1 Introduction

IQ 810 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.

Indications for Use

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 810 is indicated for retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation, iridotomy, and other diode laser treatments. The following are examples of applications for the IQ 810.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetic Retinopathy</td>
<td>Panretinal Photocoagulation (PRP); Focal and Grid Laser Treatments</td>
</tr>
<tr>
<td>• Nonproliferative Retinopathy</td>
<td></td>
</tr>
<tr>
<td>• Macular Edema</td>
<td></td>
</tr>
<tr>
<td>• Proliferative Retinopathy</td>
<td></td>
</tr>
<tr>
<td>Glaucoma</td>
<td>Laser Trabeculoplasty; Iridotomy; Transscleral Cyclophotocoagulation (TSCPC)</td>
</tr>
<tr>
<td>• Primary Open Angle</td>
<td></td>
</tr>
<tr>
<td>• Closed Angle</td>
<td></td>
</tr>
<tr>
<td>• Refractory Glaucoma (recalcitrant/uncontrolled)</td>
<td></td>
</tr>
<tr>
<td>Retinal Tears, Detachments, and Holes</td>
<td>Transscleral Retinal Photocoagulation (TSRPC); Focal and Grid Laser Treatments</td>
</tr>
<tr>
<td>Lattice Degeneration</td>
<td>PRP; Focal and Grid Laser Treatments</td>
</tr>
<tr>
<td>Age-Related Macular Degeneration (AMD) with Choroidal Neovascularization (CNV)</td>
<td>Focal and Grid Laser Treatments</td>
</tr>
<tr>
<td>Intra-Ocular Tumors</td>
<td>Focal and Grid Laser Treatments</td>
</tr>
<tr>
<td>• Choroidal Hemangioma</td>
<td></td>
</tr>
<tr>
<td>• Choroidal Melanoma</td>
<td></td>
</tr>
<tr>
<td>• Retinoblastoma</td>
<td></td>
</tr>
<tr>
<td>Retinopathy of Prematurity</td>
<td>PRP; TSRPC; Focal and Grid Laser Treatments</td>
</tr>
<tr>
<td>Sub-Retinal (choroidal) Neovascularization</td>
<td>Focal and Grid Laser Treatments</td>
</tr>
<tr>
<td>Central and Branch Retinal Vein Occlusion</td>
<td>PRP; Focal and Grid Laser Treatments</td>
</tr>
</tbody>
</table>
References

Compatible Delivery Devices

These IRIDEX delivery devices are compatible with the IQ 810 laser systems:

- EndoProbe®, DioPexy™ Probes, G-Probe™
- Slit Lamp Adapters (SLA), Operating Microscope Adapters (OMA)
- Laser Indirect Ophthalmoscopes (LIO)

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

Pulse Types

Three pulse types are available: CW-Pulse™, MicroPulse™, and LongPulse™.

**CW-Pulse**

Continuous wave (CW) is a laser delivery in single, repeat, or continuous (Paint) modes.

**NOTE:** Group and PowerStep functions are not available in continuous (Paint) mode. Setup is not available in Paint mode.
**MicroPulse**

MicroPulse (µP) delivers laser energy in a burst of very short pulses and separating intervals. You may adjust MicroPulse duration and MicroPulse interval or select from three preset duty cycle values.

Duty cycle refers to the percentage of time the treatment laser is activated during each pulse; duty cycle is calculated according to this formula:

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

**LongPulse**

LongPulse consists of extended-length CW pulses.
**Advanced Pulse Types**

Available in CW-Pulse and MicroPulse are:

- Group
- PowerStep™
- Group and PowerStep

**GROUP**

The number of pulses in each Group is specified. Single or multiple groups can be programmed.
POWERSTEP

Power is programmed to increase between pulses.

GROUP AND POWERSTEP

Combined use of these functions results in power increase between pulse groups.

Contraindications

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

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

Specific Warnings and Precautions

It is essential that the surgeon and attending staff be trained in all aspects of 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” in this chapter. Proper eye protection must be utilized for the specific treatment laser wavelength in use (810 nm).

Warnings and Cautions

DANGER:

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

WARNINGS:

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

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

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

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

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

US federal law restricts this device to sale by or on the order of a healthcare practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.
Use of controls or adjustments or performing of procedures other than those specified herein may result in hazardous radiation exposure.

Do not operate the equipment in the presence of flammables or explosives, such as volatile anesthetics, alcohol, and surgical preparation solutions.

Laser plume may contain viable tissue particulates.

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

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The Netherlands
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Fax: (31) (0) 70 346-7299

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
- Spare fuses
- Operator Manual (not shown)
- Laser warning sign (not shown)
- Optional accessories (not all shown)
Choosing a Location

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

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

In the US, this equipment must be connected to an electrical supply source at 120V or 240V with a center tap. To ensure that all local electrical requirements can be met, the system is equipped with a hospital-grade (green dot) three-wire grounding plug. When choosing the location, ensure that a grounding-type AC outlet is available; it is required for safe operation.

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

**CAUTIONS:**

- Do not defeat the purpose of the grounding pin. This equipment is intended to be electrically grounded. Contact a licensed electrician if your outlet prevents you from inserting the plug.
- Do not position or use the system near open flames.

Connecting the Components

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

**NOTES:**

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

The Auxiliary Output contact supports low voltage electrical signaling circuits of up to five amperes and 24 volts AC or DC. Ensure that all wiring conforms to local electrical codes.
3 Operation

Front Panel Controls

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.
10. Keep the protective cap over the fiber-optic connector when the delivery device is not in use.
Using the IQ 810

System Interface

NOTES:

Depending on the screen, the function of each button or control knob may change or might be disabled.

Holding down a button displays a Help screen for that function.
Main Screen

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>System screen.</td>
</tr>
<tr>
<td>B</td>
<td>Information screen.</td>
</tr>
<tr>
<td>C</td>
<td>Select highlighted preset.</td>
</tr>
<tr>
<td>D</td>
<td>Scroll presets.</td>
</tr>
<tr>
<td>E</td>
<td>Select treatment type.</td>
</tr>
</tbody>
</table>
**Treat Screen**

Actual screen varies by selected pulse type.

---

**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.
Setup Screen

From the Treat screen, press SETUP.

From the Setup screen, press SETUP to

- A PRESET menu
- I Pulse Info.
- B 5, 10, 15% MicroPulse mode only. CW defaults to Group settings.

- C Return to previous screen.
- D MicroPulse duration.
- E MicroPulse interval.
- F Information display.
- G Group screen.
- H PowerStep screen.
- I Information screen.

* MicroPulse mode only. CW defaults to Group settings.
**CW-Test Pulse (MicroPulse)**

From the MicroPulse Treat screen, press CW-TEST PULSE.

![Diagram of CW-Test Pulse screen with labels A, B, and C]

- **A** Toggle MicroPulse or CW-Test pulse.
- **B** Pulse interval.
- **C** Pulse power.

**WARNING:** Pulses are CW, not MicroPulse. Initiate test pulses at very low power settings to prevent unintended damage.

**NOTE:** Power Settings on CW-Test Pulse and MicroPulse screens are controlled independently.
Advanced Pulse Types

GROUP PROGRAMS

**NOTE:** You cannot create a Group if duration is set to Paint or if the interval is set to OnePulse.

From the Treat screen, select the desired values for Duration, Power, and Interval, then press SETUP.

---

**A** Number of pulses per group.

**B** Number of groups.

**C** Information display.

**D** Clear settings.

**E** Enter PowerStep screen.

**F** Return to previous screen.
**POWERSTEP PROGRAMS**

From the Treat screen, select the desired values for Duration, Power, and Interval, and press **SETUP**.

![PowerStep Program Diagram]

- **A** Number of steps.
- **B** Power.
- **C** Power increment.
- **D** Start Powerstep (return to previous screen).
- **E** Information display.
- **F** Clear settings (return to previous screen).
- **G** Return to previous screen (PowerStep not activated).

**NOTES:**

*The laser will not permit combinations of power increment and number of steps that result in a final power in excess of the limits for the attached delivery device.*

*PowerStep settings are saved unless you clear them.*

*Return to PowerStep screen to restart PowerStep using the previous settings.*

**GROUP WITH POWERSTEP PROGRAMS**

1. From the Treat screen, select the desired values for Duration, Power, and Interval, then press **SETUP**.
2. Program Group first, then PowerStep, as described.
3. Press **START** in PowerStep screen.
## TREAT SCREEN WITH GROUP AND POWERSTEP PROGRAMS

<table>
<thead>
<tr>
<th>Main Menu</th>
<th>CW-Pulse LIO</th>
<th>Setup</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reset</td>
<td>Pulses 0</td>
<td>% 50</td>
</tr>
<tr>
<td>Treat</td>
<td>6 Steps, 80 -&gt; 480 mW</td>
<td>5 Pulses, One Group</td>
</tr>
<tr>
<td>Standby</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### A
- PowerStep settings.

### B
- Group settings.

### C
- Pulse duration.

### D
- Power (adjustments disabled with PowerStep program).

### E
- Pulse interval.

**NOTE:** To erase all Group settings, press CLEAR on the Setup Group screen. To erase all PowerStep settings, press CLEAR on the Setup PowerStep screen.
Setting User Preferences

Adjusting Aiming Beam and LIO

From the Treat screen, press AIMING.

| A | LIO illumination intensity (when attached). |
| B | Aiming beam intensity. |
Changing System Settings

To access the System screen, press AIMING, then press SYSTEM from any pulse type. Alternatively, press SYSTEM.

A Language.
B Volume.
C Screen brightness.
D Set initial screen.
E Set aiming beam mode:
  • ON or OFF in Standby.
  • ON or OFF in Treat.
F Operate a warning light or auditory signal outside the treatment room. Toggle warning signal activation when:
  • Laser status is set to Treat.
  • Keyswitch is set to On.
G Set power increment for remote and footswitch.
  Note: Setting to 0 mW will disable the power increment on the accessories.
H Return to initial screen.
Preset Screen

25 unique presets can be saved.

To create a preset, press SETUP from the Treat screen, then press PRESET MENU from the Setup screen.

**To Modify a Saved Preset:**

1. Select the desired preset.
2. Modify the parameters.
3. Go to the Preset screen, and overwrite the preset name with the same spelling.
4. Press SAVE.
5. Press OK to save.
4 Troubleshooting

General Problems

<table>
<thead>
<tr>
<th>Problem</th>
<th>User Action(s)</th>
</tr>
</thead>
</table>
| 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. |
### Status Panel Messages

<table>
<thead>
<tr>
<th>Status Message</th>
<th>User Action(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Connect Fiber</td>
<td>Connect an appropriate delivery device.</td>
</tr>
<tr>
<td>Connect Footswitch</td>
<td>• Verify that the footswitch or receiver is properly connected.</td>
</tr>
<tr>
<td></td>
<td>• Verify that two footswitches are not connected.</td>
</tr>
<tr>
<td>Connect SmartKey</td>
<td>Verify that the SmartKey is properly installed.</td>
</tr>
<tr>
<td>Emergency Stop. Error Code 23</td>
<td>• Turn the system off (using the key) and wait several seconds.</td>
</tr>
<tr>
<td></td>
<td>• Turn the system on.</td>
</tr>
<tr>
<td>Safety Filter Out / Insert Safety Filter</td>
<td>Verify that the eye safety filter is properly installed.</td>
</tr>
<tr>
<td>Footswitch Stuck / Release Footswitch</td>
<td>Remove foot or other object from footswitch.</td>
</tr>
<tr>
<td>Connect Remote Interlock</td>
<td>• Verify that the remote interlock plug is properly inserted.</td>
</tr>
<tr>
<td></td>
<td>• Verify that the door switches or other circuits are closed.</td>
</tr>
<tr>
<td>Incorrect Fiber (actual probe connected)</td>
<td>Disconnect the fiber optic from the fiber port. Connect the correct fiber-optic connector.</td>
</tr>
</tbody>
</table>
5
Maintenance

Inspecting and Cleaning the Laser

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

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

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

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

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

Inspecting and Cleaning the Footswitch

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 25°C to achieve a high level of disinfection
   - 10 minutes at 20°C to 25°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.

### Changing the AC Line Fuses

Each leg of the AC line is independently fused. The fuse holder is integral to the power inlet on the laser console.

**To check and change fuses:**

1. Remove the power cord from the inlet receptacle.
2. Unlatch and open the fuse carrier.
3. Remove and inspect both fuses.
4. Replace any blown fuses.
5. If newly replaced fuses also blow, contact your local IRIDEX Technical Support representative.

### 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.

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.

---

Calibration date for power meter and sensor: __________________________

<table>
<thead>
<tr>
<th>Power (mW)</th>
<th>Exposure Duration (ms)</th>
<th>Meter Reading (mW)</th>
<th>Acceptable Range (mW)</th>
</tr>
</thead>
<tbody>
<tr>
<td>200</td>
<td>2000–5000</td>
<td></td>
<td>160–240</td>
</tr>
<tr>
<td>500</td>
<td>2000–5000</td>
<td></td>
<td>400–600</td>
</tr>
<tr>
<td>1000</td>
<td>2000–5000</td>
<td></td>
<td>800–1200</td>
</tr>
<tr>
<td>2000</td>
<td>2000–5000</td>
<td></td>
<td>1600–2400</td>
</tr>
</tbody>
</table>

Date: _______________ 
Calibrated by: __________________________

Of: __________________________
6 Safety and Compliance

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

• To prevent exposure to laser energy, except as a therapeutic application from either direct or diffusely reflected laser beams, always review and observe the safety precautions outlined in the operator manuals before using the device.

• This device is intended for use only by a qualified physician. The applicability of the equipment and treatment techniques selected is your sole responsibility.

• Do not use any device if you think it is not functioning properly.

• Laser beams reflected from specular surfaces can harm your eyes, the patient’s eyes, or others’ eyes. Any mirror or metal object that reflects the laser beam can constitute a reflection hazard. Be sure to remove all reflection hazards near the laser. Use non-reflecting instruments whenever possible. Be careful not to direct the laser beam at unintended objects.

CAUTION: Changes or modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment.

Protection for the Physician

Eye safety filters protect the physician from backscattered treatment laser light. Integral eye safety filters are permanently installed in every compatible Slit Lamp Adapter (SLA) and Laser Indirect Ophthalmoscope (LIO). For endophotocoagulation or for Operating Microscope Adapter (OMA) use, a separate discrete eye safety filter assembly must be installed into each viewing path of the operating microscope. All eye safety filters have an optical density (OD) at the laser wavelength sufficient to permit long-term viewing of diffuse laser light at Class I levels.

Always wear appropriate laser safety eye wear when performing or observing laser treatments with the unaided eye.

Protection for All Treatment Room Personnel

The Laser Safety Officer should determine the need for safety eyewear based on the Maximum Permissible Exposure (MPE), Nominal Ocular Hazard Area (NOHA), and Nominal Ocular Hazard Distance (NOHD) for each of the delivery devices used with the laser system, as well as the configuration of the treatment room. For additional information, refer to ANSI Z136.1, ANSI Z136.3, or European Standard IEC 60825-1.
The following formula was used to calculate the most conservative NOHD values:

\[ \text{NOHD} = \frac{1.7}{\text{NA}} \left( \frac{\Phi}{\pi \text{MPE}} \right)^{0.5} \]

where:

\( \text{NOHD} \) = the distance, in meters, at which the beam irradiance equals the appropriate corneal MPE  
\( \text{NA} \) = the numerical aperture of the beam emerging from the optical fiber  
\( \Phi \) = the maximum possible laser power, in watts  
\( \text{MPE} \) = the level of laser radiation, in \( \text{W/m}^2 \), 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.

\textbf{NOTE: } Not all delivery devices are available for all laser models.

<table>
<thead>
<tr>
<th>NOHD Values for Various Delivery Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delivery Device</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>EndoProbe</td>
</tr>
<tr>
<td>G-Probe</td>
</tr>
<tr>
<td>DioPexy Probe</td>
</tr>
<tr>
<td>Slit Lamp Adapter (SLA)</td>
</tr>
<tr>
<td>Large Spot Slit Lamp Adapter (LS-SLA)</td>
</tr>
<tr>
<td>Laser Indirect Ophthalmoscope (LIO)</td>
</tr>
<tr>
<td>Large Spot Laser Indirect Ophthalmoscope (LS-LIO)</td>
</tr>
<tr>
<td>Symphony Slit Lamp Adapter (810 nm)</td>
</tr>
<tr>
<td>Operating Microscope Adapter (OMA)</td>
</tr>
</tbody>
</table>
Safety Compliance


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

The IRIDEX IQ 810 uses solid-state electronic switching power supply that meets strict EN60601-1 and ISO60601-1 performance and safety standards. A dedicated microprocessor continuously monitors the safe function of all subsystems within the laser console.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergency Stop</td>
<td>Immediately disables the laser.</td>
</tr>
<tr>
<td>Protective housing</td>
<td>The external housing prevents unintended access to laser radiation above Class I limits.</td>
</tr>
<tr>
<td>Safety interlock</td>
<td>An electronic interlock at the fiber port prevents laser emission if a delivery device is not properly connected.</td>
</tr>
<tr>
<td>Remote interlock</td>
<td>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.</td>
</tr>
<tr>
<td>Keyswitch</td>
<td>The system operates only with the proper key. The key cannot be removed while in the On position.</td>
</tr>
<tr>
<td>Laser emission indicator</td>
<td>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.</td>
</tr>
<tr>
<td>Beam attenuator</td>
<td>An electronic beam attenuator prevents any laser radiation from exiting the console until all requirements for emission are met.</td>
</tr>
<tr>
<td>Viewing optics</td>
<td>Eye safety filters are required when using the laser system.</td>
</tr>
<tr>
<td>Manual restart</td>
<td>If laser emission is interrupted, the system goes into Standby mode, the power drops to zero, and the console must be manually restarted.</td>
</tr>
<tr>
<td>Internal power monitor</td>
<td>Two monitors independently measure the laser power before emission. If the measurements differ significantly, the system enters Call Service mode.</td>
</tr>
<tr>
<td>Footswitch</td>
<td>The console 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).</td>
</tr>
</tbody>
</table>
Labels

NOTE: The actual label may vary with laser model.

Serial Number (rear panel)

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.

Ground (bottom of laser)

Footswitch

Wireless Receiver

Remote Control
Laser Warning

VISIBEL AND INVISIBLE LASER RADIATION
AVOID EYE OR SKIN EXPOSURE TO
DIRECT OR SCATTERED RADIATION
CLASS 4 LASER PRODUCT
CLASS 7 LASER PRODUCT
(IEC 60825-1:2007)

RAYONNEMENT LASER VISIBLE ET
INVISIBLE EXPOSITION DANGEREUSE DE
L’OEIL OU DE LA PEAU AU
RAYONNEMENT DIRECT OU DIFFUS
APPAREIL A LASER DE CLASSE 4
APPAREIL A LASER DE CLASSE 2
(CEI 60825-1:2007)

\[ \lambda = 810 \text{ nm} \quad P_0 = 4 \text{ W} \]
\[ \lambda = 650 \text{ nm} \quad P_0 = 1 \text{ mW} \]
Symbols (As Applicable)

- Aiming Beam
- Angle
- Aspirating Probe
- Caution
- Audible Signal
- CE Mark
- Connector Type
- Do Not Use if Package is Damaged
- Duration
- Duration with MicroPulse
- Emergency Stop
- ETL Mark
- ETO Sterile
- EU Authorized Representative
- Expiration Date
- Footswitch
- Footswitch In
- Footswitch Out
- Fuse
- Gauge
- Protective Earth (Ground)
- Illuminating Probe
- Decrease/Increase
- Interval
- Interval with MicroPulse
- Laser Aperture at End of Fiber
- Laser Warning
- Illumination
- LOT
- Manufacturer
- Manufacture Date
- Off
- On
- Part Number
- Power
- Pulse Count
- \( \sum_n = 0 \)
- Pulse Count Reset
- No-ionizing Electromagnetic Radiation
- 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.
- Pattern is Activated
Temperature Limitations

IPX4 Protections Against Splash Water Coming from all Directions

IPX8 Protections Against Continuous Immersion

Refer to Instruction Manual/Booklet (in blue)

Initial Power (PowerStep)

Interval between Groups

Number of Pulses (Group)

Number of Steps (PowerStep)

Power (MicroPulse)

Power Increment

Power Increment (PowerStep)

Parameter is Locked

USB

Port Indicators

Laser Firing

Laser Preparing

Speaker

Screen

System Brightness

Latex Free

Prescription

Warning, Replace with fuses as indicated
## Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment wavelength</td>
<td>810 nm (nominal)</td>
</tr>
<tr>
<td>Treatment power</td>
<td>50 – 3000 mW, depending on delivery device.</td>
</tr>
</tbody>
</table>
| Duration               | **CW-Pulse:** 10 ms – 9000 ms in 29 increments and continuous pulse up to 60 seconds  
                          | **MicroPulse:** 0.025 – 1.0 ms in 22 increments                                
                          | **LongPulse:** 10 seconds to 30 minutes in 26 increments                      |
| Repeat interval        | **CW-Pulse:** 50 – 1000 ms in 11 increments and One Pulse                    
                          | **MicroPulse:** 1.0 – 9.5 ms in 26 increments                                 |
| Aiming beam            | Red laser diode. User-adjustable intensity; 1 mW maximum; coaxial with treatment beam |
| Electrical             | 100 – 240 VAC, 50/60 Hz, <0.8 A                                              |
| Cooling                | Air cooled                                                                  |
| Operating temperature  | 10° C to 35° C (50° F to 95° F)                                             |
| Storage temperature    | -20° C to 60° C (-40° F to 140° F)                                          |
| Relative humidity      | 10% to 90% (non-condensing)                                                 |
| Dimensions             | 30.5 cm × 30.5 cm × 17.8 cm (12 in. W × 12 in. D × 7 in. H)                  |
| Weight                 | 5 kg (11 lb.)                                                               |
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:

<table>
<thead>
<tr>
<th>Footswitch LED Display</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Green flash following pedal depression</td>
<td>Footswitch OK</td>
</tr>
<tr>
<td></td>
<td>Batteries OK</td>
</tr>
<tr>
<td>Amber flash following pedal depression</td>
<td>Footswitch OK</td>
</tr>
<tr>
<td></td>
<td>Batteries low</td>
</tr>
<tr>
<td>Blinking red LED for 10 seconds following pedal depression</td>
<td>No RF communication</td>
</tr>
</tbody>
</table>
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 Règlement sur le matériel brouilleur du Canada.
EMC Requirements for Console and Accessories

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class A</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Class A</td>
</tr>
<tr>
<td>Voltage fluctuations/ Flicker emissions</td>
<td>Complies</td>
</tr>
</tbody>
</table>

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.
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.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>±6 kV contact ±8 kV air</td>
<td>±6 kV contact ±8 kV air</td>
<td>Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical fast transient/burst IEC 61000-4-4</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines</td>
<td>±2 kV for power supply lines Not Applicable</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>±1 kV differential mode ±2 kV common mode</td>
<td>±1 kV differential mode ±2 kV common mode</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</td>
<td>&lt;5% $U_T$ (&gt;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 &lt;5% $U_T$ (&gt;95% dip in $U_T$) for 5 sec</td>
<td>&lt;5% $U_T$ (&gt;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 &lt;5% $U_T$ (&gt;95% dip in $U_T$) for 5 sec</td>
<td>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.</td>
</tr>
<tr>
<td>(50/60 Hz) magnetic field IEC 61000-4-8</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>3 Vrms</td>
<td>3 Vrms</td>
<td>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:</td>
</tr>
<tr>
<td>IEC-61000-4-6</td>
<td>150 kHz to 80 MHz</td>
<td></td>
<td>$d = 1.2 \sqrt{P}$</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 Vrms</td>
<td>3 V/m</td>
<td>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:</td>
</tr>
<tr>
<td>IEC 61000-4-3</td>
<td>150 kHz to 80 MHz</td>
<td></td>
<td>$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz</td>
</tr>
</tbody>
</table>

^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.
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.

<table>
<thead>
<tr>
<th>Rated Maximum Output Power of Transmitter (W)</th>
<th>Separation Distance According to Frequency of Transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td></td>
<td>(d = 1.2 \sqrt{P})</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.37</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.7</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

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.
Appendix A

Additional regulatory requirements

Compliance to IEC 60601-1 (2010)

Class I

Warning Statement for Class I ME Equipment

WARNING: To avoid risk of electric shock, this equipment must be only connected to a supply mains with protective earth

Electrical Ground Symbol

Warning re. Reciprocal Interference posed by Medical Equipment during specific investigations or treatments.

WARNING: For CLASS I ME EQUIPMENT, where operation from either a SUPPLY MAINS or an INTERNAL ELECTRICAL POWER SOURCE is specified: the INTERNAL ELECTRICAL POWER SOURCE is to be used if the integrity of the PROTECTIVE EARTH CONDUCTOR or the protective earthing system in the installation is in doubt.

Disposal of waste products

Best available treatment, recovery and recycling techniques as mandated by local and federal laws should be used provided that they ensure human health, safety, and high environmental protection. Please contact your Sales/Distributor for specific requirements in your area.

Safe Operating Conditions

See Operator Manual (p. 10, p.30)

Service

MANUFACTURER will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist SERVICE PERSONNEL to repair those parts of ME EQUIPMENT that are designated by the MANUFACTURER as repairable by SERVICE PERSONNEL.

The IQ 810 schematics are for the specific use of IRIDEX authorized and trained service personnel who have received formal service training. It is a company policy not to distribute schematics outside of the IRIDEX organization and possession of the IQ 810 schematics does not authorize repair or modification or adjustments made by non-authorized personnel. Please contact IRIDEX technical support for further information.

Warranty + Service Life

2 years + 7 years, respectively
PACKAGING, SHIPPING, AND HANDLING

Return Procedure

If your laser system or any of its accessories need to be returned to IRIDEX for any reason, it is important that they be properly packaged, preferably in their original shipping containers. Since the laser is small and lightweight, improper packaging may cause additional damage when in transit, which, if severe enough, could lead to a very expensive repair. The following steps should be taken to ensure safe delivery of the unit to IRIDEX:

Contact an IRIDEX technical support representative to explain why the unit is being returned (Voice: 650.940.4700 or Fax: 650.962.0486). Please have the serial number of the device available and the date that you need the unit returned. Obtain a return merchandise authorization (RMA) number.

Use the original shipping containers. If the original containers are unavailable, contact IRIDEX and replacement-shipping parts will be sent. You will be billed for these materials at our cost and for the shipping charges.

Remove all accessories from the laser console. Remove On/Off keys, footswitch plugs, and power cord. These parts are not needed by our service personnel and if left installed during shipment, may get broken.

Package the equipment in the same way that it was originally received. Brief instructions are provided on the next page. If there are any questions about how to package the equipment, call IRIDEX for instructions.

**WARNING:** Improperly packaged equipment is not covered under warranty. If you are unsure of how to pack the unit, contact IRIDEX for instructions.

Packaging Instructions for IQ 810

Use the original packing material or request material from IRIDEX.

Place the large foam insert in the bottom of the box with the cavity upward.

Place the IQ 810 in the plastic bag provided and tape closed.

Place the IQ 810 in the bottom foam aligning with the cavity.
Place the two smaller foam inserts on each side of the IQ 810 matching the cutouts with the shape of the IQ 810.

Place the cardboard support into the rectangular opening on between the two foam inserts.

Close the top flaps and securely tape closed. Other accessories are packaged separately.

**WARNINGS:** Use Best available treatment, recovery and recycling techniques as mandated by local and federal laws should be used provided that they ensure human health, safety, and high environmental protection.

**COMPLIANCE to IEC 60601-2-22 (2007)**

**TECHNICAL CHARACTERISTICS**

See NOHD Table p. 31

Additional Information:

The IQ810 is manufactured that Beam Divergence and cumulative measurement uncertainties errors will not exceed ± 20%.

**CAUTION:** Laser fume and/or plume may contain viable tissue particulates.

**WARNING:** A risk of fire and/or explosion exists when the LASER OUTPUT is used in the presence of flammable materials, solutions or gases, or in an oxygen enriched environment”. The high temperatures produced in NORMAL USE of the laser equipment may ignite some materials, for example cotton wool when saturated with oxygen. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. Attention should also be drawn to the danger of ignition of endogenous gases.

**Beam Delivery System**

Refer to the Information for Use (Operator Manual) for the specific Delivery Device used.

**Non-compatible Delivery Devices**

Delivery Devices specified for use with this laser may only be used. Delivery devices manufactured by other than IRIDEX Corp. will not be recognized by the laser and will not function. If an IRIDEX Corp. delivery device specified for use with this Laser fails to function upon initialization call your Distributor/Sales representative for assistance.
WARNING: A risk of fire and/or explosion exists when the LASER OUTPUT is used in the presence of flammable materials, solutions or gases, or in an oxygen enriched environments.

High temperatures produced in NORMAL USE of the laser equipment may ignite some materials (e.g. cotton wool when saturated with oxygen), and solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used.