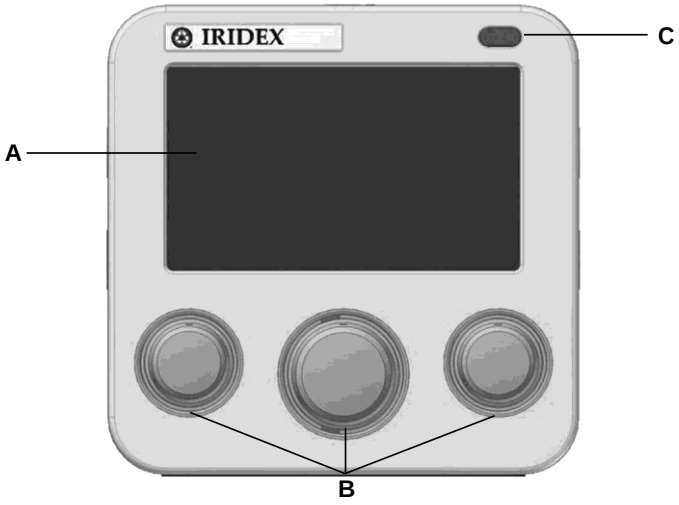
1. Turn on the laser.
2. Reset the counter.
3. Set the treatment parameters.
4. Position the patient.
5. If required, select an appropriate contact lens for the treatment.
6. Ensure that all ancillary personnel in the treatment room are wearing the appropriate laser safety eyewear.
7. Select Treat mode.
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. Dispose of the delivery device, it is single-use.
8. If a contact lens was used, handle the lens according to the manufacturer's instructions.

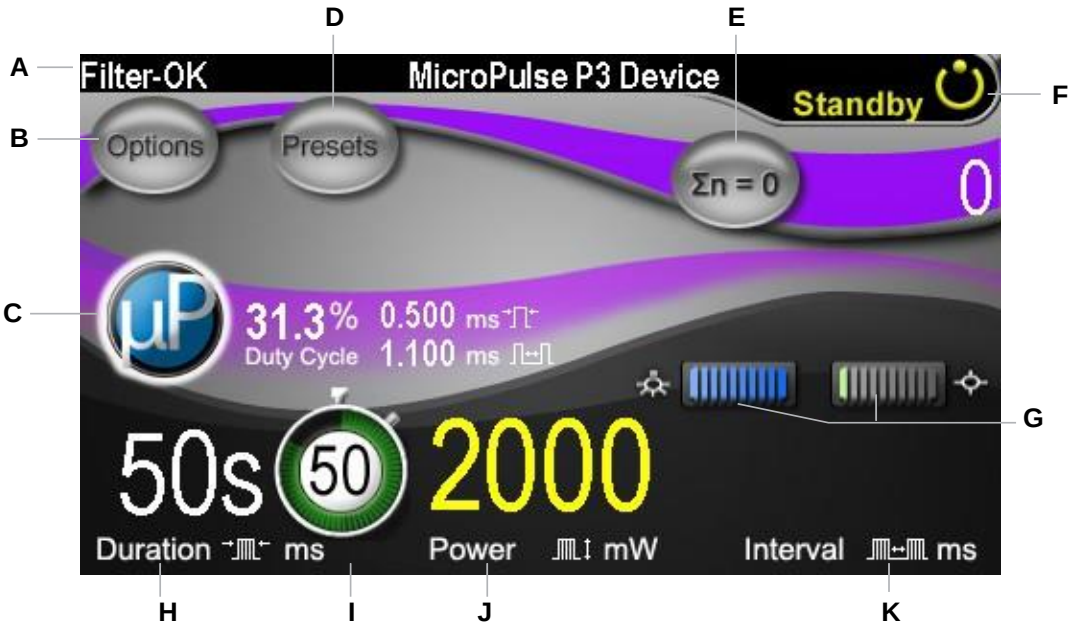
Using the Laser System

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.

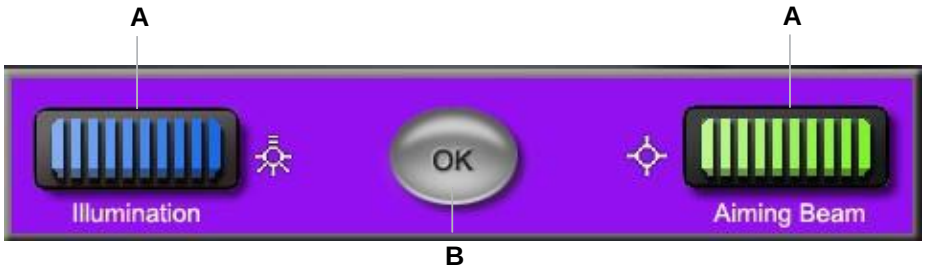
Treat Screen



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	Reset pulse counter.
F	Indicates laser mode: • Ready: Laser is ready; will fire when footswitch is pressed. • Standby: Laser is disengaged. • Treat: Laser is firing (footswitch pressed).
G	Aiming Beam and Illumination
H	Displays pulse duration. Adjust with control knob.
I	Countdown timer
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.

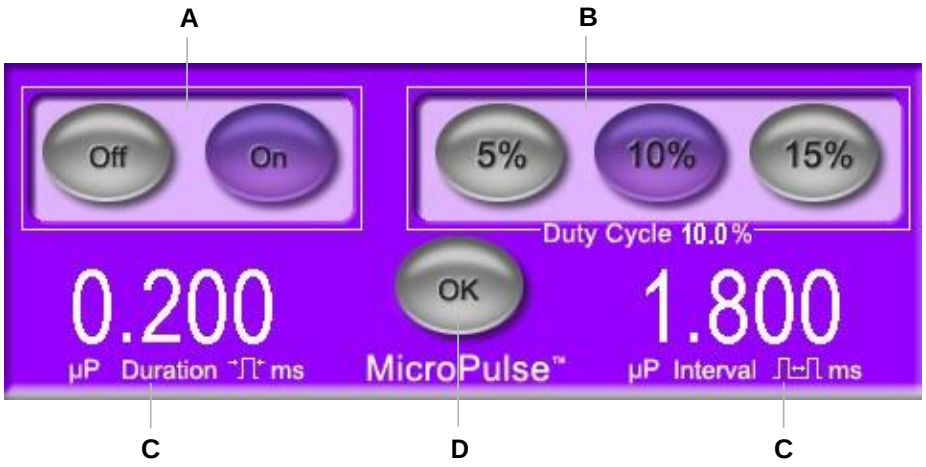
WARNING: *Except during actual treatment, the laser must always be in Standby mode. Maintaining the laser in Standby mode prevents accidental laser exposure if the footswitch is inadvertently pressed.*

ILLUMINATION/AIMING BEAM SETTINGS



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

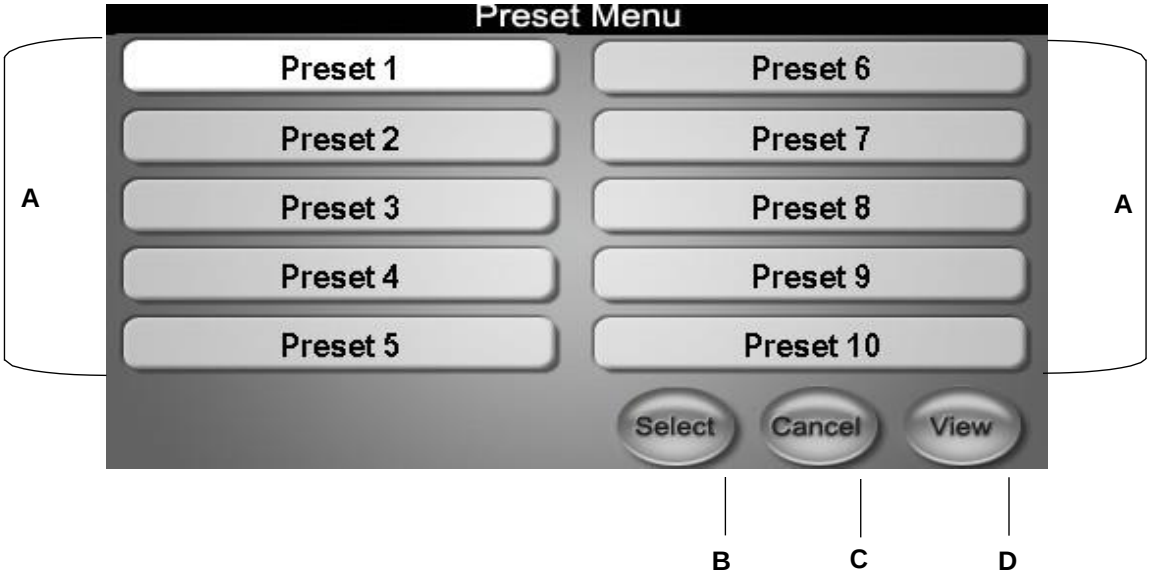
MICROPULSE® SETTINGS



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.

Preset Menu

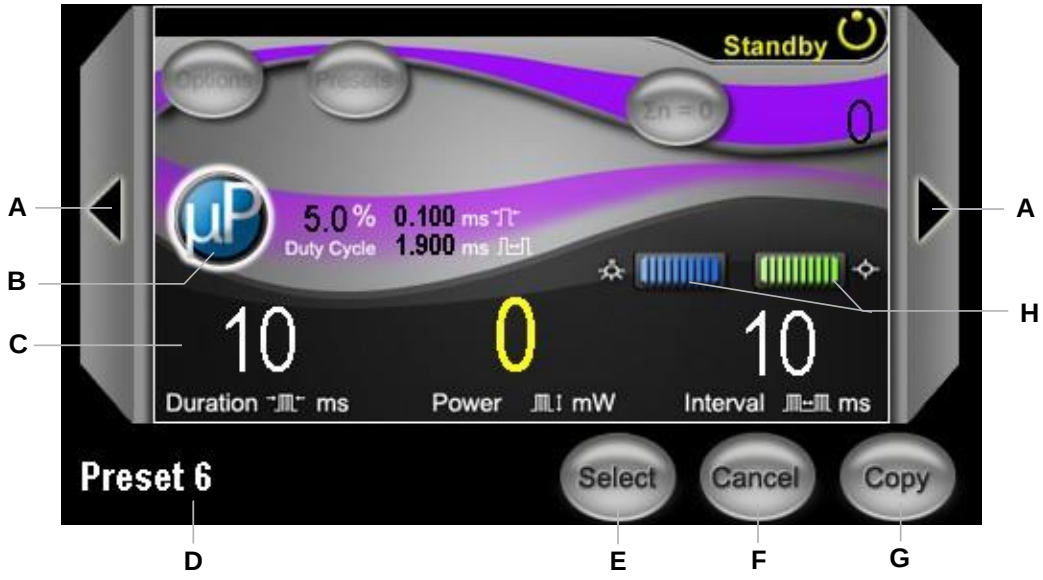
To access the Preset Menu, at the Standby screen, touch PRESETS.



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.

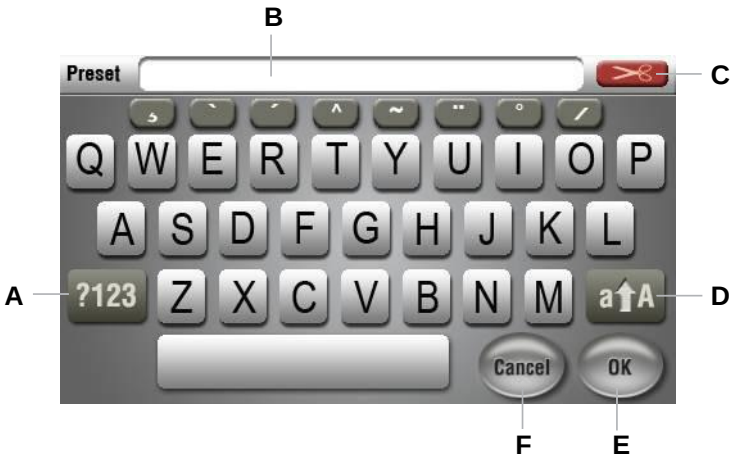
Presets Screen

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 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 Illumination adjustments.

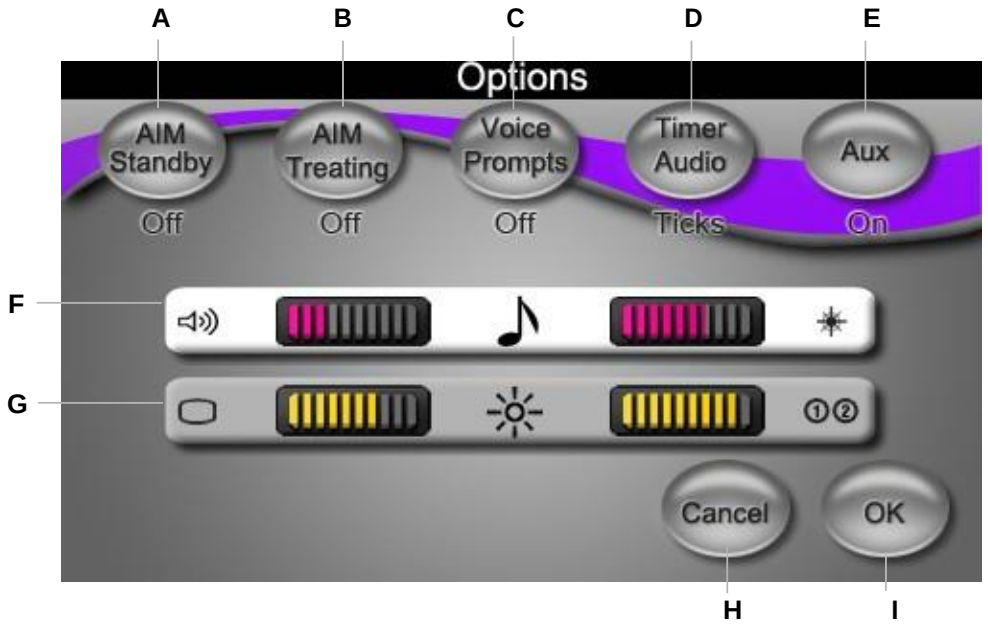
KEYBOARD MODE



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	Countdown timer audio setting
E	Set Auxiliary: ON in Standby or ON in Treat. Operate a warning light or auditory signal outside the treatment room.
F	Press bar to select it (white=active bar). Use control knobs to set volume.
G	Press bar to select it (white=active bar). Use control knobs to set brightness.
H	Discard changes and return to Treat screen.
I	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. If there is still no treatment beam, contact your local IRIDEX Technical Support representative.
No illumination light	• Verify that the illumination connector is connected to the console. • Verify that the control knob is not between detents. If there is still no illumination light, contact your local IRIDEX Technical Support representative.
Illumination light is too dim	• Verify that the control knob is not between detents. If the illumination light is still too dim, contact your local IRIDEX Technical Support representative.

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.

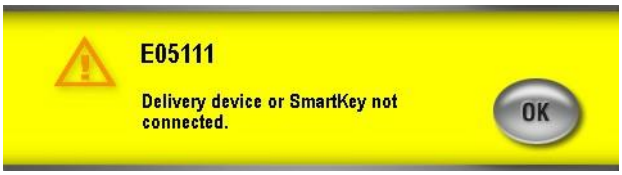
User Action: Turn the keyswitch Off and then On. The system will attempt to correct itself. If the error persists, write down the error code (example: E05002) and contact IRIDEX Service.

Error Code	Error Message
E00004	Software Version Mismatch.
E00701	System controller watchdog failure.
E01003, E01009	System needs calibration.
E03002, E03003	Invalid sensor reading. Turn key OFF then ON to reset.
E03010, E03020, E03040	Laser temperature invalid. Turn key OFF then ON to reset.
E03050	Heat sink reading invalid values.
E04018, E04033, E04050, E04051, E04052, E04120, E04121, E04950, E04951	Voltage supply out of range. Turn key OFF then ON to reset.
E04099	Laser watchdog failure.
E05000	Clock set failure. Turn key OFF then ON to reset.
E05002	Emergency STOP pressed. Turn key OFF then ON to reset.
E06001, E06010	Laser power output out of range.
E06003	Missing pulse error. Check connections and turn key OFF then ON to reset.
E06006	Photocell detector readings do not match.
E06030, E06102	Invalid laser output detected. Turn key OFF then ON to reset.
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 Error

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.
E05102	Time has expired.	Time has expired. This laser only supports single-use.	Attach a new delivery device.
E05103	Dead battery warning.	Dead battery	Please contact IRIDEX Customer Service.
E05108	Invalid spot size.	Spot size on delivery device not in correct position.	Turn SLA to select desired spot size.
E05109	Simultaneous connection of 2 AUX devices not allowed.	System detected 2 AUX devices.	Disconnect a 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.	Average power too low	Laser will attempt to operate at a lower setting. Decrease power setting.
W0001	Verify an 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.*

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 60825-1 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 LASER CONSOLE POWER CALIBRATION:

1. Make sure all persons in the room are wearing the appropriate laser safety eyewear.
2. Connect a clean and properly functioning IRIDEX delivery device or test fiber.

   NOTE: *If a G-Probe, MP3 Device, or other device with a ball-shaped tip is used to perform these tests, immerse its distal (output) tip in a clear glass container of deionized water to a depth of 5-10 mm (a laboratory beaker or Petri dish is suitable). Otherwise, incorrect measurements will result.*

3. Center the aiming beam on the power meter sensor. Measurement equipment must be capable of measuring several watts of continuous optical power. Position devices with their tips immersed in water directly above the upward facing power meter sensor. Direct the aiming beam through the bottom of the container onto the meter sensor.

   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, Interval to Single Pulse, 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 sensor, following the power meter instructions for sampling the laser power.
8. Actuate the footswitch to deliver the treatment beam. Power measured by the meter should stabilize before the end of the timed exposure. If it does not, increase the Duration appropriately. 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. When using CW devices, measurements ranging between 80% and 120% of displayed power are acceptable. When using MicroPulse devices, measurements ranging between 40% and 60% of displayed power are acceptable (since laser MicroPulse Duty Factor using the above settings is 50%). If the readings fall outside these acceptable levels, check the power meter, ensure that the beam is accurately positioned on the power meter detector surface, and check the readings again with another IRIDEX delivery device.
13. If the measurements are still outside acceptable levels, contact your local IRIDEX Technical Support Representative.
14. Place a signed copy of the tabulated data in your device records for reference during later use and service.

Power Measurements using a CW Delivery Device			
Exposure Duration (ms)	**Indicated Power (mW)**	**Measured Power (mW)**	**Acceptable Range (mW)**
1000–3000	200		160–240
1000–3000	500		400–600
1000–3000	1000		800–1200
1000–3000	2000		1600–2400

Data for power measurement equipment: _ Calibration Date _

Meter Model and Serial Number: _ Calibrated By: _

Meter Calibration Date _

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: _

Meter Calibration Date _

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.

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 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.

Cyclo G6™ NOHD Values for Delivery Devices

Delivery Device	MPE (W/m^2)	Numerical Aperture (NA)	Maximum Power Φ (W)	NOHD (m)
MicroPulse® P3	16	0.25	3.000	1.7
G-Probe™	16	0.25	3.000	1.7
G-Probe™ Illuminate	16	0.25	3.000	1.7

Optical density of laser safety glasses for 810nm with maximum power output of 3W should have an OD > 4.

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.

The IRIDEX Cyclo G6™ uses Medical grade, universal input switching power supply that meets EN 60601-1 performance and safety requirements. A removable power cord provides a means of isolating the equipment from the supply main. The equipment shall be located at a location where the power cord is not difficult to remove. A dedicated microprocessor continuously monitors the functions of all subsystems in the laser console.

CE marked devices comply with all requirements of European Council Directive 93/42/EEC ('Medical Device Directive').

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 IEC 60529) and is shrouded for safety (ANSI Standard Z136.3, 4.3.1).

Labels

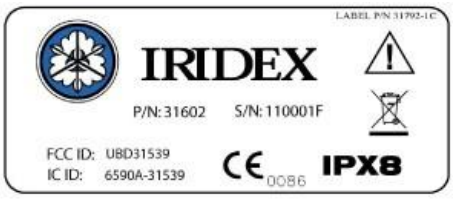
NOTE: *The actual label may vary with laser model.*

Serial Number (Rear Panel)

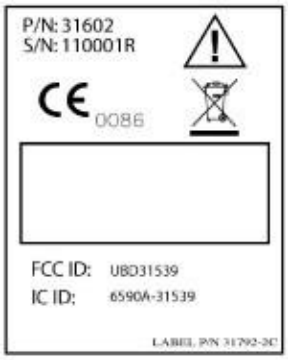
Ground (bottom of laser)

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

SERIALIZE #s: RCI0100 to RCI9999

Laser Warning
Rear Panel of Console

Symbols (As Applicable)


Aiming beam


Angle


Aspirating probe


Caution


Audible signal

CE marking


Connector type


Do not use if package is damaged

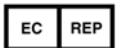

Duration


Duration with MicroPulse

Emergency stop

ETL mark

Sterilized using ethylene oxide



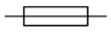
Authorized representative in the European Community


Expiration date


Footswitch

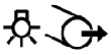

Footswitch in


Footswitch out


Fuse

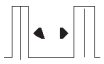

Gauge


Protective earth (Ground)


Illuminating Probe


Decrease/Increase


Interval


Interval with MicroPulse


Laser aperture at end of fiber


Laser warning


Illumination

Lot number


Manufacturer


Date of manufacture


Off

On

Part number

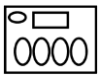

Power

Σ_n
Pulse count

$\Sigma_n = 0$
Pulse count reset


No-ionizing electromagnetic radiation


Consult instructions for use

	Remote control		Remote interlock		Serial number
	Single use		Standby		Treat
	Type B Applied Part - Applied Parts degree of protection against electrical shock - Type B Symbol IEC 60417-5840: IEC 60601-1:2005, Clause 7.2.10. Label applied to Probe Connector		Waste Electrical and Electronic Equipment (WEEE)		Pattern is activated
 OPERATING TEMPERATURE RANGE 10°C to 35°C SHIPPING TEMPERATURE RANGE -20°C to 60°C	Temperature limitations: Label placed on Console Shipping Package & Probe Box	**IPX4**	Enclosure protected against splashing water sprayed from all angles	**IPX8**	Enclosure protected against continual submersion in water under identified conditions
	Refer to instruction manual		Initial power (PowerStep)		Interval between groups
	Number of pulses (group)		Number of steps (PowerStep)		Power (MicroPulse)
	Power increment		Power increment (PowerStep)		Parameter is locked
	Universal serial bus (USB)		Port indicators		Laser firing
	Laser preparing		Speaker		Screen
	System brightness		Not made with natural rubber latex		By prescription only
	Warning, replace with fuses as indicated		Item or surface can be hot and should not be touched without taking care		CSA Group Mark Health Canada
	Warning of Optical Radiation				

Specifications

Specification	Description
Treatment wavelength	810 nm infrared
Treatment power	50 – 3000 mW, depending on delivery device
Exposure Duration	**CW-Pulse™**: 10 ms – 9000 ms in 606 increments and continuous pulse up to 60 seconds **MicroPulse®**: 0.05 – 1.0 ms in 19 increments
Exposure interval	**CW-Pulse™**: 10 – 3000 ms in 598 increments and One Pulse **MicroPulse®**: 1.0 – 10.0 ms in 90 increments
Aiming beam	635 nm (nominal) laser diode 1 mW maximum User-adjustable intensity; coaxial with treatment beam
Illumination	LED, white 0 – 5 mW
Electrical	100 – 240 VAC, 50/60 Hz, <0.8 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) for storage and operation
Dimensions	27 cm (W) × 29.5 cm (D) × 19.7 cm (H) (10.6 in × 11.6 in × 7.8 in)
Weight	4.8 kg (10.5 lb)

7
Wireless Footswitch and EMC

Setting Up the Wireless Footswitch

The wireless footswitch comprises:

- 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 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz 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.