NORLASE®

Leaf™

Green Laser Photocoagulator

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.

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Indications for use / Intended use

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

Introduction

The Norlase Leaf is a monolithic green laser system/delivery device designed to be user-detachable from the Slit Lamp. Leaf is controlled via a wireless tablet user interface utilizing touch screen or voice control of parameters. The system may be used for all standard single shot photocoagulation procedures listed in the indications for use section of this manual.

The Norlase Leaf 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 package 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.

Slit Lamp Laser Adapter

Houses the key switch, emergency laser stop button, foot switch and power inputs, green treatment laser, red aiming laser, Spot size adjusting optics and control electronics. Recommended connectivity to Haag-Streit style slit lamps. Check with Norlase or your authorized distributor for complete list of compatible slit lamps.

Touchscreen Tablet Control Panel

Provides controls for selecting treatment parameters, voice communication and audible feedback and displays for monitoring system 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 Leaf photocoagulator. The use of any unauthorized applications may affect the performance of the system 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.

Footswitch

Activates laser treatment beam when depressed while system is in READY mode.

Laser Power Supply

Medical grade power supply to be connected between wall outlet and connection on Laser system.

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 to the system.

System Preparation and Setup

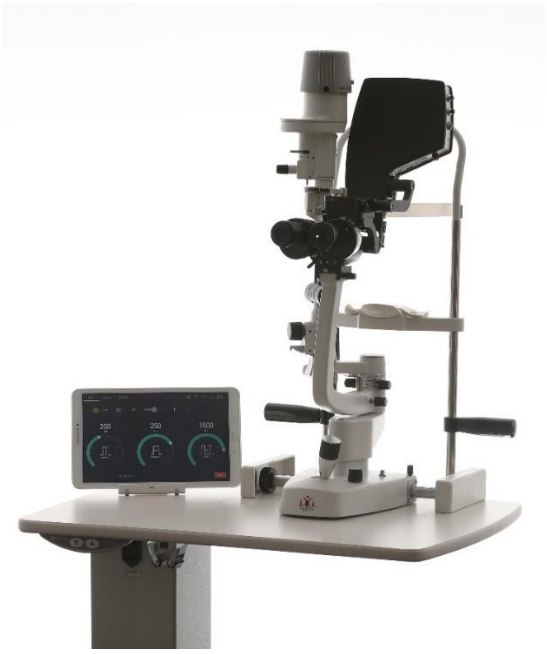
Norlase certified personnel will perform the initial installation and setup. The instruction of User's staff to setup the device will be part of the initial in-service training.

Norlase Leaf is intended for use by trained Ophthalmologists for diagnosis and treatment of ocular pathology in both the posterior and anterior segments. The system is designed for installation on a compatible slit lamp and use in a darkened office or surgery room. Optimal system performance and viewing is achieved in low ambient light conditions.

Norlase Leaf power supply is equipped with a 3-wire AC power cord. When selecting the location for system installation, ensure that the AC wall power outlet is correctly grounded. Follow local electrical codes to ensure proper grounding of the AC wall power outlet. A correctly grounded power connection is required for safe system operation.

Select an appropriate location that can accommodate the system size and allow for easy access by both the patient and the physician. Ensure proper ventilation, temperature and relative humidity. Select a well-ventilated space in an office or surgery room. Proper system operation requires temperatures between 15°C (59°F) and 35°C (95°F), with relative humidity between 20% and 85% non-condensing. 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 system. Allow at least 5 cm (2 in) of clear space around the laser system to provide adequate system cooling airflow. Use care when routing system cables to prevent a tripping hazard and to protect the optical fiber from damage by being crushed under foot or being rolled over by a chair. If the cord must cross a floor where there is traffic, use of a floor cord/cable cover is recommended.

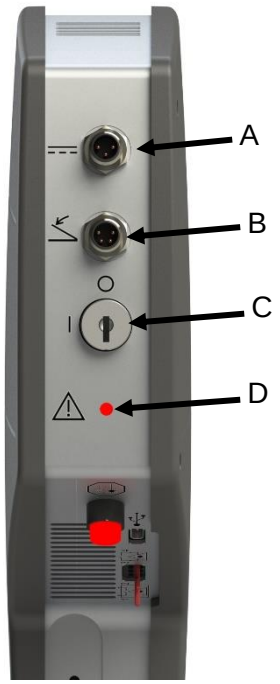


Example of Norlase Leaf attached to a slit lamp

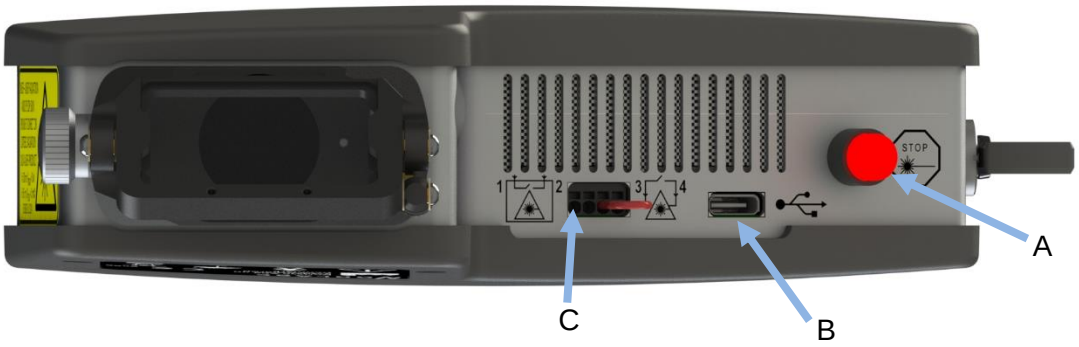
Connecting the System Components

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

Side Panel Functions



A	DC Power Supply Connection
B	Foot Switch Connection
C	Key Switch
D	System Status LED 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



Bottom Panel Functions

A	Emergency Off Switch
B	Micro USB Connection
C	Door Interlock / Warning Light Connection

NOTE

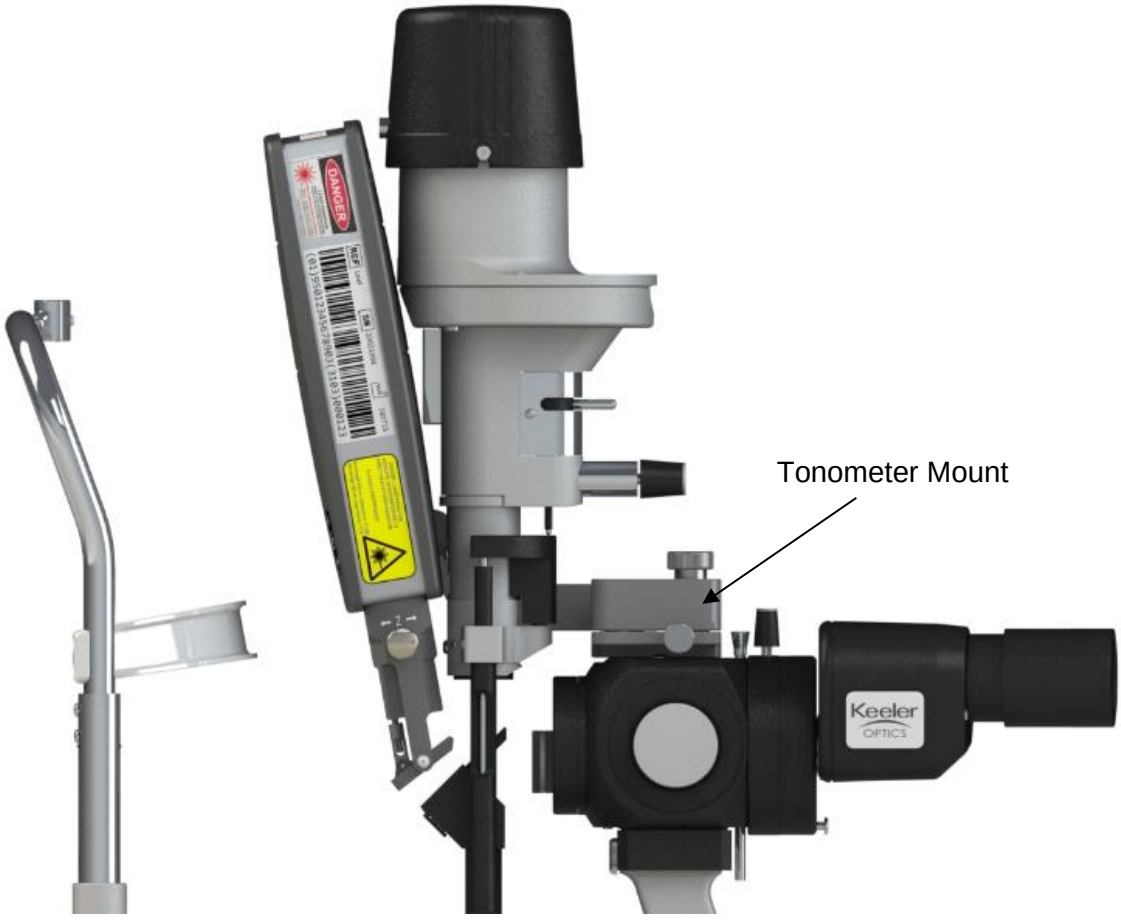
If using an external door interlock, a qualified electrical professional must install the external switch, and the total length of the cable should not exceed 5 m (16 ft).

Attaching the Norlase Laser to a Slit Lamp

The Norlase Leaf Laser System is designed to attach to the tonometer mount of Haag Streit (top illumination) style slit lamps. Consult Norlase technical support or your local Norlase distributor for compatibility information.

CAUTIONS

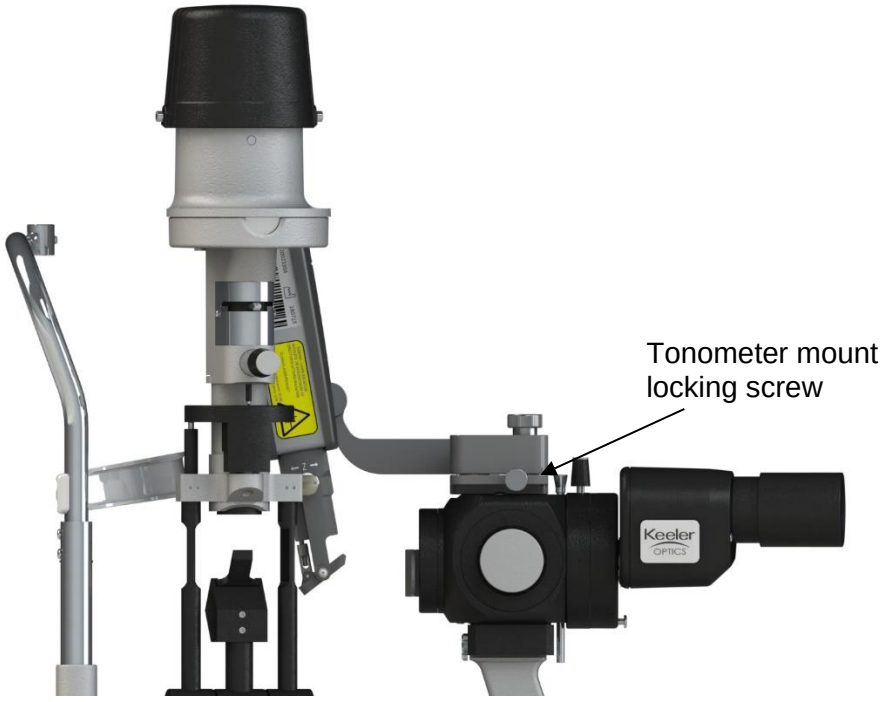
Attempting to attach the laser system to a non-compatible slit-lamp may result in compromised system and slit lamp performance and possible mechanical damage.



Laser mounted on Haag-Streit style slit lamp

1. Swing the slit lamp illumination tower to the left side ~45 degrees from the center.
2. Carefully place the Laser on the tonometer mount post using the mounting hole in the adapter plate. If the illumination tower does not clear the laser unit, loosen the adjustment screw and reposition the laser unit. Then tighten the adjustment screw.

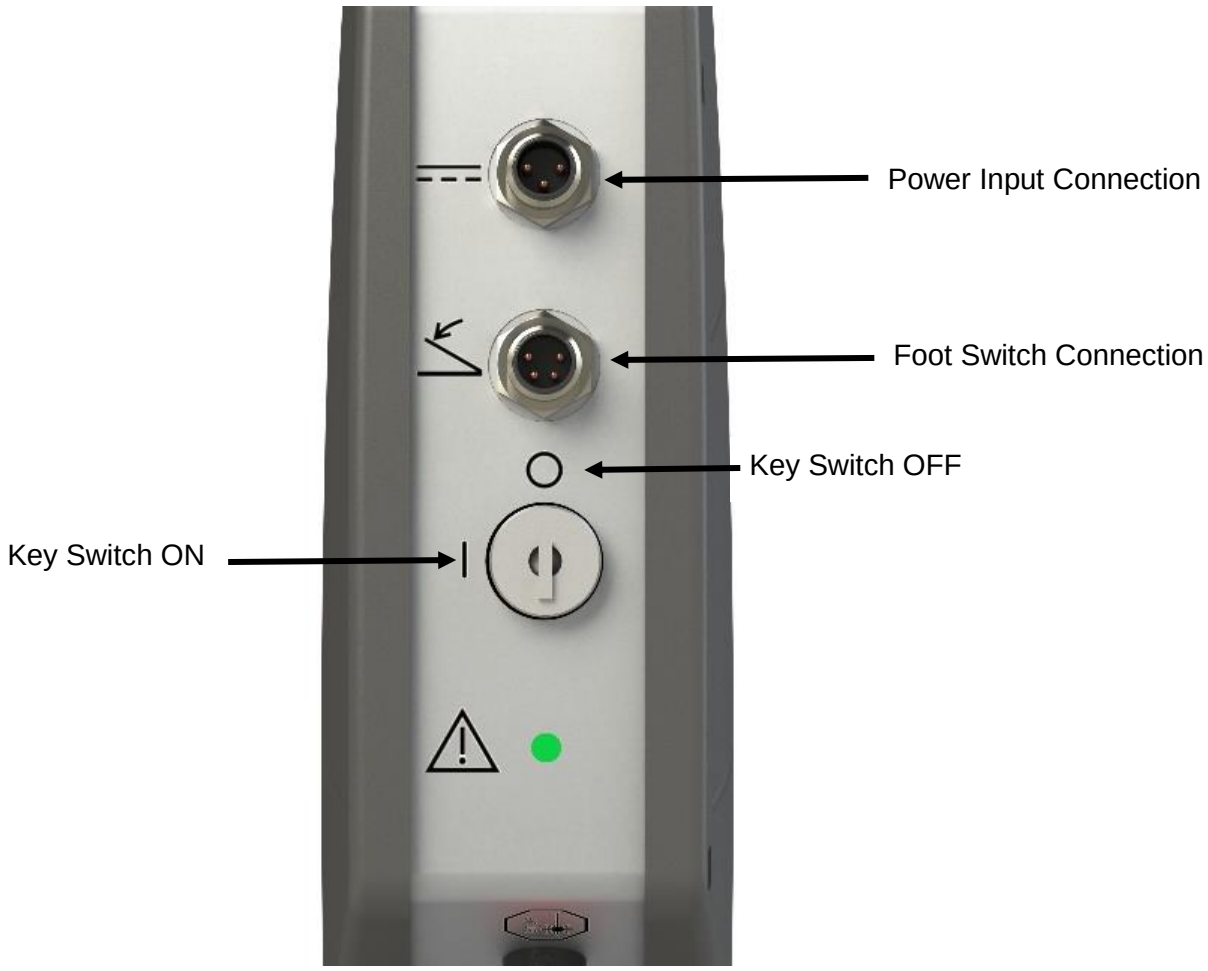
3. Make sure the plate is completely seated onto the tonometer mount and tighten locking screw.
4. Swing the illumination tower back in behind the laser.



System Start-up and Shut-down

Starting the System

1. Connect system power supply to a wall power outlet.
2. Connect power cable to laser. Please note this connector is keyed so it must be inserted in the proper orientation.
3. Connect footswitch cable to laser. Please note this connector is keyed so it must be inserted in the proper orientation.
4. Insert key into key switch.
5. Turn key to the ON position.



Cable Connections & Key Switch

6. Press and hold the “ON” button of the display tablet until the tablet powers up.

7. The laser status LED will illuminate green when the tablet and laser have established a connection.

Shutting Down the System

Standard Shut-down

From the Treatment screen:

1. Place system in STANDBY mode.
2. Turn key switch on Laser to OFF position.
3. Remove key to prevent unauthorized use of system.
4. Press and hold tablet power button until “Power Off” is displayed. Select “Power Off” until tablet screen shuts off.

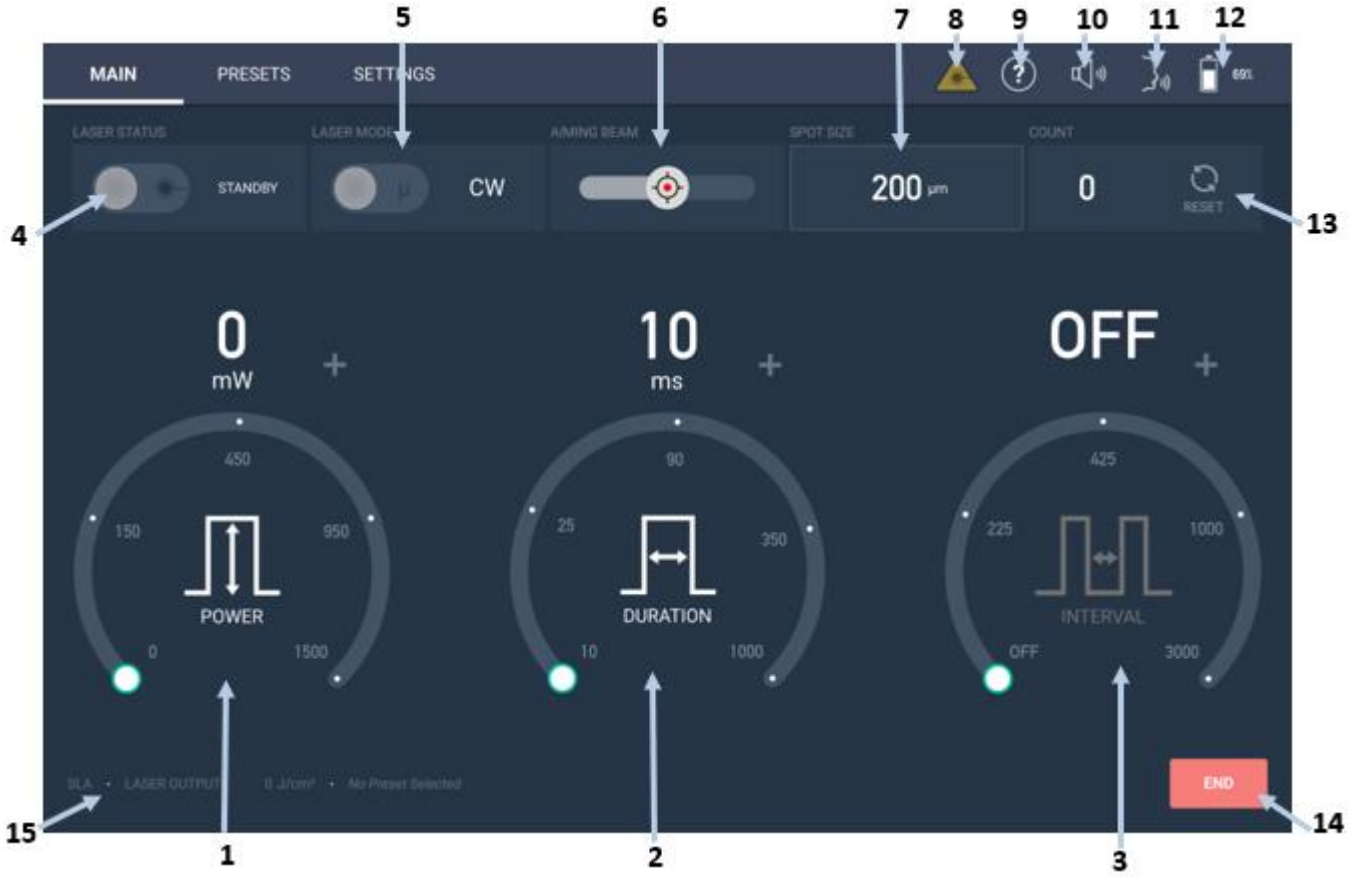
NOTE

If the power cable is still connected to the electrical source, some internal circuits remain energized (current comsumption is less than 0.1 Watts). To de-energize all internal circuits, unplug the power cable from the wall.

Emergency Shut-down

If the system becomes unresponsive during laser emission, press the emergency laser stop button on the front of the console. Turn the key switch to the OFF position.

Home Screen



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	**Laser Mode Select**: Toggle between Continuous Wave (CW) and µSec (Optional) Modes
6	**Aiming Beam Brightness**: Adjust aiming laser percentage (10% to 100%)
7	**Spot Size Select**: Select laser spot size from 50µ to 500 µ
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	**Pulse Count and Reset**: Displays Pulse Count. Press "RESET" to zero count
14	**End Treatment**: Ends current selection of parameters and returns settings to default
15	**Status Summary**: Indicates Delivery Device, Energy Density, Selected Preset

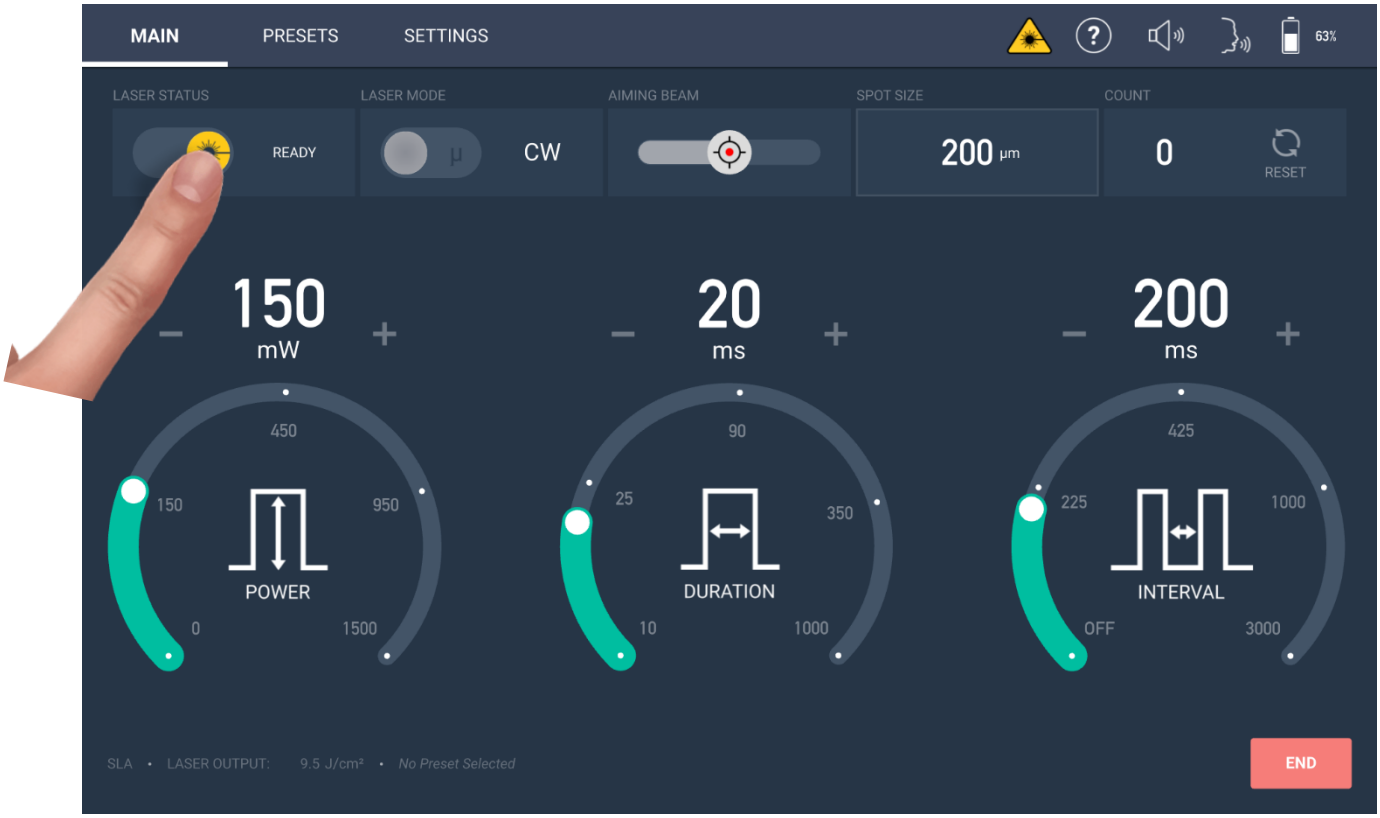
Using the Touchscreen Interface

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.

To toggle between Continuous Wave (CW) and µSec (Optional) modes, touch within the active region. The active setting will be displayed

Aiming Beam intensity can be adjusted by using the slider to select the desired intensity and can be adjusted from 10-100%. 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.

Changing the Spot Size Diameter

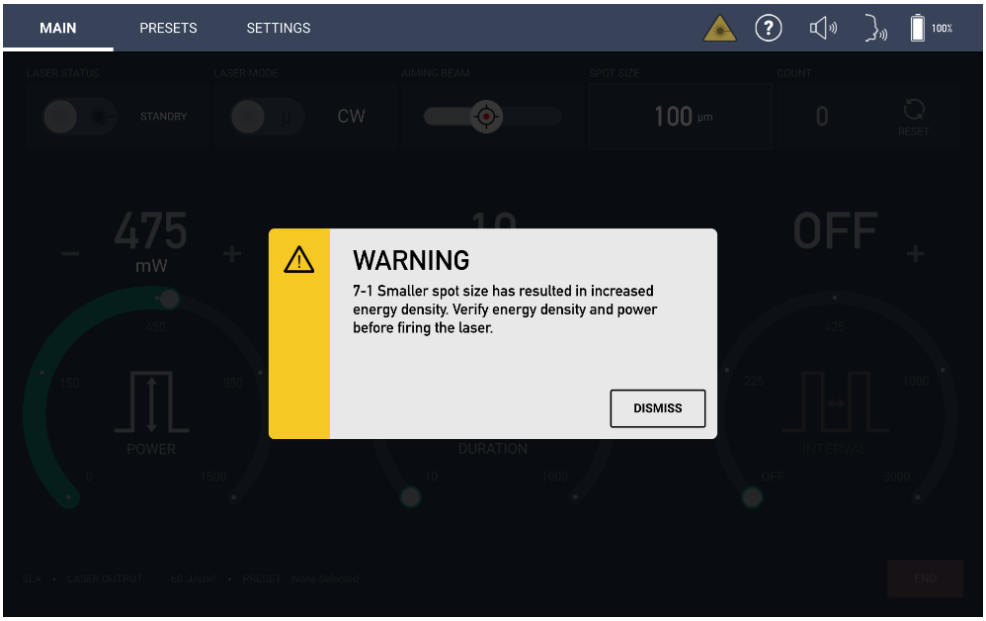
The Norlase Leaf is equipped with an electronic spot size adjustment selected from the User Interface. To change the delivered spot size:

1. Select the User Interface toggle to enable the Spot Size popup

2. To change spot size, 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 touch point 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.

3. Select "Apply" to change the Spot Size to the new value.

If the spot diameter is reduced after a power level has been selected, the following warning will be displayed:



This warning describes an energy density increase to target tissue when a spot size is reduced and the Power and Duration levels remains the same. It is important to understand the relationship between the power level, pulse duration, spot size and subsequent energy density within the laser spot size.

As an example, if the Power and Duration remain constant and the spot size is reduced by half, the energy density increases by FOUR TIMES the original level.

- Energy Density Examples:

Power	Duration	Spot Size	Energy Density
100 mw	100 ms	200 µ	32 J/cm^2
100 mw	100 ms	100 µ	127 J/cm^2
100 mw	100 ms	50 µ	509 J/cm^2

WARNING: Any reduction in spot size during treatment may result in too high of energy delivery to the patient.

The energy density of any given spot is displayed in the “Status Summary” at the bottom left of the User Interface for easy reference.

Using Voice Control (Optional Feature)

The Norlase Leaf 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 system 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.

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 system to listen for a recognized command. Immediately after hearing “OK Norlase” the system 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 system 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	System	1 second	User	System 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	System Action	Audible Response	Full Command Set
Enter Treat	Places the system into the “Ready” Mode	Treat Mode Selected	“OK Norlase” ♫ “Enter Treat”
Enter Standby	Places the system 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”

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.

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.

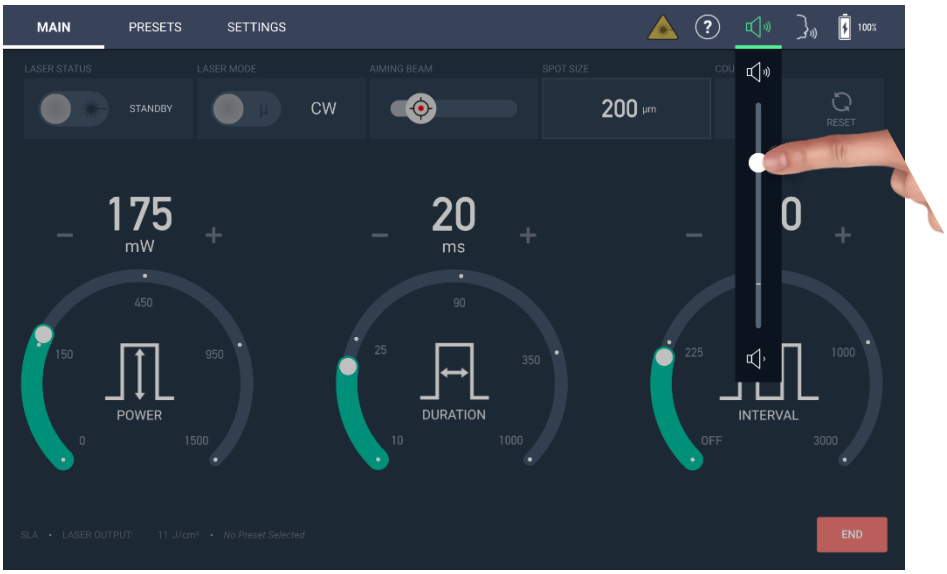
2. If selecting the voice control does not highlight the green circle and the icon displays  , voice control is not available on this system. Call Norlase or an authorized Distributor to purchase this feature.

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.

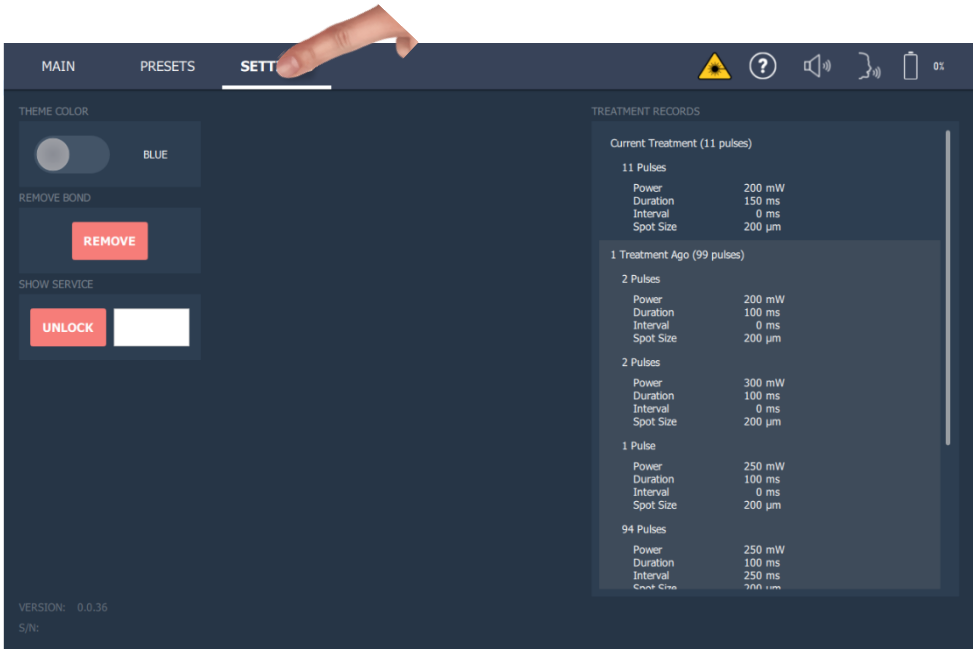
2. Adjust the slider to the desired volume level.



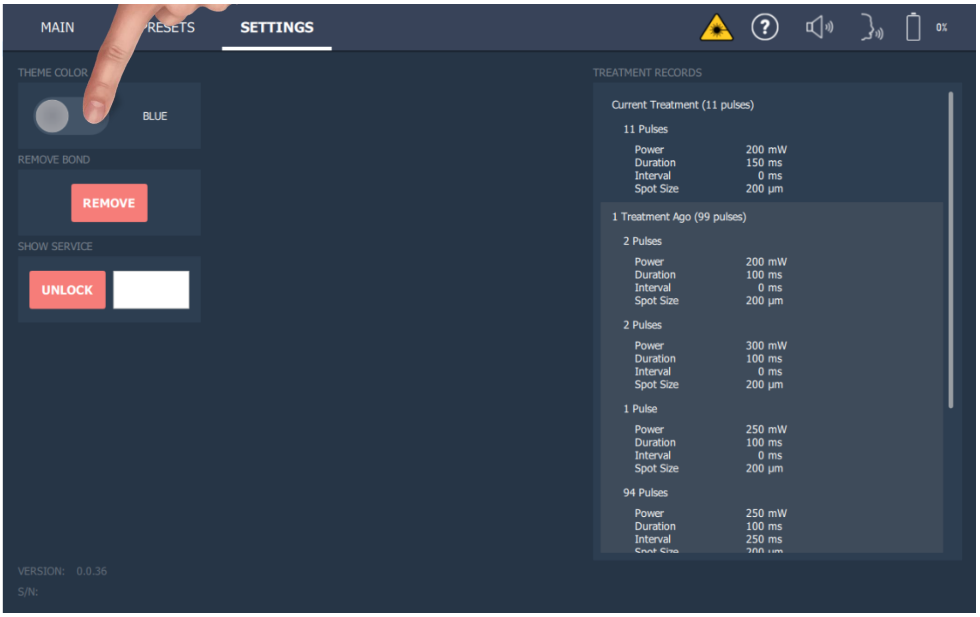
Changing Background Color on Tablet

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

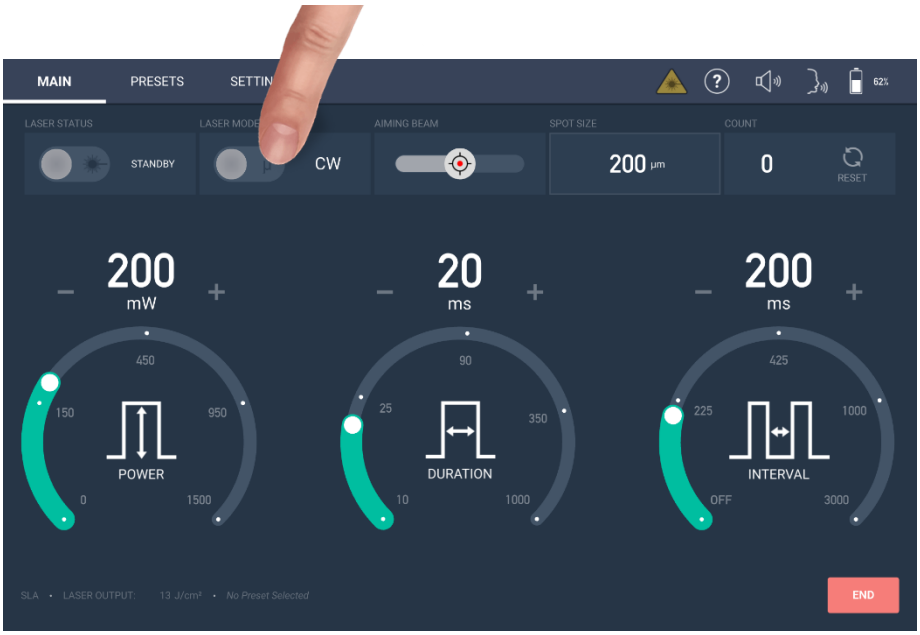


Using µSec Mode

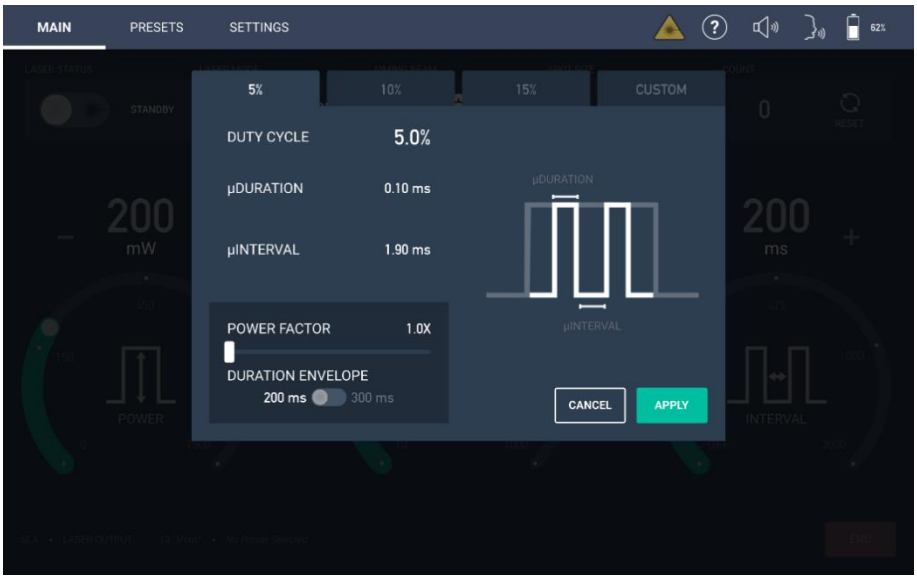
The µSec mode allows the delivery of green laser pulses into the 100's of microsecond range to achieve photo-thermal stimulation of tissue as reported in multiple clinical reports. Most clinical protocols suggest titration in normal CW mode to set the baseline, and then switch to the µSec treatment to deliver photo-thermal stimulation to tissue. The Leaf photocoagulator is designed to utilize this recommended treatment sequence.

1. While in normal CW mode, titrate to the recommended clinical level of the desired protocol to set the baseline power level for the patient.

2. Enter the µSec Mode using the toggle to initiate the µSec menu popup.



3. Select the desired Duty Cycle Tab. The Duty Cycle is preset at 5%, 10%, 15% or Custom.



4. Select the Pulse Duration Envelope to either 200ms or 300ms as specified by the desired protocol.

5. Select the Power Factor specified by the desired protocol. The Power Factor is adjustable from 1X (default) to 4X the titration power level. The Power Factor will multiply the titration power by the desired level automatically when in µSec mode. The circle in the display will show the original titration level for the Power and Duration for reference. In the example below, the titration power is 200mw, the Power Factor is 2X, so 400mw will be delivered during the 5% Duty Cycle µSec treatment. The Duration shows the titration level at 20ms and the Pulse Duration Envelope of the µSec treatment.

   Please Note: If the titration power multiplied by the Power Factor equals a non-standard power setpoint, the nearest power setpoint will be used and the displayed Power Factor will be adjusted accordingly.

6. Begin treatment in the desired area.

7. Press “END” when treatment is complete.

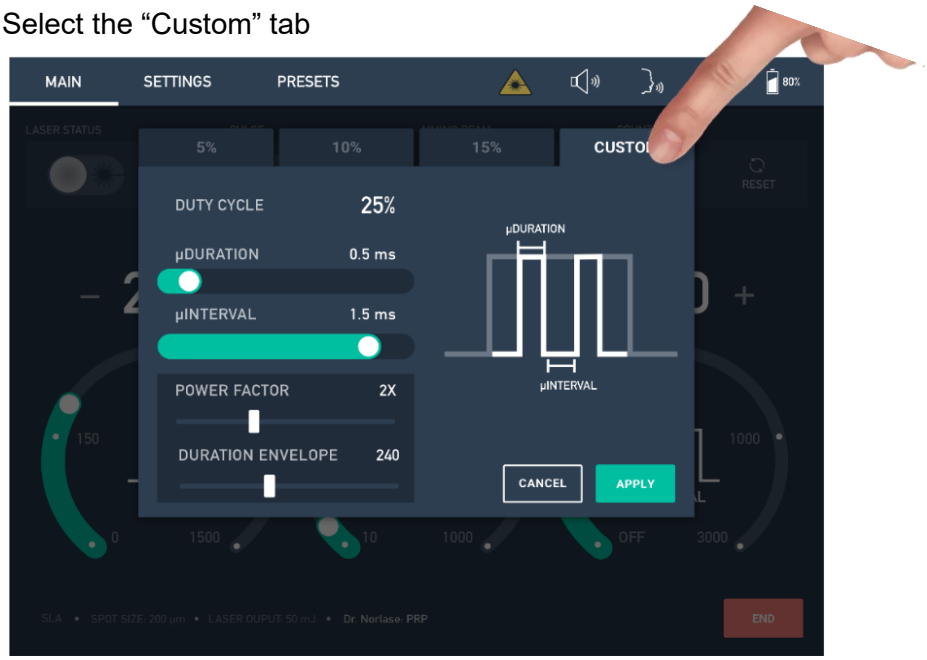
Setting a Custom µSec Duty Cycle

If a Duty Cycle other than the default 5%, 10% and 15% is needed:

1. While in normal CW mode, titrate to the recommended clinical level of the desired protocol to set the baseline power for the patient.

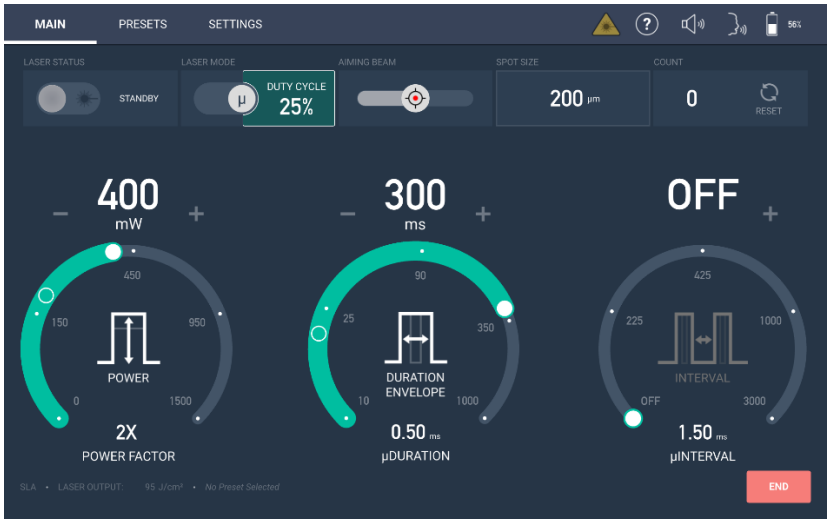
2. Enter the µSec Mode using the toggle to initiate the µSec menu popup.

3. Select the “Custom” tab



4. Adjust the µDuration and µInterval levels to set the desired Duty Cycle. Please note that the “Period” will always be 2.0ms offering 2.5% increments up to 50% Duty Cycle.

5. Adjust the Power Factor and Duration Envelope to desired levels and press “Apply”.



6. Begin treatment in the desired area.

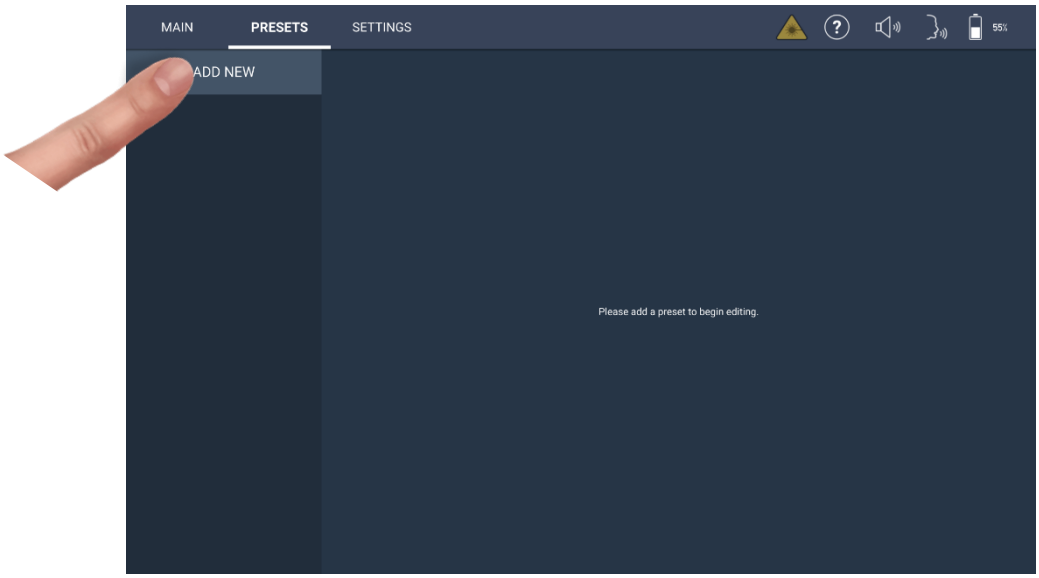
7. Press “END” when treatment is complete.

Presets Menu

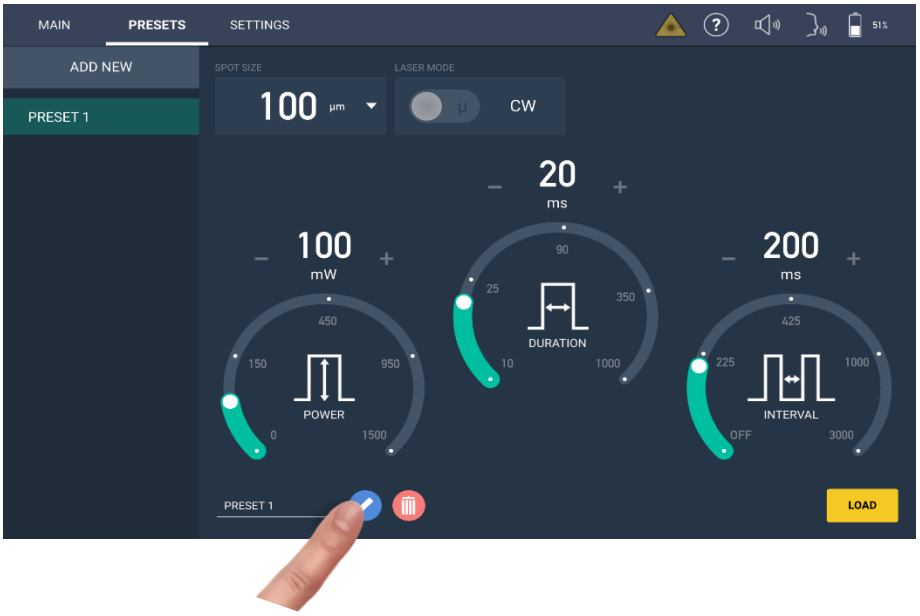
The “Presets” menu allows the saving and recall of commonly used parameters. These “Presets” are commonly named after the condition being treated or the physicians name and preference. The “Presets” will save the Power, Duration, Interval, Spot Size and Mode of operation.

To create a new “Preset”:

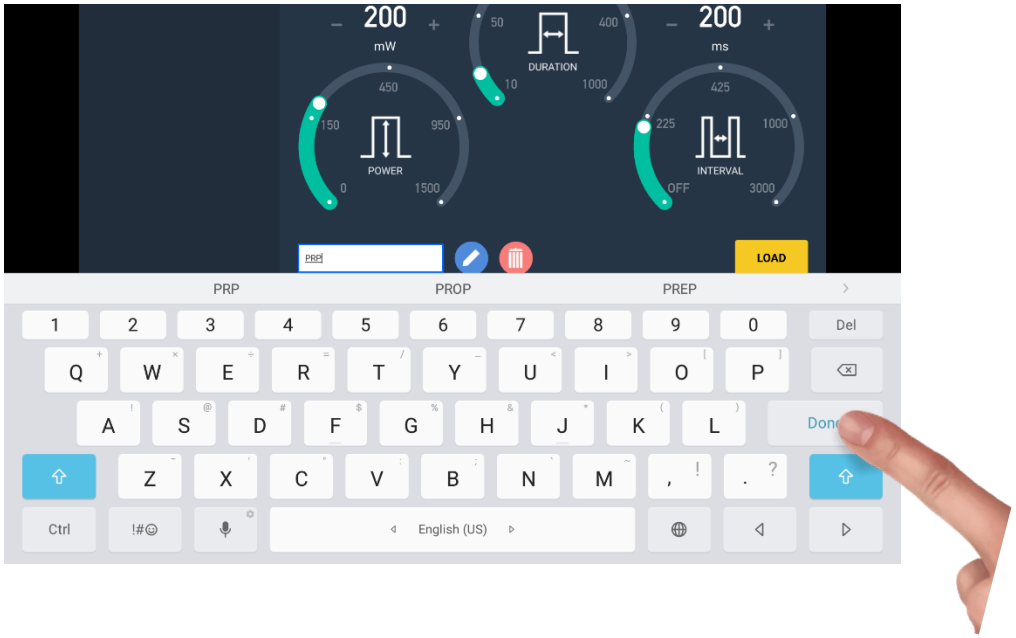
1. Select the “Presets” Tab at the top of the screen and press “ADD NEW”.



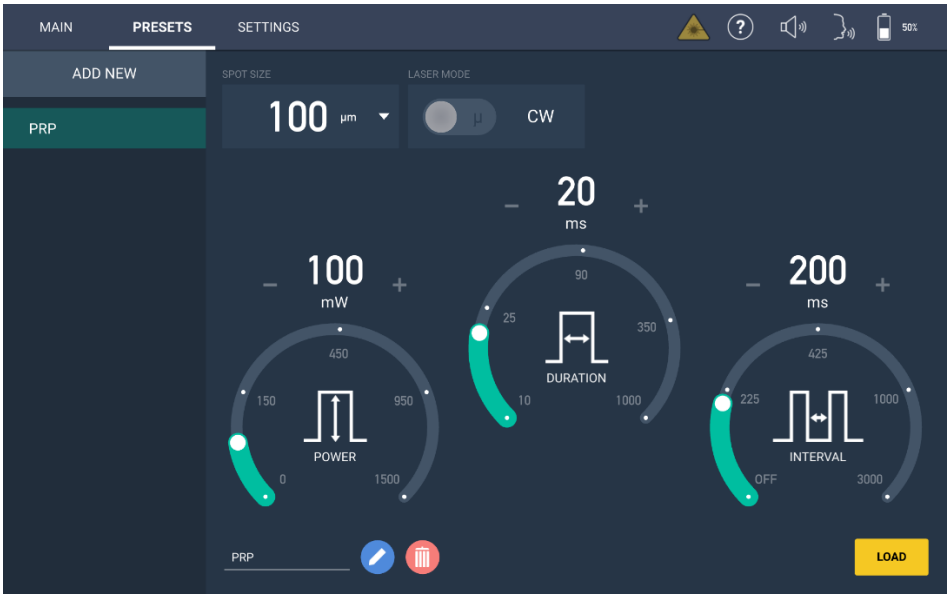
2. Set the parameters to the desired level. When done press the “pencil” icon to enter the Preset name.



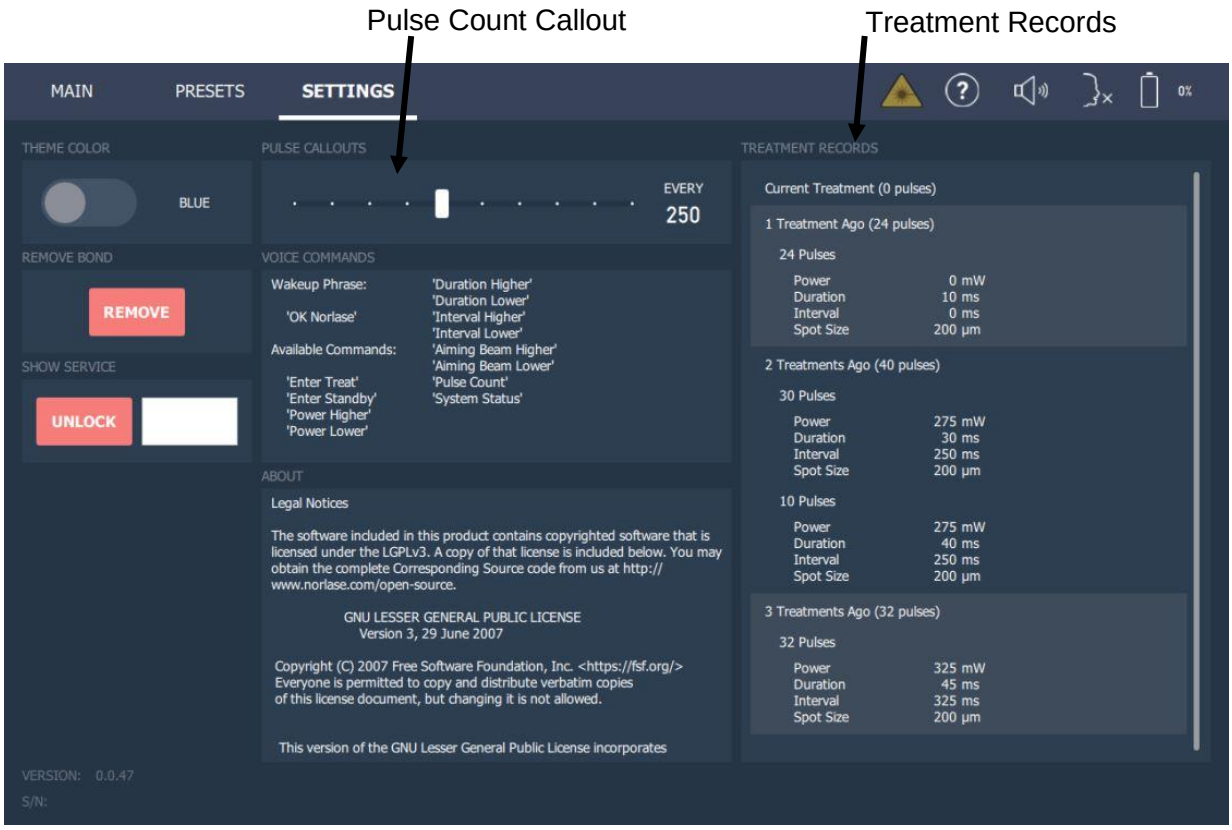
3. A keyboard will be displayed. Enter the name of the Preset and press “Done”.



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



Settings Tab



Pulse Count Callout

This feature enables the system 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 system will audibly callout the number of pulses when 250, 500, 750, 1000 and every 250 pulses thereafter. This feature can be set to OFF, 50, 100, 250, 300, 350, 400, 450 & 500.

Treatment Record Log Files

The system 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 parenthesis next to the identifying treatment and then the number of pulses for each Power, Duration, Interval and spot size change made during the procedure.

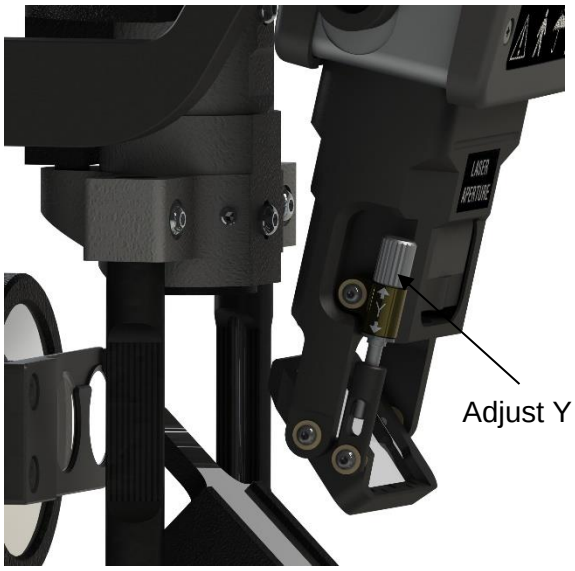
Aligning the Laser to the slit lamp visual and illumination axis

1. Power on the slit lamp illumination and adjust slit lamp oculars for the User vision correction setting, if any, and verify the illumination and visual axis are parfocal using a target card or the slit lamp focus post.

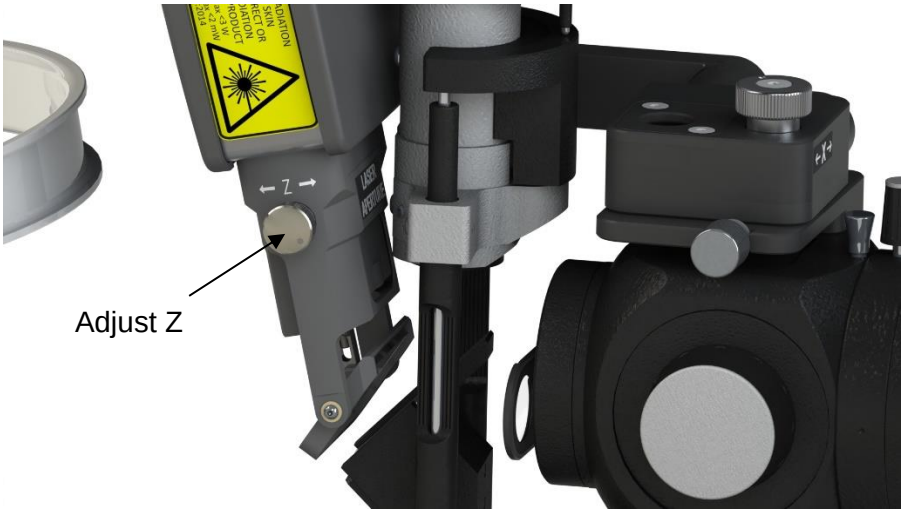
2. Turn on the laser and place into Treat mode so the aiming laser is present and select a spot size of 500 microns.

3. Adjust the illumination slit width to ~ 500 microns.

4. Observe the location of the aiming beam and rotate the Laser X and Y axis adjustments to center the aiming beam in the slit illumination.



5. After the aiming beam is centered, adjust the laser spot size on the tablet to 50 microns and adjust the Z axis focus to the smallest spot possible. The laser is now parfocal with the visual and illumination axis.



Intraoperative Instructions

Slit Lamp Treatment Procedure

Perform the following procedure in conjunction with the instructions in the Slit Lamp operator manual.

1. Connect the SLA to the slit lamp, as described in the “Connecting the Slit Lamp Adapter (SLA)” section.
2. Verify that the slit lamp eyepieces are adjusted to your settings, as described in the slit lamp operator manual.
3. Position the patient at the slit lamp with their chin on the chin rest and forehead pressed firmly against the head rest.
4. Select the laser treatment spot diameter, exposure time and beginning treatment power level.
5. Position the contact lens on the patient's eye.
6. Select READY mode. The aiming beam will turn on.
7. Adjust the aiming beam intensity.
8. Focus the slit lamp 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 with the slit lamp joystick or micromanipulator.
9. Depress and hold down the footswitch to deliver the treatment laser beam to the tissue
10. Adjust the laser treatment power as needed for therapeutic effect.
11. Prior to continuing treatment, verify that the power and other parameters are within acceptable ranges.
12. 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 system in STANDBY mode if there is a prolonged pause in treatment.

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

If the system remains idle for 30 minutes, it will END the current treatment and return all parameters to the default position. The pulse count will retain the same pulse count of the prior treatment and can only be reset by pressing the Reset button  *on the user interface.*

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 chin rest and head rest using mild soap and water following standard disinfect procedures. Dry with a soft cloth.
3. Disinfect the contact lens following the contact lens manufacturer instructions.

System Shut-down

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

1. Shut down Norlase Leaf as described in “Shutting Down the System”.
2. Remove the key to prevent unauthorized use of the system.
3. Clean the system as described in “Inspection and Cleaning”.
4. Place a dust cover over the slit lamp.

Annual Maintenance

Preventive maintenance, safety, power and calibration checks may be performed annually. Maintenance shall only be performed by Norlase-certified personnel to ensure proper laser performance.

System Repair

All Norlase Leaf repairs must be performed by Norlase-certified personnel to ensure proper system performance.

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

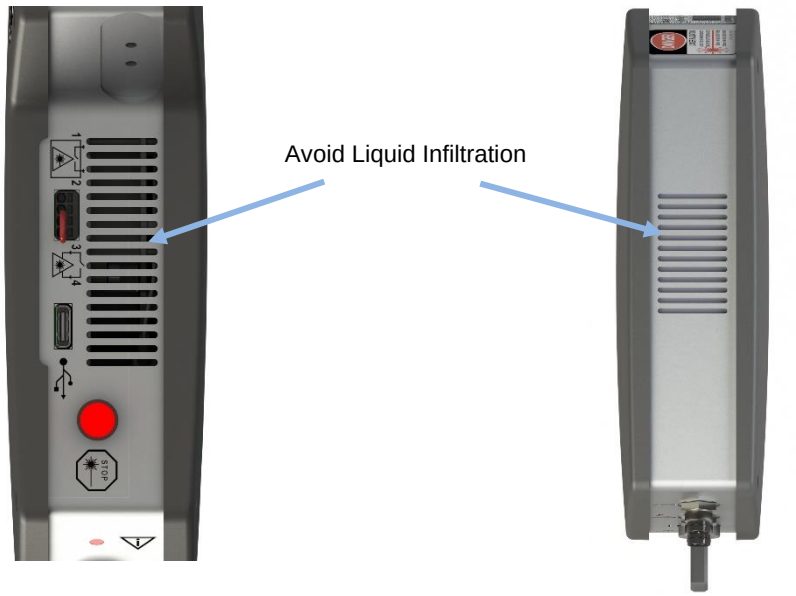
Inspection and Cleaning

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

Cleaning the Console External Surfaces

Clean the external surfaces of the 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 console as needed. Dry with a clean cloth or allow to air dry. Do not spray or pour cleaning agents directly onto the console.

Do not spray or pour liquids into the air vents at the top and bottom of the laser.



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 Control Panel Screen

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

Inspecting the Power Supply

Inspect the Power Supply cabling for any cuts or abrasions to the cabling. If any noticeable trauma has occurred, please contact Norlase Technical Support or your authorized Distributor to replace the power supply.

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

Norlase Leaf Specifications

[Specifications are subject to change without notice.]

Treatment Beam	
Type	Semiconductor Laser
Wavelength	520 nm
Power output	0 – 1500 mW ; 0-1250mW @ 50 micron spot size
Duty cycle	100%
Pulse durations	50 µSec – 1000 ms
Pulse interval	Off, 50 ms to 3000 ms
Laser beam diameter at focus	50 to 500 µm (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	
Voltage	90-240V~, 50/60Hz
Rated power	NORMAL 12 watts, MAXIMUM 60 watts
Product Classifications per IEC 60601-1	
Class I equipment	
Type B equipment	
Standard equipment, Footswitch is IPX7	
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
EN/IEC 60825-1	Safety of laser products

	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	
Console height	11 in (27.94 cm)
Console width	6 in (15.24 cm)
Console depth	1.6 in (4.06 cm)
Console weight	< 3 lbs. (< 1.4 kg)
Power cable length	3 m (10 ft)
Footswitch cable length	3 m (10 ft)
Latex	This product is latex free
Laser Safety Eyewear	
USA (ANSI)	Minimum OD of 5 at 520 nm per ANSI Z136.1
EU (CE)	D LB6 at 520 nm per EN 207 Personal Eye Protection

Troubleshooting Guide

If the instrument 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 system may display. This will aid in the diagnosis and servicing of the equipment.

If the system 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 wall circuit breaker is in the ON position.
2. Verify that the power cable is correctly attached to the system and the wall outlet.
3. Verify that the system Key switch is in the "**I**" (ON) position.
4. Verify that the door interlock plug is securely connected and, if a door interlock is in use, that the door switch is closed.
5. Verify that the footswitch cable is securely connected.
6. Verify that the User Interface Control tablet is powered on and connected with the laser console.
7. Verify that the emergency laser stop button is not activated.

System does not turn on.

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

Probable Cause:	System is not plugged in.
Suggestion:	Plug in system. Verify power cable is well seated in wall outlet and in main power receptacle.

Probable Cause:	Wall circuit breaker is in off/tripped position.
Suggestion:	Turn on wall circuit breaker.

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

Probable Cause:	Internal system error.
Suggestion:	Turn key switch to OFF position, wait at least one minute and then turn to ON position. If system fails to start, contact service.

System User Interface is blank for more than 30 seconds.

Probable Cause:	Internal system 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:	Footswitch is not connected.
Suggestion:	Connect footswitch. Check footswitch cable integrity.

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, system goes to STANDBY.
Suggestion:	Switch mode from STANDBY to READY.

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

Probable Cause:	Footswitch and/or footswitch cable damaged.
Suggestion:	Inspect for damage.

Probable Cause:	Internal system error.
Suggestion:	Contact Norlase Technical Support

Other unexpected System behavior

Probable Cause:	Unauthorised access to system
Suggestion:	Turn Key OFF, then ON on laser console and reboot tablet. If problem persists, contact Norlase customer service

Probable Cause:	Electronic component failure
Suggestion:	Turn Key OFF, then ON on laser console and reboot tablet. If problem persists, contact Norlase customer service

Pairing an Unpaired Tablet with Laser Console

A user interface tablet 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 Type C USB to Micro USB cable supplied with the tablet.
2. Turn on laser system. The status LED on side of laser system will be flashing blue.
3. Turn on user interface tablet.
    a. The tablet will display “Create Bond”.
4. Plug one end into the Micro USB port on the bottom of the Laser Console and the other end into the Micro 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 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 Type C USB to Micro USB cable supplied with the tablet.
2. Turn on laser system.
3. Turn on user interface tablet.
    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 into the Micro USB port on the bottom of the Laser Console and the other end into the Micro 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.

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 system to immediately go to a safe state.

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

Warning indicates a problem with the system that does not represent a serious safety issue and does not require any system 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.
1-20	Spot Size Zero	X			Spot Size mechanism not returning to default state	Turn Key OFF, then ON Call service if error persists.
1-21	Spot Size Stuck	X			Spot Size mechanism not responding to commands	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.

Code	Message	Critical	Clearable	Warning	Description	Action
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.
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.
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.
2-31	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
2-32	Failed Descriptor Write Async			X		Verify hardware is powered on and within range Call service if error persists.
2-33	Failed characteristic read sync			X		Verify hardware is powered on and within range Call service if error persists.
2-34	Failed characteristic read Async			X		Verify hardware is powered on and within range Call service if error persists.
2-35	Failed characteristic write sync			X		Verify hardware is powered on and within range Call service if error persists.
2-36	Failed characteristic write Async			X		Verify hardware is powered on and within range Call service if error persists.
2-37	Action timed out			X		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.
5-5	Invalid spot size	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.
5-8	Invalid Micropulse Duration	X			Laser parameter error	Turn Key OFF, then ON Call service if error persists.
5-9	Invalid Micropulse Interval	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.
6-3	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.
7-6	Spot Size 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.
8-1	Reduced Spot Size			X	Laser Error	Smaller spot size has resulted in increased energy density. Verify energy density and power before firing laser.
8-2	Power Factor Railed			X	Laser Error	Selected power factor resulted in a power higher than the maximum. Power was set to the maximum allowed.

Calibration Check Procedure

Regulatory agencies require that manufacturers of US FDA CDRH Class II and IV and European IEC 60825 Class 2 and 4 medical lasers supply customers with power calibration check instructions.

Calibration must be performed by a Norlase certified engineer or technician qualified to work on energized electronic laser equipment.

Disclaimer Warning

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

Calibration Check Instructions

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 system and user interface tablet.
2. Set the system at 500 mw Power, 1000ms Duration
3. Place the spot size at 200 microns
4. Enter "Treat" mode and ensure aiming beam is a minimum of 3 mm diameter on the power meter detector.
5. Ensure all personnel in the area are wearing laser safety glasses labeled for protection of OD>5 (ANSI Z136.1) or D LB6 (EN 207) at 520 nm.
6. Press and hold the footswitch for the entire one second and read the power output. Power should measure between 400-600 mw.
7. If power level is outside specification please call Norlase Technical Support or a Norlase authorized Distributor.
8. If power is within specification, record the measurement and date for future reference.

System Relocation Instructions

To move Norlase Leaf to another location:

1. Ensure that both the wall circuit breaker and the system main power switch are turned off.

2. Remove the power cable from the wall outlet and the system main power receptacle.

3. If a remote door interlock is utilized, remove the interlock plug and cable from the interlock port and transport separately.

4. Disconnect the footswitch cable from the footswitch port and transport separately. Never drag the footswitch.

5. Mount the system onto the tonometer mount of the desired slit lamp. PLEASE NOTE: The system may be relocated to the same type or similar slit lamp. If the slit lamp is not exactly the same as the previously mounted system there may be subtle differences that do not allow the system to function as before. Consult with Norlase Technical support or your authorized distributor.

6. If there are changes in environmental conditions (temperature or humidity) allow system to acclimate for 4 hours prior to use to prevent condensation.

Room Preparation

1. Verify that the system power cable and plug are correctly connected, as instructed in the preoperative instructions.

2. Verify environmental conditions are within limits for operation.

   NOTE

   For systems configured with an electrical wall circuit breaker, always place the electrical wall circuit breaker in the off position before inserting the plug into the receptacle.

3. Verify that the electrical service is turned on.

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.

General Safety and Regulatory Information

Norlase laser systems are precision medical instruments. The systems have undergone extensive testing. With proper handling, they are useful and reliable clinical instruments. To protect operating personnel and patients, this safety section and the appropriate slit lamp and delivery system 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 (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 laser system is used.

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 system 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 slit lamps, 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.

Laser Safety Eyewear

Laser safety eyewear is routinely required with most lasers. When using Norlase Leaf, 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 slit lamp and 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)
Slit Lamp	62 m (204')

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.

An eye safety filter is provided with the Norlase Leaf SLA and is required for safe use. Laser safety eyewear is not required by the physician who views the procedure through the slit lamp 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, this equipment must only be connected to a supply main with protective earth. Hospital Grade Cord grounding reliability can only be achieved when equipment is connected to an equivalent receptacle marked "Hospital Grade" or "Hospital only".

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

Do not use power cables other than the power cable provided with the system. Do not use extension cables with the system.

Disconnect the laser system from the electrical outlet when inspecting the fuses.

Never open the laser console protective covers. Opening the covers will expose you to high voltage components, the laser resonator and possible laser radiation. Only certified personnel shall work inside the console.

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

Although not required for the operation of the equipment, 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 15cm Do not set items on or under the cable assembly.

Fire Hazard

Do not use the laser system 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 Leaf. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser system 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 system must always be in STANDBY mode. Maintaining the system 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 equipment.

Verify eye safety filter is properly attached to the slit lamp prior to use.

Verify adjustments to laser parameters on the monitor before pressing the footswitch.

Verify that the slit lamp eyepieces are adjusted to your settings before each use, especially in a multi-user practice. Only when the eyepieces are properly adjusted is the laser parfocal with the slit lamp. The laser spot diameter will not be accurate and may result in over treatment or under treatment if the eyepieces are not properly adjusted.

When the system is in READY mode, if the aiming beam is not present, is distorted, or is incomplete, do not proceed with treatment. Turn off the machine 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 system 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 system using the key switch.

If the control panel will not connect to the laser for more than 60 seconds during system start-up, verify that the power indicator LED on the side of the laser is illuminated. If it is not illuminated, then check the power cord and cables from the wall outlet. If the control panel remains blank, turn off the system with the key; verify that all control panel cables are plugged in and fully seated; and then restart the system. If the system still has no power, turn off the system and contact service.

It may take longer for the equipment 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 slit lamp is the expected size. If the aiming beam size appears inappropriate or distorted, do not proceed with treatment. Readjust the slit lamp focus. 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 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 equipment.*
- *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 equipment without authorization of the manufacturer.

When the laser system 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 laser system, as this may result in the increased electromagnetic emissions or decreased immunity to such emissions.

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

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

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

Regulatory Compliance Safety Features

Norlase Leaf 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 system 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 system.

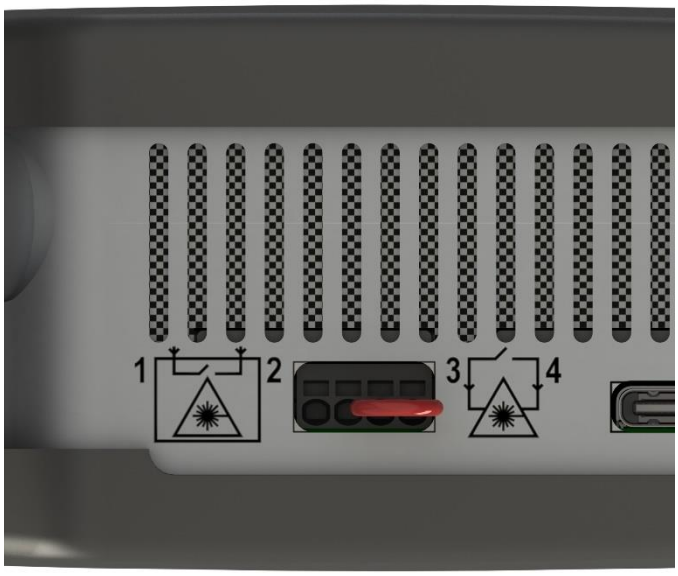
Laser Emission Indicator

A laser emission indicator is displayed to warn the user that the system 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 / External Emission Indicator

A door interlock may be used in conjunction with a remote switch to disable the system 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 system console. If a remote switch is used, the system can be set in the READY mode only when the remote switch is closed. Breaking the connection by opening the switch (door) disables the system and the system returns to STANDBY mode with “<Door Interlock>” displayed on the control panel. The switch must have a maximum of 40 ohms and >1500 V isolation.

An external emission indicator may be triggered by connecting to pins 3 & 4. A maximum of 24 V 100mA isolated supply may be used



Emergency Stop

When pressed, immediately turns off power to the laser.

Protective Housing

The system 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 certified personnel.

Safety Interlocks

The protective housing is not designed to be removed by the user during operation or maintenance. Therefore, the system 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 laser system utilizes an electronic laser safety shutter. The system 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 system 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 touch screen control panel.

Manual Reset

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

If laser emission is interrupted by main electrical power loss, the system will automatically turn off. To resume treatment after an electrical power loss, the system must first be manually restarted by rotating the key switch to the ON position.

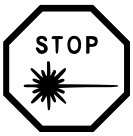
Electrical Fault Detection Circuitry

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 operator. 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 instrument 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.

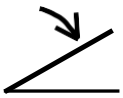
Console Labels

	**Emergency Stop**
	**Laser warning label includes:** • Laser Emission Warning • Wavelength • Power • Laser Class • Standard reference
	**Laser Emission Warning**
	**Laser Aperture Label**

System Information Label, includes:

- Manufacturer
- REF Reference Number
- SN 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**.**

	**Danger label includes:** • Laser Emission Warning • Wavelength • Power • Laser Class
	**USB Connections**
	**Remote Door Interlock Connection**
	**Footswitch Connection**
I	**ON**
O	**OFF**

Slit Lamp Adapter (SLA) Labels

Laser Aperture Label

Additional Labels

Foot Switch Label[1]:

Control Tablet Label[1]:

Power Supply Label[1]:

[1] "XX" denotes the version number.

Electromagnetic Compatibility

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

NOTE

Norlase Leaf laser systems 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 laser system.

Guidance and Manufacturer's Declaration: Electromagnetic Emissions		
Norlase Leaf is intended for use in the electromagnetic environment specified below. The customer or the user of the laser system should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic Environment: Guidance**
Conducted emissions EN 55011:2009+A1:2010, CISPR 11:2009+A1:2016, FCC Part 15 Subpart B: 2011.	Class B Group 1 150 kHz to 30 MHz	Norlase Leaf 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.
Radiated Emissions EN 55011:2009+A1:2010, CISPR 11:2009+A1:2010, FCC Part 15 Subpart B: 2011.	Class B Group 1 30 MHz to 1 GHz	

Guidance and Manufacturer's Declaration: Electromagnetic Immunity			
Norlase Leaf is intended for use in the electromagnetic environment specified below. The customer or the user of the laser system 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.
Surge 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 Leaf 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 Leaf is intended for use in the electromagnetic environment specified below. The customer or the user of the laser system 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 Leaf			
Norlase Leaf is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the laser system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the laser system 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 system 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 Leaf Laser System 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 Operators 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 system must be thoroughly understood. Adverse events and adverse device effects may occur if this manual is not read and understood.
- Only Norlase trained service personnel are allowed to adjust or service the device. 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 system malfunction may occur.
- Do not operate the system where flammable anesthetic gas is used.
- All personnel, other than the doctor and patient, in the space where the laser system is being used must wear laser safety glasses rated as described under Laser Safety Eyewear in the Norlase Leaf Specifications section. Instructions must also be given to avoid direct viewing of the laser emission, even if wearing the laser safety glasses.
- Never leave the laser system unattended while ready for use. The key can be removed to prevent unauthorized use of the system.
- Be sure to use a grounded power outlet and ensure the line voltage is within the range of 90-240VAC.
- Only use the device if the environmental conditions are within the specifications listed in this manual under the “Norlase Leaf 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 system.
- 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 laser system.

Usage Precautions (During Use)

- Use of this device other than specified in the instructions contained in this Operators 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 system errors are encountered, stop treatment and follow system 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 laser or user interface.
- Confirm that no reflective objects are in the laser beam path.
- If the user encounters green laser flashback through the slit lamp 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 system 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.

Usage Precautions (After Use)

- Press the “END” button on the User Interface to automatically place the system in Standby and return all parameters to the default settings.
- Record all required treatment parameters before powering off the system.
- Power down the laser system, remove key and place in secure location.
- Check the battery level on the tablet User Interface, plug in charger, if required and power down the tablet.
- If placing a dust cover over the laser/slit lamp, ensure the key switch to the laser is off. Failure to do so may cause overheating of the laser device.
- Remove 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
- 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:

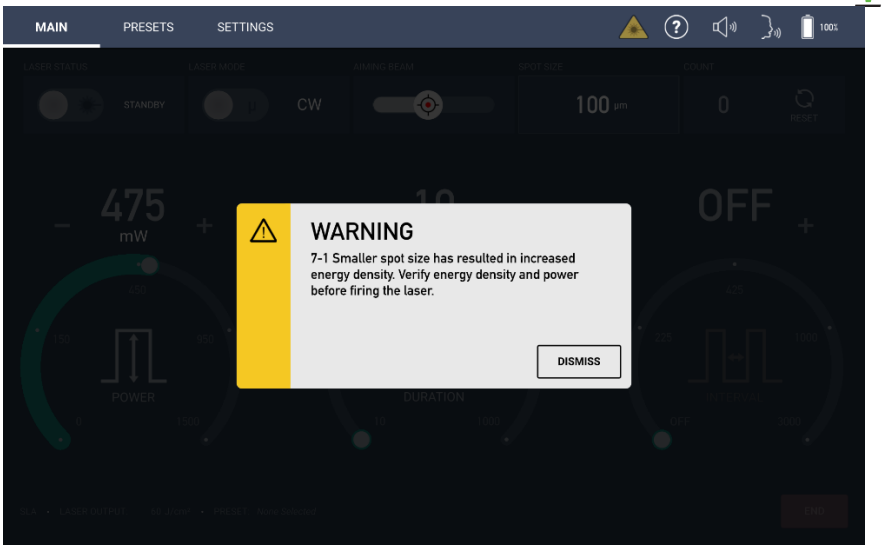
- **Clear view of the target tissue:**
  Corneal opacities, opaque ocular media and vitreous hemorrhage can interfere with the view of the target structures and may result in damage adjacent to the target tissue. Treatment should be delayed or an alternative method of treatment should be implemented.

- **Proper focusing of laser & slit lamp visual and illumination axis**
  See section “Aligning the Laser to the slit lamp visual and illumination axis” in this manual for proper parfocality adjustment.

- **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. The system automatically warns the user of a reduction in spot size during treatment, but it is up to the User to adjust the power appropriately. The following WARNING appears:



It is recommended to reduce power significantly and repeat titration at the new spot size to redetermine the desired endpoint. See the “Changing Spot Diameter” section of this manual for additional information.

- **Photocoagulation of pigmented tissue**
  The Norlase Leaf 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 system 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 system 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.

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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)

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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

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Warranty Information

Norlase warrants Norlase Leaf laser systems to be free from defects in material and workmanship at the original purchaser's location for 12 months.

In order to comply with this 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' 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 Norlase' warranty some of which are stated above in this manual. Reference should be made to the terms and conditions of sale attached to Norlase' purchase agreement.

Warranty Shipments, Returns, and Adjustments

A warranty claim must be made promptly and must be received during the applicable warranty period by Norlase. If it becomes necessary to return a product for repair and/or adjustments, authorization from Norlase must be obtained. Instructions as to how and where products should be shipped will be provided by Norlase. Any product or component returned for examination and/or warranty repair shall be sent insured and prepaid via the means of transportation specified by Norlase. 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' determination with regard thereto will be final.

The foregoing Warranty is exclusive and in lieu of all other warranties, whether written, oral or implied, and shall be the purchaser's sole remedy and Norlases' sole liability on contract or warranty or otherwise for the product. Norlase disclaims any implied warranty or merchantability or fitness for a particular purpose. In no event shall Norlase be liable for any incidental or consequential damages arising out of or in connection with the use or performance of the goods delivered hereunder. The essential purpose of this provision is to limit Norlase' potential liability arising out of this sale.

Decontamination of Returned Equipment

To comply with United States postal and transportation law, equipment 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 equipment is 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: 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 equipment 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 Leaf

Serial Number: _____

Norlase
RMA Number: _____

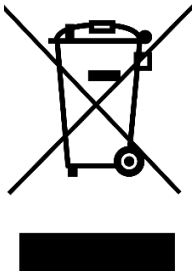
Position/Title: _____

Name (Printed): _____

_____ _____

Signature Date (DD/MM/YYYY)

WEEE Disposal



Contact your local representative for disposal information.