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1 Introduction

Product Description

The DioVet™ is a semiconductor diode laser that delivers true continuous wave infrared laser (810 nm) 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

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

IRIDEX does not make recommendations regarding the practice of medicine. References in literature are provided as a guide. Individual treatment should be based on clinical training, clinical observation of laser tissue interaction, and appropriate clinical endpoints. The DioVet is indicated for retinal photocoagulation, transsceral cyclophotocoagulation, transsceral retinal photocoagulation, and other diode laser treatments.
Pulse Types

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

CW-Pulse

CW-Pulse allows you to select either a single, continuous-wave pulse or repetitive pulses. CW-Pulse is active after each key start.

LongPulse

LongPulse involves exposure durations in excess of 9 seconds using a large spot delivery device.

Compatible Delivery Devices

- IR LIO+ (13152-X)
- LS-LIO+ (13153-X)
- Dual LIO+ (30903-X)
- EndoProbe Family
- DioPexy™ Probe
- G-Probe™/TS-600
- OMA
NOTE: Refer to the appropriate delivery device manual for indications for use, contraindications, precautions, and adverse effects information.

**Contraindications**

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

**Potential Side Effects or Complications**

- Specific to retinal photocoagulation: inadvertent foveal burns; choroidal neovascularization; paracentral scotomata; transient increased edema/decreased vision; subretinal fibrosis; photocoagulation scar expansion; Bruch’s membrane rupture; choroidal detachment; exudative retinal detachment; pupillary abnormalities from damage to the ciliary nerves; and, optic neuritis from treatment directly or adjacent to the disc.
- Laser iridoplasty: inadvertent corneal or lens burns/opacities; iritis; iris atrophy; IOP spike; and, rarely, retinal detachment.
- 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 “Pulse Types” 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.
IRIDEX Corporation Contact Information

IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View, California 94043-1824 USA
Telephone:  (650) 940-4700
(800) 388-4747 (US only)
Fax:  (650) 962-0486
Technical Support:  (650) 940-4700
(800) 388-4747 (US only)
technical@iridex.com

Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands
Tel: (31) (0) 70 345-8570
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 (Wireless Footswitch - Optional Accessory)
- Footswitch jumper cable
- Spare Fuses
- Remote Interlock plug
- Operator Manual (not shown)
- Laser warning sign (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 100-240 VAC 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

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

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

![DioVet Rear Panel Connectors](image)
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.
Activating the Pulse Type

<table>
<thead>
<tr>
<th>To activate this pulse type:</th>
<th>From this laser state or mode:</th>
<th>Do this:</th>
</tr>
</thead>
<tbody>
<tr>
<td>CW-Pulse</td>
<td>After key-start or self-test</td>
<td>No action. CW-Pulse is the default type.</td>
</tr>
<tr>
<td></td>
<td>LongPulse</td>
<td>Turn the Duration control counter-clockwise until “CW-Pulse units” appears in the Duration display.</td>
</tr>
<tr>
<td>LongPulse</td>
<td>Any state or mode</td>
<td>Turn the Duration control clockwise until “LP” appears in the laser status display.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Note:</strong> A large-spot delivery device must be attached to the laser.</td>
</tr>
</tbody>
</table>

Setting Treatment Parameters

**NOTE:** Adjustments cannot be made while pressing the footswitch.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power</td>
<td>Set the treatment pulse power.</td>
</tr>
<tr>
<td>Duration</td>
<td>Set the treatment pulse duration (CW-Pulse and LongPulse).</td>
</tr>
<tr>
<td>Interval (CW-Pulse)</td>
<td>Interval between treatment pulses (CW-Pulse).</td>
</tr>
<tr>
<td></td>
<td><strong>CW-Pulse:</strong> To select a single, fixed-treatment pulse, turn the control counter-clockwise until the Interval display is blank. To select multiple treatment pulses, turn the control clockwise.</td>
</tr>
<tr>
<td>Counter</td>
<td>Press the <strong>COUNTER RESET</strong> button to reset to zero.</td>
</tr>
<tr>
<td>Aiming Beam</td>
<td>Adjust the aiming beam intensity.</td>
</tr>
<tr>
<td>LIO</td>
<td>Adjust the LIO illumination intensity.</td>
</tr>
<tr>
<td>Volume</td>
<td>Adjust the volume of audible indicators.</td>
</tr>
</tbody>
</table>

Selecting the Laser Mode

Press the TREAT/STANDBY button to select the laser mode:

- **Yellow** = Standby mode
  The footswitch and the treatment beam are disabled.
- **Green** = Treat mode
  The footswitch is enabled. Press the footswitch to deliver the treatment beam.

**WARNINGS:**

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.

Verify that all persons in the treatment room are wearing the appropriate laser safety eyewear before placing the laser in Treat mode. Never substitute prescription eyewear for laser safety eyewear.
Selecting User Preferences

To view or change user preference settings:

1. Place the laser in Standby mode.
2. Press and hold the MODE button until “User Preferences” appears in the laser status display.
3. Press MODE to activate the first menu option, Aiming Beam.
4. Press COUNTER RESET to toggle Aiming Beam on or off in Standby mode.
5. Press TREAT/STANDBY to access Languages, then press COUNTER RESET to scroll through the languages (English, Spanish, French, German, Italian, or Portuguese).
6. Press TREAT/STANDBY twice to access Message Review (view only), then press COUNTER RESET to review.
7. To activate your selection(s) and exit User Preferences mode, press MODE.

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.
## 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                                            | - 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). |
| No illumination light (LIO only)                                 |                                                                                                                                                                                                             |
| Illumination light is too dim                                    | - Verify that the special function control is not between detents.  
- Adjust the console illumination intensity control. |
<p>| The aiming beam is large or out of focus on the patients' retina | Readjust your working distance between the LIO headset and the examination lens. The aiming beam should be sharply defined and at its smallest diameter when in focus. |
| (LIO only)                                                       |                                                                                                                                                                                                             |</p>
<table>
<thead>
<tr>
<th>Problem</th>
<th>User Action(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The treatment lesions are variable or intermittent (LIO only)</td>
<td>• The LIO may be slightly out of focus. This decreases power density. Re-adjust your working distance to obtain the smallest spot size.</td>
</tr>
<tr>
<td></td>
<td>• A poorly centered laser beam may be clipping on the examination lens or on the patient’s iris. Adjust the laser beam in the illumination field.</td>
</tr>
<tr>
<td></td>
<td>• The laser treatment parameters may be too close to the tissue response threshold for consistent response. Increase the laser power and/or exposure duration, or select a different lens.</td>
</tr>
<tr>
<td>Does not fit on the mounting plate (OMA only)</td>
<td>• Inspect and clean the mounting plate.</td>
</tr>
<tr>
<td></td>
<td>• Verify that the mounting plate corresponds to your microscope.</td>
</tr>
<tr>
<td>Laser and viewing systems are not focussed at the same point (OMA only)</td>
<td>• Verify installation of a 175 mm microscope objective lens on the microscope.</td>
</tr>
<tr>
<td></td>
<td>• Turn on the aiming beam to determine focus position and adjust as necessary.</td>
</tr>
<tr>
<td>View is blocked or partially blocked by OMA (OMA only)</td>
<td>Set magnification to 10X or more.</td>
</tr>
</tbody>
</table>
## Status Panel Messages

<table>
<thead>
<tr>
<th>Status Panel Message</th>
<th>User Action(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calibration Required</td>
<td>Contact your local IREDIX Technical Support representative.</td>
</tr>
<tr>
<td><strong>Call Service</strong></td>
<td>Press the MODE button. A description of the fault displays briefly on the status panel. The console restarts and performs a self-test. If the message displays again, contact your local IREDIX Technical Support representative.</td>
</tr>
<tr>
<td><strong>Connect Fiber</strong></td>
<td>Connect an appropriate delivery device.</td>
</tr>
<tr>
<td><strong>Connect Footswitch</strong></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><strong>Connect SmartKey or No SmartKey</strong></td>
<td>Verify that the SmartKey is properly installed.</td>
</tr>
<tr>
<td><strong>Emergency Stop</strong></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><strong>Eye Safety Filter? or 810 nm Safety Filter?</strong></td>
<td>Verify that the eye safety filter is properly installed, and press MODE to continue.</td>
</tr>
<tr>
<td><strong>Footswitch Stuck / Release Footswitch</strong></td>
<td>Remove foot or other object from footswitch.</td>
</tr>
<tr>
<td><strong>No Remote Interlock</strong></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><strong>Remove Fiber</strong></td>
<td>Disconnect the fiber optic from the fiber port.</td>
</tr>
<tr>
<td><strong>Slit Lamp Spot Size? or Spot Size?</strong></td>
<td>Verify that the spot size selector is not between positions.</td>
</tr>
<tr>
<td><strong>Unknown Fiber Type</strong></td>
<td>Connect the 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 IREDX-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

The IREDX footswitch labeled IPX8 is submersible (per IEC 60529).

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

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 CIDE® (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.

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.

Resetting the Circuit Breaker

The circuit breaker, located next to the power outlet, protects the power-supply transformer from extended overload. When conditions such as high internal operating temperatures or low line voltages threaten the reliability of the laser, the circuit-breaker button pops out.

To reset the circuit breaker:
1. Correct any power input conditions or allow the laser to cool down.
2. Press the circuit-breaker reset button.
3. If the button pops out after you have pressed it, 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 60825-1 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 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.

<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: ___________________________

15. If the readings fall outside the acceptable levels, check the power meter, ensure that you have accurately placed the beam on the power meter, and check the readings again with another IRIDEX delivery device.

16. If the readings are still outside the acceptable levels, contact your local IRIDEX Technical Support Representative.

17. Place a signed copy of the table in your device records to refer to during use and service.
6 Safety and Compliance

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

- To prevent exposure to laser energy, except as a therapeutic application from either direct or diffusely reflected laser beams, always review and observe the safety precautions outlined in the operator manuals before using the device.
- This device is intended for use only by a qualified physician. The applicability of the equipment and treatment techniques selected is your sole responsibility.
- Do not use any device if you think it is not functioning properly.
- Laser beams reflected from specular surfaces can harm your eyes, the patient’s eyes, or others’ eyes. Any mirror or metal object that reflects the laser beam can constitute a reflection hazard. Be sure to remove all reflection hazards near the laser. Use non-reflecting instruments whenever possible. Be careful not to direct the laser beam at unintended objects.

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

Protection for the Physician

Eye safety filters protect the physician from backscattered treatment laser light. Integral eye safety filters are permanently installed in every compatible 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 International Standard IEC 60825-1.
The following formula was used to calculate the most conservative NOHD values:

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

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 W/m², to which a person may be exposed without suffering adverse events

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

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

<table>
<thead>
<tr>
<th>Delivery Device</th>
<th>MPE (W/m²)</th>
<th>Numerical Aperture (NA)</th>
<th>Maximum Power ( \Phi ) (W)</th>
<th>NOHD (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EndoProbe</td>
<td>16</td>
<td>0.10</td>
<td>1.5</td>
<td>2.9</td>
</tr>
<tr>
<td>TS-600</td>
<td>16</td>
<td>0.25</td>
<td>2.0</td>
<td>1.4</td>
</tr>
<tr>
<td>DioPexy Probe</td>
<td>16</td>
<td>0.03</td>
<td>1.8</td>
<td>11</td>
</tr>
<tr>
<td>Laser Indirect Ophthalmoscope (LIO)</td>
<td>16</td>
<td>0.02</td>
<td>1.5</td>
<td>15</td>
</tr>
<tr>
<td>Large Spot Laser Indirect Ophthalmoscope (LS-LIO)</td>
<td>16</td>
<td>0.02</td>
<td>1.5</td>
<td>15</td>
</tr>
<tr>
<td>Operating Microscope Adapter (OMA)</td>
<td>16</td>
<td>0.01</td>
<td>1.3</td>
<td>27</td>
</tr>
</tbody>
</table>
Safety Compliance


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

The DioVet™ uses a solid-state electronic switching power supply that meets strict EN 60601-1 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 off</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>Key switch</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 IEC 60529) 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)

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

Laser Warning

VISIBLE AND INVISIBLE LASER RADIATION
AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION
CLASS 4 LASER PRODUCT
CLASS 2 LASER PRODUCT
(IEC 60825-1:2007)

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

\[ \lambda = 810 \, \text{nm} \quad \text{Po} = 4 \, \text{W} \]

\[ \lambda = 650 \, \text{nm} \quad \text{Po} = 1 \, \text{mW} \]
<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>🌃</td>
<td>Aiming Beam</td>
</tr>
<tr>
<td>📜</td>
<td>Angle</td>
</tr>
<tr>
<td>🌃</td>
<td>Aspirating Probe</td>
</tr>
<tr>
<td>🔴</td>
<td>Caution</td>
</tr>
<tr>
<td>🎺</td>
<td>Audible Signal</td>
</tr>
<tr>
<td>🌃</td>
<td>CE Mark</td>
</tr>
<tr>
<td>🔴</td>
<td>Connector Type</td>
</tr>
<tr>
<td>🚫</td>
<td>Do Not Use if Package is Damaged</td>
</tr>
<tr>
<td>🕒</td>
<td>Duration</td>
</tr>
<tr>
<td>🕒</td>
<td>ETL Mark</td>
</tr>
<tr>
<td>🌃</td>
<td>EIO Sterile</td>
</tr>
<tr>
<td>🌃</td>
<td>EC REP</td>
</tr>
<tr>
<td>🌃</td>
<td>EU Authorized Representative</td>
</tr>
<tr>
<td>🕒</td>
<td>Expiration Date</td>
</tr>
<tr>
<td>🌃</td>
<td>Footswitch</td>
</tr>
<tr>
<td>🌅</td>
<td>Footswitch In</td>
</tr>
<tr>
<td>🌅</td>
<td>Footswitch Out</td>
</tr>
<tr>
<td>🌅</td>
<td>Protective Earth (Ground)</td>
</tr>
<tr>
<td>🕒</td>
<td>Interval</td>
</tr>
<tr>
<td>🌅</td>
<td>Illuminating Probe</td>
</tr>
<tr>
<td>🕒</td>
<td>Decrease/increase</td>
</tr>
<tr>
<td>🕒</td>
<td>Laser Aperture at End of Fiber</td>
</tr>
<tr>
<td>🕒</td>
<td>Laser Warning</td>
</tr>
<tr>
<td>🕒</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>🕒</td>
<td>On</td>
</tr>
<tr>
<td>🕒</td>
<td>Off</td>
</tr>
<tr>
<td>🕒</td>
<td>Pulse Count</td>
</tr>
<tr>
<td>🕒</td>
<td>Power</td>
</tr>
<tr>
<td>🕒</td>
<td>Lot</td>
</tr>
<tr>
<td>🕒</td>
<td>Read Information</td>
</tr>
<tr>
<td>🕒</td>
<td>Single Use</td>
</tr>
<tr>
<td>🕒</td>
<td>Standby</td>
</tr>
<tr>
<td>🕒</td>
<td>Treat</td>
</tr>
<tr>
<td>🕒</td>
<td>Type B Equipment</td>
</tr>
<tr>
<td>🕒</td>
<td>WEEE Guidance. Contact IRIDEX or your distributor for disposal information.</td>
</tr>
<tr>
<td>🕒</td>
<td>Pattern is Activated</td>
</tr>
</tbody>
</table>
# Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment wavelength</td>
<td>810 nm</td>
</tr>
<tr>
<td>Treatment power</td>
<td>Varies by type of delivery device. The laser system displays the power delivered to the tissue. <strong>DioVet™</strong>: 0-2000 mW</td>
</tr>
</tbody>
</table>
| Duration               | **CW-Pulse:**  
10, 20, 30, 40, 50, 75, 100, 150, 200, 300, 400, 500, 600, 700, 800, 900, 1000, 1500, 2000, 2500, 3000, 3500, 4000, 4500, 5000, 6000, 7000, 8000, 9000 ms  
**LongPulse:**  
10-60 seconds (increments of 5 seconds)  
1-2 minutes (increments of 10 seconds)  
2-5 minutes (increments of 30 seconds)  
5-30 minutes (increments of 1 minute) |
| Interval               | None, 50, 100, 200, 300, 400, 500, 600, 700, 800, 900, and 1000 ms |
| Aiming beam            | Red laser diode. User-adjustable intensity; 1 mW maximum; coaxial with treatment beam; 650 nm |
| Electrical             | 115 VAC, 50/60 Hz, 0.8 A  
230 VAC, 50/60 Hz, 0.4 A |
| Operating temperature range | 10° C to 40° C (50° F to 104° F) |
| Storage temperature range | -20° C to 60° C (-4° F to 140° F)  
If stored at temperatures below 10° C (50° F), allow to rise to room temperature for 4 hours prior to operation. |
| Relative humidity      | 20% to 80% |
| Dimensions             | 30 cm x 30 cm x 10 cm (12 in. W x 12 in. D x 4 in. H) |
| Weight                 | 6.3 kg (14 lbs.) |
| Equipment Protection   | Class 1 |
7

Wireless Footswitch and EMC

Setting Up the Wireless Footswitch

The wireless footswitch comprises:

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

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

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

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

**NOTE:** The footswitch is designed to operate within 15 feet (4.57 m) 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

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.

<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>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 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.

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.

<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</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</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.
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>IEC-61000-4-6</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>Radiated RF</td>
<td>IEC 61000-4-3</td>
<td>3 Vrms</td>
<td>$d = 1.2 \sqrt{P}$</td>
</tr>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
<td>3 V/m</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>

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).

Fields strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

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.

<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 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.
8
TS-600

Product Description

The IRIDEX TS-600 delivers laser energy to perform a transscleral cyclophotocoagulation procedure. The TS-600 is a fiber-optic laser delivery device. It consists of a handpiece with a plastic handle that terminates with a contact 600µ quartz fiber tip that has been rounded to a hemisphere. The fiber-optic cable is 2 meters (6 feet).

Product Specifications

| Treatment Beam: | Laser Diode: 800-830 nm |
| Aiming Beam:    | Laser Diode: 650 nm (red) |
| Laser Spot Sizes: | Laser delivery optics in the hemisphere tipped TS-600 produces a 550 micron spot at the fiber tip and a 400 micron spot on the plane of the ciliary body. Therapeutic lesion size will be larger than the theoretical spot size due to thermal conduction. A typical lesion size at a 2 second duration is approximately 2 mm diameter. |
Warnings and Cautions

1. Excessive power settings may cause ciliary body hemorrhage.
2. Excessive number and/or short pulse durations may result in subretinal choroidal hemorrhage.
3. Excessive energy may cause peripheral lens damage.
4. Tissue absorption is directly dependent upon presence of pigmentation. Therefore, eyes with higher pigmentation will require lower energy to obtain equivalent results.
5. Presence of heavy perilimbal conjunctival pigmentation can result in local absorption and burns. Therefore, avoid areas of intense pigmentation. Dissection of heavily pigmented conjunctiva may be required.
6. Fiber-optic tip must be kept clean to avoid thermal damage at site of application. If during the procedure the tip becomes dirty, then clean tip gently with alcohol swab. If dirt or discoloration on the tip cannot be removed by gentle cleaning, then discard TS-600.
7. More than slight conjunctival burns are not typical. If they occur, then replace TS-600.
8. Avoid areas of significant scleral scarring which may be thin and inelastic.
9. Fiber-optic tip must be protected from damage. If damage is suspected to the fiber tip, then discard TS-600.
10. Keep conjunctiva well irrigated at all times. Do not drag or rotate TS-600 on the globe.
11. Operator and any observers should wear Laser Safety Eyewear with a minimum OD= 2 at 810 nm.
12. TSCPC should be approached cautiously in the region of a pigmented intraocular lens haptic located in the ciliary sulcus.

Connecting the TS-600

Install the TS-600 into the laser port on the front of the DioVet™ console. All laser control functions automatically maintain calibration to display the actual output power delivered out of the delivery device connected.

Use diode laser safety glasses to view the procedure.

CAUTION: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous emission of laser energy.

CAUTION: When changing delivery systems, be certain to place the protective cap on the fiber input as debris on the input face can affect transmission.

To Treat

1. Turn on the DioVet.
2. Select the desired laser power and exposure time on the DioVet control panel.
3. Place in Treat mode.
4. Adjust intensity of pilot/aiming beam as needed.
5. Place the TS-600 on the eye to be treated as described in the separate Glaucoma Treatment Protocol Sheet.
6. Depress the Foot Switch to activate the DioVet treatment beam.
To Conclude Treatment

1. Turn off the DioVet
2. Remove TS-600 from the DioVet and cover input fiber face and DioVet laser port with protective caps.

Maintenance

Routine Maintenance

The TS-600 is sold as a limited re-use device. The number of uses depends greatly on the care, cleaning and types of treatments done with the probe. Any matter that becomes fused onto the surface of the probe, will become a “hot spot” and may cause a scleral perforation if not removed. If the matter cannot be removed the probe should be discarded.

Cleaning During Treatment

If the TS-600 fiber face becomes dirty during treatment, suspend treatment and clean the fiber face as follows:
1. Wrap a lens tissue (Kodak or equivalent) around one end of a cotton-tipped swab.
2. Place several drops of 100% ethanol, 100% methanol, or 100% propanol on the tissue.
3. Wipe the fiber face gently with the swab to remove all dust and debris.
4. If the surface is still not clean, put a clean lens tissue around the end of the swab and gently wipe again.
5. If dirt or discoloration cannot be removed from the fiber face with gentle cleaning, then discard TS-600.

Probe Protection Requirements

1. Avoid striking probe ends against hard surfaces.
2. Coil the fiber-optic cable no tighter than 6 inches (15 cm) in diameter.

Cleaning After Treatment

The fiber tip should be cleaned with alcohol and a cotton swab using very light pressure and a circular motion. The black tip with the measuring finger may be removed by rotating it counterclockwise. It may also be used to protect the tip of the fiber by unscrewing it enough to cover the fiber tip.
Sterilization Instructions: Sterilize using EtO gas only

Vaccum:
Initial evacuation: 57 mmHg to 78 mmHg
54 °C to 55 °C
30 minutes

Pressure:
Gas Type: Ethylene Oxide (EtO), Oxyfurne 2000
(8.6% EtO/91.4% HCFC-124)
Operating temperature: 55 °C to 60 °C
Exposure time: 2 hours
Humidity: 30% to 80%
Pressure: 1.3 bar to 1.4 bar (20 psi to 21 psi)
Aeration: 8 hours @ 55 °C to 61 °C
Chamber load density: 0.35 g/cm³

Troubleshooting

Problem or observation Possible solution(s)
No aiming beam
• Adjust aiming beam intensity.
• Verify that the TS-600 is properly connected at the fiber port.
No tissue effect
• Verify that the TS-600 is properly connected at the fiber port.
• Disconnect the TS-600 and reconnect another delivery device to verify laser transmission.
• Adjust the power and/or duration.
• Possible broken fiber; contact IRIDEX Technical Services.
Status display reads “connect fiber”
• Connect the TS-600 to the fiber port. Finger tighten only.