Iridex® 532 Laser System
Operator Manual

Iridex® 532 Laser Operator Manual

23001-EN Rev C 09.2024

Table of Contents

1. Introduction

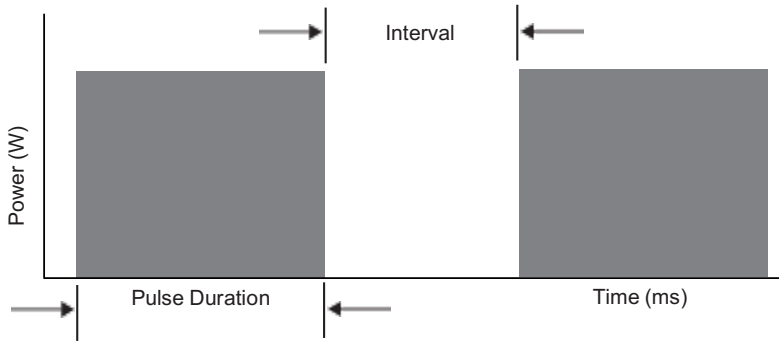
The Iridex® 532 (532 nm, green) Laser Console is a solid-state laser that is used to deliver laser energy in Continuous-Wave (CW) mode for ear, nose and throat (ENT) applications, and in CW and MicroPulse® modes for ophthalmic applications. Improper use of the laser system can result in adverse effects. Follow the instructions for use described in this operator manual.

Pulse Types

The Iridex 532 Laser can deliver a CW laser pulse in 2 modes: CW-Pulse™ mode and MicroPulse® mode.

CW-Pulse

Laser emission is continuous during the entire timed exposure.



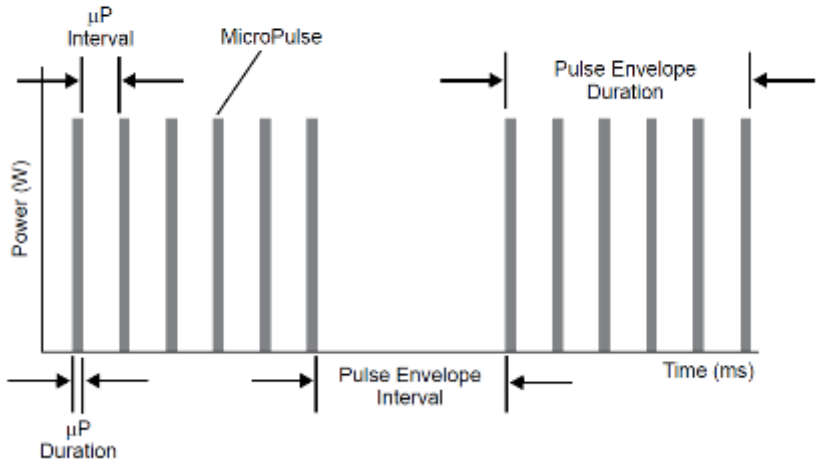
MicroPulse (Optional)

The MicroPulse Mode symbols, as shown below, represent whether the MicroPulse Treatment Option has been enabled in the Iridex 532 laser.

MicroPulse feature enabled	MicroPulse feature disabled
	

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

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



MicroPulse mode is typically used to administer subvisible threshold laser treatments to macular and perimacular targets. When used here, the terms “subvisible,” “subvisible threshold” or “subthreshold” denote that the desired endpoint is one in which treated tissue offers no ophthalmoscopically observable laser effects. MicroPulse laser treatment can be performed using 532 nm, 577 nm, or 810 nm wavelengths. Studies have confirmed that 577 nm and 810 nm subvisible laser treatment can be clinically effective while inducing no tissue changes discernible by slit lamp observation, fluorescein angiography, fundus autofluorescence, or at any time postoperatively.[1,2] Additionally, a histological study that evaluated 532 nm and 810 nm at various MicroPulse duty cycles demonstrated equivalence in protein expressions with no visibly detectable lesions.[3]

Tissues receiving subvisible MicroPulse laser treatment show no such changes because the total laser energy of such doses is only a percentage (often chosen by clinicians to be 20 – 70%) of that energy needed to produce a visible endpoint.

Energy (J) is equal to [Laser Power (W)] x [Exposure Duration(s)] × [Duty Factor (%/100)]. Duty Factor is often 5% to 15% when using MicroPulse Mode, and is 100% when using CW Mode. Clinicians have reported various strategies to adjust these parameters relative to suprathreshold burns to achieve clinically effective subvisible endpoints.[1,2,4,5]

Additional parameters to consider in any laser treatment protocol, and particularly during MicroPulse, is spacing between laser treatment spots, and the total number of treatment spots administered. Due to the limited thermal spread of MicroPulse exposures, subvisible treatments often call for the administration of a greater number of treatment spots with denser spacing than that used for threshold laser grid treatments.[5]

References

1. Vujosevic S, Bottega E, Casciano M, Pilotto E, Convento E, Midena E. Microperimetry and fundus autofluorescence in diabetic macular edema: Subthreshold micropulse diode laser versus modified early treatment diabetic retinopathy study laser photocoagulation. *Retina* 2010;30(6):908-916.
2. Vujosevic S, Martini F, Convento E, Longhin E, Kotsafti O, Parrozzani R, Midena E: Subthreshold Laser Therapy for Diabetic Macular Edema: Metabolic and Safety Issues. *Curr Med Chem* 2013.

3. Yu AK, Merrill KD, Truong SN, Forward KM, Morse LS, Telander DG: The Comparative Histologic Effects of Subthreshold 532- and 810-Nm Diode Micropulse Laser on the Retina. *Invest Ophthalmol Vis Sci* 2013;54(3):2216-2224.
4. Figueira J, Khan J, Nunes S, Sivaprasad S, Rosa A, de Abreu JF, Cunha-Vaz JG, Chong NV. Prospective randomised controlled trial comparing sub-threshold micropulse diode laser photocoagulation and conventional green laser for clinically significant diabetic macular oedema. *Br J Ophthalmol* 2009;93(10):1341-4.
5. Lavinsky D, Cardillo JA, Melo LA, Jr., Dare A, Farah ME, Belfort R, Jr. Randomized clinical trial evaluating mETDRS versus normal or high-density micropulse photocoagulation for diabetic macular edema. Invest *Ophthalmol Vis Sci* 2011; 52(7):4314-23.

Compatible Iridex 532 Delivery Devices

IMPORTANT! The Iridex 532 Laser may be used with compatible Iridex delivery devices that have either resistive or RFID connectors.

***NOTE**: Before using a compatible delivery device, refer to the Operator Manual and/or Instructions for Use supplied with the delivery device, which includes device-specific information such as the intended use, indications for use, contraindications, warnings, precautions, adverse effects information, and delivery-device use instructions.*

Compatible Delivery Devices	Continuous-Wave Mode	MicroPulse Mode
EndoProbe® Handpieces	•	•
Laser Indirect Ophthalmoscopes (LIO)		
Iridex® LIO Plus (Single-Mirror)		
• 532 nm Model	•	•
• Dual 810/532 nm Model	•	•
TruFocus LIO Premiere® (Dual-Mirror)		
• 532 nm Model	•	•
• Dual 810/532 nm Model	•	•
Slit Lamp Adapters (SLA)	•	•
TxCell™ Scanning Laser Delivery System	•	•
ENT Delivery Devices	•	

Indications for Use

The Iridex® 532 Laser Console is a solid-state laser that is used to deliver laser energy in either continuous-wave pulse (CW-pulse) or MicroPulse® mode, for ophthalmic and for Ear, Nose, and Throat (Otolaryngology) applications.

The Iridex 532 Laser is indicated for use in soft and fibrous tissue, including osseous tissue incision, excision, coagulation, vaporization, ablation and vessel hemostasis in the medical specialties of, ear, nose and throat (ENT)/ otolaryngology, and ophthalmology as follows:

Ophthalmology

Indicated for retinal photocoagulation (RPC), laser trabeculoplasty, iridotomy, iridoplasty including:

- Retinal photocoagulation for the treatment of
    - Diabetic retinopathy, including:
        - Nonproliferative retinopathy
        - Macular edema
        - Proliferative retinopathy
    - Retinal tears and detachments
    - Lattice degeneration
    - Age-related macular degeneration (AMD)
    - Retinopathy of prematurity
    - Sub-retinal (choroidal) neovascularization
    - Central and branch retinal vein occlusion
- Laser trabeculoplasty, iridotomy, iridoplasty for the treatment of glaucoma, including
    - Primary open angle/Closed angle

Ear, Nose and Throat (ENT)/Otolaryngology

Otosclerotic hearing loss and/or diseases of the inner ear:

- Stapedectomy
- Stapedotomy
- Myringotomies
- Lysis of Adhesions
- Control of Bleeding
- Removal of Acoustic Neuromas
- Soft tissue Adhesion in Micro/Macro Otologic Procedures

Procedural Recommendations

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

Contraindications

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

Potential Side Effects or Complications

OPHTHALMIC:

- Specific to retinal photocoagulation: inadvertent foveal burns; choroidal neovascularization; paracentral scotomata; transient increased edema/decreased vision; subretinal fibrosis; photocoagulation scar expansion; Bruch's membrane rupture; choroidal detachment; exudative retinal detachment; pupillary abnormalities from damage to the ciliary nerves; and optic neuritisfrom 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; intraocular pressure (IOP) spike; and rarely, retinal detachment.
- Specific to laser trabeculoplasty: IOP spike and disruption of the corneal epithelium.

ENT:

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

Anesthesia Considerations

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

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

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

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

- **ANSI Z136.3**, **The Safe Use of Lasers in Health Care Facilities**, American National Standards 2007.
- **Recommended Practices: Laser Safety in the Practice Setting**. *AORN Journal*, March 1993, Vol. 57 No. 3, Pg. 720-727.
- **Safety Considerations for the Use of Medical Lasers, The Nursing Spectrum of Lasers**, Pfister, Kneedler, Purcell, *Education Design*, 1988, Pg. 70-72.
- **Prevention of Fires and Protection of Non-Target Tissues, Airway Precautions**, *Plan for Success: A Practical Guide for Your Carbon Dioxide Laser Surgery Program*, Lewis, Coherent 1989,Pg. 16-17.

- **Laser Resistant Stainless Steel Endotracheal Tube: Experimental and Clinical Evaluation**, Fried MP, Mallampati SR, Liu FC, Kaplan S, Caminear DS, Samonte BR. *Lasers in Surgery and Medicine*, 11:301-306 (1991).
- **Evaluation & Discussion: Issues in Using and Selecting Laser Resistant Endotracheal Tubes (LRETTs) and Wraps**, *ECRI, Health Devices*, July-August 1991, Vol. 20 Nos. 7-8.
- **Diffuse Reflections, Endoscopic Surgery: Is Laser Safety Eyewear Really Needed?**, *Radiant Resources Newsletter*, Winter 1992, Rockwell Laser Industries.

Specific Warnings and Precautions

It is essential that the surgeon and attending staff be trained in all aspects of these procedures. No surgeon should use these laser products for ophthalmic and ENT surgical procedures without first obtaining detailed instructions in laser use.

Refer to "Warnings and Cautions" for more information. Proper eye protection for 532 nm light must be utilized. Follow the Eye Protection Policy at your facility.

Laser Settings

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

532 nm Typical Laser Treatment Parameters for Ocular Photocoagulation

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

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

532 nm Typical Laser Treatment Parameters for ENT Photocoagulation[1-3]

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

1. Hodgson RS, Wilson DF: Argon Laser Stapedotomy. *Laryngoscope* 1991;101(3):230-3.
2. D'Eredita R, Shah UK: Contact Diode Laser Myringotomy for Medium-Duration Middle Ear Ventilation in Children. *Int J Pediatr Otorhinolaryngol* 2006;70(6):1077-80.
3. Horn KL, Gherini S, Griffin GM Jr: Argon Laser Stapedectomy Using an Endo-Otoprobe System. *Otolaryngol Head Neck Surg* 1990;102(2):193-8.

Warnings and Cautions

DANGER:

Do not remove laser console 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
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	(800) 388-4747 (US only)
Fax:	(650) 962-0486
Technical Support:	(650) 962-8100
	techsupport@Iridex.com

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.

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.*

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 damage or defect caused by the use of non-Iridex devices.

WEEE Guidance. For disposal contact an electronic waste and/or recycling center compliant with local regulations. For further information contact Iridex or your distributor.

Rx only

CAUTION:

Federal law restricts this device to sale by or on the order of a physician or licensed healthcare professional.

2. Console Setup

Unpack the System

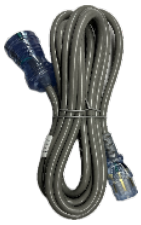
Make sure you have all components that were ordered. Check all components for damage before use.

NOTE: *Contact Iridex Customer Service if there are problems with your order.*

Iridex® 532 Laser Console

Remote Interlock Connector

Standard Wired Footswitch



Power Cord

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

Not shown:

- Keys
- Operator manual
- Laser warning sign
- Optional wired and wireless footswitches
- Other optional accessories

Choose 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.

CAUTION:

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.

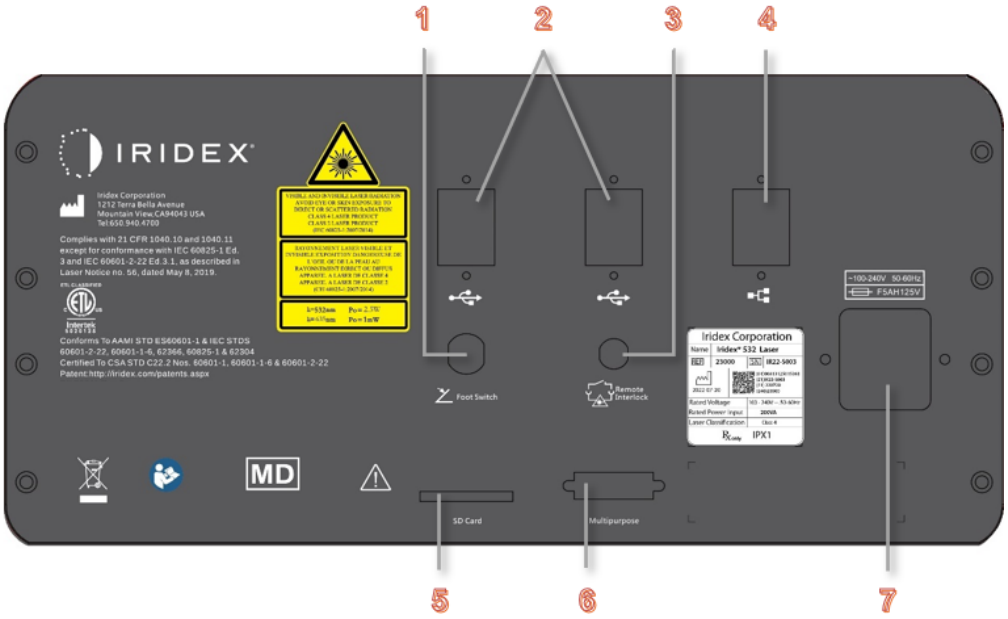
Connect the Components

Connect the power cord and the footswitch and interlock connectors to the ports on the rear panel.

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

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

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



1. Footswitch outlet
2. USB ports
3. Remote interlock
4. Ethernet port
5. SD card
6. Multipurpose port : Use this port to connect an optional Iridex wired or wireless footswitch. NOTE: If using an optional Iridex footswitch, there should not be a footswitch connected in the footswitch outlet.

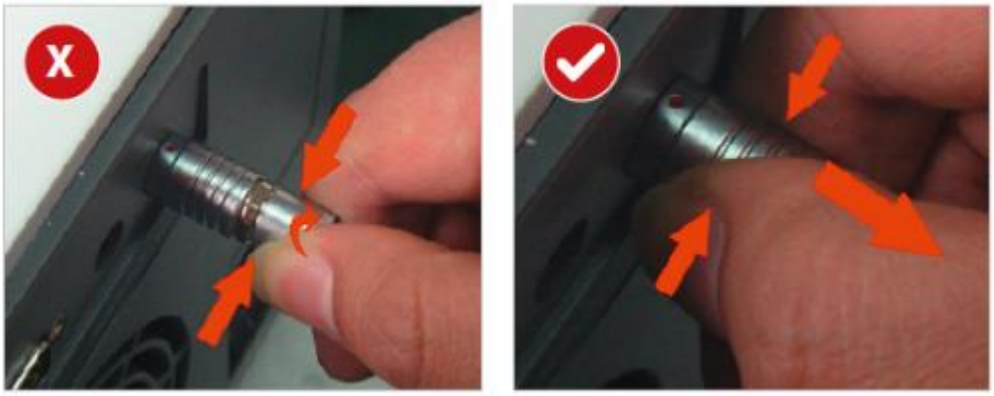
   The Multipurpose port is also used to connect the TxCell scanner control box to the laser console. If the TxCell scanner is used with an optional Iridex wired or wireless footswitch, connect the TxCell serial cable into the laser console multipurpose port and connect the footswitch into one of the two serial ports on the rear panel of the TxCell control box.
7. Power outlet

Inserting Connectors

The remote interlock connector must be properly installed for the laser to operate.

Insert the standard footswitch and interlock connectors with the red dot facing upwards.

Removing Connectors



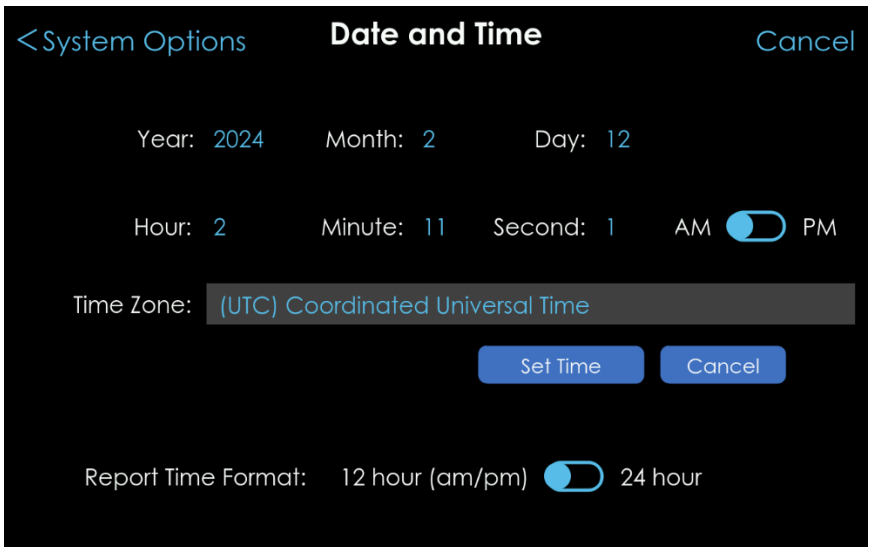
Remove the standard footswitch and interlock connectors by pulling the connector straight out. Do not twist the connector.

Set Date and Time

Content on the DATE AND TIME SCREEN is used to populate the Treatment Report; therefore, it is important to set the date, time, and time zone as applicable to your location ***before*** the laser is used for treatment. Also, you may choose either a 12-hour or 24-hour format. These settings will be retained.

Note*: There is no internet connection, and therefore, the Time Zone is not set or adjusted automatically.*

1. After the console is powered on, the IDLE SCREEN appears.
2. Select SETTINGS.
3. In the SETTINGS Screen, select System Options, and then Select Date and Time.
4. In the DATE AND TIME SCREEN, set the date, time, and time zone as appropriate.
5. Select **Set Time**.

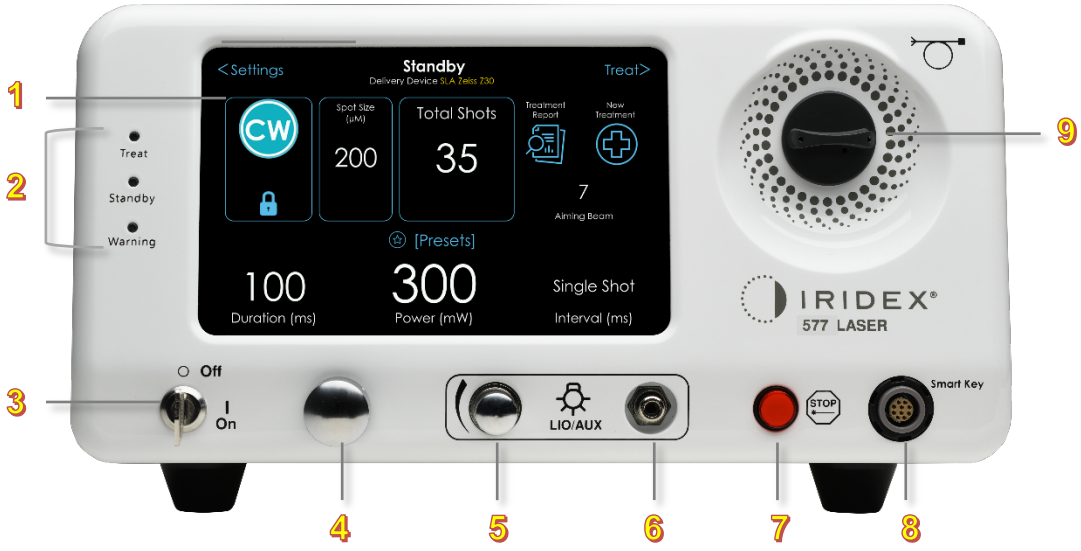


6. To return to the SETTINGS SCREEN:
   - Select System Options in the upper-left corner.
   - From the SYSTEM OPTIONS SCREEN, select Settings in the upper-left corner.

3. Console Controls

Overview

The laser console's front panel controls and other features are described below. For information on the user interface, see Chapter 4. "System Settings Screens" and Chapter 5. "User Interface Screens".



1. **Color LCD Touchscreen**. Used to select or initiate an action. See "Color Touchscreen".
2. **Indicator LEDs**. See "Indicator LEDs".
   - Treat: Green light indicates laser is in Ready-to-Treat mode and ready to fire when the foot pedal is depressed.
   - Standby: Amber light indicates laser is on and in Standby mode.
   - Warning: Red light indicates an error.
3. **Key switch**. Off/On. See "Key Switch".
4. **Control Knob**. Used to adjust the value in the parameter fields, such as Power, Duration, Interval; and in the system set-up fields, such as aiming beam, display brightness, and volume. See "Control Knob".
5. **External illumination intensity control**.
6. **External Illumination connector port**.
7. **Emergency laser stop**. See "Emergency Laser Stop".
8. **Smart Key**. Used with a slit lamp adapter delivery device. Communicates the spot size and safety filter information to the Iridex laser console.
9. **Fiber port**. See "Fiber Port".

Color Touchscreen

The 7” high-resolution touchscreen with dimmable LED-backlit color display allows the user to easily navigate between laser status screens and treatment options.

Attention:

Do not put heavy objects or apply excessive pressure on the touchscreen to prevent distorting the touchscreen display.

Avoid touching the screen with sharp items to prevent damage to screen.

Do not apply liquid to the surface of the touchscreen.

Indicator LEDs

- The treat indicator light turns green when the laser is in Ready-to-Treat mode and will fire the laser when the foot pedal is depressed.
- The standby indicator light turns amber when the laser is on and in Standby mode.
- The warning indicator light turns red to indicate an error. When the system is in error status, the laser is unable to fire.

Key Switch

The key switch for the unit is at the front of the device. The device cannot be operated without a key. Follow your institution’s safety protocol for managing and carrying the key. The key switch is the main system activator.

To turn on the laser, turn the key switch to the “|” (On) position. The power light indicator will appear. To turn off the laser, turn the key switch to the “O” (Off) position.

Attention*: To prevent unauthorized use, remove the key from the key switch when the system is not in use, and store it in a safe place.*

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

In an emergency, press the red Emergency Laser Stop button. This immediately disables the console and all laser related circuits.

Warning:

Except during actual treatment, the laser must always be in Standby mode when a delivery device is connected or Idle mode when no delivery device is connected. Maintaining the laser in Standby mode prevents accidental laser exposure if a pedal on 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.

Control Knob

The control knob is used to:

- Navigate from one field to another field.
- Change the value in fields, such as the following (partial list of fields):
  - Power
  - Duration
  - Interval
  - Aiming beam
  - Display brightness
  - Volume
  - TxCell pattern option
  - List selections

Use the control knob in conjunction with the touchscreen or as an alternative to using the touchscreen. Below are the control knob actions:

- When a field is deactivated, turn the control knob (clockwise or counter-clockwise) to navigate the fields. A white border around a field shows the current position, and that the field can be selected and activated.
- Press the control knob to activate a field. An activated field will display a colored background. After a field is activated, turn the control knob to adjust the field's value (clockwise to increase the value; counter-clockwise to decrease the value).
- Press the control knob to deselect or deactivate a field.

Emergency Laser Stop

In the event of an emergency, press the Emergency Laser Stop button to immediately stop laser emission. Follow the instructions on the user interface screen to restart the laser system. Instructions to restart the laser will display on the touch screen.

Attention:

Press the Emergency Laser Stop button to terminate laser emission.

Fiber Port

The fiber port accepts resistive and Iridex RFID delivery devices.

Warning:

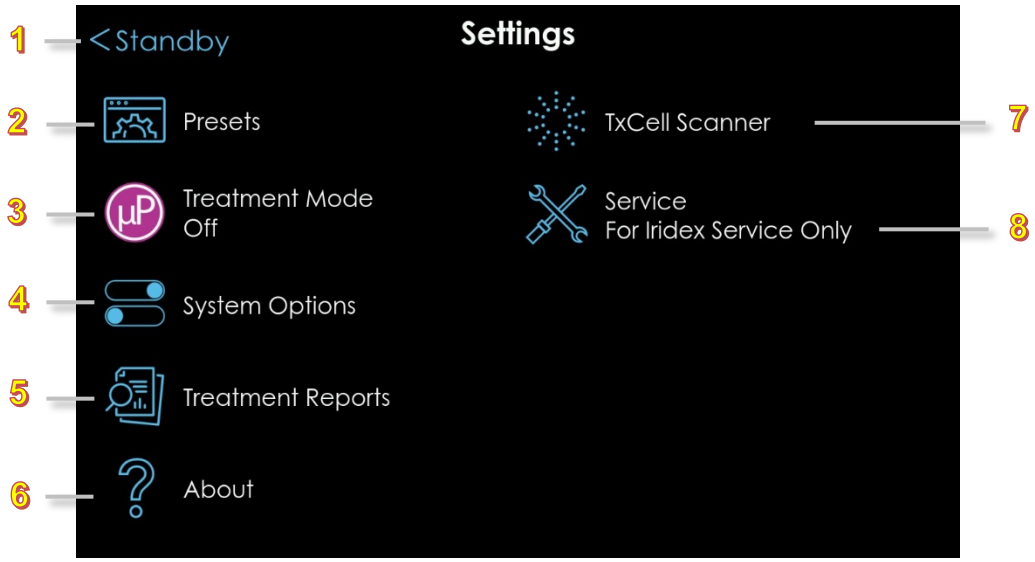
Do not remove the fiber during the use of the device. The fiber cannot be sharply bent. The bend radius must be more than 15 cm (6 in.).

The fiber port cap acts as a protection for the laser fiber port. When the fiber is removed, replace the fiber port cap over the fiber port.

Attention:

When the laser is not in use, replace the fiber port cap over the fiber port. It is important to protect the fiber port from contamination from dust, liquid, oil, or any other material; otherwise, the output power of the laser may decrease or even the inner laser system may be damaged.

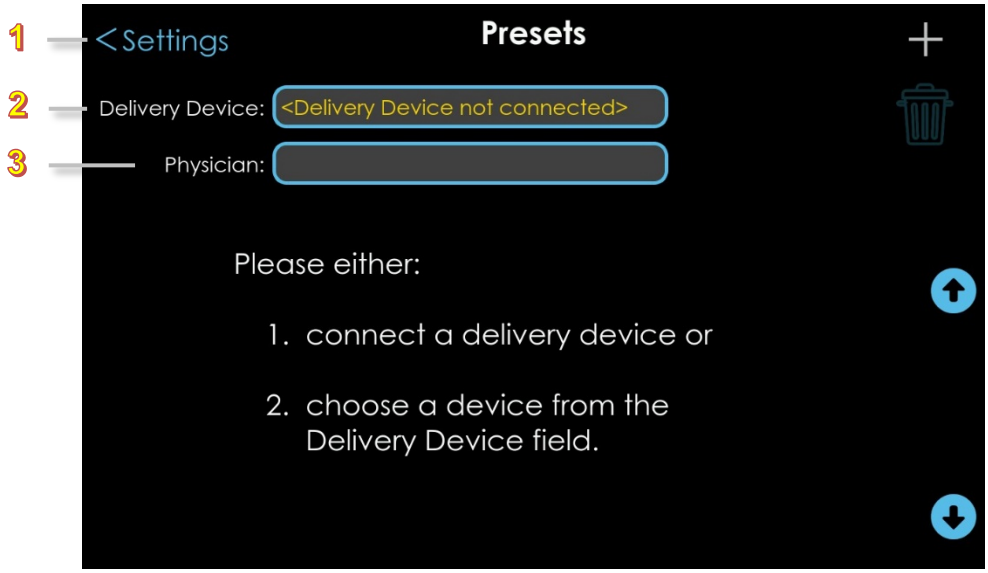
4. System Settings Screens



1. **Screen Navigation, Left Arrow**. Select to return to the previous screen (either the STANDBY SCREEN or the IDLE SCREEN)**.**
2. **Presets.** Select the icon to access the PRESETS SCREEN. The selected preset is displayed under "Presets".
3. **Treatment Mode**. Displays the selected treatment mode, i.e., MicroPulse or Continuous-Wave. The current settings are displayed under "Treatment Mode".

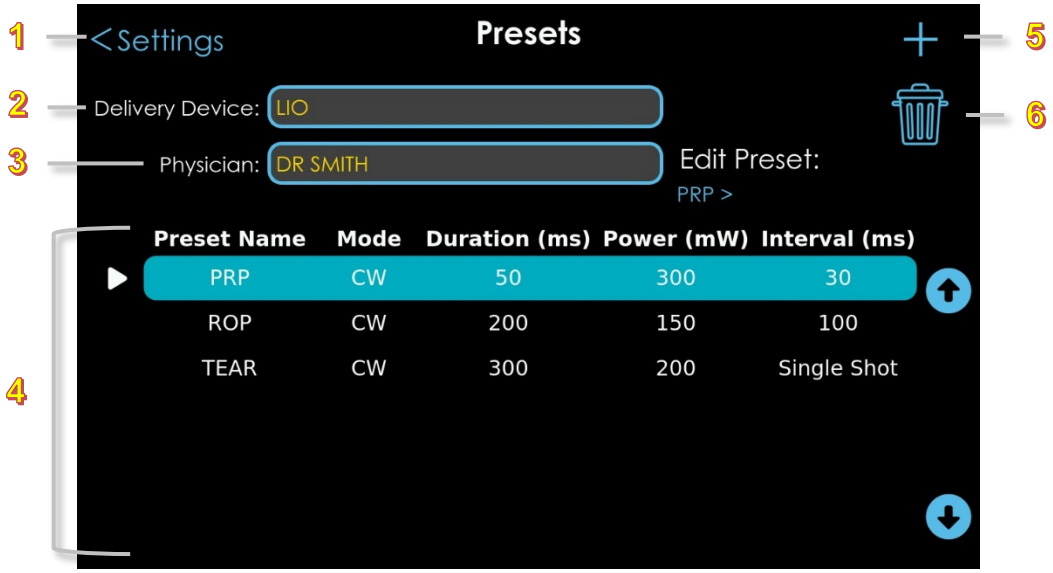
   Select the icon to access the TREATMENT MODE SCREEN. In the TREATMENT MODE SCREEN, select a Duty Cycle or customize the settings, or switch to Continuous-Wave mode.
4. **System Options.** Select the icon to access the SYSTEM OPTIONS SCREEN.
5. **Treatment Reports.** Select the icon to access the TREATMENT REPORTS SCREEN.
6. **About.** Select the icon to access the ABOUT SCREEN.
7. **TxCell Scanner (appears only when TxCell is connected to the laser console).** Select the icon to access the TXCELL OPTIONS SCREEN.
8. **Service**. Password-protected and accessible only by Iridex Technical Support.

Presets Screen Without Delivery Device Connected



1. **Screen Navigation, Left Arrow.** Select to return to the SETTINGS SCREEN.
2. **Delivery Device.** Displays “<Delivery Device not connected>” by default. Select field to choose from a drop-down list of delivery devices.
3. **Physician.** This field is blank upon first system use. When this field is populated, use the pop-up keyboard to select a physician or enter a new physician name.

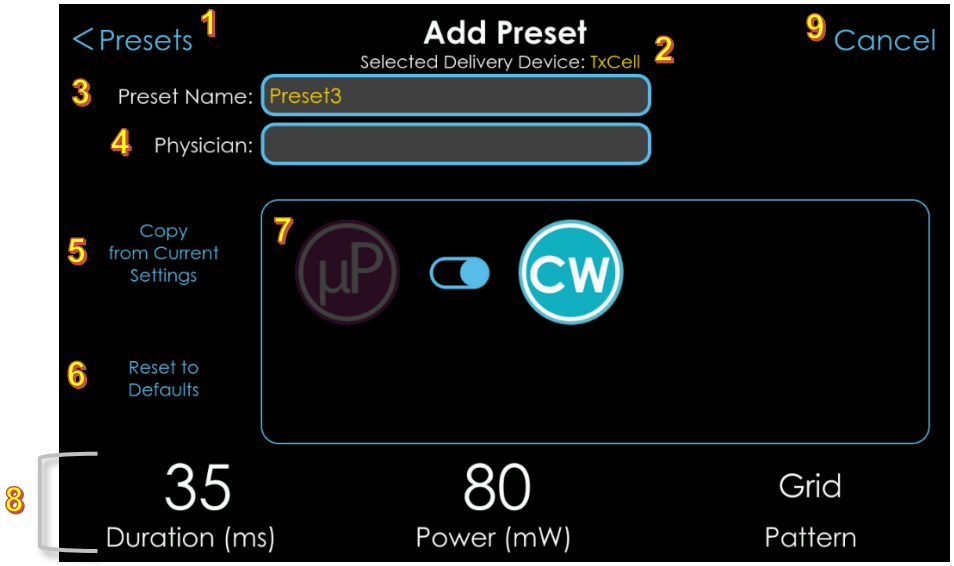
Presets Screen With Delivery Device Connected



1. **Screen Navigation, Left Arrow.** Select to return to the SETTINGS SCREEN.
2. **Delivery Device.** Displays the name of the connected delivery device. Select this field to display a list of known delivery devices in a pop-up window. Choose the desired device.
3. **Physician.** Displays the name of the physician. Select this field to display a list of physicians, or you can enter a new physician.
4. **Edit a Preset** Select a preset to edit. The selected row is highlighted. To Edit the selected preset, select Edit, or double click the Preset name to go to the Edit Preset screen. Use the up and down arrows located on the right side of the screen for scrolling long lists.
5. **Add New Preset.** Select to access the ADD PRESET SCREEN.
6. **Delete Preset.** To delete a preset, highlight the preset and then select the trash can icon.

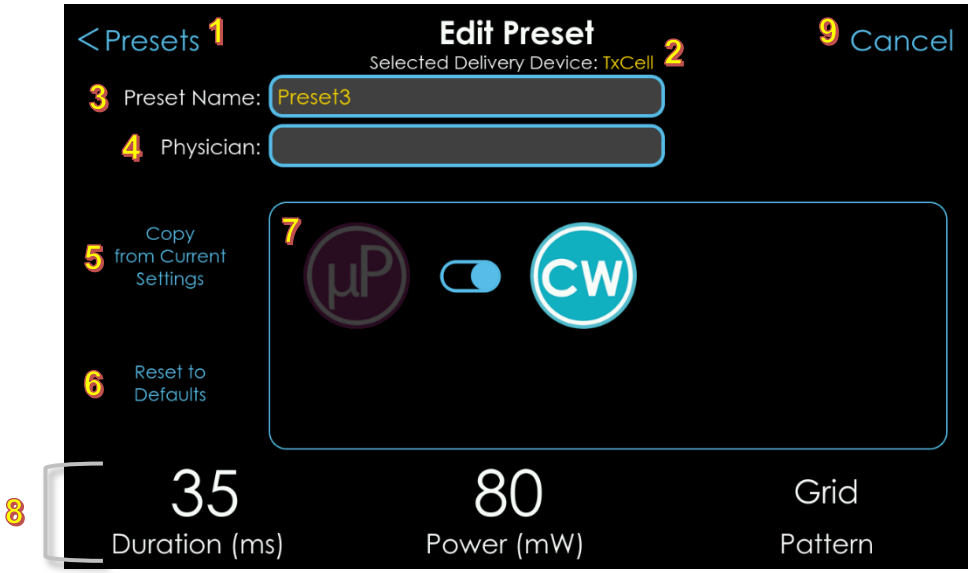
Add Preset Screen

NOTE: *Up to 1,000 presets can be stored.*



1. **Screen Navigation, Left Arrow.** Select to save the new preset and return to the PRESETS SCREEN. The new preset will be selected automatically in the PRESETS SCREEN.
2. **Selected Delivery Device**. Displays the name of the selected delivery device.
3. **Preset Name**. Enter a name that describes the set of parameters used in the preset. Preset names are limited to 32 characters. Characters include: A-Z (uppercase); a-z (lowercase); 0-9 (numeric); and hyphen (-), slash (/), colon (:), semicolon (;), parentheses (), dollar sign ($), ampersand (&), at symbol (@), period (.), comma (,), question mark (?), exclamation point (!), quotation marks, single and double (' "), percentage symbol (%).
4. **Physician**. Select this field to choose a physician from a pop-up window, or add a new name. Physician names are entered in the PRESETS SCREEN. A physician name is not required; however, by adding physicians' names when multiple physicians use the laser, each physician can filter the presets based on their name in the PRESETS SCREEN.
5. **Copy from Current Settings**. Select to copy the current settings for the connected delivery device shown on the STANDBY SCREEN. When no delivery device is connected to the laser, the copy feature is greyed out.
6. **Reset to Defaults**. Select to reset all parameters to their default values.
7. **Treatment Mode.** The icon for the selected mode will be highlighted, and the other icon will be greyed out. When MicroPulse mode is selected, select the 5%, 10%, or 15% Duty Cycle button to change the Duty Cycle. Optionally, select the Custom button and then select Duration and/or Interval to manually adjust the Duty Cycle values using the control knob.
   To change to CW treatment mode, use the toggle-switch.
8.
   - **Duration.** Use the control knob or touchscreen to select and activate the field; use the control knob to adjust Duration in ms.
   - **Power.** Use the control knob or touchscreen to select and activate the field; use the control knob to adjust Power in mW.
   - **Interval.** Use the control knob or touchscreen to select and activate the field; use the control knob to adjust Interval in ms.
9. **Cancel**. Select to cancel changes and return to the PRESETS SCREEN.

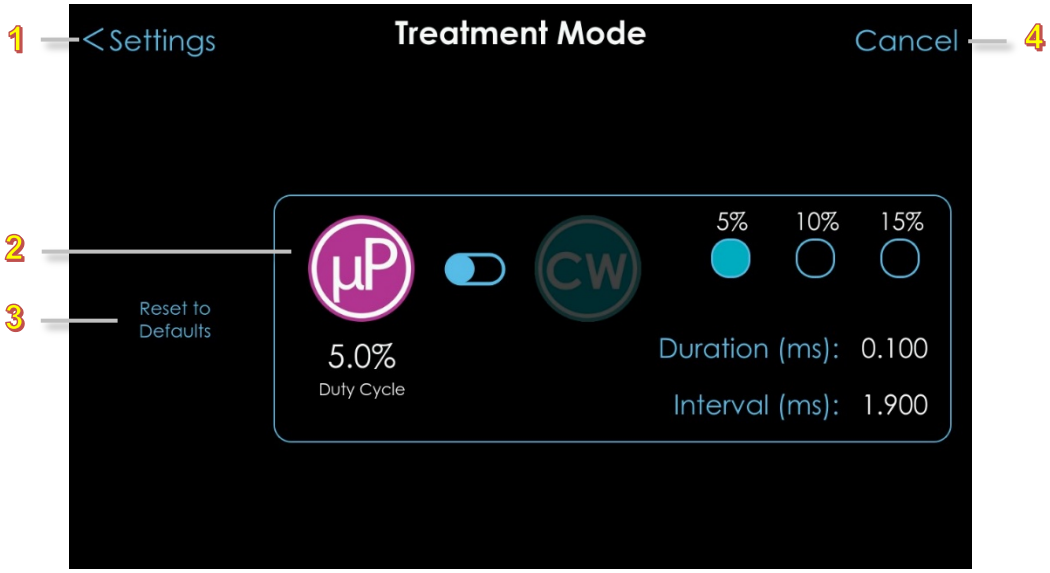
Edit Preset Screen



1. **Screen Navigation, Left Arrow.** Select to save changes and return to the PRESETS SCREEN.
2. **Selected Delivery Device**. Displays the name of the selected delivery device.
3. **Preset Name**. Select this field to view a pop-up keyboard. Edit the name as desired.
4. **Physician**. Select this field to view a pop-up keyboard. Edit the name as desired.
5. **Copy from Current Settings**. Select to copy the current settings for the connected delivery device shown on the STANDBY SCREEN. When no delivery device is connected to the laser, the copy feature is greyed out.
6. **Reset to Defaults**. Select to reset all parameters to their default values.
7. **Treatment Mode.** The icon for the selected mode will be highlighted, and the other icon will be greyed out. When MicroPulse mode is selected, select the 5%, 10%, or 15% Duty Cycle button to change the Duty Cycle. Optionally, select the Custom button and then select Duration and/or Interval to manually adjust the Duty Cycle values using the control knob.

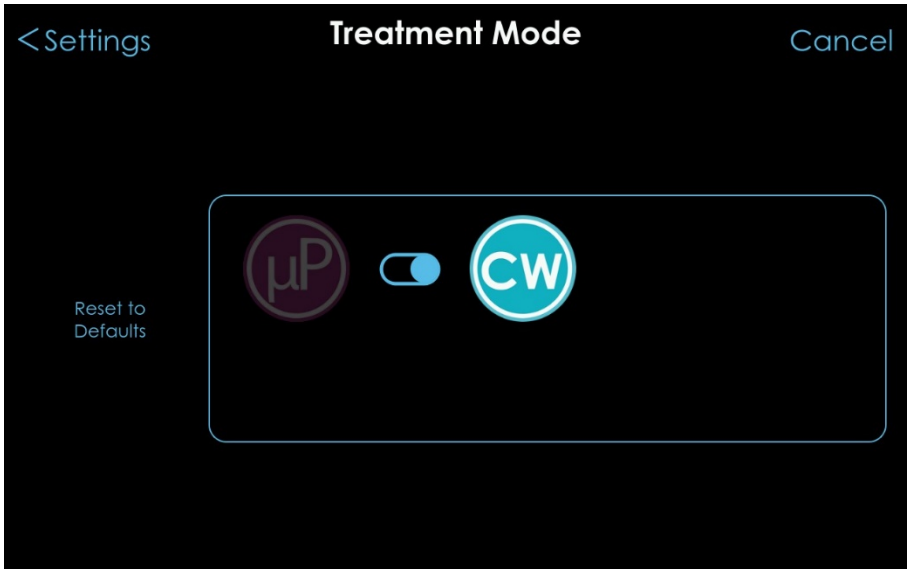
   To change to CW treatment mode, select the toggle-switch.
8.
   - **Duration.** Use the control knob or touchscreen to select and activate the field; use the control knob to adjust Duration in ms.
   - **Power.** Use the control knob or touchscreen to select and activate the field; use the control knob to adjust Power in mW.
   - **Interval.** Use the control knob or touchscreen to select and activate the field; use the control knob to adjust the Interval in ms.
9. **Cancel**. Select to cancel changes and return to the PRESETS SCREEN.

Treatment Mode Screen

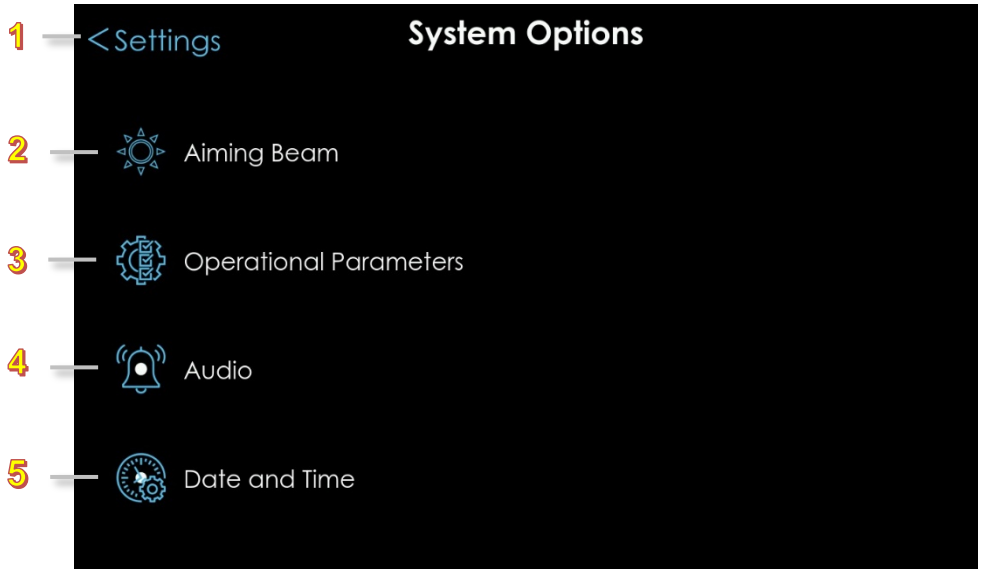


1. **Screen Navigation, Left Arrow.** Select to save changes and return to the SETTINGS SCREEN.
2. **MicroPulse Duty Cycle**. When MicroPulse mode is selected, the selected Duty Cycle is displayed. Select either the 5%, 10%, or 15% default duty cycles, or select 'Duration (ms)' and/or 'Interval (ms) to manually adjust the duty cycle values using the control knob.

   To enter Continuous-Wave mode, select the toggle-switch (the MicroPulse icon will be greyed out and the CW icon will be highlighted as shown below). Conversely, to enter MicroPulse mode again, select the toggle-switch.
3. **Reset to Defaults.** Select to reset the parameters to their default values (5% Duty Cycle).
4. **Cancel.** Select to cancel changes and return to the SETTINGS SCREEN.

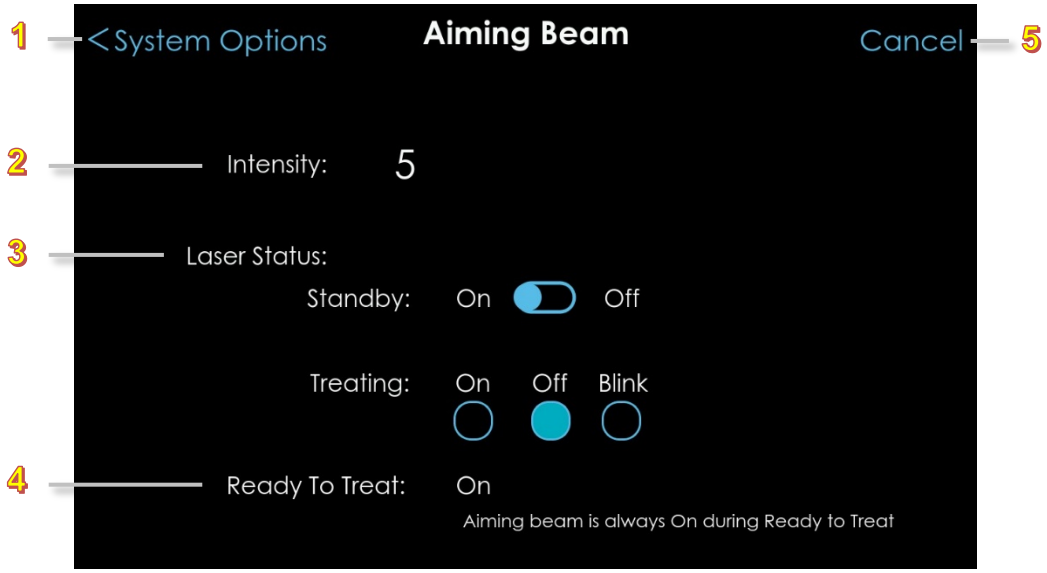


System Options Screen



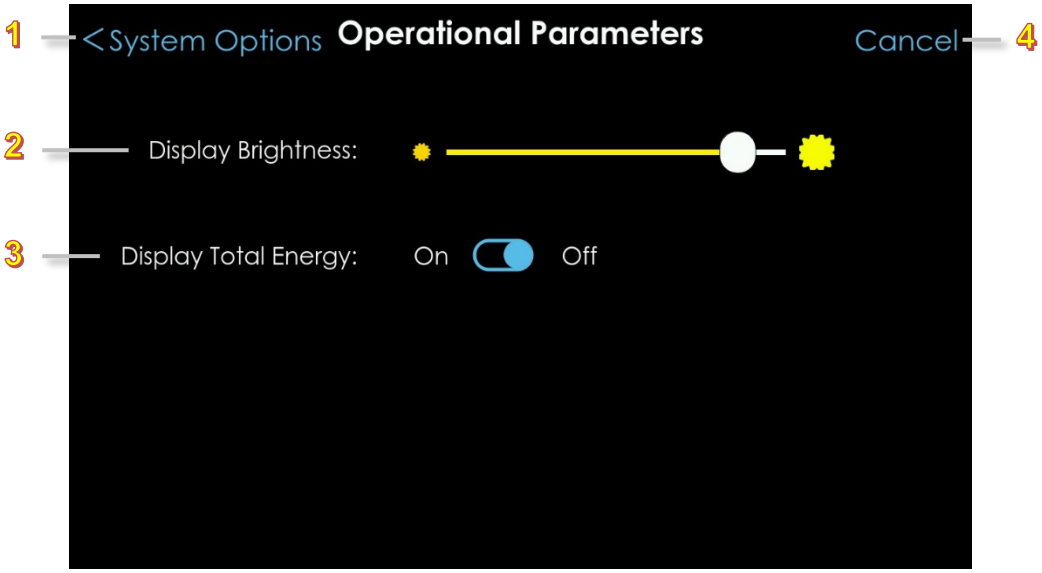
1. **Screen Navigation, Left Arrow**. Select to return to the SETTINGS SCREEN.
2. **Aiming Beam.** Select the icon to access the AIMING BEAM SCREEN.
3. **Operational Parameters.** Select the icon to access the OPERATIONAL PARAMETERS SCREEN.
4. **Audio**. Select the icon to access the AUDIO SCREEN.
5. **Date and Time.** Select the icon to access the DATE AND TIME SCREEN.

Aiming Beam Screen



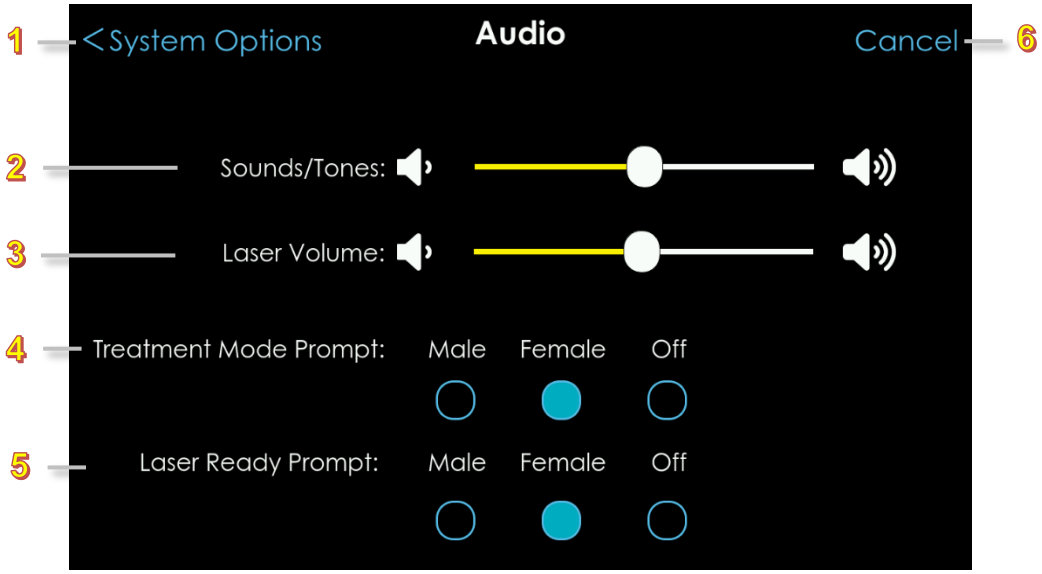
1. **Screen Navigation, Left Arrow**. Select to save changes and return to the SYSTEM OPTIONS SCREEN.
2. **Intensity**. Select and activate the field and use the control knob to adjust the aiming beam illumination from 1 (dimmest) to 20 (brightest).
3. **Laser Status**:
   - **Standby**. Select On or Off.
   - **Treating**. Select On, Off, or Blink.
4. **Ready to Treat**. View only. Aiming beam is always On during Ready to Treat.
5. **Cancel**. Select to cancel changes and return to the SYSTEM OPTIONS SCREEN.

Operational Parameters Screen



1. **Screen Navigation, Left Arrow**. Select to save changes and return to the SYSTEM OPTIONS SCREEN.
2. **Display Brightness**. Slide left or right to adjust Display Brightness level.
3. **Display Total Energy**. Select On or Off. When On, Total Energy displays on the STANDBY, READY TO TREAT, and TREATING screens.
4. **Cancel**. Select to cancel changes and return to the SYSTEM OPTIONS SCREEN.

Audio Screen



1. **Screen Navigation, Left Arrow**. Select to save changes and return to the SYSTEM OPTIONS SCREEN.
2. **Sounds/Tones**. Slide left or right to adjust Sounds/Tones volume. Sound/Tones can be turned off.
3. **Laser Volume** (applies only when delivering treatment). Slide left or right to adjust Laser volume. Laser volume cannot be turned off.

4 **Voice Prompt**

Treatment Mode: Select Male, Female, or Off

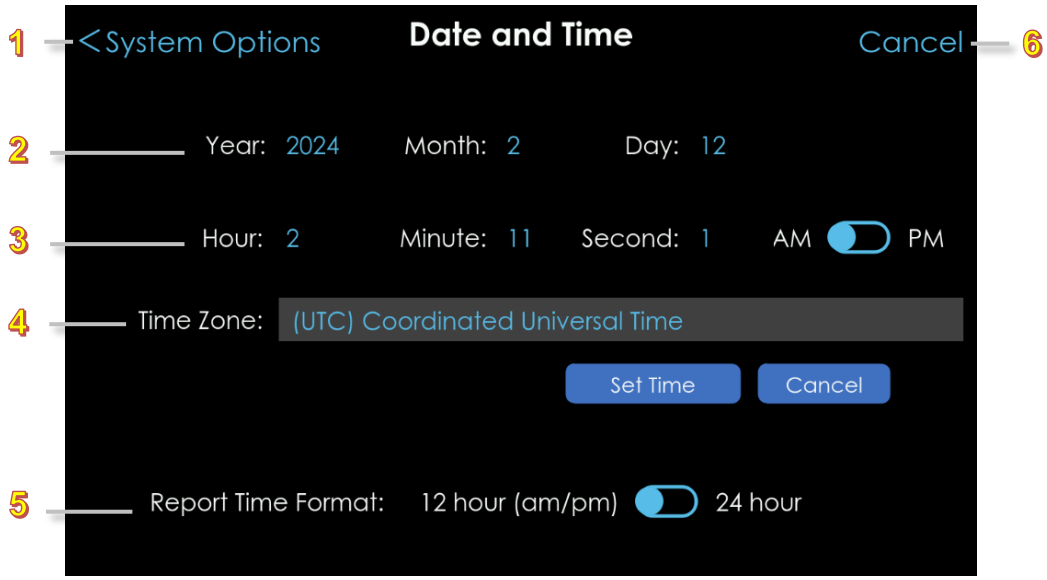
5. **Voice Prompt**

Laser Ready: Select Male, Female, or Off

6. **Cancel**. Select to cancel changes and return to the SYSTEM OPTIONS SCREEN.

Date and Time Screen

Content on the DATE AND TIME SCREEN is used to populate the Treatment Report; therefore, it is important to set the date, time, and time zone as applicable to your location *before* the laser is used for treatment. Also, you may choose either a 12-hour or 24-hour format. CHANGES made in the DATE AND TIME SCREEN are saved and retained after the console is turned off and then on again.



1. **Screen Navigation, Left Arrow**. Select to save changes and return to the SYSTEM OPTIONS SCREEN.
2. **Date**. Use the control knob or touchscreen to select and activate a field. Use the control knob to set the date: Year, Month, and Day.
3. **Time**. Use the control knob or touchscreen to select and activate a field. Use the control knob to set the time: Hour, Minute, Second.

   Select the time of day, AM or PM.
4. **Time Zone**. Use the control knob or touchscreen to select and activate this field. Use the control knob to select the desired Time Zone.

   ***NOTE**: There is no internet connection, and therefore, the Time Zone is not set or adjusted automatically.*

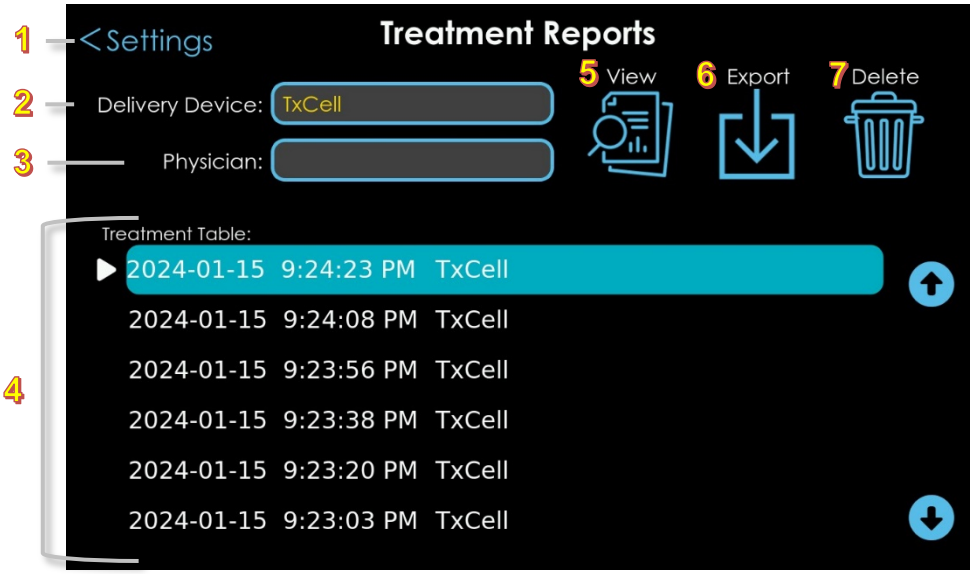
5 **Report Time Format**. Select the desired time format for treatment reports, 12 hour or 24 hour.

6. **Cancel**. Select to cancel changes and return to the SYSTEM OPTIONS SCREEN.

Treatment Reports Screen

The TREATMENT REPORTS SCREEN displays up to 1,000 treatment reports and includes options to view, export, and delete a selected treatment report.

***NOTE**: After 1,000 reports are stored, the next new report will overwrite the oldest report without warning.*



1. **Screen Navigation, Left Arrow.** Select to return to the SETTINGS SCREEN.
2. **Delivery Device**. Select a delivery device to filter the list by delivery device. This filter is required and cannot be empty.
3. **Physician**. Select a physician name to filter the list by that physician. This filter is optional and may be empty.
4. **Treatment Table** (The most recent report is displayed at the top of the list). Select the desired report to view, export, or delete.
5. **View**. Select to view the selected report in the TREATMENT REPORT SCREEN, or double click the highlighted report. The View icon is greyed out if no report is selected.
6. **Export**. Select to export the selected treatment report to a USB drive. For more information, see "Exporting Treatment Reports". The Export icon is greyed out if no report is selected, or if this optional feature is not enabled.
7. **Delete**. Select to delete the selected report. This icon is greyed out if no report is selected.

   Deleting a report is permanent. After it is deleted, the report is no longer available.

   ***NOTE**: You cannot delete the report for the current treatment.*

Exporting Treatment Reports (Optional)

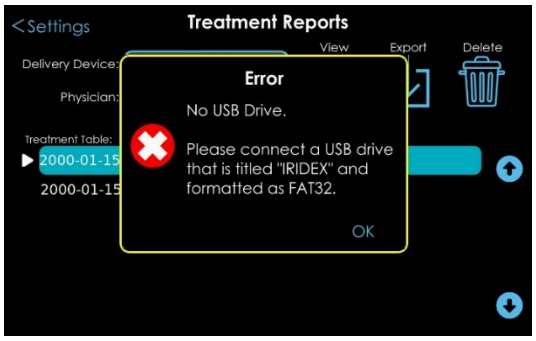
The Export Report icons, as shown below, represent whether the Exporting Treatment Reports option has been enabled in the Iridex 532 laser.

Exporting Treatment Reports feature enabled	Exporting Treatment Reports feature disabled
	

Only one report can be selected at a time to export to a USB. The file name of each exported treatment report will be labeled with the date and time of export and will not overwrite other files already in the USB drive.

1. Before you can export a treatment report to a USB, connect a properly-formatted, working USB drive.

   If no USB drive is connected, or if the USB drive is not properly formatted, a pop-up message is displayed.



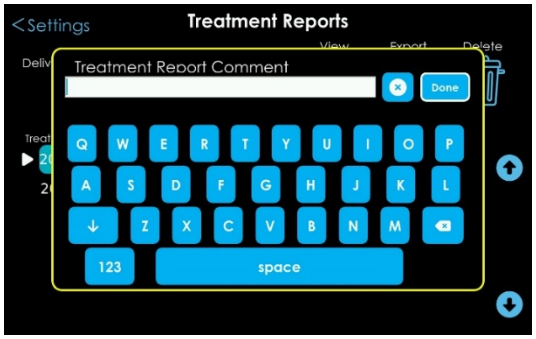
   For a successful export, the USB drive must be:

   - Formatted to FAT32 on a PC or Mac computer
   - Labeled as follows in all uppercase letters: IRIDEX
   - Working (not corrupt)

   Select **Okay** and try again with a properly formatted, working USB drive.

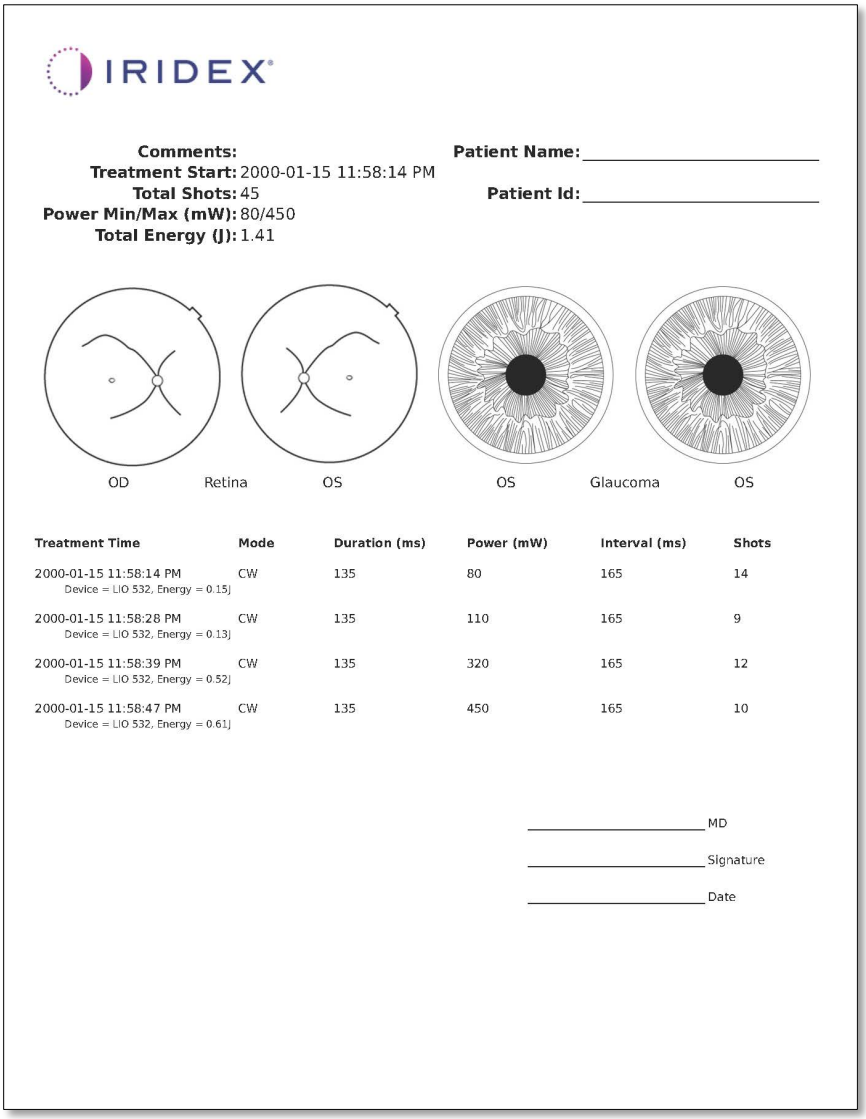
2. After you connect the USB drive, a pop-up is displayed to allow you to enter a comment or a file name. The comment you enter is displayed in the Treatment Report PDF (see "Treatment Report Example". A comment is limited to 64 characters. Also, the date and time are automatically appended to the comment you enter.

   ***NOTE**: If you do not enter a comment, "Export" is automatically added by default.*



3. When you are finished, select **Done**.
4. The Export Complete pop-up message displays. Select **Okay** and remove the USB drive.

Treatment Report Example



IRIDEX

Comments:
Treatment Start: 2000-01-15 11:58:14 PM
Total Shots: 45
Power Min/Max (mW): 80/450
Total Energy (J): 1.41

Patient Name: _____
Patient Id: _____

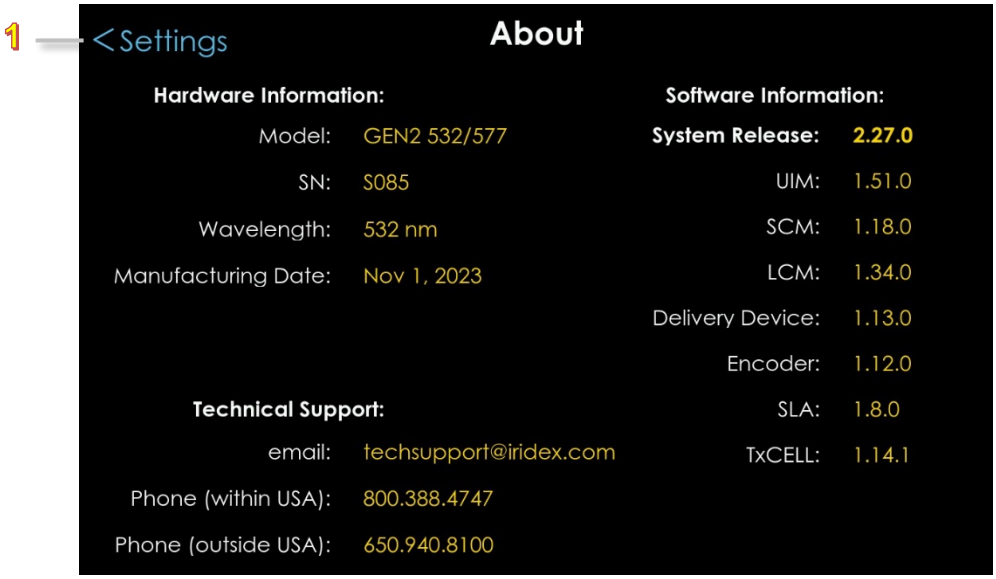
OD Retina OS OS Glaucoma OS

Treatment Time	Mode	Duration (ms)	Power (mW)	Interval (ms)	Shots
2000-01-15 11:58:14 PM Device = LIO 532, Energy = 0.15J	CW	135	80	165	14
2000-01-15 11:58:28 PM Device = LIO 532, Energy = 0.13J	CW	135	110	165	9
2000-01-15 11:58:39 PM Device = LIO 532, Energy = 0.52J	CW	135	320	165	12
2000-01-15 11:58:47 PM Device = LIO 532, Energy = 0.61J	CW	135	450	165	10

_____ MD
_____ Signature
_____ Date

About Screen

Displays laser console hardware information, software information, and Iridex Technical Support contact information.



1. **Screen Navigation, Left Arrow.** Select to return to the SETTINGS SCREEN.

5. User Interface Screens

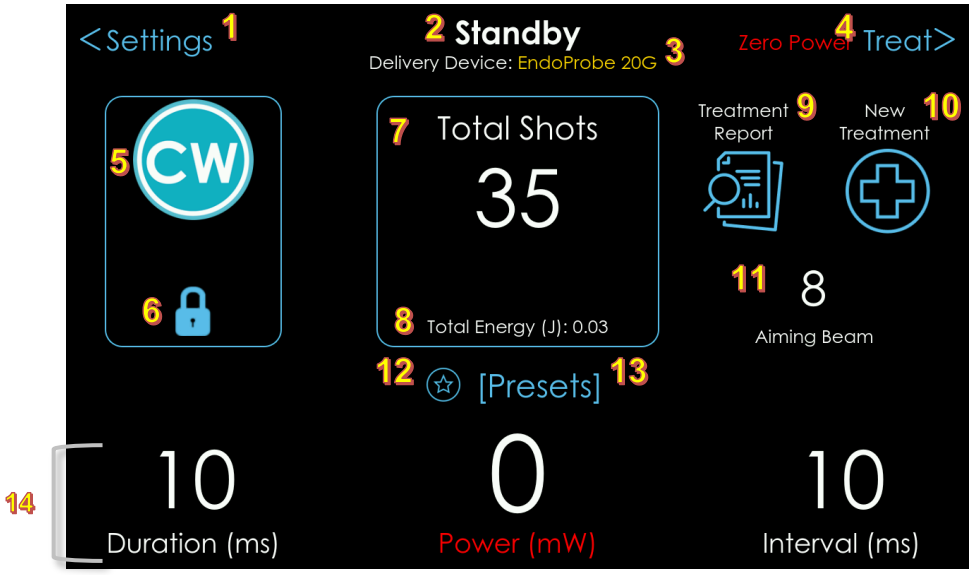
Idle Screen

This screen appears automatically only if no delivery device is connected.

1. **SETTINGS.** Select to go to the SETTINGS SCREEN.

Standby Screen

A delivery device must be connected to access the STANDBY SCREEN. The STANDBY SCREEN is used to enter treatment parameters for a given procedure.



1. **Settings**. Select to return to the SETTINGS SCREEN.
2. **Active state of laser.**
3. **Delivery Device**. Displays the name of the connected delivery device.
4. **Screen Navigation, Right Arrow.** Select to access the READY-TO-TREAT SCREEN.
5. **Displays Laser Treatment mode, i.e., MicroPulse or Continuous-Wave mode**
6. **Treatment Mode Lock.** Select the lock icon to unlock treatment mode, then select the Mode icon to switch Treatment mode. After you change Treatment mode, the mode then relocks automatically.
7. **Total Shots.** Displays the accumulated number of shots during treatment.
8. **Total Energy (J).** Displays the Total Energy generated during treatment. This is visible when Total Energy is turned On in the OPERATIONAL PARAMETERS SCREEN.

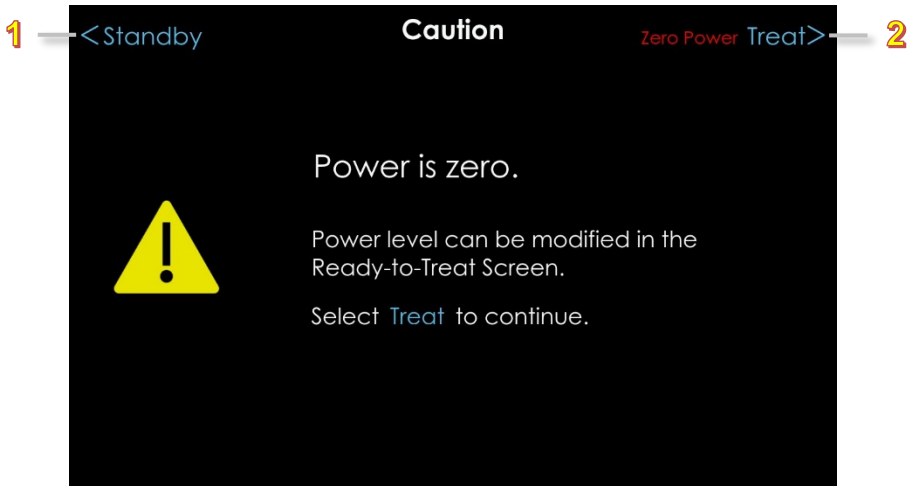
   Total Energy will appear on the Treatment Report, regardless of whether Total Energy is enabled (On).
9. **Treatment Report.** Select to view the active treatment report. After a New Treatment reset, this icon will be greyed out.
10. **New Treatment.** Select to reset the number of shots to zero. The treatment report is reset for the new treatment. After the reset, the New Treatment icon will be greyed out until laser energy is delivered.
11. **Aiming Beam Adjustment**. Select and activate the field and use the control knob to adjust the aiming beam illumination from 1 (dimmest) to 20 (brightest).
12. **Favorites**. Select to create and name a new preset based on the treatment parameters displayed on this screen.

13. **Selected Preset**. Select the Preset name (or [Presets] if no Preset is selected) to go to the SELECT PRESET SCREEN. After a Preset is selected, and then a parameter is changed, the preset name changes to [Presets].

14.
- **Duration.** Use the control knob or touchscreen to select and activate the field, and the control knob to adjust the Duration in ms.
- **Power.** Use the control knob or touchscreen to select and activate the field, and the control knob to adjust Power in mW.
- **Interval.** Use the control knob or touchscreen to select and activate the field, and the control knob to adjust Interval in ms, or turn to select single shot.

Power Selection Warning Messages

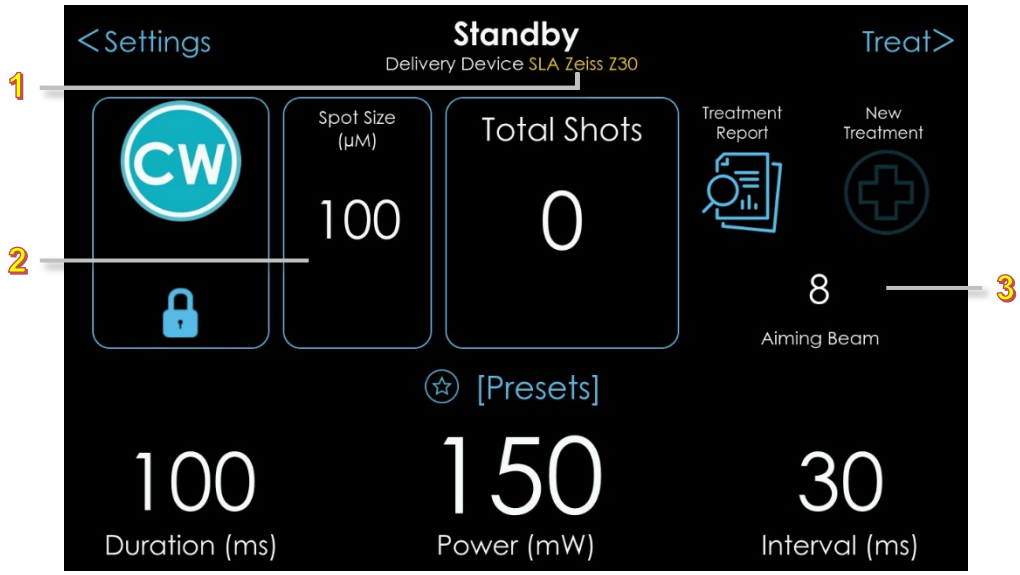
Zero Power



1. **Screen Navigation, Left Arrow**. Select to return to the STANDBY SCREEN.
2. **Screen Navigation, Right Arrow.** Select Treat to continue to the READY-TO-TREAT SCREEN.

Standard Slit Lamp Adapter and TxCell (Single-Spot Delivery) Standby Screen

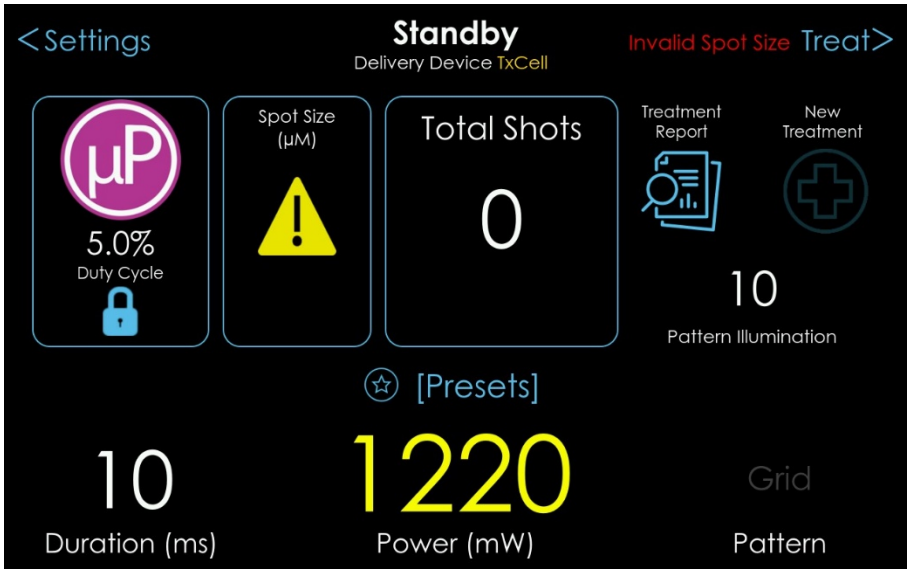
When a standard slit lamp adapter is connected, or if a TxCell is connected and single-spot delivery is chosen, the STANDBY SCREEN displays as shown below. For complete information on TxCell, refer to the TxCell Scanning Laser Delivery System Operator Manual.



1. **Delivery Device**. Displays the name of the connected delivery device.
2. **Spot Size**. Displays the spot size selected on the Spot Size dial. See "Spot Size Warning".
3. **Aiming Beam Intensity**. Displays when a standard slit lamp adapter is connected or when the TxCell is connected and set for single-spot delivery.
4. **Interval/Pattern**. Use the touchscreen or turn the control knob counterclockwise until you reach "Single Shot", or continue to turn the knob counterclockwise to select a grid pattern: "Grid", "Circle", or "Triple Arc". To change the parameters of a selected pattern, press the control knob to go to the Pattern Editor.

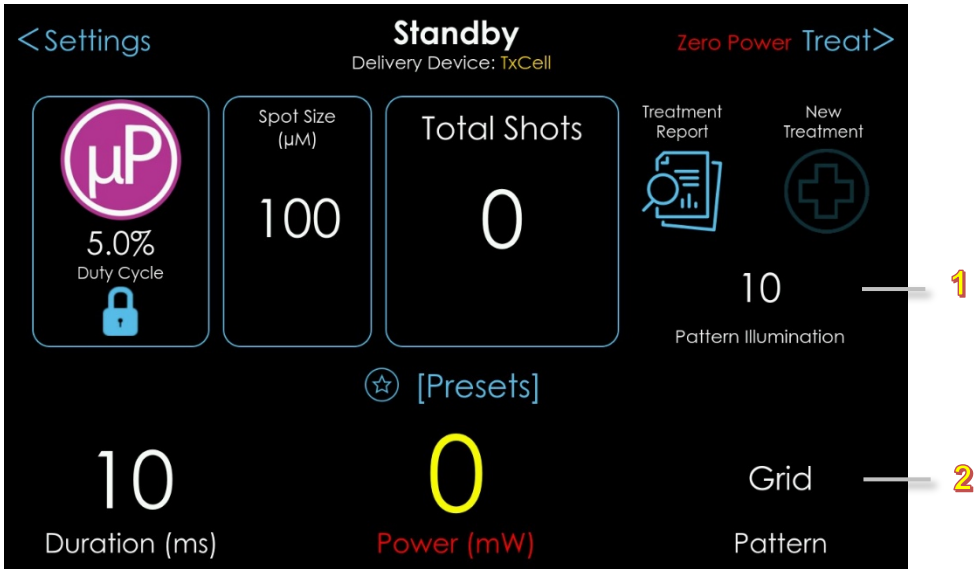
Spot Size Warning

While in either single-spot or pattern delivery [(see "TxCell Standby Screen: Pattern Delivery (Scanner Mode)"], if the Spot Size dial on a standard slit lamp adapter or on the TxCell slit lamp adapter is turned to an invalid position for longer than 1 second, a warning is displayed. Turn the dial until it "clicks" to indicate that the intended Spot Size is locked in.



TxCell Standby Screen: Pattern Delivery (Scanner Mode)

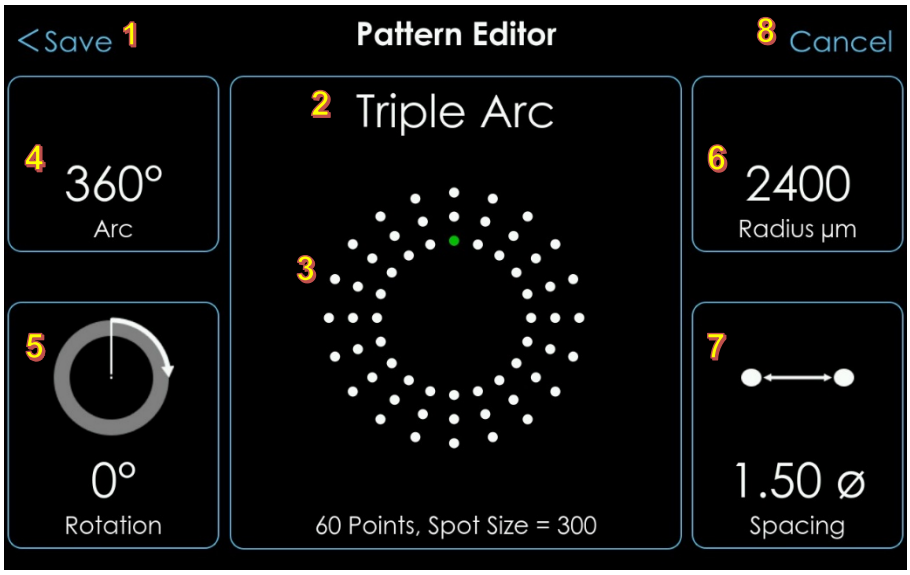
To choose pattern delivery from single-spot delivery, select and activate the Interval field and rotate the control knob counterclockwise until your chosen pattern (circle, grid, or triple arc) is displayed. When a TxCell is connected and pattern delivery is chosen, the STANDBY SCREEN displays as shown below. For complete information on TxCell, refer to the TxCell Scanning Laser Delivery System Operator Manual.



1. **Pattern Illumination**. Use the control knob or touchscreen to select and activate the field; and use the control knob to adjust the pattern illumination intensity from 1 (dimmest) to 20 (brightest).

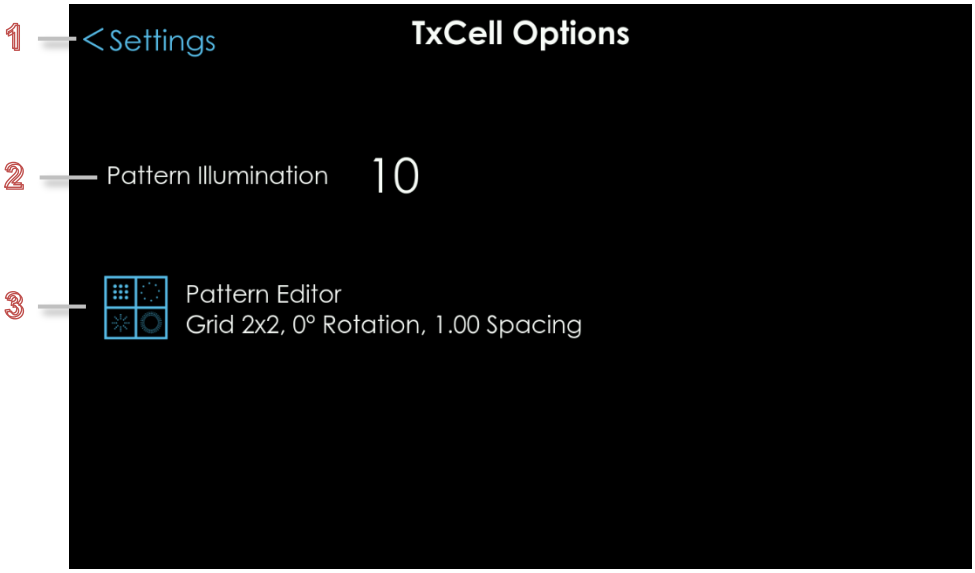
2. To change the parameters of a selected pattern, use the touch screen to double-tap the Pattern field to enter the Pattern Editor.

TxCell Pattern Editor



1. **Screen Navigation, Left Arrow**. Select to save changes and return to the STANDBY SCREEN.
2. **Pattern Selection**. Displays the name of the selected pattern for editing. The patterns are: Grid, Triple Arc, and Circle. Pattern settings are listed at the bottom as selections are made.
3. **Graphical Display**. Displays the pattern as edits are applied. The user cannot edit this field directly.
4. **Arc**. Use the touchscreen or control knob to select and activate the field; use the control knob to increase or decrease the Arc angle of the pattern in increments of 45°.
5. **Rotation**. Use the touchscreen or control knob to select and activate the field; use the control knob to adjust the pattern rotation (Grid and Triple Arc only).
6. **Radius**. Use the touchscreen or control knob to select and activate the field; use the control knob to adjust the Radius in microns (Triple Arc and Circle only).
7. **Spacing**. Use the touchscreen or control knob to select and activate the field; use the control knob to adjust the spacing between spots for all patterns.
8. **Cancel**. Select to cancel any changes and return to the STANDBY SCREEN.

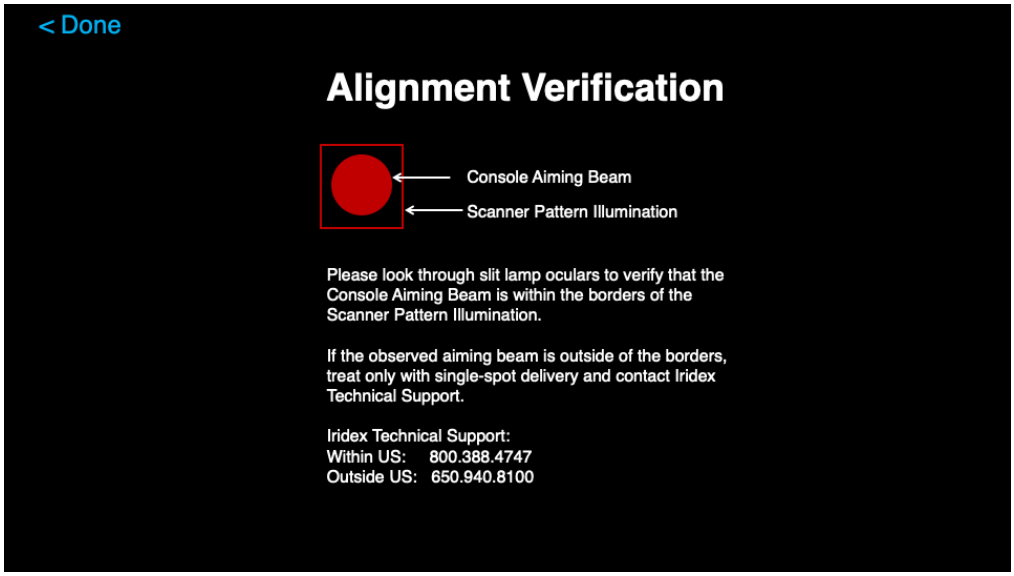
TxCell Options via the Settings Menu



1. **Settings**. Select to return to the SETTINGS SCREEN.
2. **Pattern Illumination**. Use the control knob to adjust the pattern illumination intensity from 1 (dimmest) to 20 (brightest).
3. **Pattern Editor**. Select to go to the TxCell Pattern Editor.

Alignment Verification

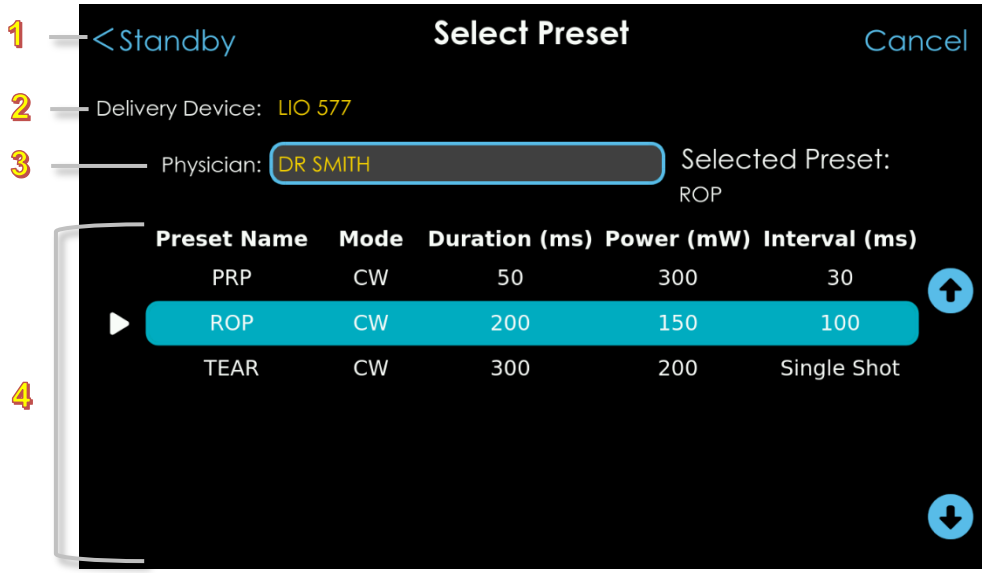
The laser system will display an alignment verification notice for the user to confirm that the Console aiming beam is aligned within a scanner pattern cell. The notice displays every 18 hours following the last time the alignment verification prompt was accepted.



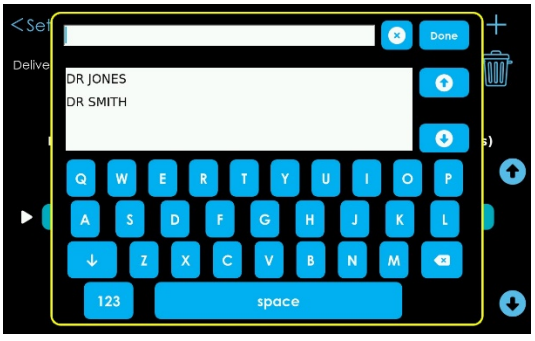
1. Look through the slit lamp oculars to verify that the Console Aiming Beam is within the borders of the Scanner Pattern Illumination.
2. If the observed circle is outside of the square, do not treat with pattern scanning and contact Iridex Technical Support. You may treat using TxCell with single-spot delivery. See “Iridex Corporation Contact Information”.
3. Select **Done**.

***NOTE**: When the spot size is set to 50 microns, pattern scanning is not available.*

Select Preset Screen



1. **Screen Navigation, Left Arrow**. Select to return to the STANDBY SCREEN.
2. **Delivery Device**. Displays the connected delivery device.
3. **Physician**. If desired, select to display a pop-up dialog with a list of physician names. Choose the desired physician name and select **Done**. Note: A physician name is not required to select a preset.
4. **Presets List**. Select the desired preset from the list, and then either double click the selected preset, or press the white arrow in the selected preset row, or press <Standby to save the selection and return to the STANDBY SCREEN.



Prepare-to-Treat Screen

This screen appears briefly as a transition screen from Standby to Ready To Treat.

Ready-to-Treat Screens

LIO, EndoProbe, and ENT Delivery Devices

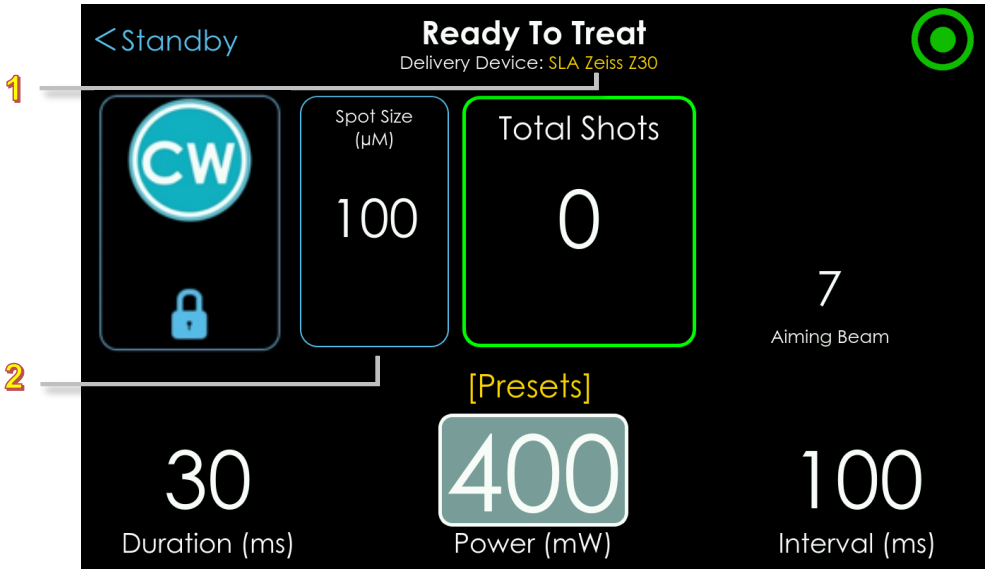
***NOTE**: This description applies to LIO, EndoProbe, and ENT delivery devices only. If there is no activity for 5 minutes on the READY-TO-TREAT SCREEN, the system will automatically revert to the STANDBY SCREEN.*

When the READY-TO-TREAT SCREEN appears, the Power field will be the active field by default. The Duration and Interval fields also can be adjusted in this screen. Use the touchscreen or control knob to select and activate a field and the control knob to adjust the value.

1. **Screen Navigation, Left Arrow.** Select to return to the STANDBY SCREEN.
2. **Active state of laser.**
3. **Delivery Device**. Displays the name of the connected delivery device.
4. Indicates laser is in Treat mode and **ready to fire** when the foot pedal is depressed.
5. **Displays Laser Treatment mode, i.e., MicroPulse mode or Continuous-Wave mode**.
6. **Treatment Mode Lock.** Select the lock icon to unlock treatment mode, then select the Mode icon to switch Treatment mode. After you change Treatment mode, the mode then relocks automatically.
7. **Total Shots.** Displays accumulated number of shots fired during treatment.
8. **Aiming Beam Adjustment**. Select and activate the field and use the control knob to adjust the aiming beam illumination from 1 (dimmest) to 20 (brightest).
9. **Selected Preset**. Displays the name of the selected preset.
10. **Power Adjustment.** The Power field defaults to the activated field in the READY-TO-TREAT SCREEN. Use the control knob to adjust the Power.

Standard Slit Lamp Adapter (SLA)

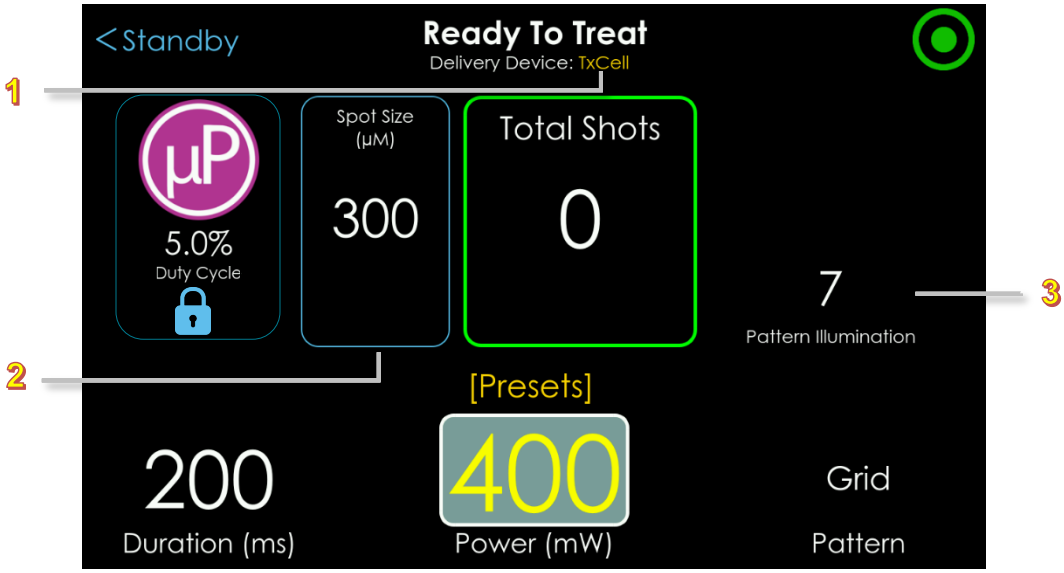
For treatment with Iridex standard SLAs, the READY-TO-TREAT SCREEN adds a Spot Size field as shown below.



1. **Delivery Device**. Displays the name of the connected delivery device.
2. **Spot Size**. Displays the spot size selected on the SLA Spot Size dial.

TxCell Scanning Laser Delivery System

For treatment with an Iridex TxCell, the READY-TO-TREAT SCREEN adds a Spot Size field as shown below.



1. **Delivery Device**. Displays the name of the connected delivery device.
2. **Spot Size**. Displays the spot size selected on the TxCell spot-size dial.
3. **Pattern Illumination Intensity**. Displays when a pattern is selected. Select and activate the field and use the control knob to adjust the pattern illumination intensity from 1 (dimmest) to 20 (brightest).

Treating Screens

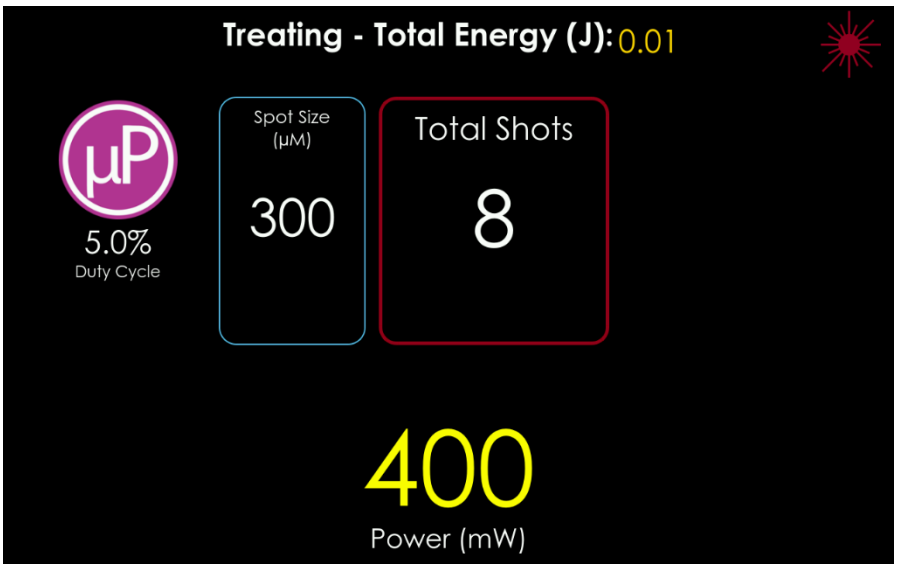
LIO, EndoProbe, and ENT Delivery Devices

The TREATING SCREEN is displayed when the user depresses the foot pedal and the laser is firing. All fields and aiming beam illumination are locked when the laser is firing. When the user releases the foot pedal, the system returns to the READY-TO-TREAT SCREEN.

1. **Active state of laser**.
2. **Total Energy**. This is visible only when Display Total Energy is On in the OPERATIONAL PARAMETERS SCREEN.
3. **Displays selected Treatment mode.**
4. **Displays Total Shots.** Displays accumulated number of shots fired during treatment.
5. **Displays selected Power.**
6. **Indicates laser is firing.**

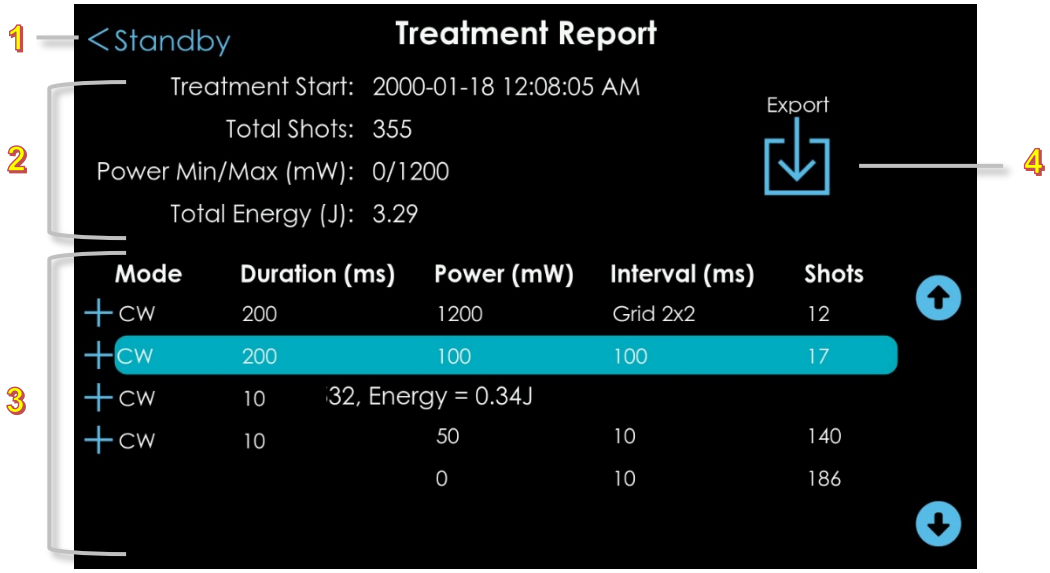
Standard SLA and TxCell Scanning Laser Delivery System

For treatment with either a standard SLA or TxCell Scanning Laser Delivery System, the TREATING SCREEN adds a Spot Size field as shown below.



Treatment Report Screen

The TREATMENT REPORT SCREEN summarizes the active treatment. An example treatment report is shown in "Treatment Report Example".



1. **Screen Navigation, Left Arrow.** Select to go to the STANDBY SCREEN.
2. **Treatment Summary**. Displays the treatment start date and time, total shots generated, power minimum/maximum (mW), and total energy.
3. **Treatment Table**. Displays treatment parameters. Select the plus/minus sign to expand and collapse the detailed view of a treatment. Use the arrows on the right to scroll up or down as necessary.
4. **Export**. Select to export the selected treatment report to USB. For more information, see "Exporting Treatment Reports".

6. Treating Patients

Before Treating a Patient

- Ensure that the laser components and delivery device(s) are properly connected, including the SmartKey® when connecting a standard SLA.
- Ensure that the eye safety filter (as appropriate) is properly installed.
- Post the laser warning sign outside the treatment room door.

NOTE: *Refer to "Safety Compliance" in this manual 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. Connect delivery device. Note: Upon connection of delivery device, a pop-up screen will require the user to confirm awareness of eye-safety requirements.
3. Select **New Treatment**.
4. Set the treatment parameters.
5. Position the patient.
6. If required, select an appropriate contact lens for the treatment.
7. Ensure that all ancillary personnel in the treatment room are wearing the appropriate laser safety eyewear.
8. Select Treat (in the upper-right corner of the touchscreen) to activate Ready-to-Treat mode.
9. Position the aiming beam on the treatment site.
10. Focus the laser aiming beam or adjust the delivery device as applicable.
11. Actuate the footswitch to deliver the treatment beam.

To Conclude Patient Treatment

1. Select Standby mode.
2. View the treatment report and record treatment information.
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.

7. Troubleshooting

General Problems

Problem	Possible Cause	User Action(s)*
After the key is turned to the “On” position, the laser does not power up.	1. The power cable is not plugged in. 2. The remote interlock is not connected. 3. The fuse is blown.	1. Plug in the power cable. 2. Connect the remote interlock. 3. Unplug the laser from the AC outlet and inspect fuses. If a fuse is blown, replace with a new fuse as indicated on panel label.
Warning messages 1. Fiber not connected! 2. Remote interlock! 3. Footswitch Opened!	1. The fiber is not properly connected. 2. The remote interlock is not connected. 3. The footswitch is not connected.	1. Connect the fiber and ensure the connection is secure. 2. Connect the remote interlock. 3. Ensure the footswitch is securely connected.
No or dim aiming beam	Aiming beam is set to “OFF” or set too low.	Adjust aiming beam level. If aiming beam is not visible or bright enough, contact Iridex.
Error message		1. Turn Key Switch to “Off”, wait a few seconds, and then turn Key Switch to “On.” 2. If error does not clear, contact Iridex.
** If the user actions are not successful, contact Iridex. See "Iridex Corporation Contact Information" for Iridex contact information.*		

Laser Indirect Ophthalmoscope Related Problems

Problem	User Action(s)*
No illumination light (LIO only)	• Adjust the console illumination intensity control. • Verify that the illumination connector is connected. • Check bulb/LED and replace it (if necessary).
Illumination light is too dim (LIO only)	Adjust the console illumination intensity control.
The aiming beam is large or out of focus on the patient’s retina (LIO only)	Readjust your working distance between the LIO headset and the examination lens. The aiming beam should be sharply defined and at its smallest diameter when in focus.

Problem	User Action(s)*
The treatment lesions are variable or intermittent (LIO only)	• The LIO may be slightly out of focus. This decreases power density. Readjust your working distance to obtain the smallest spot size. • A poorly centered laser beam may be clipping on the examination lens or on the patient's iris. Adjust the laser beam in the illumination field. • The laser treatment parameters may be too close to the tissue response threshold for consistent response. Increase the laser power and/or exposure duration, or select a different lens.
** If the user actions are not successful, contact Iridex. See "Iridex Corporation Contact Information" for Iridex contact information.*	

8. Maintenance

Cleaning and Inspecting the Laser System

Cleaning the Laser Console

- Before cleaning the laser console, turn off the console and unplug the power cord.
- Clean the outside console covers with a soft cloth moistened with a mild detergent. Avoid abrasive or ammonia-based cleaner.
- Do not allow liquid into the laser console or the fiber connector area.

Cleaning the Touchscreen

- Clean the touchscreen with a damp soft cloth.
- Do not touch the touchscreen with hard or sharp materials.
- Do not scrub the touchscreen with a reagent.

Cleaning the Footswitch

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

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

Inspecting the Laser System

- Periodically inspect the laser console:
  - The equipment covers should be securely attached.
  - All knobs and dials should be in proper working order.
  - The Emergency Stop should be intact.
- Periodically inspect the power cords, footswitch, cables, etc., for wear. Do not use the laser if there are exposed or broken wires or broken connectors.
- All eye safety glasses should be the correct type (wavelength and OD). There should be no cracks or damage that may cause unintended stray laser light.

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 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.).

Verifying the Power Calibration

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

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

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

To Verify the Power Calibration:

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

CAUTION:

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

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

Power Measurements using a CW Delivery Device or Test Fiber

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

Data for power measurement equipment: _____ Calibration date: _____

Meter Model and Serial Number: _____ Calibrated by: _____

Power Measurements using a MicroPulse® Delivery Device or Test Fiber

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

Data for power measurement equipment: _____ Calibration date: _____

Meter Model and Serial Number: _____ Calibrated by: _____

9. 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, 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:

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

where:

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

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

Φ = the maximum possible laser power, in watts

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

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

Iridex 532 NOHD Values for Various Delivery Devices				
Delivery Device	**MPE (W/m^2)**	**Numerical Aperture (NA)**	**Maximum Power Φ (W)**	**NOHD (m)**
EndoProbe	10	0.100	2.000	4.3
Oto/ENT Probes (Iridex 532)	10	0.100	2.500	4.8
Oto/ENT Probes	10	0.100	6.000	7.4
Laser Indirect Ophthalmoscope (LIO)	10	0.013	2.000	33.0
Slit Lamp Adapter (SLA) and TxCell Delivery Device	10	0.012	1.800	33.9

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

Safety Compliance

Complies with 21 CFR 1040.10 and 1040.11 except for conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1, as described in Laser Notice No. 56, dated May 8, 2019. The laser uses a solid-state electronic switching power supply that meets strict EN60601-1 performance and safety standards.

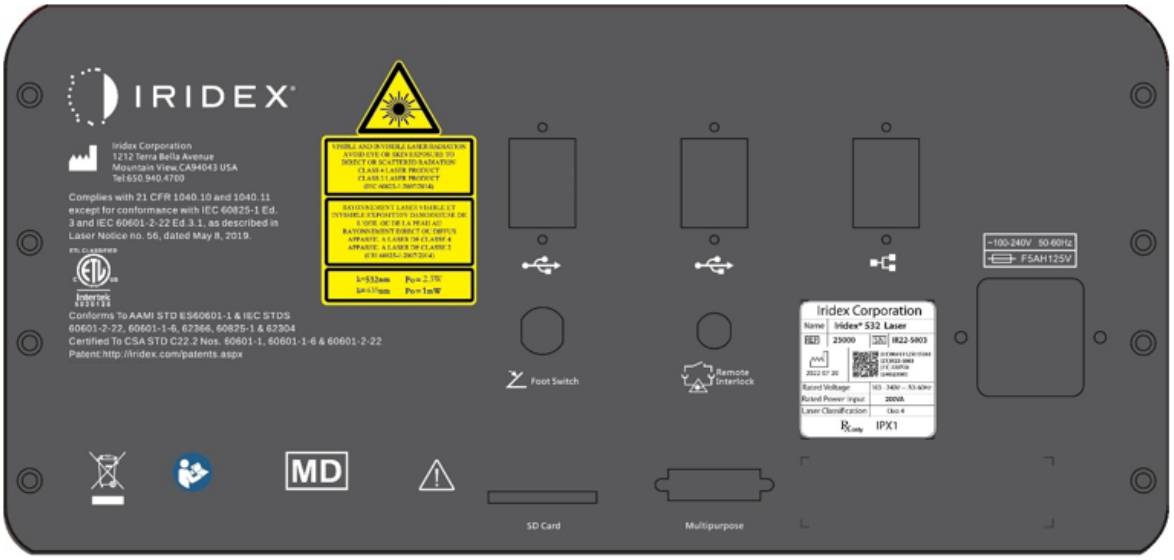
A dedicated microprocessor continuously monitors the safe function of all subsystems within the laser console.

Feature	Function
Emergency off	Immediately disables the laser.
Protective housing	The external housing prevents unintended access to laser radiation above Class I limits.
Safety interlock	An electronic interlock at the fiber port prevents laser emission if a delivery device is not properly connected.
Remote interlock	An external remote interlock connector is provided with each laser as a safety feature. The console will not operate if the interlock is not connected to the remote interlock plug on the back panel.
Keyswitch	The system operators only with the proper key. The key cannot be removed while in the “ON” position.
Laser emission indicator	The 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 foot pedal is depressed while in Treat mode. An audible tone indicates that the console is delivering laser energy. The audible indicator volume can be adjusted.
Beam indicator	An electronic beam attenuator prevents any laser radiation from exiting the console until all requirements for emission are met.

Feature	Function
Viewing optics	Eye safety filters are required when using the laser system.
Internal power monitor	Two monitors independently measure the laser power before emission. If the measurements differ significantly, the system enter Call Service mode.
Footswitch	The console cannot be placed in Treat mode if the footswitch is damaged or improperly connected. The footswitch can be cleaned (IPX8 per IEC60529) and is shrouded for safety (ANSI Standard Z1363, 4.3.1).

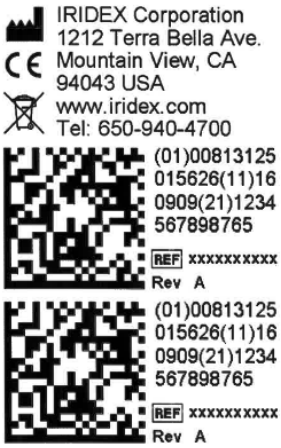
Labels

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



Serial Number (rear panel)	Iridex Corporation Name: Iridex® 532 Laser REF 23000 SN IR22-S003 2022-07-20 (01)00813125015381 (21)IR22-S003 (11) 220720 (240)23000 Rated Voltage: 100 - 240V ~ .50-60Hz Rated Power Input: 200VA Laser Classification: Class 4 Rx only IPX1
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.
Footswitches	IRIDEX 1212 Terra Bella Avenue Mountain View, CA 94043 USA Tel: 650-940-4700 Fax: 650-940-4710 www.iridex.com MADE IN THE USA The instructions for use and the symbols glossary are provided in the Operator Manual of the compatible Iridex Laser console(s). REF 31821 SN XXXXXF FCC ID: UDB31539 IC ID: 6590A-31539 EC REP Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands IPX8 MD Rx ONLY CE 2797 LABEL P/N: 33030-1D REF 31821 SN XXXXXXR CE 2797 MD Rx ONLY FCC ID: UDB31539 IC ID: 6590A-31539 The instructions for use and the symbols glossary are provided in the Operator Manual of the compatible Iridex Laser console(s). LABEL P/N: 33030-2D

Footswitches



Label PN 60645D

Footswitches

Laser Warning
Rear panel of console

Symbols (As Applicable)

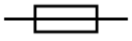
Regulatory Symbols

Symbol	Symbol Title	Standard Title	Description	Standard Reference
	Caution	Medical devices—Symbols to be used with information to be supplied by the manufacturer—Part 1: General requirements	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	ISO 15223-1, Reference no. 5.4.4. (ISO 7000-434A)
	Warning	Graphical symbols - Safety colours and safety signs - Registered safety signs	Signifies a general warning	ISO 7010, Reference no. W001
	CE conformity marking	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices	To indicate that the device conforms to the provisions of the EU Directive 93/42/EEC	EU Directive 93/42/EEC (Medical Device Directive) Annex XII CE Marking of conformity
	Prescription only	Labeling—Prescription devices	Requires prescription in the United States	21 CFR 801.109
	Warning: Laser Beam	Graphical symbols—Safety colours and safety signs—Registered safety signs	To warn of a laser beam	IS0 7010-W004
	Refer to instruction manual/booklet	Graphical symbols—Safety colors and safety signs—Registered safety signs	To signify that the instruction manual/booklet must be read	ISO 7010-M002

Symbol	Symbol Title	Standard Title	Description	Standard Reference
	Consult instructions for use	Medical devices—Symbols to be used with information to be supplied by the manufacturer—Part 1: General requirements	To indicate the need for the user to consult the instructions for use	ISO 15223-1 Reference no 5.4.3
	ETL Listed Mark (North America, Canada and US)	N/A	To demonstrate compliance to the requirements of widely accepted product safety standards, as determined through testing and inspections by Intertek	N/A
	Waste Electrical and Electronic Equipment Directive (WEEE)	Waste Electrical and Electronic Equipment Directive	Signifies waste from electrical and electronic equipment	WEEE Directive 2012/19/EC, EN 50419:2005
	Type B applied part	Medical electrical equipment—Part 1: General requirements, for basic safety and essential performance	To identify a type B applied part complying with IEC 60601-1	IEC 60601-1, Table D.1, Symbol 19 (IEC 60417-5840)
	Catalogue or model number	Medical devices—Symbols to be used with information to be supplied by the manufacturer—Part 1: General requirements	To indicate the manufacturer's catalogue number so that the medical device can be identified	ISO 15223-1 Reference no. 5.1.6. (ISO 7000-2493)

Symbol	Symbol Title	Standard Title	Description	Standard Reference
	Use-by date	Medical devices—Symbols to be used with information to be supplied by the manufacturer—Part 1: General requirements	To indicate the date after which the medical device is not to be used	ISO 15223-1: 2021 Reference no. 5.1.4. (ISO 7000-2607)
	Do not re-use	Medical devices—Symbols to be used with information to be supplied by the manufacturer—Part 1: General requirements	To indicate that the medical device is intended for one single use only NOTE: Synonyms for "Do not reuse" are "single use" and "use only once"	ISO 15223-1 Reference no. 5.4.2. (ISO 7000-1051)
	Do not use if package is damaged and consult *instructions for use*	Medical devices—Symbols to be used with information to be supplied by the manufacturer—Part 1: General requirements	To indicate that the medical device should not be used if the package has been damaged or opened and that the user should consult the *instructions for use* for additional information	ISO 15223-1: 2021 Reference no. 5.2.8. (ISO 7000-2606)
CH REP	Authorized representative in Switzerland	Information sheet Obligations Economic Operators CH	Indicates the authorized representative in Switzerland	MU600_00_016e
EC REP	Authorized representative in the European Community/ European Union	Medical devices—Symbols to be used with information to be supplied by the manufacturer—Part 1: General requirements	To indicate the authorized representative in the European Community/European Union	ISO 15223-1 Reference no. 5.1.2.

Symbol	Symbol Title	Standard Title	Description	Standard Reference
	Batch code	Medical devices—Symbols to be used with information to be supplied by the manufacturer—Part 1: General requirements	To indicate the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1 Reference no. 5.1.5. (ISO 7000-2492)
	Serial number	Medical devices—Symbols to be used with information to be supplied by the manufacturer—Part 1: General requirements	To indicate the manufacturer's serial number so that a specific *medical device* can be identified	ISO 15223-1 Reference no. 5.1.7 (ISO 7000-2498)
	Manufacturer	Medical devices—Symbols to be used with information to be supplied by the manufacturer—Part 1: General requirements	To indicate the *medical device manufacturer*	ISO 15223-1 Reference no. 5.1.1. (ISO 7000-3082)
	Date of Manufacture	Medical devices—Symbols to be used with information to be supplied by the manufacturer—Part 1: General requirements	To indicate the date when the *medical device* was manufactured	ISO 15223-1 Reference no. 5.1.3. (ISO 7000-2497)

Symbol	Symbol Title	Standard Title	Description	Standard Reference
	Non-ionizing electromagnetic radiation	Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic compatibility—Requirements and tests	To indicate generally elevated, potentially hazardous, levels of nonionizing radiation, or to indicate equipment or systems e.g., in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment	IEC 6060-1-1-2:2007, Clause 5.1.1 (IEC 60417-5140)
	Product is not made with natural rubber latex		Indicates that natural rubber latex was not used in the manufacturing of the product, its container, or its packaging	
	Universal Serial Bus (USB), port/plug	Universal Serial Bus interfaces for data and power Part 2-1: Universal Serial Bus Specification, Revision 2.0 (TA 14)	To indicate that the device is plugged into a USB port or is compatible with a USB port	IEC 62680-1-2 (ISO 7000-3650)
	Protective Earth; protective ground	Medical electrical equipment—Part 1: General requirements for basic safety and essential performance	To identify any terminal which is intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode	IEC 60601-1 Reference no. Table D.1, Symbols 6 (IEC 60417 – 5019)
	Fuse	Graphical symbols for use on equipment	To identify fuse boxes or their location	IEC 60417 (IEC 60417-5016)

Symbol	Symbol Title	Standard Title	Description	Standard Reference
STERILE EO	Sterilized using ethylene oxide	Medical devices—Symbols to be used with information to be supplied by the manufacturer—Part 1: General requirements	To indicate the medical device has been sterilized using ethylene oxide	ISO 15223-1 Reference no. 5.2.3. (ISO 7000-2501)
IPX8	IP Code	Degrees of protection provided by enclosures (IP Code)	Ingress Protection, X = Not tested for solid foreign objects, 8 = Protected against the effects of continuous immersion in water	IEC 60529
IPX4	IP Code	Degrees of protection provided by enclosures (IP Code)	Ingress Protection, X = Not tested for solid foreign objects, 4 = Protected against splashing water	IEC 60529
IPX1	IP Code	Degrees of protection provided by enclosures (IP Code)	Ingress Protection, X = Not tested for solid foreign objects, 1 = Protected against vertically falling water drops	IEC 60529
MD	Medical device	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	To indicate the item is a *medical device*	ISO/DIS 15223-1 Reference no. 5.7.7
	Computer network	Graphical symbol for electrical equipment in medical practice	To identify the computer network itself or to indicate the connecting terminal of the computer network	IEC-60878 Symbol 5988

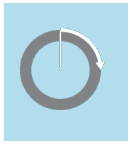
Symbol	Symbol Title	Standard Title	Description	Standard Reference
	Temperature Limit	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	To indicate the temperature limits to which the *medical device* can be safely exposed	ISO 15223-1 Reference no. 5.3.7

Product Symbols

Symbol	Title
	Decrease/Increase
	Emergency Stop
	Footswitch
	Gauge
	Illumination
	Laser Aperture at End of Fiber
	Off
	On
	Remote Interlock

User Interface Symbols and Icons

Touchscreen Icon	Title
	About
	Add Preset
	Aiming Beam
	Audio
	Audio Off
	Audio Volume (Low)
	Audio Volume (High)
	Caution
	Date and Time
	Delete Report; Delete Preset
	Emergency Stop
	Error
	Expand/Collapse List
	Export Report *Note: If the icon is greyed out as shown below, the Export Report feature is not enabled on the laser.* 

Touchscreen Icon	Title
	Go to Previous Screen
	Go to Next Screen
	Laser
	New Treatment
	Export Complete
	Operational Parameters
	Pattern Editor
	Prepare to Treat
	Preset Favorites
	Presets
	Ready to Treat
	Rotation
	Scroll Up/Scroll Down List
	Service. For Iridex Service Only
	Spot Spacing

Touchscreen Icon	Title
	System Options
	Toggle Switch
	Treatment Mode, Continuous Wave
	Treatment Mode, MicroPulse *Note: If the icon is greyed out as shown below, the MicroPulse Treatment Option is not enabled laser.* 
	Treatment Mode, Unlock/Lock
	Treatment Reports
	TxCell Scanner
	View Treatment Report

Specifications

Specification	Description
Treatment wavelength	532 nm
Treatment power	50 – 2500 mW (delivered), depending on delivery device.
Duration	**CW-Pulse**: 10 ms – 3000 ms or CW to 60 seconds **MicroPulse (Optional)**: 0.05 ms – 1.0 ms
Repeat interval	**CW-Pulse**: 10 ms – 3000 ms or single pulse **MicroPulse**: 1.0 ms – 10.0 ms
Aiming beam	635 nm laser diode. User-adjustable; <1 mW maximum
Electrical	~100 – 240 VAC, ~.50/60 Hz, <3 A
Operating temperature range	10° C to 35° C (50° F to 95° F)
Transport and Storage temperature conditions	- 20° C to 55° C (-4° F to 131° F); 500 hPa to 1060 hPa
Relative humidity	20% to 80%
Dimensions	30 cm W x 30 cm D x 17 cm H (11.8 in. W x 11.8 in. D x 6.7 in. H)
Weight	5.85 kg (12.9 lbs)

10. Wireless Footswitch (Optional) and EMC

Setting Up the Wireless Footswitch

The wireless footswitch comprises:

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

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

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

CAUTION:

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

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

Testing the Batteries

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

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

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

EMC Guidance

1. This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.
2. Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
3. Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!
4. Caution: This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

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 equipmentand may result in increased emissions or decreased immunity of the laser system.

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

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

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

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

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

Guidance and Manufacture's Declaration – Electromagnetic Emission

The laser is intended for use in the electromagnetic environment specified below. The customer or the user of the laser should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The laser user RF energy for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	
The laser suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply Harmonic network that supplies buildings used for domestic purposes.		

Guidance and Manufacture's Declaration – Electromagnetic Immunity

The laser is intended for use in the electromagnetic environment specified below. The customer or the user of the laser should assure that it is used in such an environment.

Immunity test	EC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	EC 60601 test level	Compliance level	Electromagnetic environment – guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_t (>95% dip in U_t) for 0.5 cycle 40% U_t (60% dip in U_t) for 5 cycles 70% U_t (30% dip in U_t) for 25 cycles <5% U_t (>95% dip in U_t) for 5 sec	<5% U_t (>95% dip in U_t) for 0.5 cycle 40% U_t (60% dip in U_t) for 5 cycles 70% U_t (30% dip in U_t) for 25 cycles <5% U_t (>95% dip in U_t) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the laser requires continued operation during power mains interruptions, it is recommended that the laser be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz magnetic field IEC 6100-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
***NOTE**: U_t is the a.c. mains voltage prior to application of the test level.*			
Conducted RF IEC 6100-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the laser, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1, 2 \sqrt{P}$ $d = 1, 2 \sqrt{P}$ 80 MHz to 800 MHz $d = 1, 2 \sqrt{P}$ 80 MHz to 25 GHz • Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). • Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], 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: 
Conducted RF IEC 6100-4-6 Radiated RF IEC 61000-4-3	3 V/m	3 V/m	

NOTE: At 80 MHz and 800 MHz, the higher frequency range applies. 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 is used exceeds the applicable RF compliance level above, the laser should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the laser.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Laser

The laser is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the laser can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the laser as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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**: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*