NORLASE®

LION™

Laser Indirect Ophthalmoscope

Operator Manual

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BEFORE USE, PLEASE READ THIS MANUAL
Be sure to read this operator's manual in its entirety prior to using the device to understand the safety precautions and operating procedures. United States federal law restricts this device to sale by or on the order of a licensed physician. Safety precautions must be strictly followed at all times. Please see the appropriate sections of this manual for detail pertaining to Warnings, Cautions and Precautions. Keep this manual handy for reference.

In the contents of this manual are signal words attached to the ⚠ symbol to designate the degree or level of safety alerting. The definitions are as follows:
WARNINGS Indicates a potentially hazardous situation which, if not avoided, may result in death or serious injury.
CAUTIONS Indicates a potentially hazardous situation which, if not avoided, may result in minor, moderate or severe injury or property damage.
PRECAUTIONS Indicates potentially hazardous situations which should be completely understood before attempting any use of the system on a patient.

Table of Contents

Indications for use / Intended use

The Norlase LION Photocoagulator is intended to be used in ophthalmic laser procedures including retinal and macular photocoagulation, iridotomy, and trabeculoplasty.

Introduction

The Norlase LION is a Laser Indirect Ophthalmoscope where the laser source is built into the headset, eliminating the need for an external laser console. LION is controlled via a wireless tablet user interface utilizing touch screen or voice control of parameters. LION is powered by a rechargeable battery built into the foot switch. The device may be used for all standard single shot photocoagulation procedures listed in the indications for use section of this manual.

The Norlase LION enables the physician to deliver laser energy via footswitch depression emitting a single spot or series of laser pulses by utilizing auto repeat mode of operation. The red aiming beam displays the target location for the green laser emission

Norlase accepts full responsibility for safety, reliability and performance of the device only if:

- Service, readjustments, modifications and/or repairs are performed exclusively by Norlase-certified personnel.
- The electrical installation of the treatment room complies with the applicable IEC, CEC and NEC requirements.

The warranty is void if any of these warnings are disregarded.

Norlase reserves the right to make changes to the device(s) herein. Device(s), therefore, may not agree in detail with the published design or specifications. All specifications are subject to change without notice. Please contact Norlase or your local Norlase representative for information on changes and new products.

Package Contents

The Contents of the will contain the following major components. Other accessories may be included depending on the configuration. Please consult the packing list in the shipping box for the complete component and accessory list.

Laser Indirect Ophthalmoscope

The Norlase LION is a laser indirect ophthalmoscope with the laser console integrated into the headset. The laser console located on the back of the headset houses the key switch, emergency laser stop button, foot switch and power inputs, green treatment laser, red aiming laser, and control electronics. The binocular block on the front of the headset houses the oculars, LED, illumination apertures and illumination filters.

Touchscreen Tablet Control Panel

Provides controls for selecting treatment parameters, voice communication and audible feedback and displays for monitoring device information.

The tablet Operating System (OS) and other control functions are locked (kiosk mode) to prohibit the installation and use of any consumer grade applications. The tablets sole use is intended for the operation of Norlase LION photocoagulator. The use of any unauthorized applications may affect the performance of the device and is prohibited.

The tablet Wi-Fi is locked to prevent connection to any network and cannot access the internet. Power charging cable and power supply are included.

Touchscreen User Interface

Footswitch with battery

Activates laser treatment beam when depressed while device is in READY mode.The battery is built into the foot switch shroud and powers both the white light illumination and laser sources.

Norlase LION Power Supply

Medical grade power supply to be connected between wall outlet and the charging connection on the foot switch.

Keys

User removable keys (2) to turn on laser system.

Tablet charger and cable

Wall-plug charger and power charging USB cable.

Pairing cable

USB pairing cable.

Tablet Stand

A sturdy stand to allow easy access to the touch screen interface of the tablet.

User Manual

Provides User instruction for operating laser system. It also provides important safety and specification information.

WARNING: The USB connectors in the tablet and in the laser console are dedicated to the 2 USB cables provided in the package. No other items, devices or cables must be inserted into the USB connectors. Doing so risks unauthorised access or permanent damage to the device.

Device Preparation and Setup

The initial installation and setup will be performed under the supervision of Norlase-certified personnel. The instruction of User's staff to setup the device will be part of the initial in-service training.

Norlase LION is intended for use by trained Ophthalmologists for treatment of ocular pathology in both the posterior and anterior segments. The device is designed for use in a darkened office or surgery room. Optimal device performance and viewing is achieved in low ambient light conditions.

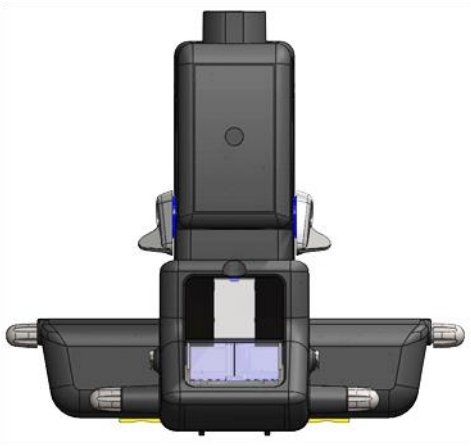
Norlase LION power supply used for charging the battery is equipped with a 2-wire AC power cord. Follow local electrical codes to ensure proper wiring of the AC wall power outlet.

Proper device operation requires temperatures between 15°C (59°F) and 35°C (95°F). The relative humidity must be between 20% and 85% (non-condensing) up to 25°C (77°F) and between 20% and 60% (non-condensing) up to 35°C (95°F). Position the system to aim the treatment beam away from windows and doors. Post a laser safety sign at the entrance to the treatment room.

Do not block cooling airflow or cooling vents on the laser. Allow at least 5 cm (2 in) of clear space around the laser to provide adequate system cooling airflow. The headband should be worn over the users hair. Do not route the users hair through the headband. Use care when routing device cables to prevent a tripping hazard.

Setting up and using the Norlase LION

The Norlase LION is a fully self contained laser delivery device built into the viewing path of the binocular block. The user can adjust the angle of projection of the laser by approximately +/- 3 degrees. The illumination field is separately adjustable.



Oculars- Patient Side

Oculars- Physician Side

Adjusting the headband

Comfortable Fit

Adjust the size (fig.1) and the height (fig.2), so that the headset is supported comfortably around and on top of the head.

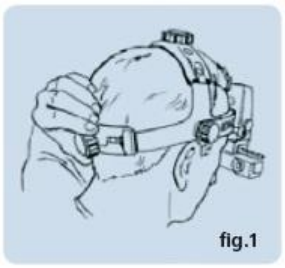


fig.1

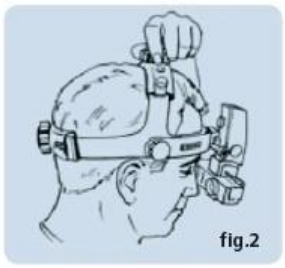
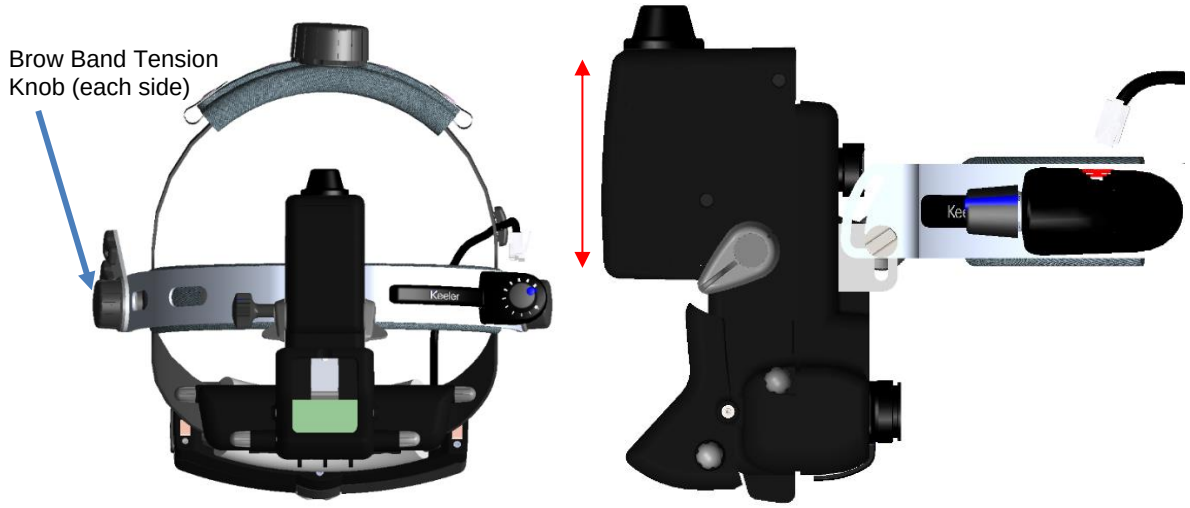


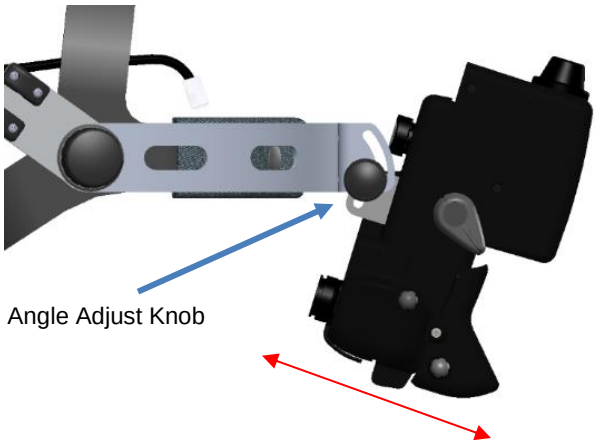
fig.2

Ophthalmoscope Angle Alignment

For vertical alignment of the eyepieces and binocular block, adjust the height of the Metal Outer Brow Bar if necessary by using the brow band tension knobs located on the sides of the headset.



Position the Binocular Block as close to the eyes or spectacles as possible for maximum field of view. Slightly loosen the ophthalmoscope angle knob to allow for adjustment and tighten when in position.



Interpupillary Distance Setting Control

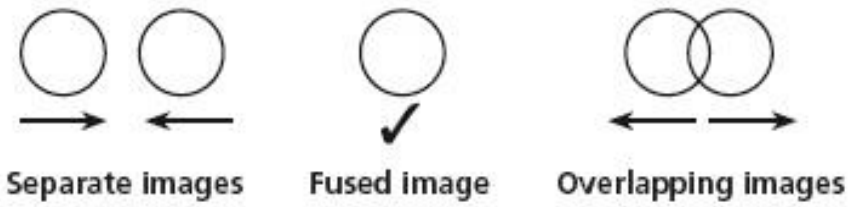
Because the eyes are dissociated, particular care must be taken to ensure the optics (eyepieces) are set properly in front of each eye.

Always set the Aperture Selection to the large light patch for this exercise.

Place an object, perhaps the thumb, approximately 40cm from the face and centre it horizontally in the light patch. Then, close one eye. Using the thumb and forefinger of the opposite hand, slide the P.D. Control of the open eye (located directly under each eyepiece) so that your object moves into the centre of the field, keeping the object in the centre of the light patch. Repeat for the other eye.

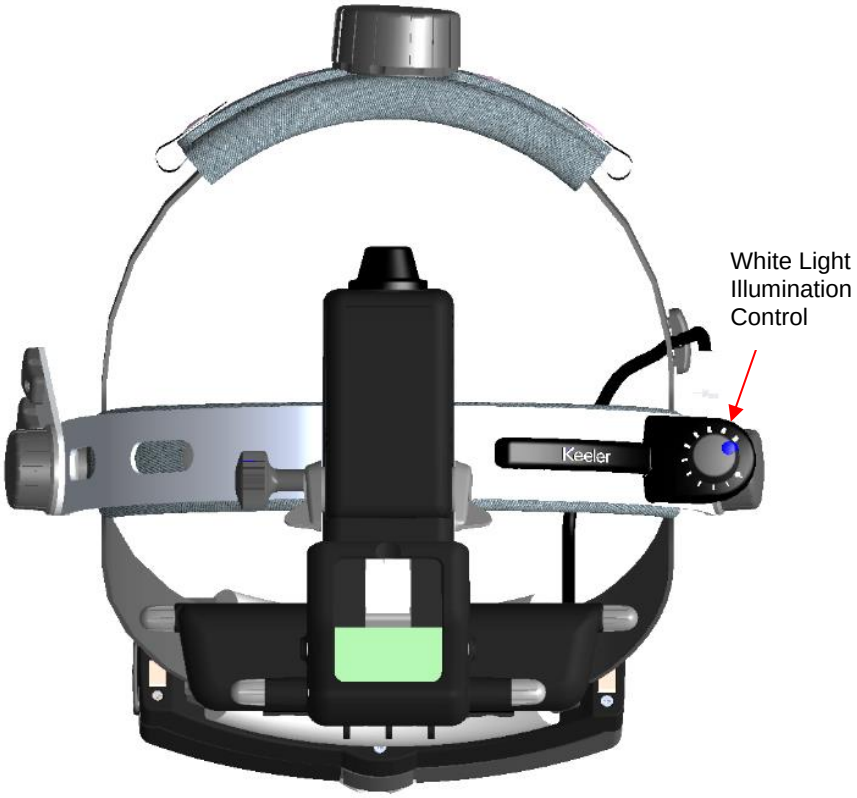
Obtaining a fused image

Ensure that a singular, fused image is obtained as follows:



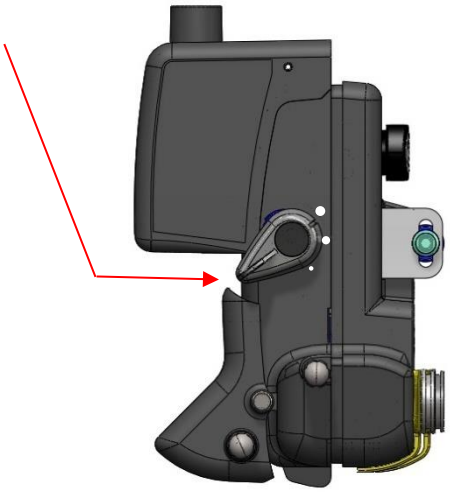
White Light Illumination

Turn the illumination on by rotating the headband dimmer in the clockwise direction.



Setting the Illumination Aperture

Select different apertures by rotating the lever on the left side of the unit.



The Norlase LION has three light apertures which offer maximum stereopsis. When you select the aperture, the illumination and viewing mirrors automatically adjust for maximum stereopsis.

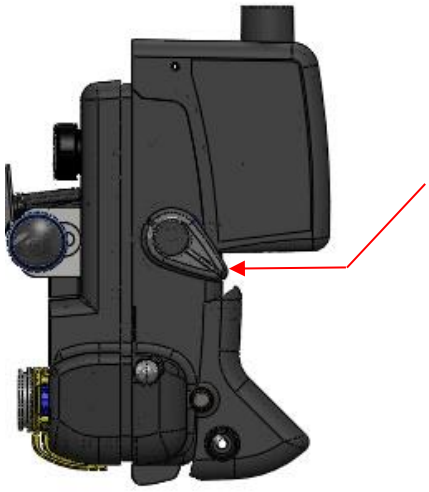
Large
The large, round, homogeneous patch is suitable for routine examinations through fully dilated pupils. In this position the mirror remains in the forward position and the optics are diverged.

Intermediate
The intermediate patch is designed to reduce reflections when entering a partially or poorly dilated pupil (3mm). It is also ideal for closer inspection of particular fundal areas. The mirror and optics stay in the mid position.

Small
This light patch is ideal for small, undilated pupils. The mirror moves back and the optics automatically converge.

Filter Selection

Select different filters by rotating the lever on the right side of the unit:



Blue Circle
Cobalt blue filter for fluorescein angioscopy.

White Circle
Clear light – Select the clear with no filter when inspecting a specific pathology and a brighter, whiter light is desired.

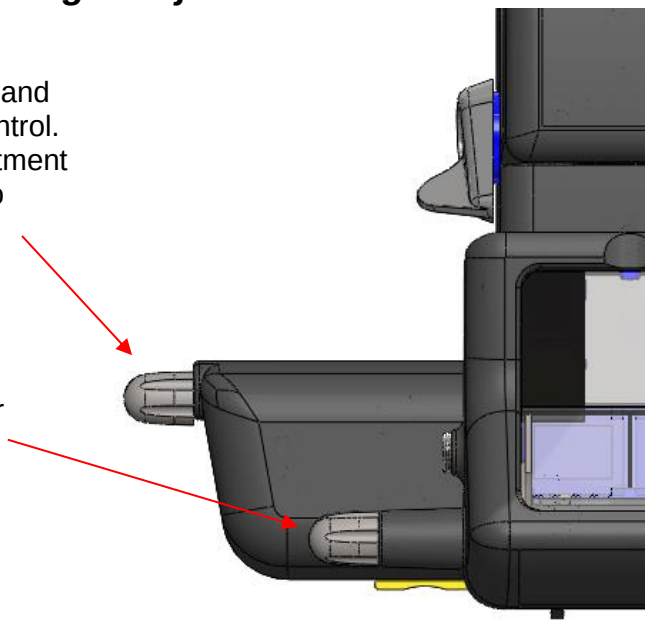
Green Circle
Red Free filter – this filter reduces the red light, so blood will appear black, silhouetted against a dark background.

Diffuser
This unique extra wide beam of diffused light permits a more relaxed technique during more challenging fundus examinations. Beginners may also find this aperture particularly helpful since the alignment between the headset, the condensing lens and the pupil, in order to achieve a full lens image, is not as critical as with the conventional beam.

Headset Illumination and Laser Angle Adjustment

Illumination adjustment
The illumination patch can be adjusted up and down using the illumination adjustment control. The illumination control has a larger adjustment range than the laser control, so it is best to adjust the laser first then overlay the illumination.

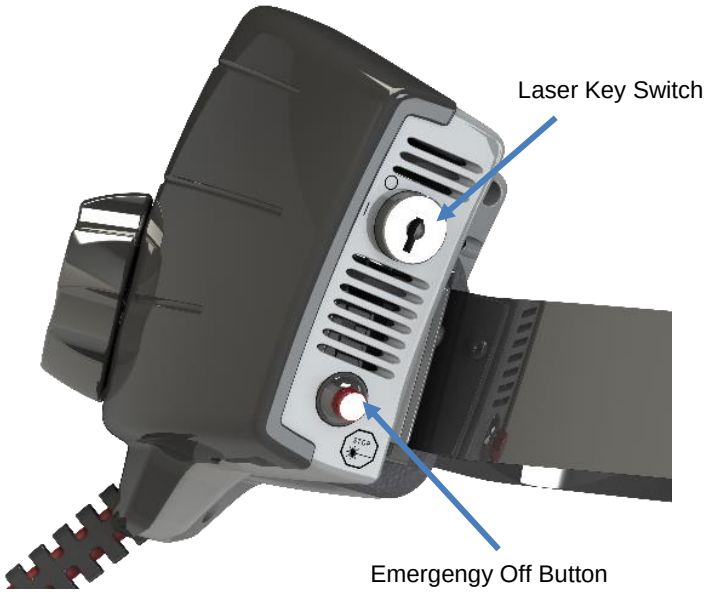
Laser angle adjustment
The vertical angle of projection of the laser can be adjusted up or down the front mounted control.



Device Functions

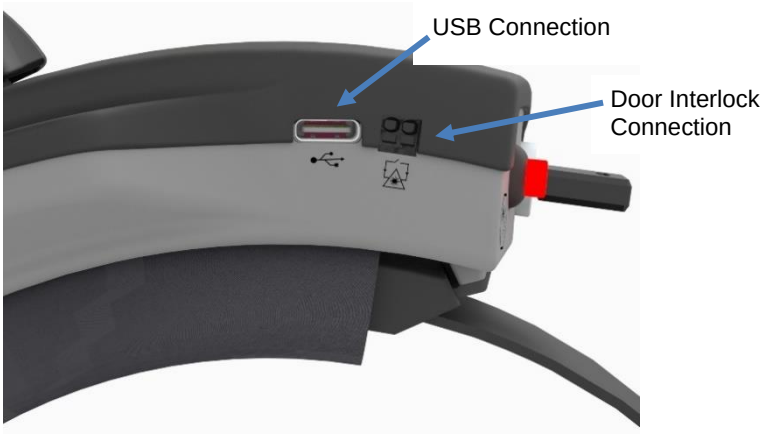
Refer to the following diagrams for the location of device component connections on the side panels of the laser console.

Side Panel Functions



Laser Console Side Panel

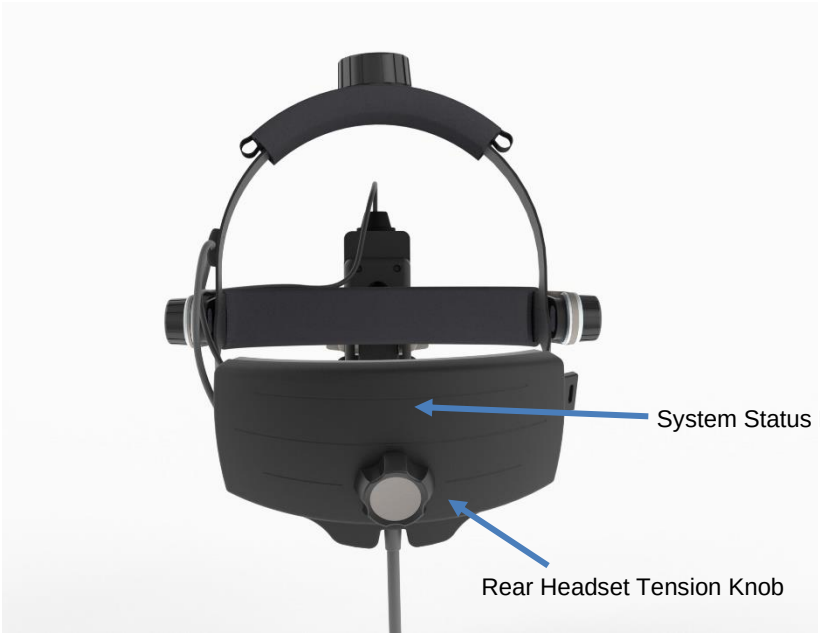
Bottom Panel Functions



Laser Console Bottom Panel

NOTE
If using an external door interlock, a qualified electrical professional must install the external switch. The total length of the cable should not exceed 5 m (16 ft).

Rear Panel Functions



Laser Console Rear Panel

System Status LED Meaning:

Flashing Blue - Searching for Tablet

Solid Green - Tablet Connected and in STANDBY

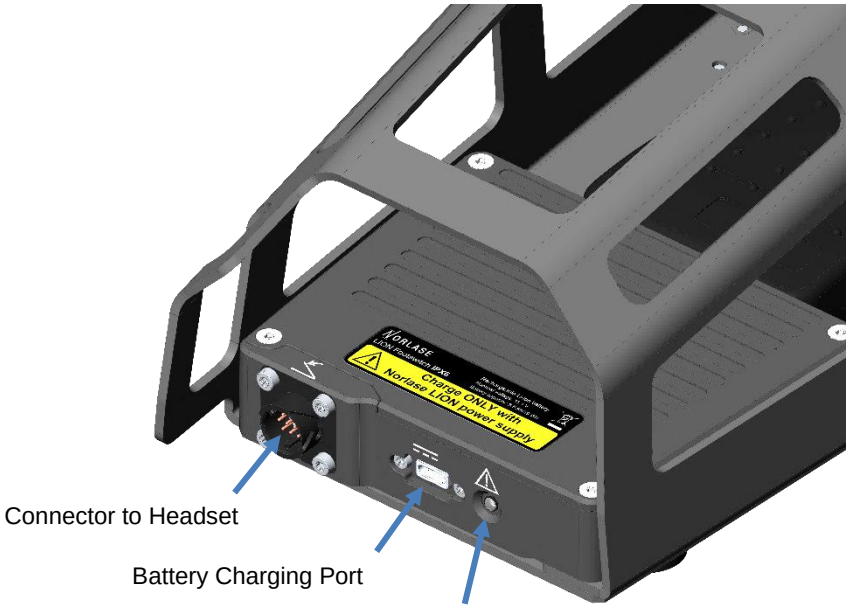
Solid Yellow - Tablet Connected and in TREAT

Flashing Yellow - Tablet Connected, in TREAT and footswitch is pressed

Solid Red – System Error, Turn Key OFF then ON

Flashing Red – System Error with No Tablet Connected, Turn Key OFF then ON and connect tablet

Foot Switch Panel Functions



Foot Switch Panel

Charging the LION Battery

The charging port for the LION battery is located on the rear of the foot switch. Plug in the supplied power supply to a wall outlet (100-240 VAC) and the output end into the battery charging port. A full charge will be obtained from a depleted battery in ~3 hours.

NOTE: Use only the Norlase LION power supply to charge the battery. Using any other power supply may cause permanent device damage and risk of fire. Using any other power supply will immediately void the warranty. The batteries may only be replaced by Norlase-certified personnel.

The charging status LED will display the following:

Battery Charging LED Meaning:

Flashing Green – Battery is Charging

Solid Green – Battery is fully charged

Solid Red – Error in Charging. Remove charging cable for 1 minute and retry. If solid red LED is persistant please contact Norlase Technical Support or an authorized distributor

Laser Spot Size Considerations

There are many factors that can affect the spot size delivered to the target tissue. Among these are:

- Working distance between the physician and patient.
    - The smallest spot is obtained when the laser at its focus point ~15 inches (~381 mm) from the laser aperture.The physician should move along the focus axis while observing the aiming beam diameter and observe the point where the laser is at its smallest diameter. Treatment should be performed at this optimal focus point.
- Refractive index of the eye structures.
- Refractive status of the eye. As an example using an (A) 1100 µm aerial spot and a (B) 20D indirect lens and (C) power of the eye: A* (B/C)= spot size on the retina:
    - Emmotropic Eye (~60D) = 1100* (20/60)= 366 µm on retina
    - Hyperopic Eye (~50D) = 1100* (20/50)= 440 µm on retina
    - Myopic Eye (~70D) = 1100* (20/70)= 314 µm on retina
- Power of the indirect lens in an emmotropic eye:
    - 20D Lens = 366 µm on the retina
    - 25D Lens = 458 µm on the retina
    - 28D Lens = 513 µm on the retina
    - 30D Lens = 550 µm on the retina

The above is an example only. The refraction power will vary patient to patient.

Device Start-up and Shut-down

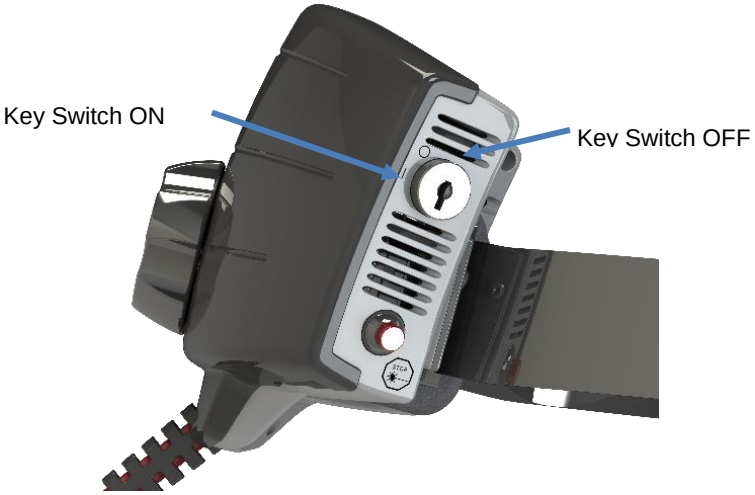
Starting the Device

1. Prior to mounting the headset, connect the LION headset cable to rear of foot switch mating cable receptacle. Please note this connector is keyed, so it must be inserted in the proper orientation with the arrow on the connector facing UP.

2. Push connector into the foot switch receptacle until it “clicks” and locks into place

3. Insert key into key switch.

4. Turn key to the ON position.



5. Press and hold the power button of the display tablet until the tablet powers up and the Norlase User interface Home screen is displayed.

6. The laser status LED on the back of the headset will illuminate green when the tablet and laser have established a connection.

Shutting Down the Device

Standard Shut-down

From the Treatment screen:

1. Press “END” on the tablet control panel.
2. Press and hold the tablet power button until “POWER OFF” is displayed. Select “POWER OFF” until tablet screen shuts off.
3. Turn the key switch on the laser console to OFF position.
4. Remove the key to prevent unauthorized use of the device.

NOTE

If the power cable is still connected to the foot switch electrical source, some internal circuits remain energized (current comsumption is less than 0.1 Watts). The LION headset illumination light will still be active even if the system is powered OFF. If leaving the cable plugged into the foot switch, ensure the illumination control on the headset is turned OFF to prevent battery drain. To de-energize all internal circuits, unplug the headset cable from the foot switch.

Removing Headset Cable From the Foot Switch

To remove the headset cable from the foot switch:

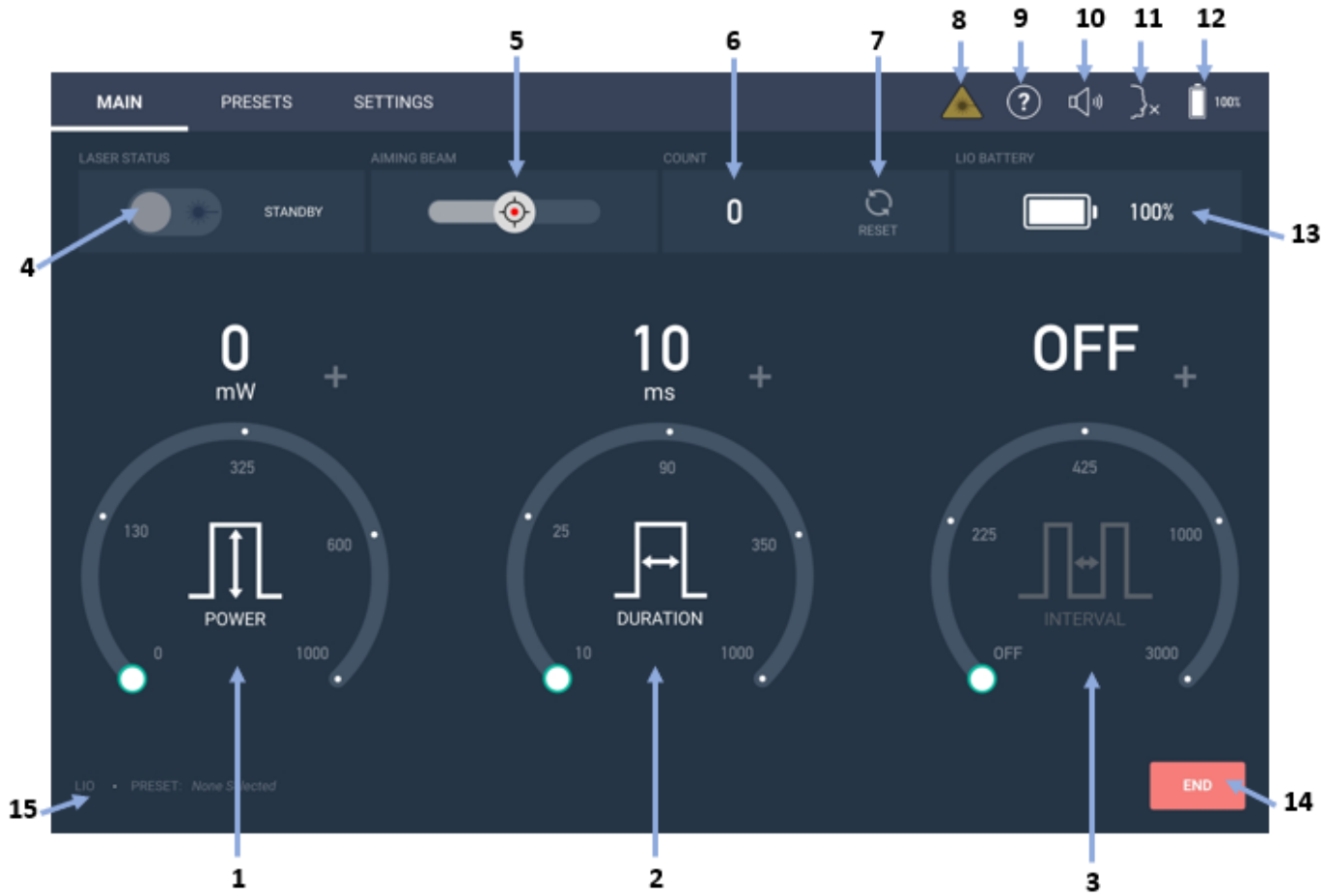
1. Ensure Key switch is in the OFF position.
2. Rotate the headset cable connector collar ¼ turn counterclockwise and pull straight out.

Emergency Shut-down

If it becomes necessary to engage the emergency shut down of the device, press the emergency laser stop button on the side panel of the laser console underneath the key switch. Turn the key switch to the OFF position for 10 seconds then back to the ON position to evaluate if the device will return to normal function.

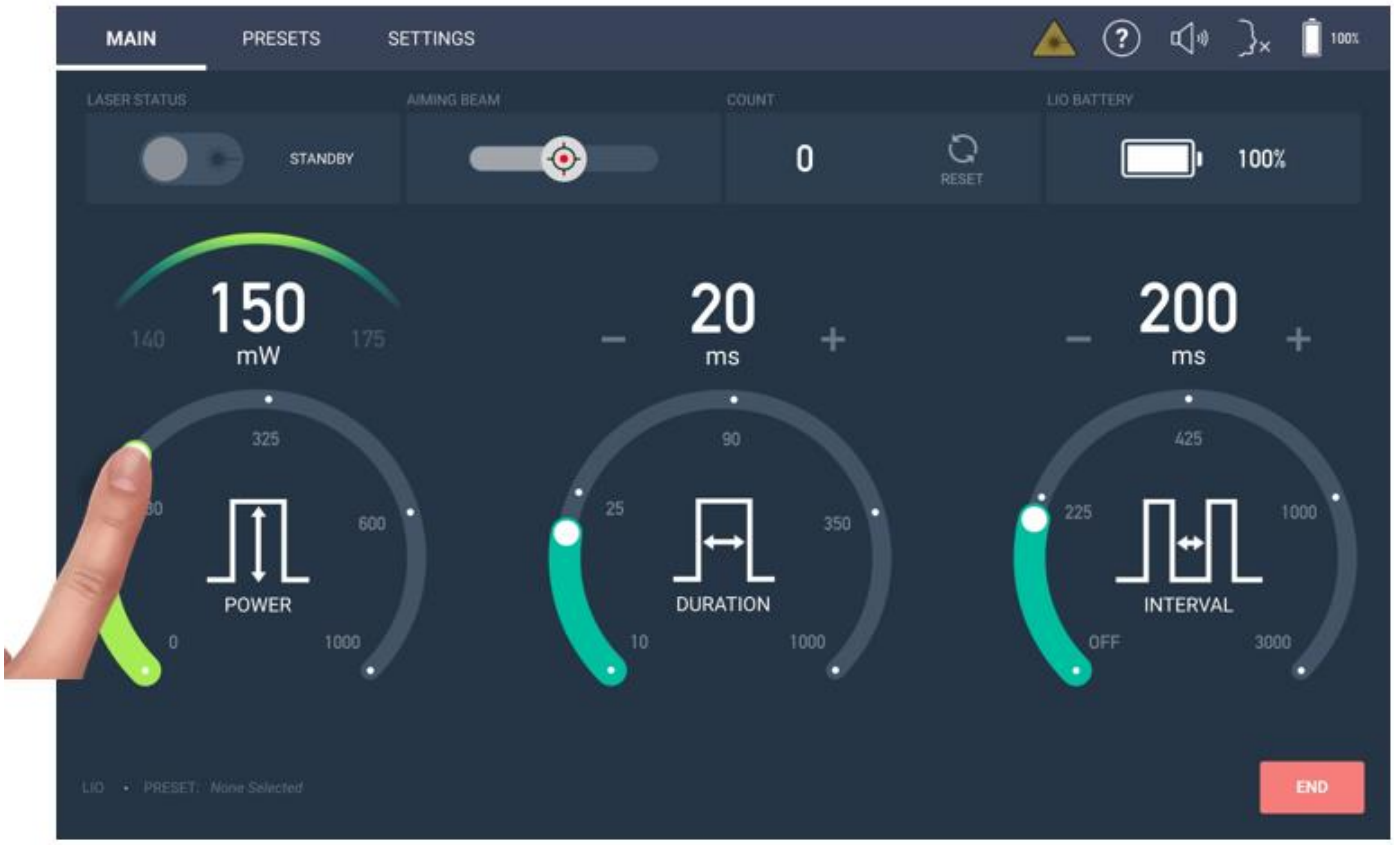
Emergency Off Switch

Home Screen (Default Display)



1	**Power Control**: Power adjustment along circular guide or press and hold desired Power along guide, or press "+" or "-" to adjust to the next increment
2	**Duration Control**: Duration adjustment along circular guide or press and hold desired Duration along guide, or press "+" or "-" to adjust to the next increment
3	**Interval Control**: Interval adjustment along circular guide or press and hold desired Interval along guide, or press "+" or "-" to adjust to the next increment
4	**Laser Status Select**: Toggle between "Ready" or "Standby"
5	**Aiming Beam Brightness**: Adjust aiming laser percentage (1% to 100%)
6	**Pulse Count**: Displays current Pulse Count
7	**Pulse Count Reset**: Resets Pulse Count to Zero
8	**Laser Emission Indicator**: Illuminates during laser emission
9	**User Manual**: Displays User Manual when selected
10	**Volume Control**: Adjusts Tablet volume
11	**Voice Parameter Control** (Optional): Enables/Disables Voice Control and adjusts volume
12	**Battery Indicator**: Indicates battery charge level on TABLET
13	**Battery Indicator**: Indicates battery charge level on LASER
14	**End Treatment**: Ends current selection of parameter and returns settings to default
15	**Status Summary**: Indicates Device connected and Selected Preset

Using the Touchscreen Interface

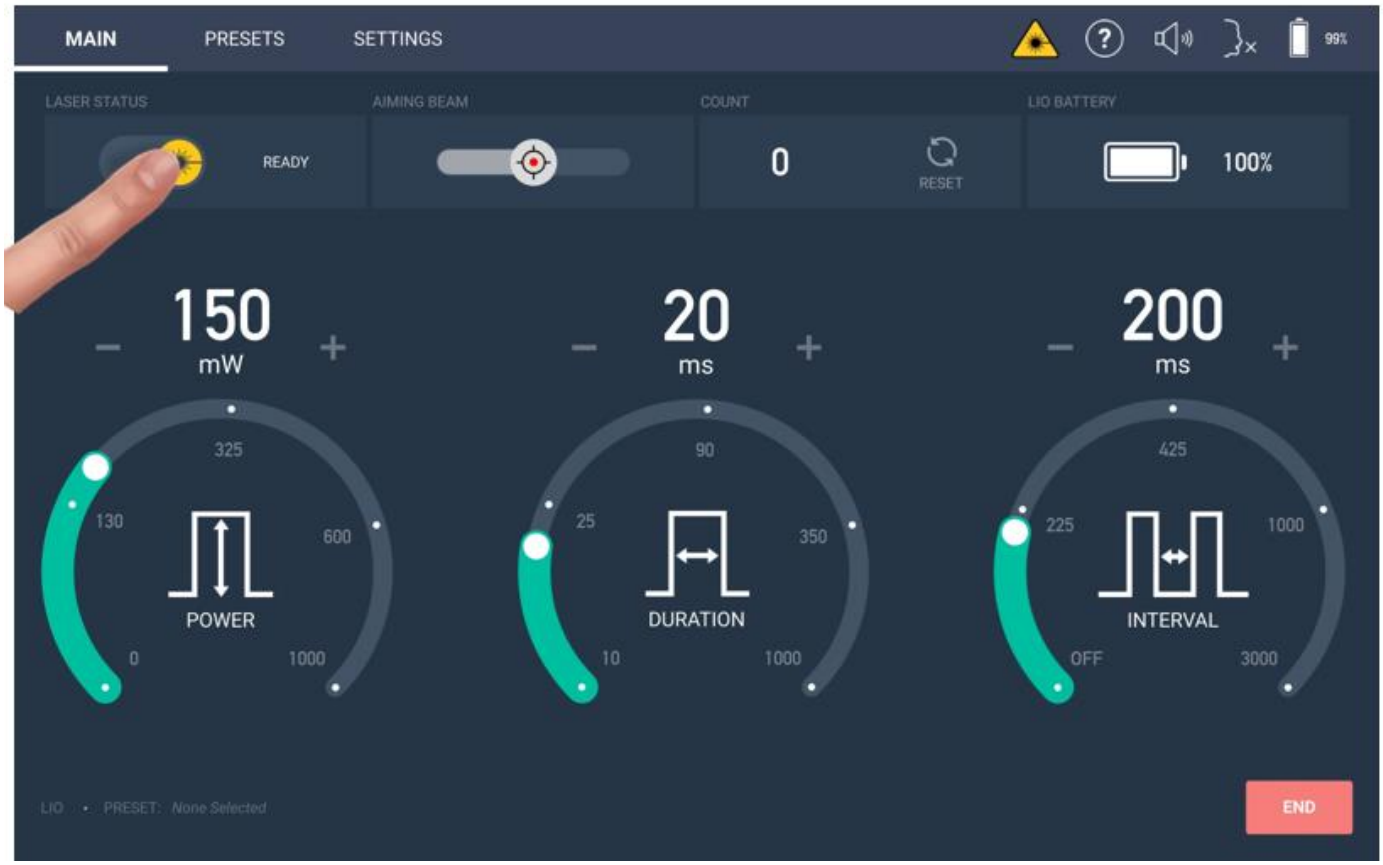


Changing Parameters on Power, Duration, and Interval

To change any parameter, lightly press your finger along the active area of the arc and slide until the desired setting is reached. The parameter selected will change colors to indicate the region is being adjusted.

Alternate methods of adjustment include touching and holding a region along the arc for 2 seconds and the value will immediately jump to the touchpoint setting on the scale.

A setting may also be incremented to the next higher or lower value by touching the "+" or "-" next to each parameter.



Changing Laser Status, Laser Mode, Aiming Beam Power, and Counter Reset

Laser status may be selected between STANDBY and READY by pressing in the active region. The selected setting will be displayed. In the READY mode, the laser starburst symbol will be highlighted in yellow. The READY mode is also be referred to as Treatment or Treat mode.

Aiming Beam intensity can be adjusted by using the slider to select the desired intensity and can be adjusted from 1-100%. At 100% setting, the power delivered to tissue is <1 mw.

The Pulse Count can be reset to zero by touching the “RESET” icon within the Count region. Please Note: The Pulse Count can only be reset by pressing the RESET button. Power cycling the system will still display the previous pulse count number.

Using Voice Control (Optional Feature)

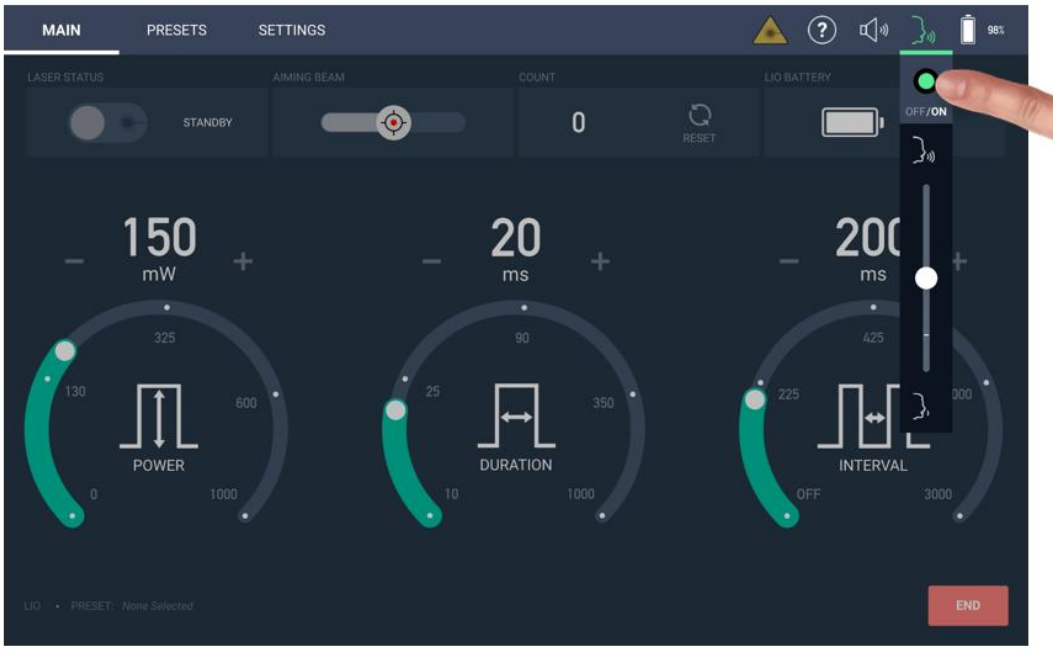
The Norlase LION photocoagulator is capable of receiving voice commands for certain parameter changes to aid the physician in changing parameters without engaging the touchscreen user interface.

The voice control feature works by listening for a “wake up” command, “**OK Norlase**”, which activates the tablet to listen for the proper parameter change command. When a command has been successfully recognized, the tablet will audibly call back the requested command and any parameter setting that has been changed. If a command is not recognized, a two note audible response will indicate no command was recognized.

Voice Control Settings

Voice Control can be enabled/disabled from the touch screen user interface. The Voice Control icon will display  when active or  when inactive or unavailable

1. Touch the Voice control Icon to display the ENABLE/DISABLE button and volume control of the audible response. The green circle indicates voice control is activated. The volume of the audible response can be adjusted using the slider control.



2. If selecting the voice control does not highlight the green circle and the icon displays  , voice control is not available on this system. Call Norlase or an authorized Distributor to purchase this feature.

Please Note: The wake-up word and voice commands must be stated EXACTLY as listed below, clearly, in English and within the microphone range of the user interface tablet to ensure high success of a recognized command. Any deviation from the exact command will not be recognized. It is helpful to memorize this list of commands in order to ensure consistent success of the voice commands.

Wake-Up Phrase: **OK Norlase**

The wake-up phrase will activate the tablet to listen for a recognized command. Immediately after hearing “OK Norlase” the tablet will respond with a two-step audible tone (♫) that indicates it is listening for the next command. The next command must be issued within 5 seconds or the tablet will return to listening for the wake-up word to be said again.

Please wait one second after the audible tone completes before issuing the desired command.

Examples of correct sequencing for Voice Control:

User	Tablet	1 second	User	Tablet Response
“OK Norlase”	“♫”	1 second	“Enter Treat”	“Treat Mode Selected”
“OK Norlase”	“♫”	1 second	“Power Higher”	“Power at XXX”
“OK Norlase”	“♫”	1 second	“Duration Lower”	“Duration at XXX”
“OK Norlase”	“♫”	1 second	“Pulse Count”	“Pulse Count at XXX”

List of Voice Commands:

XXX Indicates Current value will be read ♫ indicates audible tone heard after "**OK Norlase**"

Command	Device Action	Audible Response	Full Command Set
Enter Treat	Places the device into the "Ready" Mode	Treat Mode Selected	"OK Norlase" ♫ "Enter Treat"
Enter Standby	Places the device into the "Standby" Mode	Standby Mode Selected	"OK Norlase" ♫ "Enter Standby"
Power Higher	Increases power one increment up from current setting	Power at XXX	"OK Norlase" ♫ "Power Higher"
Power Lower	Decreases power one increment down from current setting	Power at XXX	"OK Norlase" ♫ "Power Lower"
Duration Higher	Increases Duration one increment up from current setting	Duration at XXX	"OK Norlase" ♫ "Duration Higher"
Duration Lower	Decreases Duration one increment from current setting	Duration at XXX	"OK Norlase" ♫ "Duration Lower"
Interval Higher	Increases Interval one increment up from current setting	Interval at XXX	"OK Norlase" ♫ "Interval Higher"
Interval Lower	Decreases Interval one increment down from current setting	Interval at XXX	"OK Norlase" ♫ "Interval Lower"
Aiming Beam Higher	Increases aiming beam 10% up	Aiming Beam at XX%	"OK Norlase" ♫ "Aiming Beam Higher"
Aiming Beam Lower	Decreases aiming beam 10% down	Aiming Beam at XX%	"OK Norlase" ♫ "Aiming Beam Lower"
Pulse Count	Will call out the current number of laser pulses delivered	Pulse Count at XXXX	"OK Norlase" ♫ "Pulse Count"
System Status	Will call out the current settings for Laser Status, Power, Duration, Interval and Pulse Count.	XXX Mode selected, Power at XXX, Duration at XXX, Interval at XXX, Pulse Count at XXX	"OK Norlase" ♫ "System Status"

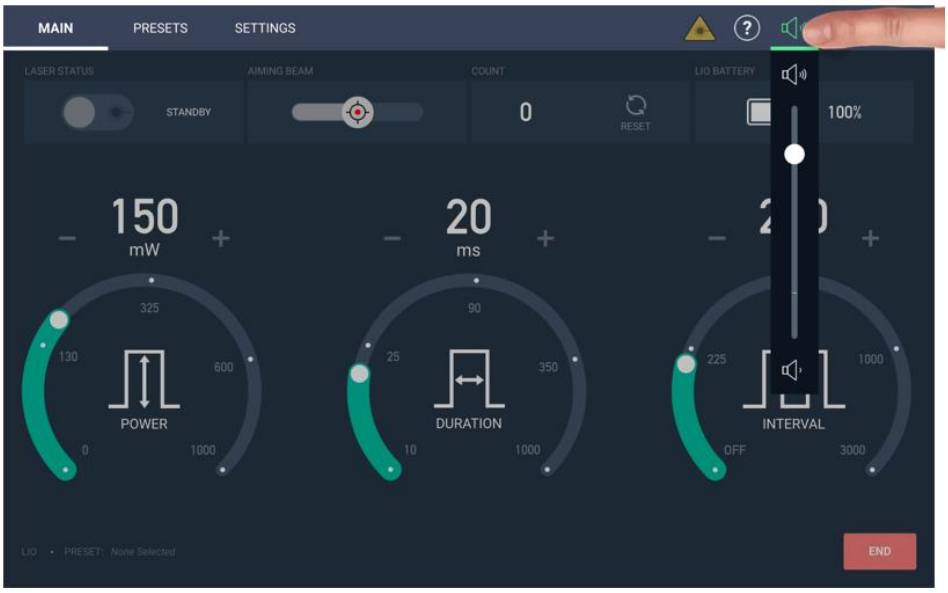
⚠ CAUTIONS

It is recommended to advise the patient that verbal commands by the Doctor and audible system response will take place during the procedure. This may help prevent any unexpected movement during this communication.

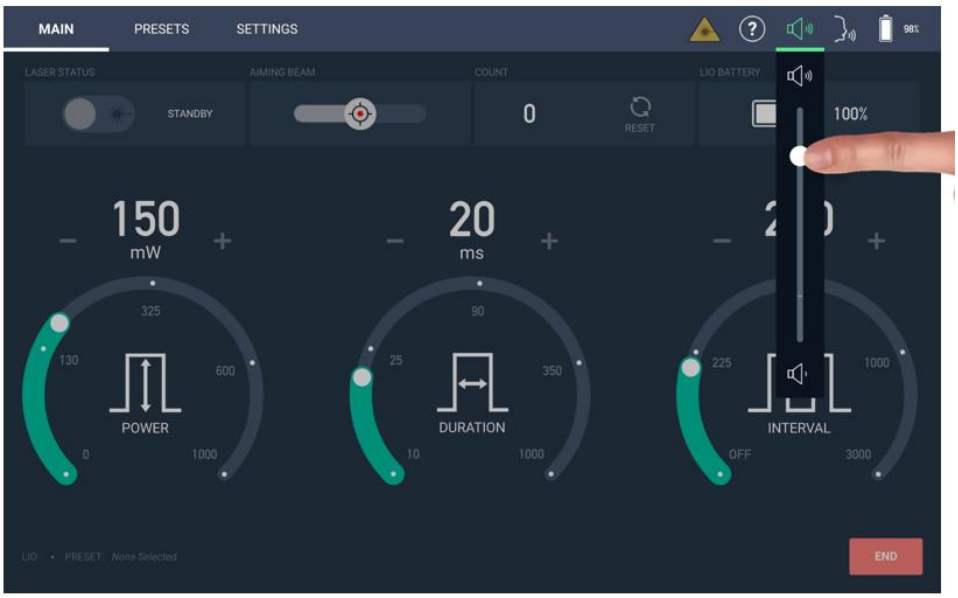
Tablet Volume Control

The tablet audio volume may be adjusted by using the slider control under the  icon

1. Touch the  icon to display the slider.



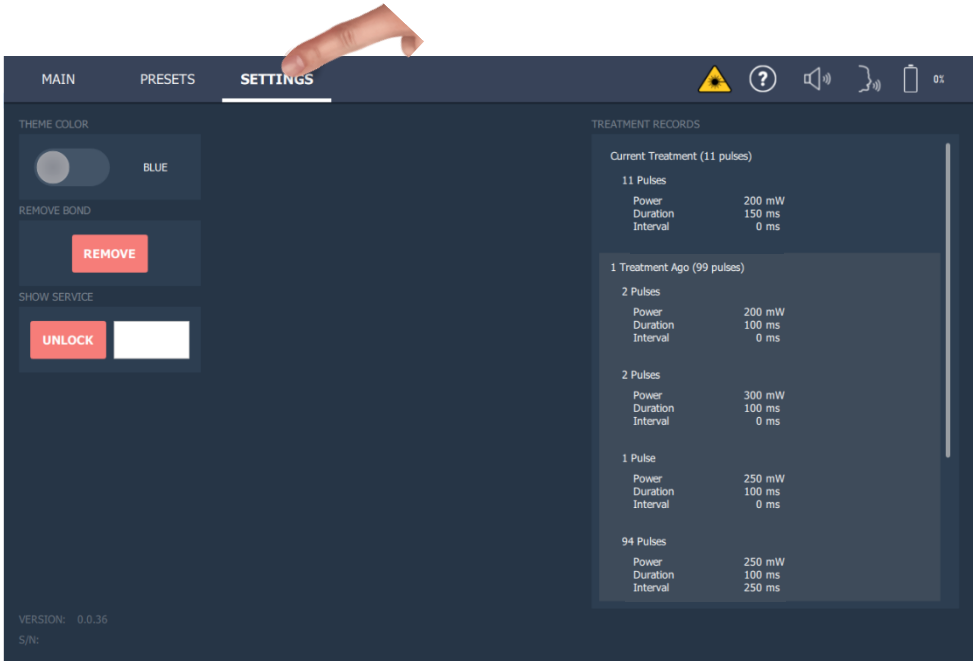
2. Adjust the slider to the desired volume level.



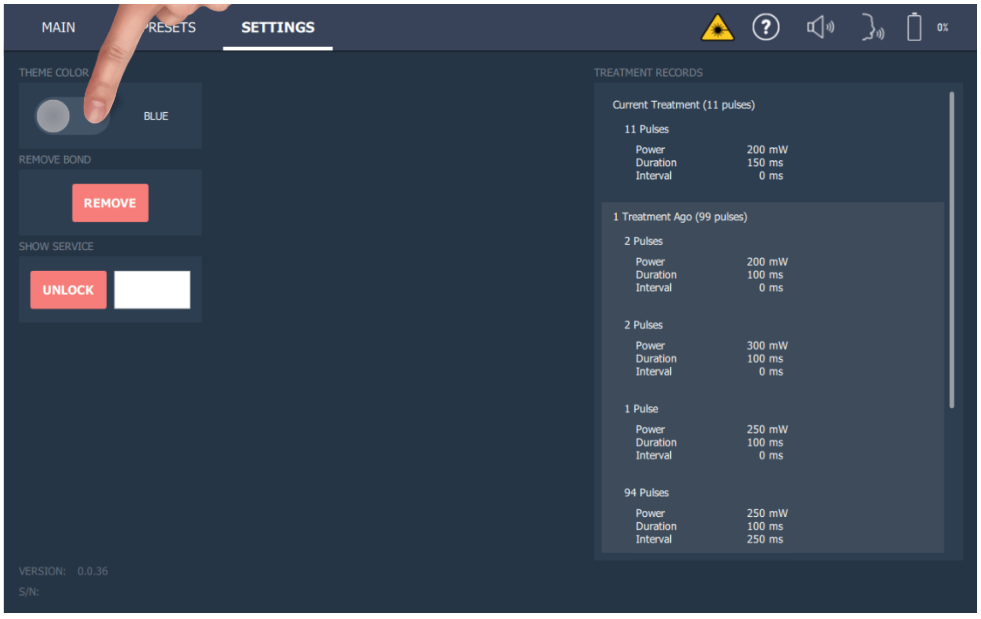
Changing Background Color on Tablet

The tablet background color may be changed from blue (default) to gray if desired.

1. Touch the SETTINGS tab.



2. Select the desired BLUE or GRAY tablet theme color

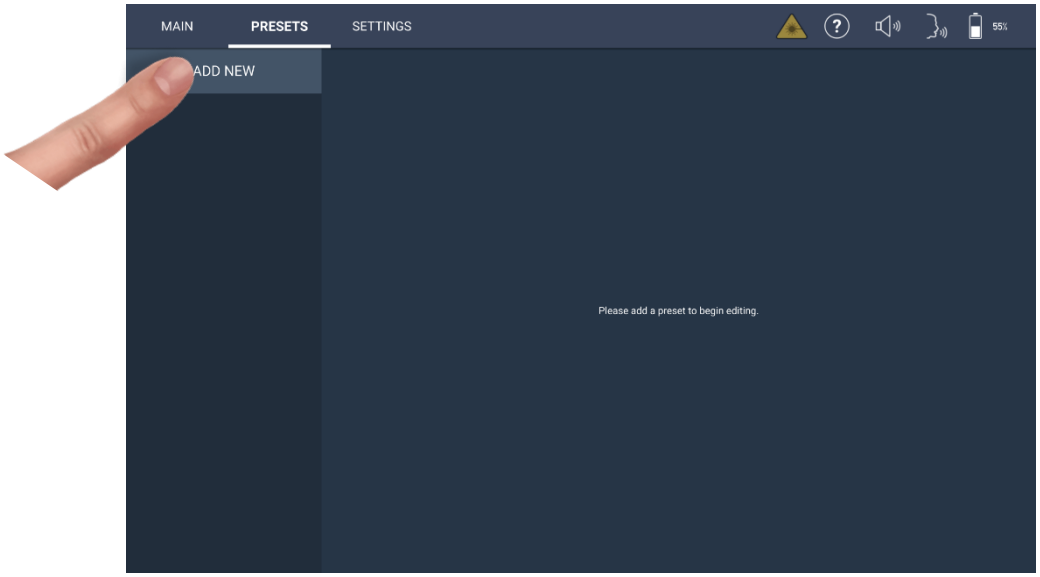


Presets Menu

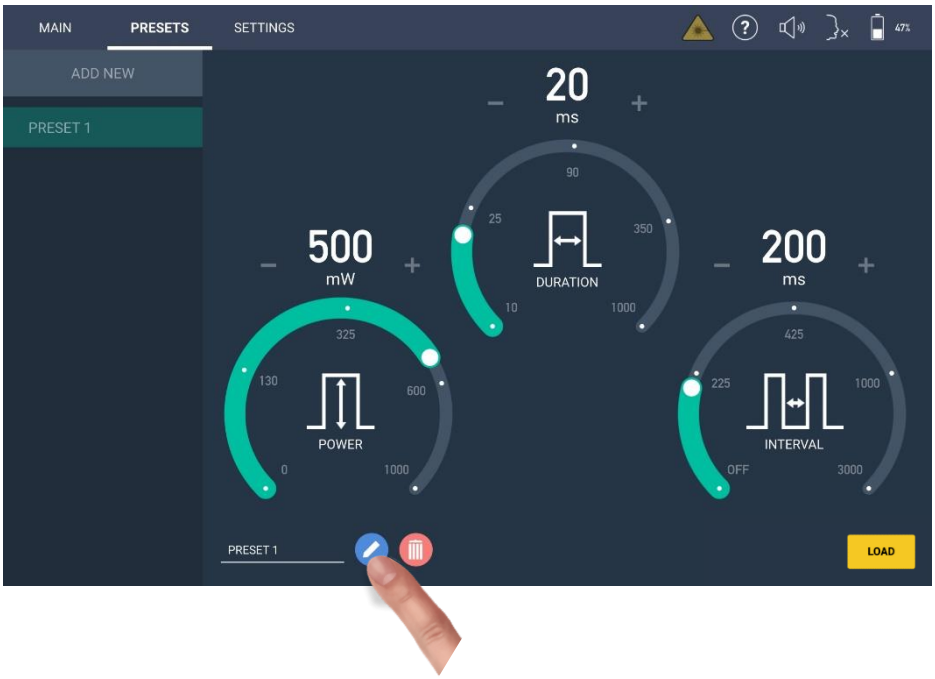
The “PRESETS” menu allows the saving and recall of commonly used parameters. These “PRESETS” are commonly named after the condition being treated or the physicians name and preference. The “PRESETS” will save the Power, Duration, Interval, Spot Size and Mode of operation.

To create a new “PRESET”:

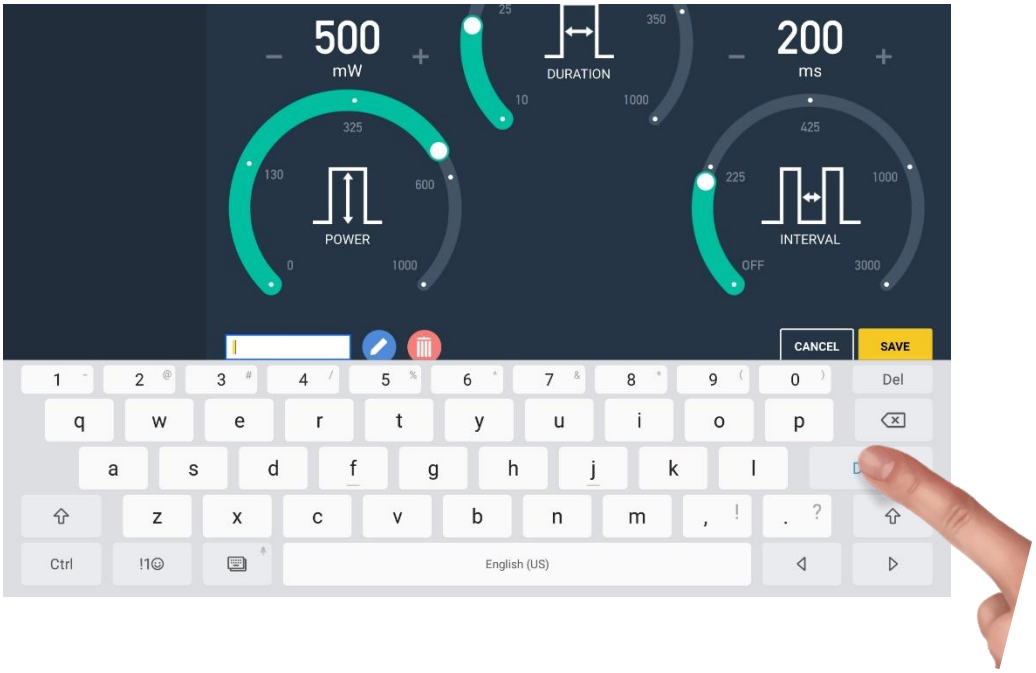
1. Select the “PRESETS” Tab at the top of the screen and press “ADD NEW”.



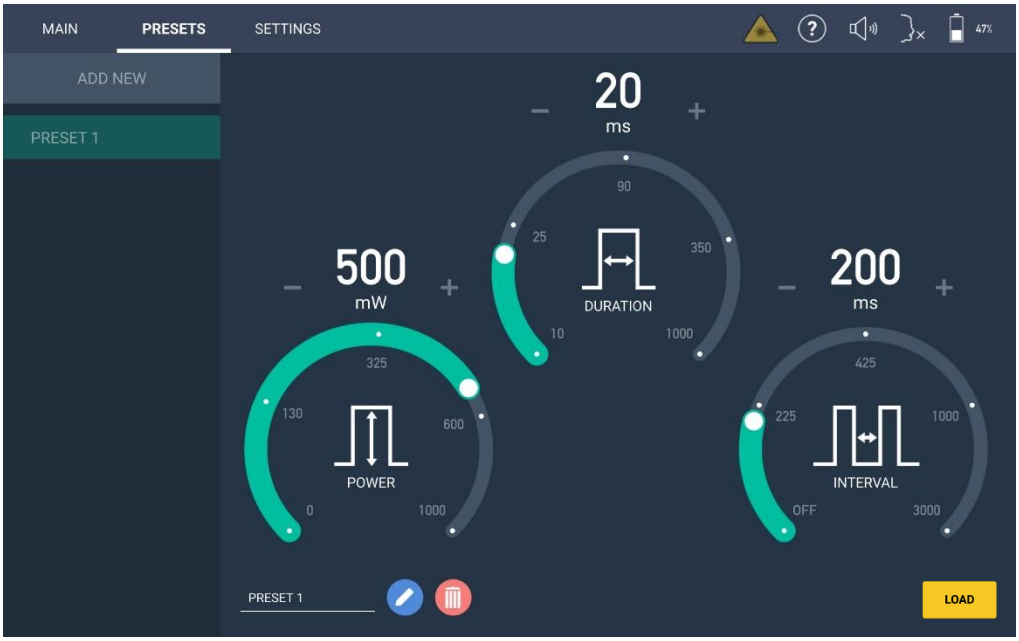
2. Set the parameters to the desired level. When done press the “PENCIL” icon to enter the Preset name.



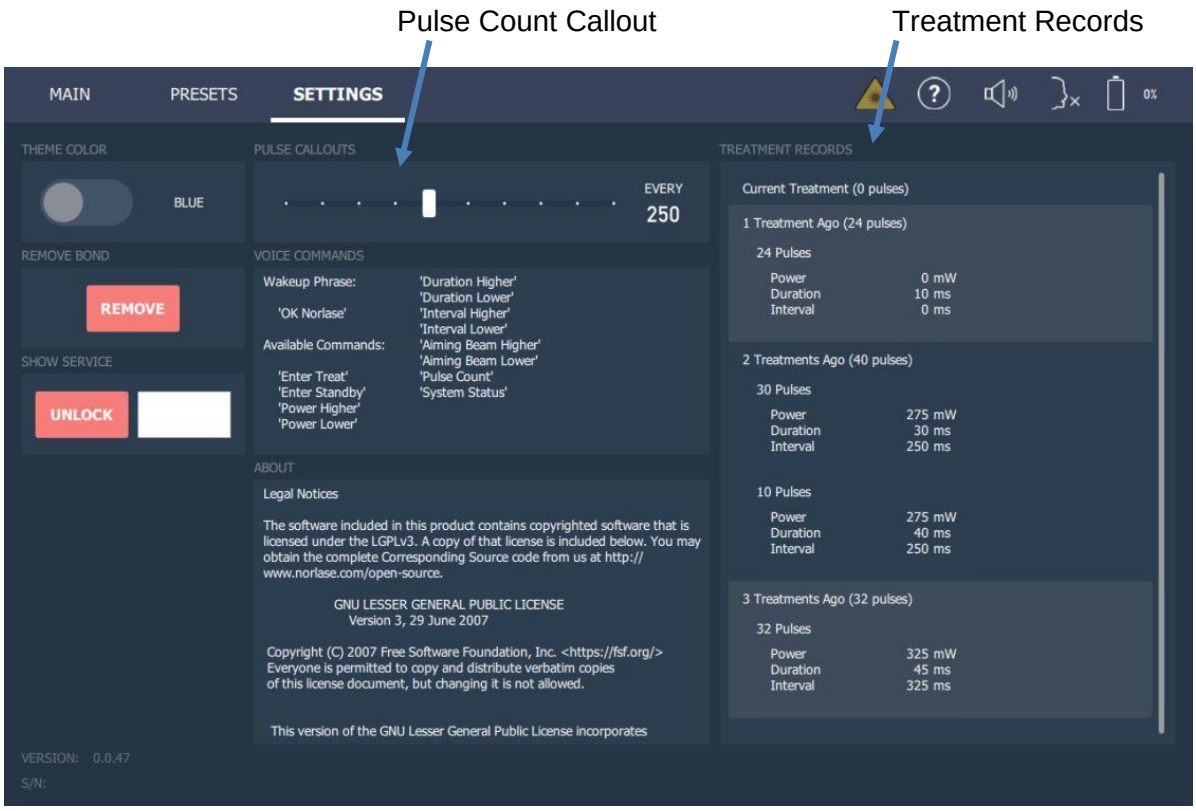
3. A keyboard will be displayed. Enter the name of the Preset and press “DONE”.



4. The Preset will be saved and will show on the list for future recall.



Settings Tab



Pulse Count Callout

This feature enables the tablet to audibly call out the Pulse Count each time a User defined setpoint is reached. As an example, if the Pulse Count Callout is set to 250, the tablet will audibly callout the number of pulses when it reaches 250, 500, 750, 1000 and every 250 pulses thereafter. This feature can be set to OFF, 50, 100, 250, 300, 350, 400, 450 to a maximum of 500.

Treatment Record Log Files

The device will retain treatment information for the current treatment and the previous four laser treatments under the “SETTINGS” tab on the User Interface. This will allow easy reference to the delivered parameters of previous cases but is NOT meant to be a historical archive, PACS storage system or a server where the information can be recalled. No patient information is recorded and the reference calls out the “Current Treatment”, “1 Treatment Ago”, “2 Treatments Ago”, “3 Treatments Ago”, “4 Treatments Ago”.

The information provided are the total number of pulses in parentheses next to the identifying treatment and then the number of pulses for each Power, Duration, Interval and spot size change made during the procedure.

Aligning the Laser to the visual and illumination axes

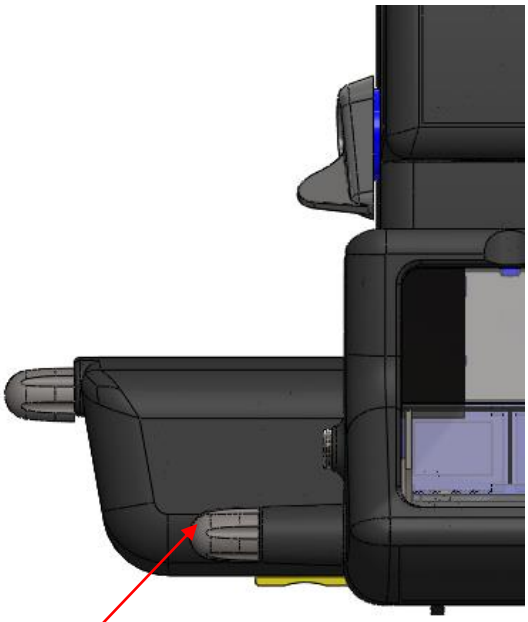
1. Ensure the device is connected and powered ON.
2. Mount the headset properly as described in previous sections.
3. Observe a target at ~38cm (15 inches) and adjust the Laser Angle Adjustment to the center of your field of view.
4. If necessary, adjust the Illumination Adjustment to center the illumination in the field of view.

Illumination adjustment

The illumination patch can be adjusted up and down using the illumination adjustment control. The illumination control has a larger adjustment range than the laser control, so it is best to adjust the laser first then overlay the illumination.

Laser angle adjustment

The vertical angle of projection of the laser can be adjusted up or down the front mounted control.



Illumination and Laser Position Adjustment

Intraoperative Instructions

Laser Indirect Ophthalmoscope Treatment Procedure

NOTE: Use of the LION is limited to physicians trained to perform photocoagulation with a Laser Indirect Ophthalmoscope.

1. Connect the LION headset cable to the foot switch/battery.
2. Verify that the headset is properly mounted and the PD settings are correct.
3. Position the patient in a location that is easy to view the disease entity to be treated.
4. Power ON the LION device
5. Select the desired LION starting (titration) parameters.
6. Select READY mode. The aiming beam will turn on.
7. Position the viewing lens above the patient's eye.
8. Adjust the aiming beam intensity to desired level.
9. Move your head position into focus ~15 inches (38cm) from patient and observe the red aiming beam imaged on the patient's eye. Verify that the laser spot is round and undistorted. Establish proper placement of the laser beam.
10. Depress and hold down the footswitch to deliver the treatment laser beam to the tissue
11. Adjust the laser treatment power as needed for therapeutic effect.
12. Prior to continuing treatment, verify that the power and other parameters are within acceptable ranges.
13. When treatment is complete, press END to return the main screen to default parameters.

Please Note: Treatment may be interrupted at any point by releasing the footswitch.

NOTE

Always place the device in STANDBY mode if there is a prolonged pause in treatment.

If the device is in READY mode and remains idle for 5 minutes, it automatically reverts to STANDBY mode. To resume treatment, place the device back into READY mode.

If the device remains idle for 30 minutes and no movement is detected, it will automatically shut down except for the illumination. All parameters will return to the default position.

To wake up the device, first turn the key to the OFF and then to the ON position.

Between Patient Treatments

At the completion of each patient treatment:

1. Press END to exit the Treatment screen and all settings return to default.

2. Disinfect the Indrect lens following the contact lens manufacturer instructions.

Device Shut-down

At the end of the day, or during an extended period of inactivity:

1. Shut down Norlase LION as described in “Shutting Down the Device”.

2. Remove the key and store in a secure place to prevent unauthorized use of the system.

3. Clean the system as described in “User Maintenance”.

4. Store the LION in an area where it is safe.

Annual Maintenance

The Norlase LION does not require preventive maintenance, safety, power and calibration checks. Maintenance shall only be performed by Norlase-certified personnel to ensure proper device performance. If in doubt about the device performance please contact Norlase Technical Support or a Norlase authorized distributor.

System Repair

All Norlase LION repairs must be performed by Norlase-certified personnel to ensure proper device performance.

WARNING: Device repair or alterations performed by untrained personnel may cause harm both during repair and in future operation. Unauthorized repair immediately voids device warranty and may affect device safety and performance.

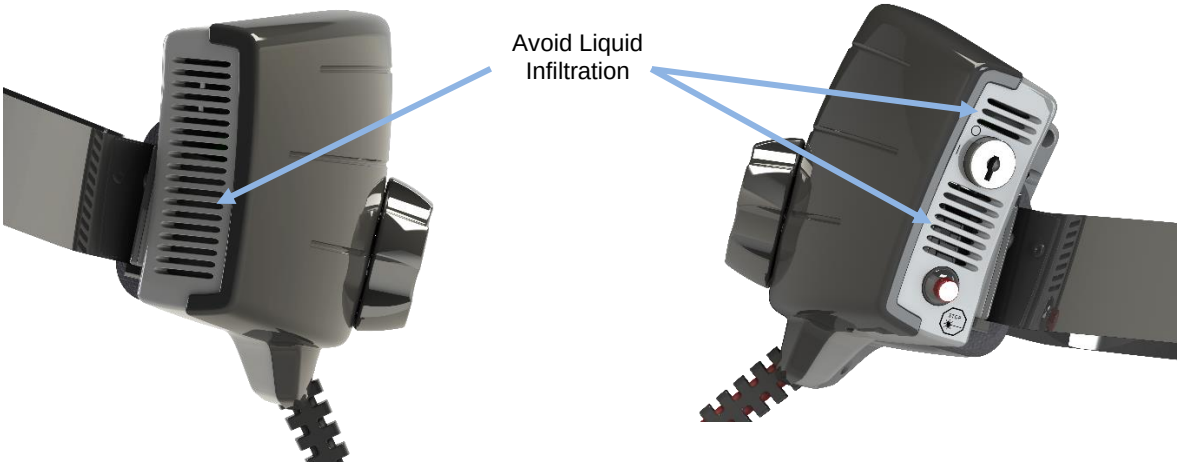
Inspection and Cleaning

The following procedures can be performed by the user to ensure proper performance of Norlase LION. During inspection and cleaning, the device shall be disconnected from the AC wall power outlet.

Cleaning the Laser Console External Surfaces

Clean the external surfaces of the laser console daily, after use. Use a cloth dampened with a non-caustic cleaning solution (e.g., soap and water) to clean the external non-optical surfaces of the laser console as needed. Dry with a clean cloth or allow to air dry. Do not spray or pour cleaning agents directly onto the laser console.

Do not spray or pour liquids into the air vents at the sides of the laser console.



Left Side Vents *Right Side Vents*

Do not clean any optical surface unless you have proper training. Using anything other than lens paper may scratch coating surfaces and affect the performance and protection of any optical coatings.

Cleaning the Tablet Control Panel Screen

Use a soft, dry cloth to apply antistatic glass or plastic cleaner to the tablet control panel screen.

Inspecting the Headset Cable

Inspect the LION headset cabling for any cuts or abrasions to the cabling. If any noticeable damage has occurred, please contact Norlase Technical Support or your authorized Distributor.

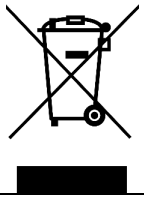
The power supply must be replaced with a factory authorized replacement or damage to the device may occur. Any warranty will be immediately voided by use of an unauthorized power supply.

Norlase LION Specifications

[Specifications are subject to change without notice.]

Treatment Beam	
Type	Semiconductor Laser
Wavelength	520 nm
Power output	0 – 1000 mW
Laser	CW
Pulse durations	10 ms – 1000 ms
Pulse interval	Off, 50 ms to 3000 ms
Laser beam diameter at focus	~1100 microns (in air)
CDRH classification	Class IV
European MDD laser classification	Class 4
Aim Beam	
Type	Diode
Wavelength	635 nm
Power output	< 1 mW

Electrical Requirements	
Rated Input	100-240 VAC, 50-60 Hz, 0.6 A
Product Classifications per IEC 60601-1	
Internally Powered ME Equipment (Class II when connected to Norlase LION power supply)	
Type B equipment	
Standard equipment, Footswitch is IPX6	
Non-sterile product	
Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	
Continuous operation	
Classifications & Approvals	
EN/IEC 60601-2-22	Laser Safety Requirements for Diagnostic and Therapeutic Laser Equipment
EN/IEC 60601-1	International Safety Requirements for Medical Electrical Equipment
EN/IEC 60601-1-2	EMC Requirements for Medical Electrical Equipment

	WEEE (Waste of Electrical and Electronic Equipment) Directive 2002/96/EC
Environmental Requirements (Operating)	
Operating temperature	15° to 35°C (59° –95°F)
Maximum humidity	15° to 25°C: 85% (non-condensing) 25° to 35°C: 60% (non-condensing)
Environmental Requirements (Storage and shipping)	
Maximum altitude	Standard commercial shipping altitude
Non-operating temperature	-10° to +55°C (14° to 131°F)
Maximum humidity	85% (non-condensing)
Other	
Expected Service Life	Minimum seven years from Customer Installation

Physical Characteristics	
Headset Length	14 in (35.56 cm)
Headset Width	9 in (22.86 cm)
Headset Depth	8 in (20.32 cm)
Headset Weight	1lb 14 oz l (0.85 kg)
Foot Switch Height	5.1 in (12.95 cm)
Foot Switch Width	5.75 in (14.61 cm)
Foot Switch Depth	9.37 in (23.8 cm)
Footswitch cable length	10 ft (3 M)
Latex	This product is latex free
Laser Safety Eyewear	
Non-CE eyewear	Minimum OD of 5 at 520 nm per ANSI Z136.1
CE eyewear	D LB6 at 520 nm per EN 207 Personal Eye Protection

Norlase LION Power Supply Specifications

Norlase LION Power Supply

NOTE: Use only the Norlase LION power supply to charge the battery. Using any other power supply may cause permanent device damage and risk of fire. Using any other power supply will immediately void the warranty.

Norlase LION Power Supply Specifications	
Class	II
Rated Input	100-240 VAC, 50-60 Hz, 0.6 A
Output Voltage	5 VDC
Rated output power	15 Watt (Continuous duty)
Output Connector Type	USB C
Means of protection	2 x MOPP

Troubleshooting Guide

If the device fails to operate properly, this Troubleshooting Guide will help you to locate and correct the malfunction. Should a major malfunction occur, contact Norlase Technical Support or your authorized Distributor. Please note any messages or Error Codes the device may display. This will aid in the diagnosis and servicing of the equipment.

If the device fails to turn on, please check for the following items. If none of these solutions remedies the problem, consult the Troubleshooting Guide, call Norlase Technical Support, or your local authorized Distributor:

1. Verify that the cable is correctly attached to the laser console and to the foot switch.
2. Verify that the device Key switch is in the "**I**" (ON) position.
3. Verify that the door interlock plug is securely connected and, if a door interlock is in use, that the door switch is closed.
4. Verify that the tablet control panel is powered on and connected with the laser console.
5. Verify that the emergency laser stop button is not activated.

Device does not turn on.

Probable Cause:	Laser console is not plugged in to foot switch battery.
Suggestion:	Plug in laser console to foot switch battery. Verify cable is well seated.

Probable Cause:	Key is absent or in OFF position.
Suggestion:	Insert key and rotate to ON position.

Probable Cause:	Battery drained
Suggestion:	Plug charger into the battery charging port, turn the key first to the OFF and then to the ON position to wake up the device. Battery should now be charging. This should be indicated by charging status LED on footswitch flashing green.

Probable Cause:	Wall outlet main power switch, if present, is in **O** (off) position
Suggestion:	Place switch in **I** (on) position.

Probable Cause:	Internal device error.
Suggestion:	Turn key switch to OFF position, wait at least five minute and then turn to ON position. If the device fails to start, contact Norlase Technical service or an authorized distributor.

System User Interface is blank for more than 30 seconds.

Probable Cause:	Internal tablet error during boot-up.
Suggestion:	Press and hold power button to repower the tablet

Probable Cause:	Tablet battery is dead.
Suggestion:	Recharge tablet battery or operate with recharging cable connected and plugged into wall outlet

No aiming beam is present when in READY mode and/or no laser treatment light is delivered when the footswitch is depressed and/or the beams are of poor quality.

Probable Cause:	Laser is in STANDBY mode, not READY mode.
Suggestion:	Select READY mode on control panel.

Probable Cause:	Aiming beam is on low intensity setting.
Suggestion:	Adjust aiming beam intensity on user interface.

Probable Cause:	After five minutes of non-use, the device goes to STANDBY.
Suggestion:	Switch mode from STANDBY to READY.

Probable Cause:	Remote interlock has been activated and has disabled the device.
Suggestion:	Ensure the action that activated remote interlock has ceased and proceed.

Probable Cause:	Foot switch and/or foot switch cable damaged.
Suggestion:	Inspect for damage. If damaged call Norlase Technical Support or an authorized distributor.

Probable Cause:	Internal device error.
Suggestion:	Contact Norlase Technical Support or an authorized distributor.

Other unexpected System behavior

Probable Cause:	Unauthorised access to device
Suggestion:	Turn Key OFF, then ON on laser console and reboot tablet. If problem persists, contact Norlase Technical Support or an authorized distributor.

Probable Cause:	Electronic component failure
Suggestion:	Turn Key OFF, then ON on laser console and reboot tablet. If problem persists, contact Norlase Technical Support or an authorized distributor.

Pairing an Unpaired Tablet with LION Laser Console

A tablet control panel is paired with a laser console at the Norlase factory. If it becomes necessary to pair a new tablet with a laser console please use the following procedure:

1. Obtain the pairing cable supplied with the tablet.
2. Turn on laser console. The status LED on side of laser console will be flashing blue.
3. Turn on tablet control panel.

a. The tablet will display CREATE BOND.

4. Plug one end of the pairing cable into the USB port on the bottom of the laser console and the other end into the USB port of the tablet.
5. Press the CREATE BOND button and observe the status LED on the laser console.
6. When the Status LED turns green the tablet has been successfully paired.

Pairing a Paired Tablet to a different LION Laser Console

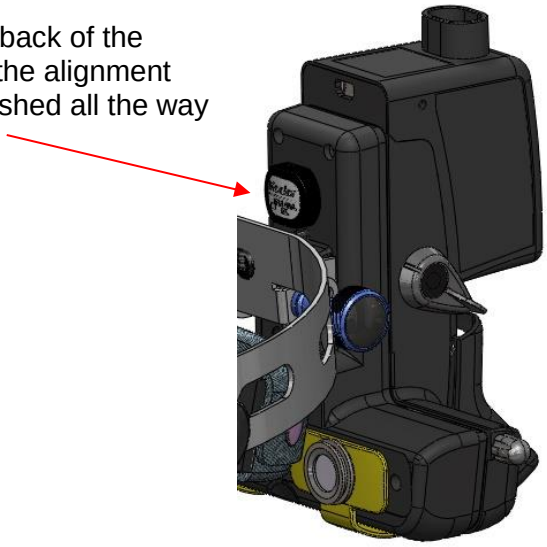
If it becomes necessary to pair a tablet with a different laser console than it was previously paired with, please use the following procedure:

1. Obtain the pairing cable supplied with the tablet.
2. Turn on LION laser console.
3. Turn on tablet control panel.
    a. From the default start up screen select the “SETTINGS” tab at the top of the screen.
    b. Select the REMOVE toggle under the REMOVE BOND section.
4. Plug one end of the cable into the USB port on the bottom of the laser console and the other end into the USB port of the tablet.
5. Press the CREATE BOND button and observe the status LED on the laser console.
6. When the Status LED turns green the tablet has been successfully paired.

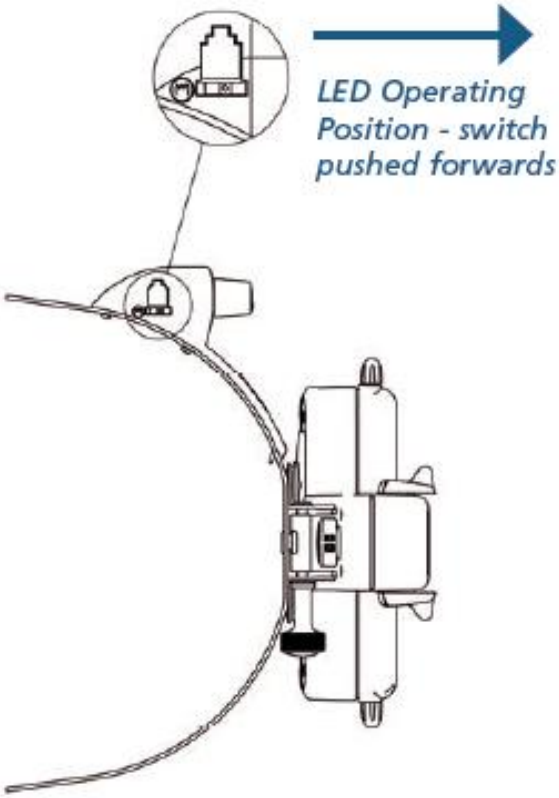
Illumination LED replacement

Caution, the LED may get hot during prolonged use.

Allow the LED to cool. Remove the LED from the back of the binocular block and insert the new LED ensuring the alignment key is properly oriented. Make sure the LED is pushed all the way into the binocular block.



Note that the LION should only be used with the LION LED. Ensure that the red switch on the rheostat is in the direct shown in the figure below. The symbol shown on the rheostat indicates a bulb light source.



Error Messages

Error States

If error occurs regularly, contact Norlase technical support or your authorized Distributor.

Critical Error implies a safety issue that requires the device to immediately go to a safe state.

Clearable Error indicates a problem with the device that requires that the device be put into a safe state until the error is acknowledged by the user or returns within specification.

Warning indicates a problem with the device that does not represent a serious safety issue and does not require any device functions to be interrupted but does require that the user be notified.

Code	Message	Critical	Clearable	Warning	Description	Action
1-1	Low Supply Voltage	X			Power Supply Voltage is too low	Turn Key OFF, then ON Call service if error persists.
1-2	Memory Problem	X			Internal Memory Error	Turn Key OFF, then ON Call service if error persists.
1-3	Clock Failure	X			Footswitch has malfunctioned or been disconnected	Turn Key OFF, then ON Call service if error persists.
1-4	Board Temperature out of range		X		Internal Temperature is outside operating specifications	Let temperature stabilize until error clears. Call service if error persists.
1-10	Laser Temp Range		X		Laser Temperature is outside operating specifications	Let temperature stabilize until error clears. Call service if error persists.
1-11	Laser Over Current	X			Laser/aiming beam over current detected	Turn Key OFF, then ON Call service if error persists.
1-12	Laser Power Monitor Failure	X			Power detectors not responding	Turn Key OFF, then ON Call service if error persists.
1-13	Laser Power Out of Range	X			Power detectors reading outside calibrated range	Turn Key OFF, then ON Call service if error persists.
1-30	Footswitch not detected	X			Footswitch not responding	Check foot switch connection and cable for damage. Call service if error persists.
1-40	Interlock Reset Timeout		X		Interlock not reset in time	Check interlock Connection Turn Key OFF, then ON Call service if error persists.
1-41	Interlock Power Low		X		Interlock voltage too low or not present	Check interlock Connection Turn Key OFF, then ON Call service if error persists.
1-42	Interlock Door Open		X		Door Interlock connection is OPEN	Close Room Door Check Door interlock Connection Turn Key OFF, then ON
1-43	Interlock Key Switch	X			Key Switch Contacts Failure	Turn Key OFF, then ON Call service if error persists.

Code	Message	Critical	Clearable	Warning	Description	Action
1-44	Interlock Relay Failure	X			Key Switch Relay Contacts Failure	Turn Key OFF, then ON Call service if error persists.
1-45	Emergency Shut Down		X		Emergency Off Switch Engaged	Turn Key OFF, then ON Call service if error persists.
1-61 to 1-91	Analog Signal Integrity	X			Hardware error	Turn Key OFF, then ON Call service if error persists.
1-100	Battery temperature out of range	X			Battery temperature out-of-range	Turn Key OFF, then ON Call service if error persists.
1-101	Battery charger	X			Unknown charger	Connect the Norlase LION Power supply. Call service if error persists.
2-1	Failed to create Bluetooth adapter	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-2	Failed to create Bluetooth LE Scanner	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-3	Failed to create Bluetooth GATT	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-4	Failed to initiate Create Bond	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-5	Failed to initiate Set Pin	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-6	Failed to create Bluetooth device	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-7	Failed to initiate discover services	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-8	Failed to discover services	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-9	Failed to create Bluetooth GATT Services	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-10	Failed to bond to correct device	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-11	Failed to validate Services	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-12	Characteristic indication unexpected	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-13	Characteristic read empty queue	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.

Code	Message	Critical	Clearable	Warning	Description	Action
2-14	Characteristic read queue mismatch type	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-15	Characteristic read queue mismatch UUID	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-16	Characteristic read Bad size	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-17	Characteristic read unexpected	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-18	Characteristic write empty queue	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-19	Characteristic write queue mismatch type	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-20	Characteristic write queue mismatch UUID	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-21	Characteristic write queue mismatch value	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-22	Characteristic write bad size	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-23	Characteristic write unexpected	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-24	Characteristic write empty queue	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-25	Characteristic write queue mismatch type	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-26	Characteristic write queue mismatch C UUID	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-27	Descriptor write queue mismatch D UUID	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-28	Descriptor write queue mismatch value	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-29	Failed to delete bond	X			Bonding failure	Turn Key OFF, then ON & reboot tablet Call service if error persists.
2-30	Failed descriptor write sync			X	Bonding failure	Verify hardware is powered on and within range Call service if error persists.

Code	Message	Critical	Clearable	Warning	Description	Action
2-31	Failed descriptor write Async			X	Bonding failure	Verify hardware is powered on and within range Call service if error persists.
2-32	Failed characteristic read sync			X	Bonding failure	Verify hardware is powered on and within range Call service if error persists.
2-33	Failed characteristic read Async			X	Bonding failure	Verify hardware is powered on and within range Call service if error persists.
2-34	Failed characteristic write sync			X	Bonding failure	Verify hardware is powered on and within range Call service if error persists.
2-35	Failed characteristic write Async			X	Bonding failure	Verify hardware is powered on and within range Call service if error persists.
2-36	Action timed out			X	Bonding failure	Verify hardware is powered on and within range Call service if error persists.
3-1	Failed to create USB manager	X			Cable communication error	Turn Key OFF, then ON & reboot tablet Call service if error persists.
3-2	Read when closed	X			Cable communication error	Turn Key OFF, then ON & reboot tablet Call service if error persists.
3-3	Write failed	X			Cable communication error	Turn Key OFF, then ON & reboot tablet Call service if error persists.
3-4	Read failed	X			Cable communication error	Turn Key OFF, then ON & reboot tablet Call service if error persists.
3-5	Reading timed out	X			Cable communication error	Turn Key OFF, then ON & reboot tablet Call service if error persists.
3-6	Bad SOT	X			Cable communication error	Turn Key OFF, then ON & reboot tablet Call service if error persists.
3-7	Bad escape	X			Cable communication error	Turn Key OFF, then ON & reboot tablet Call service if error persists.
3-8	Received NACK	X			Cable communication error	Turn Key OFF, then ON & reboot tablet Call service if error persists.
3-9	Received Busy	X			Cable communication error	Turn Key OFF, then ON & reboot tablet Call service if error persists.
3-10	Received ACK	X			Cable communication error	Turn Key OFF, then ON & reboot tablet Call service if error persists.
3-11	Received READ	X			Cable communication error	Turn Key OFF, then ON & reboot tablet Call service if error persists.

Code	Message	Critical	Clearable	Warning	Description	Action
3-12	Received Write	X			Cable communication error	Turn Key OFF, then ON & reboot tablet Call service if error persists.
3-13	Bad message size MAC	X			Cable communication error	Turn Key OFF, then ON & reboot tablet Call service if error persists.
3-14	Bad message size key	X			Cable communication error	Turn Key OFF, then ON & reboot tablet Call service if error persists.
3-15	Unknown message header	X			Cable communication error	Turn Key OFF, then ON & reboot tablet Call service if error persists.
3-16	Unknown register	X			Cable communication error	Turn Key OFF, then ON & reboot tablet Call service if error persists.
3-17	Failed to close	X			Cable communication error	Turn Key OFF, then ON & reboot tablet Call service if error persists.
4-1	Files vanished	X			Files system error	Reboot tablet Call service if error persists.
4-2	Files Remove	X			Files system error	Reboot tablet Call service if error persists.
4-3	Settings bad format	X			Files system error	Reboot tablet Call service if error persists.
4-4	Settings read error	X			Files system error	Reboot tablet Call service if error persists.
4-5	Settings too long	X			Files system error	Reboot tablet Call service if error persists.
4-6	Settings failed read open	X			Files system error	Reboot tablet Call service if error persists.
4-7	Settings write error	X			Files system error	Reboot tablet Call service if error persists.
4-8	Settings failed write open	X			Files system error	Reboot tablet Call service if error persists.
4-9	Settings Checksum Mismatch	X			Files system error	Reboot tablet Call service if error persists.
4-10	Settings Stream Error	X			Files system error	Reboot tablet Call service if error persists.
4-11	Presets bad format	X			Files system error	Reboot tablet Call service if error persists.
4-12	Presets read error	X			Files system error	Reboot tablet Call service if error persists.
4-13	Presets too long	X			Files system error	Reboot tablet Call service if error persists.
4-14	Presets failed read open	X			Files system error	Reboot tablet Call service if error persists.

Code	Message	Critical	Clearable	Warning	Description	Action
4-15	Presets write error	X			Files system error	Reboot tablet Call service if error persists.
4-16	Presets failed write open	X			Files system error	Reboot tablet Call service if error persists.
4-17	Presets Checksum Mismatch	X			Files system error	Reboot tablet Call service if error persists.
4-18	Preset Stream Error	X			Files system error	Reboot tablet Call service if error persists.
4-19	Record bad format	X			Files system error	Reboot tablet Call service if error persists.
4-20	Record read error	X			Files system error	Reboot tablet Call service if error persists.
4-21	Record too long	X			Files system error	Reboot tablet Call service if error persists.
4-22	Record failed read open	X			Files system error	Reboot tablet Call service if error persists.
4-23	Record write error	X			Files system error	Reboot tablet Call service if error persists.
4-24	Record failed write open	X			Files system error	Reboot tablet Call service if error persists.
5-1	Invalid System Mode	X			Laser parameter error	Turn Key OFF, then ON Call service if error persists.
5-2	Invalid Power	X			Laser parameter error	Turn Key OFF, then ON Call service if error persists.
5-3	Invalid Duration	X			Laser parameter error	Turn Key OFF, then ON Call service if error persists.
5-4	Invalid Interval	X			Laser parameter error	Turn Key OFF, then ON Call service if error persists.
5-6	Invalid Aiming Intensity	X			Laser parameter error	Turn Key OFF, then ON Call service if error persists.
5-7	Invalid Volume	X			Laser parameter error	Turn Key OFF, then ON Call service if error persists.
5-10	Invalid Warnings	X			Laser parameter error	Turn Key OFF, then ON Call service if error persists.
6-1	Auto-Off			X	Laser console is sleeping. Cycle on/off key switch to wake it up.	Turn Key OFF, then ON Call service if error persists.
6-2	Battery too low			X	Battery is too low for treatment	Connect Norlase LION power supply.
6-3	Door interlock is open			X	Interlock Open	Close door, Check interlock Call service if error persists.
6-5	System needs service soon			X	Near service parameters	Call service if error persists.
7-1	Failed to open serial connection			X	Laser Error	Verify bonding cable is connected Turn Key OFF, then ON & reboot tablet Call service if error persists.

Code	Message	Critical	Clearable	Warning	Description	Action
7-2	Failed to get response over serial			X	Laser Error	Verify bonding cable is connected Turn Key OFF, then ON & reboot tablet Call service if error persists.
7-3	Failed to bond			X	Laser Error	Verify bonding cable is connected Turn Key OFF, then ON & reboot tablet Call service if error persists.
7-4	Failed to connect			X	Laser Error	Verify laser is turned ON Turn Key OFF, then ON & reboot tablet Call service if error persists.
7-5	System mode not ready in time			X	Laser Error	Turn Key OFF, then ON Call service if error persists.
7-7	Pressed footswitch while in Standby			X	Laser Error	Place unit into Treat mode Call service if error persists.
7-8	Pressed footswitch while entering Treat			X	Laser Error	Wait until after 3 second delay entering treat Call service if error persists.
7-9	Pressed footswitch while laser is disabled			X	Laser Error	Wait after modifying parameters before pressing footswitch Call service if error persists.
7-10	Lost connection			X	Laser Error	Turn Key OFF, then ON Call service if error persists.

Calibration Check Procedure

Regulatory agencies require that manufacturers of US FDA CDRH Class II and IV medical lasers supply customers with power calibration check instructions.

Calibration must be performed by Norlase-certified personnel qualified to work on energized electronic laser equipment.

Disclaimer Warning

Calibration of the Norlase LION is a service procedure to be performed only by Norlase-certified personnel. Measurement or adjustment by anyone other than Norlase-certified personnel voids any existing manufacturer's warranty on the instrument and can result in serious personal injury.

Calibration Check Instructions

Note: At certain Power or Duration settings, the range of adjustment may be limited.

Tools Required:

- NIST-traceable calibrated optical power meter capable of measuring >1.5 W at 520nm at less than one second duration.

1. Energize the LION system and user interface tablet.
2. Set the system at 500 mw Power, 1000ms Duration
3. Enter TREAT mode and ensure aiming beam is a minimum of 3 mm diameter on the power meter detector.
4. Ensure all personnel in the area are wearing laser safety glasses labeled for protection of OD>5 (ANSI Z136.1) or D LB>6 (EN 207) at 520 nm.
5. Press and hold the footswitch for the entire one second and read the power output. Power should measure between 400-600 mw.
6. If power level is outside specification please call Norlase Technical Support or a Norlase authorized Distributor.
7. If power is within specification, record the measurement and date for future reference.

Device Relocation Instructions

To move Norlase LION to another location:

1. Ensure that the LION device is powered OFF and the Key is removed.
2. Gently coil electrical cables and place the LION in the carry case or a protective enclosure.
3. If a remote door interlock is utilized, remove the interlock plug and cable from the interlock port and transport separately.
4. Ensure the tablet control panel travels with the LION that it is paired with. The tablet control panels ARE NOT interchangeable with other LION systems.
5. If there are changes in environmental conditions (temperature or humidity) allow the device to acclimate for 4 hours prior to use to prevent condensation.

Room Preparation

1. Verify that the device foot switch power cable is correctly connected, as instructed in the preoperative instructions.
2. Verify environmental conditions are within limits for operation.
3. Place the device on a wall hook or a place that is safe and will not interfere with normal foot traffic in the exam room.
4. Verify that the laser warning sign has been posted outside of the treatment room door.
5. Ensure that all attending personnel in the treatment room are wearing appropriate eye protection goggles or eyeglasses while the device is in use.

General Safety and Regulatory Information

Norlase laser devices are precision medical instruments. The devices have undergone extensive testing. With proper handling, they are useful and reliable clinical instruments. To protect operating personnel and patients, this safety section should be read thoroughly before operation.

Norlase lasers are classified as Class IV lasers by the National Center for Devices and Radiological Health. Class IV represents the highest power lasers; for this reason, the user must take precautions to prevent exposure of laser energy to the eye and skin from either direct or diffusely reflected laser beams, except as a therapeutic application. In addition, precautions must be taken in the surgical environment to prevent the hazards of fire and electrical injury.

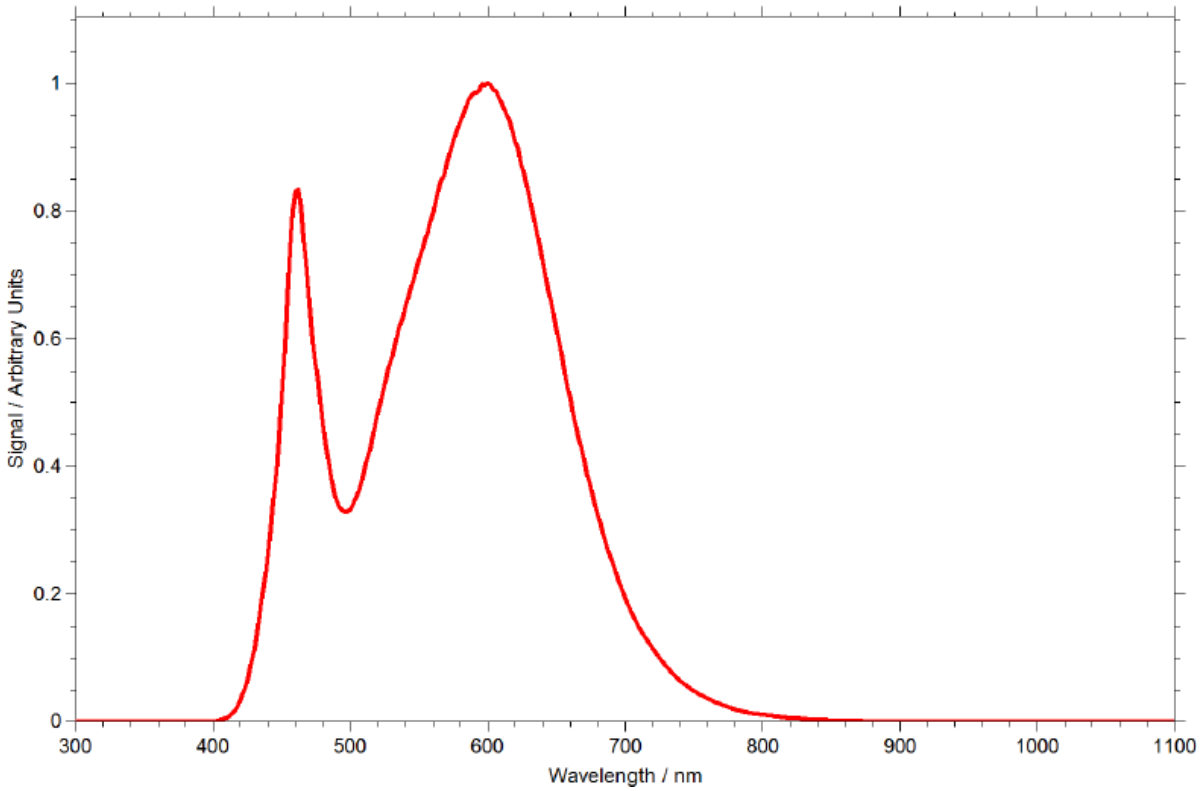
Norlase does not recommend specific clinical practices as the device is intended for use by or on the order of a licensed physician. The following precautions are extensive but may not be complete. Laser users are advised to supplement this information with technological advances in surgical products and techniques as they become available to the medical laser user community through medical literature. See also the American National Standard Institute (ANSI) publications ANSI Z136.3-2005—American National Standard for the Safe Use of Lasers in Health Care Facilities, ANSI Z136.1-2000—American National Standard for the Safe Use of Lasers, CAN/CSA-S386-2008—Laser Safety in Health Care Facilities and other national standards as may be applicable for the country in which the device is used.

Safety considerations – Illumination

It is well established that exposure of the eye to intense light sources for extended periods of time poses a risk of retinal photic injury. Many ophthalmic instruments illuminate the eye with intense light. The decision about the intensity of the light level to use in any procedure must be made on a case by case basis. In each case, the clinician must take a risk benefit judgement about the intensity of light to be used. Use of insufficient intensity may result in inadequate visualization and in adverse effects more serious than retinal photic damage. Further, despite all efforts taken to minimise the risk of retinal damage, damage may still occur. Retinal photic injury is a possible complication of the need to use bright light to clearly visualize ocular structure during delicate ophthalmic surgical procedure.

While no visible retinal lesions have been identified for ophthalmic instruments, it is recommended that illumination levels be set to the minimum level necessary to perform the function. Young children and persons with diseased eyes may be at a higher risk. The risk may also be increased if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using an intense visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography.

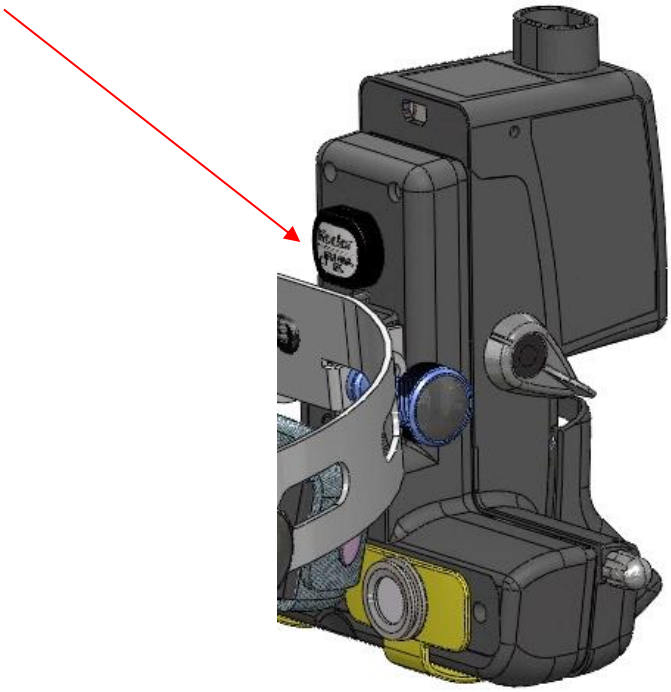
The light emitted from this device is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this device when operated at maximum intensity will exceed the safety guideline after 60 minutes using an ancillary 20D lens.



Relative spectral output of LED light source

WARNINGS

Under some single fault conditions, the temperature of the surface shown below could get hot and there is a possible risk of a burn if touched.



Ocular Protection

Never look directly into the laser aperture or scattered laser light from reflective surfaces when the treatment beam is activated. Severe eye damage could occur.

Never look into the path of a laser beam. Laser safety eyewear only offers protection against stray or diffuse laser beam energy for a maximum exposure of 10 seconds.

Never substitute glass prescription eyewear for the appropriate laser safety eyewear, as severe eye damage could occur. The glass in prescription eyewear can concentrate the laser light onto the retina. A laser beam with high energy density can also shatter glass prescription eyewear, resulting in possible severe eye damage.

Do not use eyewear that is broken or damaged.

The  *(laser emission) indicator is displayed on the Treatment screen to warn the user that the device is capable of emitting laser energy. Appropriate precautions, such as wearing appropriate eyewear in the room, should be taken.*

As a precaution against accidental exposure to the output beam or its reflection, anyone checking or adjusting calibration should wear appropriate laser safety eyewear.

Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged and the brightness setting should not exceed what is needed to provide clear visualization of the target structures. This device should be used with filters that eliminate UV radiation (<400 nm) and, whenever possible, short-wavelength blue light (<420 nm).

The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. If the value of radiance were reduced in half, twice the time would be needed to reach the maximum exposure limit.

While no acute optical radiation hazards have been identified for Laser Indirect Ophthalmoscopes, it is recommended that the intensity of light directed into the patient's eye be limited to the minimum level that is necessary for diagnosis. Infants, aphakes and persons with diseased eyes will be at greater risk. The risk may also increase if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography.

The red diode laser aiming beam has an average power varying from barely visible to 1 mW maximum. The safe (Class II) exposure duration limit at a maximum power level of 1 mW is 3.9 seconds. To protect the patient from possible retinal damage during treatment, use the lowest practical aiming beam intensity and the minimal required time duration.

The light emitted from the red diode laser aiming beam is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to the red diode laser aiming beam when operated at maximum intensity will exceed the safety guideline after 3.9 seconds.

Laser Safety Eyewear

Laser safety eyewear is routinely required with most lasers. When using the Norlase LION, the laser safety officer should determine the need for safety eyewear based on the Maximum Permissible Exposure (MPE), Nominal Hazard Zone (NHZ) and the Nominal Ocular Hazard Distance (NOHD) for each of the available laser wavelengths, as well as the wavelength itself and the configuration of the treatment room (usually within the controlled area).

ANSI Standard Z136.1-2007 defines MPE as “the level of radiation to which a person may be exposed without hazardous effect or adverse biological changes in the eye or skin”; the NHZ as “the space within which the level of direct, reflected or scattered radiation during normal operation is not expected to exceed the applicable MPE”; and the NOHD as “the distance along the axis of the unobstructed beam from the laser to the human eye beyond which the irradiance or radiant exposure during operation is not expected to exceed the appropriate MPE.”

The NOHD is measured from the delivery system laser aperture. ANSI defines the controlled areas as “an area where the occupancy and activity of those within is subject to control and supervision for the purpose of protection from laser radiation hazards.

All personnel who are within the NOHD are considered to be in the controlled area and shall wear eye protection with the appropriate optical density. Eyewear must be resistant to physical damage and photo-bleaching. The minimum optical density (OD) is 5 at 520 nm. For countries inside Europe and that comply with EN 207, the eyewear must have a protection class of D LB6 at 520 nm.

Delivery Device	**NOHD (520nm)**
Laser Indirect Ophthalmoscope (LIO)	74 m (243’)

NOTE

The type of eye protection recommended for the physician, the patient, and/or treatment room personnel within the NHZ depends on the planned procedure and the equipment required to perform that procedure.

Eye safety filters are provided with the Norlase LION and are required for safe use. Laser safety eyewear is not required by the physician who views the procedure through the LION eyepieces. All other personnel within the NHZ must wear laser safety eyewear with the recommended optical density and protection wavelength.

Along with providing the appropriate safety eyewear, the following steps should be taken to secure the controlled area:

1. Treatment should be conducted in a dedicated, enclosed room.
2. A warning sign should be placed on the outside of the treatment room door when the laser is in use. The sign is intended to alert personnel before they enter the controlled area.
3. The treatment room door should be kept closed during treatment.

Electrical Hazards

To avoid the risk of electric shock, do not touch any external connector and the patient simultaneously.

Do not use power cables or power supply other than those provided with the system. Do not use extension cables with the system.

Disconnect the device from the electrical outlet when inspecting the fuses. Only certified personnel shall inspect fuses.

Never open the laser console protective covers. Opening the covers will expose you to high voltage components, and possible laser radiation. Only certified personnel shall service any portion of the laser console.

The area around the headset and footswitch shall be kept dry. Do not operate the laser if any of the cords are faulty or frayed. The device should undergo routine inspection and maintenance per the Norlase manufacturer's recommendation and institutional standards.

Although not required for the operation of the device, an additional staff member trained in CPR should be present any time equipment is used utilizing line voltage power.

Do not pull or stress any cables. Do not exceed bend radius of 15 cm Do not set items on or under the cable assembly.

Fire Hazard

Do not use the device in the presence of flammables or explosives such as volatile anesthetics, alcohol, certain surgical preparation solutions or other such substances. An explosion and/or fire could occur.

The treatment beam can ignite most nonmetallic materials. Use fire retardant drapes and gowns. The area around the treatment site can be protected with towels or gauze sponges moistened with sterile saline solution or sterile water. If allowed to dry, protective towels and sponges can increase the potential fire hazard. A UL-approved fire extinguisher should be readily available.

Per IEC 60601-2-22: The use of flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen should be avoided. Some materials (e.g., cotton wool) when saturated with oxygen may be ignited by the high temperatures produced in normal use of Norlase LION. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the device is used. Attention should also be drawn to the danger of ignition of endogenous gases.

Protecting Non-target Tissues

Never place hands or other objects in the path of the laser beam. Severe burns could occur.

Except during actual treatment, the device must always be in STANDBY mode. Maintaining the device in STANDBY mode prevents accidental laser exposure if the footswitch is inadvertently depressed.

Only the person aiming the laser beam should have access to the footswitch. Use caution depressing the footswitch when it is in proximity to a footswitch for other equipment. Make sure the footswitch depressed is the correct one to avoid accidental laser exposure.

Operational Safety

Read this operating manual thoroughly and be familiar with its contents prior to using this device.

Verify eye safety filters are installed in each ocular of the Norlase LION.

Verify adjustments to laser parameters on the tablet control panel before pressing the footswitch.

When the device is in READY mode, if the aiming beam is not present, is distorted, or is incomplete, do not proceed with treatment. Turn off the device and contact service.

It is the responsibility of the physician to select appropriate combinations of repetition rate and exposure time to avoid overexposure or unintended exposure.

Early release of the footswitch will terminate the treatment beam before the complete pulse duration has been delivered.

Do not use wide field contact lenses for macular grid photocoagulation. Wide field lenses will enlarge the spot diameter and alter the Foveal Exclusion Zone ring diameter.

If the device becomes unresponsive at any time other than during laser emission, do not press the emergency laser stop button. Instead, turn the key to the OFF position. Wait at least one minute before restarting the device using the key switch.

If the tablet control panel will not connect to the laser console for more than 60 seconds during device start-up, verify that the power indicator LED on the side of the laser console is illuminated. If it is not illuminated, then check that the laser console is connected to the footswitch and turn the laser console off and on with the key. If the LED is still not illuminated then connect the footswitch to the power supply and ensure it charges for at least 5 minutes before trying to turn on the laser console with the key. If the laser console still has no power, turn off the laser console and contact service.

It may take longer for the device to achieve a ready state in a low-temperature environment.

It is the responsibility of the physician to verify that the aiming beam spot visualized through the Norlase LION is the expected size. If the aiming beam size appears inappropriate or distorted, do not proceed with treatment. If the problem persists, contact Norlase service or your authorized Distributor.

It is the responsibility of the physician to select the appropriate power and treatment location. The lowest practical setting should always be used to achieve the desired clinical outcome.

Do not use a wet cloth to clean the tablet control panel screen. Doing so may damage the screen.

Additional Safety Considerations

US federal law restricts this device to sale by or on order of a physician.

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Norlase medical devices are solely for use by physicians trained in the operation of laser photocoagulation and associated delivery devices.

To avoid potential injury to the user and the patient and/or damage to this device, the user must:

- *Read this manual thoroughly and be familiar with its contents prior to using this device.*
- *Be a qualified physician, having complete knowledge of the use of this device.*
- *Test this device prior to a procedure.*
- *Attempt no internal repairs or adjustments not specifically detailed in this manual.*

Do not modify this device without authorization of the manufacturer.

When the Norlase LION is interconnected with other medical electrical equipment, leakage currents may be additive. Ensure all systems are installed according to the requirements of IEC 60601-1. Do not use cables or accessories other than those provided with the device, as this may result in the increased electromagnetic emissions or decreased immunity to such emissions.

If the Norlase LION is used adjacent to or stacked with other equipment, observe and verify normal operation of the Norlase LION in the configuration in which it will be used prior to use.

Condensation may occur if the device is exposed to high humidity for an extended period of time.

Vibration or physical shock may affect the quality, performance, and reliability of the device.

Regulatory Compliance Safety Features

Norlase LION complies with 21 CFR subchapter J as administrated by the Center for Devices and Radiological Health of the Food and Drug Administration (FDA). The following FDA compliance safety features are included:

Key Lock Switch

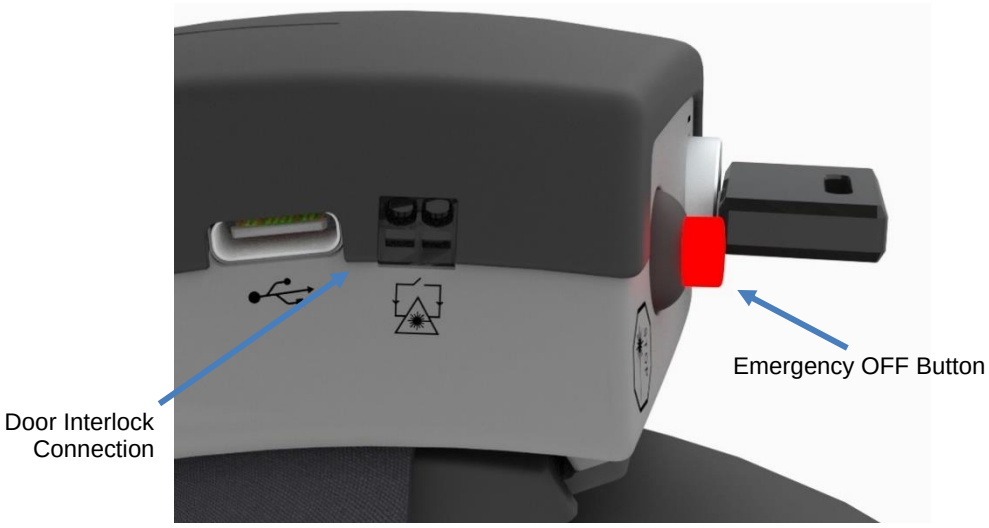
The device can be activated only with the proper key to operate the master key switch. The key cannot be removed in the ON position and the system will operate only with the key in place. When treatments are complete, always remove and secure the key to prevent unauthorized use of the device.

Laser Emission Indicator

A laser emission indicator is displayed to warn the user that the device is capable of emitting laser energy and that appropriate precautions should be taken, such as using the appropriate eyewear when in the treatment room.

Door Interlock

A door interlock may be used in conjunction with a remote switch to disable the device in case of certain external events (e.g., the opening of a treatment room door). A remote switch or interlock can be wired to the door interlock connection and connected to pins 1 & 2 on the interlock receptacle on the bottom of the laser console. If a remote switch is used, the device can be set in the READY mode only when the remote switch is closed. Breaking the connection by opening the switch (door) disables the device and the device returns to STANDBY mode with “<Door Interlock>” displayed on the tablet control panel. The switch must have a maximum of 40 ohms and >1500 V isolation.



Emergency Stop

When pressed, immediately turns off power to the laser.

Protective Housing

The laser console has a protective housing that prevents unintended human access to laser radiation above Class I limits. This housing is to be opened only by Norlase-certified personnel.

Safety Interlocks

The protective housing is not designed to be removed by the user during operation or maintenance. Therefore, the device does not have and is not required to have any safety interlock within the meaning of US FDA 21 CFR, Section 1040 or European EN 60825-1.

Safety Shutter

The device utilizes an electronic laser safety shutter. The device will not be able to emit laser light unless all safety conditions are met prior to depressing the footswitch. The safety shutter is activated when the device is off, during the self-test at turn-on, in STANDBY mode or when the safety monitor detects a fault.

Location of Controls

Controls are located on the tablet control panel.

Manual Reset

If laser emission is externally interrupted during treatment by activation of the door interlock, the device will automatically go into STANDBY and the safety shutter will revert to a closed position. To resume treatment, reset the device by placing the laser in READY.

If laser emission is interrupted by low battery, the device will automatically turn off. To resume treatment, connect the Norlase LION power supply to the footswitch and manually restart the device by rotating the key switch first to the OFF and then to the ON position.

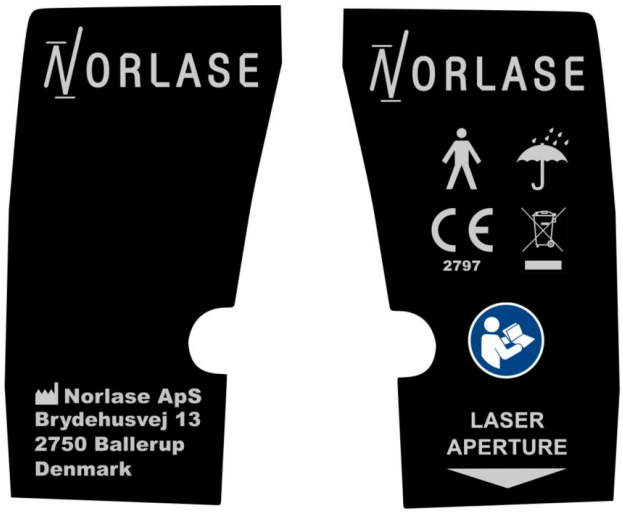
Electrical Fault Detection Circuitry

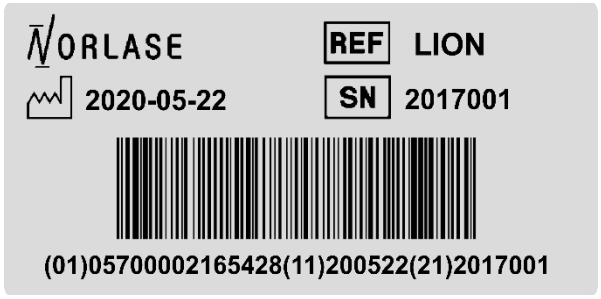
If the electronic system detects a fault condition, laser exposure cannot occur. The laser is disabled, the safety shutter is closed and the footswitch is disabled. Some fault conditions may be cleared by the User. See “Troubleshooting” for additional information.

Location of Regulatory and Other System Labels

As required by the regulatory bodies, appropriate warning labels have been mounted in specified locations on the device to indicate conditions under which the user could be subjected to laser radiation. Location and description of caution, warning and system labels are described on the following pages.

Norlase LION Labelling



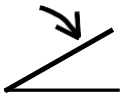


Device Information Labels include:

- Manufacturer
- Reference Number
- Serial Number
- Manufacture Date
- User must consult instruction for use for important cautionary information such as warnings and precautions
- This product is to be disposed in a separate collection of electrical and electronic equipment
- Type B applied part
- Keep dry symbol
- CE Mark

Barcode on silver label: The Unique Device Identification (UDI) is a system used to mark and identify medical devices within the healthcare supply chain**.**

Emergency Stop

	**Danger label (US) includes:** • Laser Emission Warning • Wavelength • Power • Laser Class
	**Laser warning label (EU) includes:** • Laser Emission Warning • Wavelength • Power • Laser Class • Standard reference
	**USB Connections**
	**Battery Charging Port**
	**Remote Door Interlock Connection**
	**Footswitch Connection**
I	**ON**
O	**OFF**

Norlase LION headset Labels

Manufacturer and warning labels locations.

Top: DANGER Label Location (US). Bottom: Laser warning label (EU))

Left Side Labeling

Right Side Labeling

Foot Switch Label

Additional Labels

Footswitch label[1]:

Control Tablet Label[1]:

Power Supply Label[1]:

[1] "XX" denotes the version number.

Electromagnetic Compatibility

Like other electrical medical devices, the Norlase LION require special precautions to ensure electromagnetic compatibility (EMC) with other electrical medical devices. To ensure EMC, the Norlase LION must be installed and operated according to the EMC information provided in this manual.

NOTE

The Norlase LION have been designed and tested to comply with EN/IEC 60601-1-2:2015 requirements for EMC with other devices.

Consult the tables below for guidance in placing the device.

<table>
<tr><th colspan="3">Guidance and Manufacturer's Declaration: Electromagnetic Emissions</th></tr>
<tr><td colspan="3">Norlase LION is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic Environment: Guidance</th></tr>
<tr><td>Conducted emissions EN 55011:2009+A1:2010, CISPR 11:2009+A1:2016, FCC Part 15 Subpart B: 2011.</td><td>Class B
Group 1
150 kHz to 30 MHz</td><td rowspan="2">Norlase LION uses RF energy only for 2.4 GHz wireless; therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>Radiated Emissions EN 55011:2009+A1:2010, CISPR 11:2009+A1:2010, FCC Part 15 Subpart B: 2011.</td><td>Class B Group 1
30 MHz to 1 GHz</td></tr>
</table>

Guidance and Manufacturer's Declaration: Electromagnetic Immunity			
Norlase LION is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment: Guidance**
Electrostatic Discharge (ESD) IEC61000-4-2:2009	± 8 kV contact ± 2, 4, 8, 15 kV Air	± 8 kV contact ± 2, 4, 8, 15 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 IEC61000-4-4:2012	±2kV for power supply lines ±1kV for input/output lines	±2kV line to ground ±1kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
urge Line to Line (AC Power) IEC/EN 61000-4-5:2014	±1 kV Line to Line	±1 kV Line to Line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips & Interruptions IEC/EN 61000-4-11:2004	0% Ut 0.5 cycle at: 0, 45, 90, 135, 180, 225, 270, 315 degrees 0% Ut 1 cycle at: 0 degrees 70% Ut 25 cycles at: 0 degrees 0% Ut 250 cycles at: 0 degrees	0% Ut 0.5 cycle at: 0, 45, 90, 135, 180, 225, 270, 315 degrees 0% Ut 1 cycle at: 0 degrees 70% Ut 25 cycles at: 0 degrees 0% Ut 250 cycles at: 0 degrees	If the user of the EUT requires continued operation during power mains interruptions, it is recommended that the Norlase LION be powered from an uninterruptible power supply or a battery.
Magnetic Immunity IEC/EN-61000-4-8:2009	30 A/m 50/60 Hz	30 A/m 50/60 Hz	Video display terminals and other electron-beam devices (e.g. X-ray image intensifiers) may use a justification for lower IMMUNITY COMPLIANCE LEVELS as allowed by 6.2.1.10).
NOTE: Ut is the a.c. mains voltage prior to application of the test level.			

<table>
<tr><th colspan="4">Guidance and Manufacturer's Declaration: Electromagnetic Immunity</th></tr>
<tr><td colspan="4">Norlase LION is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.</td></tr>
<tr><th>Immunity Test</th><th>IEC 60601 Test Level</th><th>Compliance Level</th><th>Electromagnetic Environment: Guidance</th></tr>
<tr><td>Radiated Immunity
IEC/EN 61000-4-3:2006 + A1 + A2</td><td>80 MHz - 2.7 GHz
3 V/m 80% @ 1 kHz</td><td>80 MHz - 2.7 GHz
3 V/m 80% @ 1 kHz</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the laser system, including its cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended Separation Distance

d = 1.17 / P

d = 1.17 / P 80 MHz to 800 MHz

d = 2.33 / P 800 MHz to 2.5 GHz

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

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:
  </td></tr>
<tr><td>Conducted Immunity (AC Power)
(I/O Lines)
IEC/EN 61000-4-6:2014</td><td>0.15 - 80 MHz 3 Vrms (6 Vrms at ISM bands) 80% @1 kHz
AC Mains</td><td>0.15 – 80 MHz 3 Vrms (6 Vrms at ISM bands) 1 kHz
AC Mains</td></tr>
<tr><td colspan="4">NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.</td></tr>
<tr><td colspan="4">NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</td></tr>
<tr><td colspan="4">(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field Strength in the location in which the laser system is used exceeds the applicable RF compliance level above, the laser system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the laser system.
(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and Norlase LION			
Norlase LION is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power (W) of transmitter	**Separation distance (m) according to frequency of transmitter**		
	150kHz to 80MHz d = 1.17 P	**80MHz to 800MHz** d = 1.17 P	**800 MHz to 2.5 GHz** d = 2.33 P
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 meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No 50, dated June 24, 2007.

Unexpected electromagnetic waves or other electronic interference may cause an unexpected device response that results in a potentially dangerous condition. Do not use this device if abnormal operation is observed in the presence of other equipment.

Indications for Use

The Norlase LION Photocoagulator is intended to be used in ophthalmic laser procedures including retinal and macular photocoagulation, iridotomy, and trabeculoplasty.

Usage Precautions (Before Use)

- Use of this device is limited to the treatment of ocular disease by qualified physicians in accordance with the instructions contained in this Operator Manual. Physicians are responsible for any use other than specified in this Operator Manual.
- This Operator Manual must be read before use and all safety precautions and use of the device must be thoroughly understood. Adverse events and adverse device effects may occur if this manual is not read and understood.
- A restricted pupil may clip the laser delivery to target tissue and cause unwanted burns to the iris. Use caution if presented with a restricted pupil.
- Only Norlase-certified personnel are allowed to adjust or service the device. Norlase will make available on request circuit diagrams, component part lists, calibration instructions or other information that will assist service personell. All warranty and product liability are void if other than a Norlase-certified personnel services the equipment.
- Never use an accessory or attachment that is not certified by Norlase.
- Never modify or touch the internal components or optical elements of the system. Electric shock or device malfunction may occur.
- Do not operate the device where flammable anesthetic gas is used.
- All personnel, other than the doctor and patient, in the space where the device is being used must wear adequate laser safety glasses as described in the section Norlase LION Specifications of this manual. Instructions must also be given to avoid direct viewing of the laser emission, even if wearing the laser safety glasses.
- Never leave the device unattended while ready for use. The key can be removed to prevent unauthorized use of the device.
- Be sure the line voltage is within the range of 90-240VAC when using charging power supply.
- Only use the device if the environmental conditions are within the specifications listed in this manual under the Norlase LION Specifications section.
- If the device is stored at any temperature under 60°F (15.6C) or over 80° F (26.7C), it must sit at room temperature for at least two hours before being used. Failure to do so may cause permanent damage to the device.
- Avoid installing the device under direct air flow from an air conditioner.
- Securely connect all cords and cables to their connectors.
- Never use power strips or extension cords to connect the device.

Usage Precautions (During Use)

- Use of this device other than specified in the instructions contained in this Operator Manual may result in hazardous exposure to laser radiation.
- To prevent accidental laser exposure, never look directly at the aiming beam emitted from the laser aperture or point the aiming beam towards others.
- When the treatment beam (520nm) is applied to tissue, the following symptoms may occur:
    - Ocular symptoms: Damage to the cornea, sclera, lens, anterior or posterior structures causing permanent, partial or temporary blindness
    - Skin symptoms: Pain, burns
- If any device errors are encountered, stop treatment and follow device instructions, or call Norlase technical support or an authorized distributor.
- If any adverse events are encountered, they must be reported to the proper regulatory authorities.
- The user is responsible for ensuring the appropriate safeguards are in place to prevent unauthorized access into the Norlase LION or tablet control panel.
- Confirm that no reflective objects are in the laser beam path.
- If the user encounters green laser flashback through the Norlase LION oculars, stop treatment and check the integrity of the laser eye safety filters before proceeding. If there is any doubt as to the integrity of the safety filters, do not use the device and call Norlase technical support or an authorized distributor.
    - It is normal to see orange/yellow fluorescence from the target site, especially when using high power levels.
- Each procedure should start with titration and slowly increasing the power level until the desired effect is obtained.
- At the end of each treatment, the END button should be pressed to return the device to STANDBY and reset to default parameters.
- Laser lenses have magnification factors that manipulate the delivered laser spot size by either increasing or decreasing the diameter from the user interface setpoint. Please consider the laser lens magnification when adjusting power levels.
- US Federal law restricts this device to sale by or order of a physician or practitioner.

- This device must only be used by clinicians trained in the use of Ophthalmic Laser devices.
- All attending personnel must wear laser safety glasses matching the operating wavelength of the laser.
- The Norlase LION contains safety filters to reduce reflected laser light to safe levels for users. Always look through the ophthalmoscope when the therapy beam is activated. Do not look over the ophthalmoscope when the therapy beam is activated.
- Check the product for signs of transport / storage damage. Do not use if the product is visibly damaged, and periodically inspect for signs of damage.
- Test the Norlase LION functionality prior to use.
- In order to minimise risk of patient movement during operation, ensure patient has been adequately prepared.
- Minimise all possible distractions prior to commencement of treatment.
- Ensure the headband is secure to remove the risk of movement during treatment.
- Route foot switch power cords to eliminate risk of tripping or damage to the device.

- Ensure the foot switch cable is routed carefully and has enough slack to prevent tugging or snagging during treatment.
- Do not use in the presence of flammable gases / liquids, or in an oxygen rich environment.
- LED's can reach high temperatures in use – allow to cool before handling.

- Do not exceed maximum recommended exposure time.

- The device should not be immersed in fluids.
- Service should only be conducted by Norlase-certified personnel. No modification of the device is allowed.
- Do not disassemble or modify the battery. There are no serviceable parts inside.
- Use only genuine Norlase approved parts and accessories or device safety and performance may be compromised.
- Follow guidance on cleaning/routine maintenance to prevent personal injury / damage to the device.
- Do not use if battery casing in foot switch or battery is deformed, leaking, corroded or visually damaged. Handle a damaged or leaking battery with care. If you come into contact with electrolyte, wash exposed area with soap and water. If it contacts the eye, seek medical attention immediately.
- The Norlase LION is intended to be used with the specified LION LED only. Any other light source used with the Norlase LION will not function.
- After removal of the LED do not touch the contacts on the LED, batteries or headband and the patient simultaneously.
- Do not charge battery in any environment where the temperature may exceed 45˚C or fall below 0˚C.

- The device has been designed to function safely when at an ambient temperature between +15°C and +35°C.
- Keep out of the reach of children.
- To prevent condensation from forming, allow the device to come to room temperature before use.
- For indoor use only (protect from moisture).
- At product end of life dispose of in accordance with local environmental guidelines (WEEE).
- Do not dispose of battery in fire, puncture or short circuit. Dispose of batteries in line with local environmental regulations.

Usage Precautions (After Use)

- Press the END button on the User Interface to automatically place the device in STANDBY and return all parameters to the default settings.
- Record all required treatment parameters before powering off the system.
- Power down the device, remove key, and place in secure location.
- Check the battery level on the tablet control panel, plug in charger, if required and power down the tablet.
- If placing a dust cover over the laser, ensure the key switch to the laser is off. Failure to do so may cause overheating of the laser device.
- Remove charging power cord from power outlet to disconnect system from power source.

Contraindications

- Foveal choroidal neovascularization (CNV)
- Myopic CNV
- Foveal disease

- Treatment in the Papillomacular bundle area that destroys the retinal nerve fiber layer.
- Treatment of the Optic Disc.
- Treatment of the fundus or anterior segment in eyes where corneal opacities, cataract formation and vitreous hemorrhage adversely affect the treating physicians view of the target tissue and the placement of laser effects on this tissue
- Aphakic eyes with vitreous in the anterior chamber.
- Neovascular glaucoma (not including photocoagulation of the fundus with the purpose of indirectly limiting or eliminating neovascular glaucoma).
- Glaucoma caused by congenital abnormalities of the angle.
- Closed anterior chamber angles or nearly closed anterior chamber angles where less than 90º of the circumference is open and eyes where low-lying peripheral anterior synechiae present.
- Significant corneal edema or a diminished aqueous clarity obscuring visualization of the anterior chamber angle.
- Glaucoma secondary to active uveitis.

Precautions in Patient Selection

Caution should be taken using this device in patients with the following conditions:

- Progressive eye disease
- Fixation difficulty due to nystagmus or have a condition that may induce nystagmus
- Infant, aphakia
- Low intraocular transparency
- Restricted pupil
- Diabetes
- Acute primary angle closure (with corneal edema)
- Late stage glaucoma with progressed visual field loss

Precautions in Photocoagulation

Caution should be taken during photocoagulation to ensure the desired effect is obtained. The following are recommendations for photocoagulation:

- **Clear view of the target tissue:**
  Corneal opacities, opaque ocular media, restricted pupil and vitreous hemorrhage can interfere with the view of the target structures and may result in damage adjacent to the target tissue. Treatment should be delayed or an alternative method of treatment should be implemented.

- **Energy Density Increase due to spot size reduction**
  When laser power is constant, the relationship between Spot Size (SS) and Power Density (PD) can be expressed as:

  $$PD = 1/ SS^2$$

  If the spot size is decreased by half, the power density is increased by 4 times. Under this condition excessive photocoagulation may occur.

  If a different viewing lens is used after treatment has begun, it is recommended to reduce power significantly and repeat titration at the new spot size to redetermine the desired endpoint. It is very important to titrate while the laser beam is in proper focus.

- **Photocoagulation of pigmented tissue**
  The Norlase LION 520 nm wavelength is highly absorbed by melanin. Pigmented tissue that contains melanin may be coagulated at lower power levels than tissue that does not contain melanin. It is recommended that each treatment begin with titration to set the desired clinical endpoint by starting at a low power level and gradually increase to the desired level. Please note that melanin is not evenly distributed through the target tissue and variable uptake may be experienced even in adjacent spots.

- **Photocoagulation through opaque tissue**
  Laser absorption or light scattering through opacities such as cataracts, corneal scars pigment, blood, and other debris may occur and cause undesirable thermal damage to the opaque tissue or may cause light scattering that may cause damage to unintended regions. Use caution when treating through opacities and visualization and transmission of laser energy may be compromised.

- **Treatment of vascular structures**
  Direct treatment of vascular structures may result in intraocular bleeding that may impair the patient's vision and/or prevent further laser treatment. Vascular structures should be treated with caution with parameters appropriate with the individual clinical problem.

- **Patient Movement**
  Patient movement during photocoagulation could result in the exposure of unintended tissues to laser therapy. If patient movement inhibits clear viewing of target tissue, consider necessary restraints to ensure patient compliance or discontinue laser treatment. If the device Interval setting is used, longer Interval settings will aid in proper tissue targeting and allow adequate physician response time in case of patient movement.

Adverse Effects and Complications

Posterior Segment Laser Procedures

The most common complication of panretinal photocoagulation is increased macular edema usually with a concurrent decrease in visual acuity. In addition, blowout hemorrhages from the areas of neovascularization, particularly on the optic nerve, have been observed and may be caused by an increase in peripheral resistance secondary to photocoagulation or by an inadvertent valsalva maneuver by the patient.

Only a contact lens specifically designed for use with laser energy should be used. Use of a standard diagnostic contact lens may result in a power loss due to reflection from the surface of the lens. The reflected energy may pose a hazard to both the patient and the physician.

Following photocoagulation, patients should be cautioned against any activity that could increase the venous pressure in the head, neck, or eyes, such as straining, lifting or holding their breath. Patients should be advised to sleep with the head of their bed elevated 15 to 20 degrees.

Patients should be cautioned against stifling a sneeze, because this raises the blood pressure within the eyes to a high level. Vigorous nose blowing should also be discouraged. Rubbing the eyes following photocoagulation may disrupt blood vessels inside the eyes. Sneezing and coughing should be controlled with cough syrup or other medications.

Immediately following treatment, patients should avoid altitudes over 2500 m (~8000 ft).

Anterior Segment Laser Procedures

Intraocular pressure should be closely monitored following laser iridotomy or trabeculoplasty.

Hemorrhage from the trabecular meshwork occasionally occurs as an ooze of blood from Schlemm's canal to the site of laser impact. This is easily stopped by increasing the pressure on the gonio lens on the cornea or by coagulating the bleeding site by application of a laser burn.

Pupillary distortion may be encountered if the iris root or peripheral iris has been treated. This distortion may or may not be permanent, depending on the severity of the accidental damage.

Intraocular pressure elevations have been reported to occur in up to 53% of eyes when 360º of the trabecular meshwork has been treated with 100 spots at the initial session. Intraocular pressure rises occur most frequently from 1 to 2 hours following laser treatment, although they may occur several hours afterward. For this reason, it is imperative to monitor patient intraocular pressure after laser treatment for up to 24 hours.

Peripheral anterior synechiae may occur when the posterior portion of the trabecular meshwork or other structures posterior to the meshwork are treated. These are best avoided by meticulous delivery of a well-focused laser beam.

Transient corneal epithelial burns have reportedly been resolved within 1 week without scarring. Endothelial burns are rarely encountered when careful focusing is employed.

Rarely, severe iritis may occur, related to either an unusual patient response or improper spot location.

Residual Risk

Patient Movement
Patient movement during photocoagulation could result in the exposure of unintended tissues to laser therapy. If patient movement inhibits clear viewing of target tissue, consider necessary restraints to ensure patient compliance or discontinue laser treatment. If the device Interval setting is used, longer Interval settings will aid in proper tissue targeting and allow adequate physician response time in case of patient movement.

Ophthalmology References

1. The Diabetic Retinopathy Study Research Group. Photocoagulation Treatment of Proliferative Diabetic Retinopathy Clinical application of diabetic retinopathy-study (DRS) findings, DRS report number 8. Ophthalmology 1981; 88:583-600.

2. Quigley HA. Long Term Follow-up of Laser Iridotomy. Ophthalmology 1981; 88:218-114

3. Fleischman JA, Swartz MA, Dixon JA. Krypton Laser Endophotocoagulation An Intraoperative Trans-Pars Plana Technique Archives of Ophthalmology, 99: 1610- 1612, 1981

4. Ritch R, Podos SM. Krypton Laser Treatment of Angle Closure Glaucoma Perspectives in Ophthalmology Vol.4, No.4, June,1980

5. Schwartz AL, et al. Al. Krypton Laser Trabecular Surgery in Uncontrolled Phakic Open Angle Glaucoma Ophthalmology Vol.88 No.3, March 1981.

6. Ophthalmic Laser Therapy Posterior Segment Laser Section Current Techniques Proliferative Diabetic Retinopathy. Edited by Michael J. Bradbury, Vol.1, No.2, 121-129

7. L'Esperance FA, Ophthalmic Lasers Third Edition Photocoagulation of Ocular Disease: Application and Technique. (1988)

8. Kurata F, et al. Intraocular pressure the day of Krypton Laser Trabeculoplasty in Primary Open-angle Glaucoma Ophthalmology 89:338, 1980

9. Thomas JV, Simmons R and Belcher CD III. Complications of Krypton Laser Trabeculoplasty Glaucoma 4:50, 1982

10. Wise JB, Errors in Laser Spot Size in Laser Trabeculoplasty Ophthalmology, 91:186, 1984

11. Kanski JJ, Clinical Ophthalmology, Second Edition. Butterworths, 1989

Cleaning

Only manual, non-immersion cleaning as described should be used for the device.

Do not autoclave or immerse in cleaning fluids.

Always disconnect power supply from source before cleaning.

1. Wipe the external surface with a clean absorbent, non-shedding cloth dampened with a water / detergent solution (2% detergent by volume) or water / isopropyl alcohol solution (70% IPA by volume). Avoid optical surfaces.
2. Ensure that excess solution does not enter the device. Use caution to ensure cloth is not saturated with solution.
3. Surfaces must be carefully hand-dried using a clean non-shedding cloth.
4. Safely dispose of used cleaning materials.

Warranty Information

For information on the warranty period please contact your sale representative at Norlase or the authorized distributor from whom the device was purchased. In the warranty period the device is warranted to be free from defects in material and workmanship at the original purchaser's location.

In order to comply with any warranty, all internal adjustments or modifications must be made by Norlase-certified personnel or with the express permission of the Norlase Service Department. The warranty does not apply in the event of misuse, negligence or accidental damage.

The liability of Norlase under valid warranty claims is limited to repair or replacement at Norlase’s facility or purchaser's place of business (or, if not practicable, a refund of the purchase price, all at the option of Norlase).

There are certain other limitations that apply to the warranty some of which are stated above in this manual. Reference should be made to the terms and conditions of sale attached to Norlase’s purchase agreement or similar terms and conditions supplied by an authorized distributor.

Warranty Shipments, Returns, and Adjustments

A warranty claim must be made promptly and must be received during the applicable warranty period. If it becomes necessary to return a product for repair and/or adjustments, authorization from Norlase or an authorized distributor must be obtained. Instructions as to how and where products should be shipped will be provided. Any product or component returned for examination and/or warranty repair shall be sent insured and prepaid via the means of transportation specified. Shipping charges for all products or components replaced or repaired under warranty shall be the sole responsibility of the purchaser. In all cases, Norlase has sole responsibility for determining the cause and nature of failure and Norlase’s determination with regard thereto will be final.

Decontamination of Returned Equipment

To comply with United States postal regulations and federal transportation law, devices shipped to Norlase for repair or return must be properly decontaminated with a chemical germicide that is commercially available and cleared for sale as a Hospital Disinfectant. To ensure that all equipment has been properly decontaminated, a signed Decontamination Certificate (provided in this section) must be enclosed in the package.

If devices are received without a Decontamination Certificate, Norlase will assume the product is contaminated and will assess the customer with decontamination costs.

Any inquiries should be directed to the Norlase Service Department. These include service of a device, assistance with troubleshooting the device and ordering accessories.

US Technical Service Information

Norlase Inc.
895 Hurlingame Ave.
Redwood City, CA 94063 USA

Phone: +1.833.667.5273 USA ONLY or
+1.650.489.0083

Decontamination Certification

Under the provisions of Postal Law, Title 18, United States Code, Section 1716 and Department of Transportation regulations contained in CFR 49, Part 173.386 and 173.387, “etiologic agents, diagnostic specimens and biological products…are nonmailable…”

The undersigned therefore certifies that the Norlase devices being returned herein by

_____ _____

Individual/Institution City, State/Province, Country

Has undergone decontamination with a commercially available germicide cleared for use as a Hospital Disinfectant and is clean and free from biohazards, including – but not limited – human or animal blood, tissue **or** tissue fluids **or** components thereof.

The undersigned also agrees to reimburse Norlase for any costs incurred in decontaminating the enclosed equipment, in the event said item is received by Norlase in a contaminated condition.

Model: Norlase LION

Serial Number: _____

Norlase
RMA Number: _____

Position/Title: _____

Name (Printed): _____

_____ _____

Signature Date (DD/MM/YYYY)

WEEE Disposal

Contact your local representative for disposal information.

CE
2797