Delivery Device

Operator Manual

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Introduction

This manual describes the connection and operation of the Lumenis Array LaserLink delivery device. The Array LaserLink delivery device adapts to a Slit Lamp for use as a therapeutic laser delivery system, utilizing a scanning pattern generator to deliver predefined patterns of treatment. It is intended for use by an Ophthalmologist within a clinic or surgeon's office environment on patients regardless of age, gender, weight, or race. As the Lumenis Array LaserLink is for professional use only the device qualifies for exemption per 21 CFR 801 Subpart D.

CAUTION – Federal law restricts this device to sale by or on the order of a physician.

When attached to a compatible Lumenis photocoagulator, treatment parameters such as power, spot size, pattern shape, and wavelength are configurable with the included touchscreen interface and remote touchpad\3D mouse.

Your local Lumenis Representative initially unpacks, inspects, sets up, and installs the Array to ensure that it is working properly. In addition, Lumenis provides in-service training to ensure that your surgical staff is experienced in the performance and safety considerations of the device.

CAUTION - Do not attempt to operate the system until a qualified Lumenis Representative has installed and checked it for proper operation.

Thereafter, you, or the nursing staff at your facility, will perform the daily maintenance routines associated with this device as directed in the maintenance section of this manual.

Lumenis laser systems and delivery devices are precision medical instruments. They have undergone extensive testing and with proper handling are useful and reliable clinical instruments. If you have questions regarding your laser or delivery device, contact your local Lumenis Representative.

WARNING - Lasers generate a highly concentrated beam of light which may cause injury if improperly used. To protect the patient and operating personnel, the entire laser and your delivery device operator manuals, including all Safety and Regulatory sections, should be carefully read and comprehended before operation.

Array LaserLink Components

The Array is comprised of the following components:

- a scanning Array LaserLink Module
- a Console
- a Touchscreen Display
- a Remote Touchpad or 3D mouse (depending on customer selection and region regulatory approvals)

Optional co-observation devices are also available. System connections and controls are described in the following pages.

Array LaserLink Module

The Array LaserLink module attaches to the Slit Lamp and delivers the treatment beam to the target tissue.

Console

The console houses the control electronics and power supply, and integrates the Array LaserLink module with the laser system.

Touchscreen Display

Use the touchscreen display to adjust laser treatment settings, such as laser mode, energy, and aiming beam intensity. It can be positioned on either side of the Slit Lamp, and duplicates the functions of the laser's remote control so that you can verify the laser treatment parameters without moving back from the Slit Lamp binoculars.

Remote Touchpad

Use the touchpad to micromanipulate the position of the aiming and treatment beams, adjust laser power, spot size, the number of spots, and several other pattern parameters.

3D Mouse

Use the 3D mouse to micromanipulate the position of the aiming and treatment beams, adjust laser power and the number of spots.

Fig. 1 Doctor and patient positioning

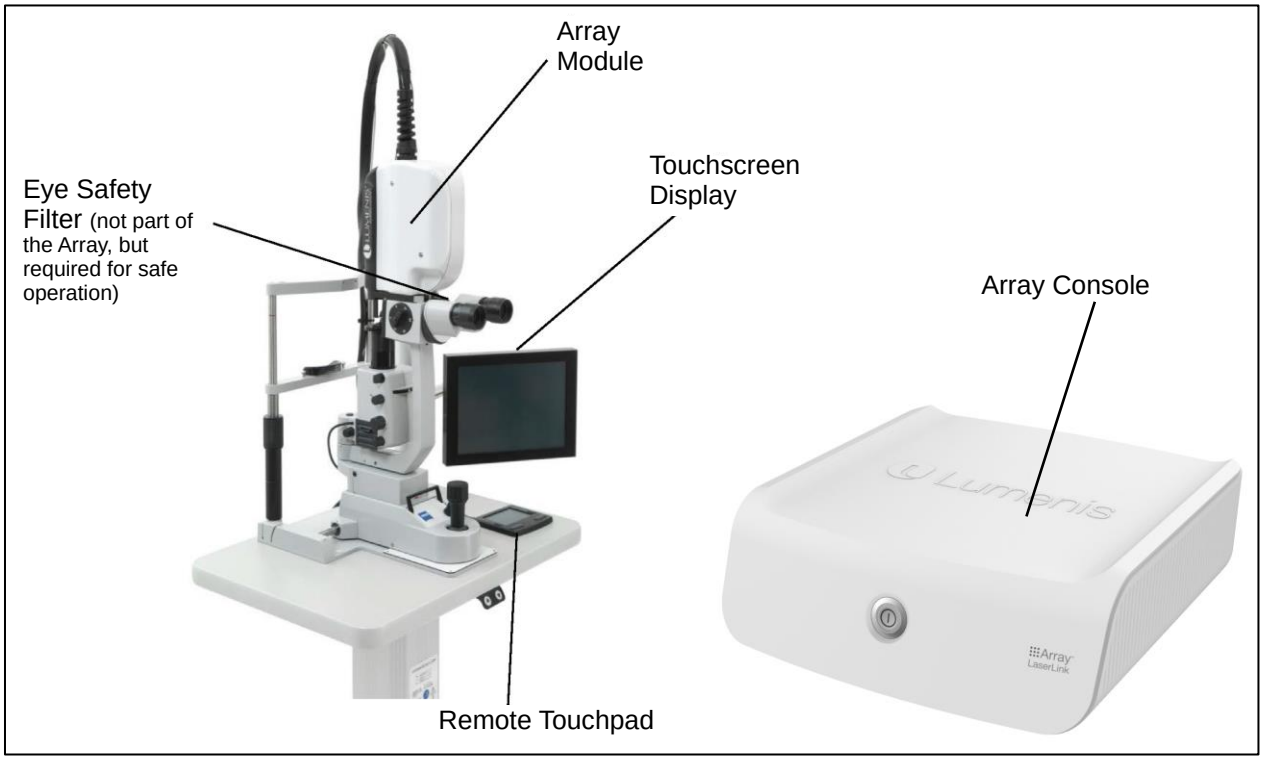

Fig. 2 Array LaserLink Components (3D Mouse not displayed)

Array LaserLink Installation

The Array LaserLink delivery device must be installed by a Lumenis-certified technician, and is only compatible with specific Lumenis laser systems:

- Novus Spectra™ Laser System (K022327*)
- Novus Spectra™ Dual Port Laser System (K022327*)
- Vision One™ Laser System (K111213*)

*Premarket FDA Clearance numbers

WARNING - The Array LaserLink shall only be connected to defined laser systems. Connecting to anything else will result in a non-functioning delivery device.

The Array LaserLink consists of the four components which are shown in Fig. 2 on the previous page.

The touch screen and touch pad\3D mouse are mounted by a qualified service technician at a location chosen by the user.

The array module (head) is attached to a Slit Lamp by the technician using the adjustable mounting plate shown in Fig. 3. The array module must be positioned, aligned, and focused by the technician to match the Slit Lamp's focal point/plane.

Fig. 3 Array Head Mounting Plate

The array module, touch screen, and touch pad\3D mouse are connected to the console by a service technician. The console is mounted to a laser system or at a location chosen by the user. The console is connected to a

laser system by the service technician. An aiming beam control port is installed in the laser system.

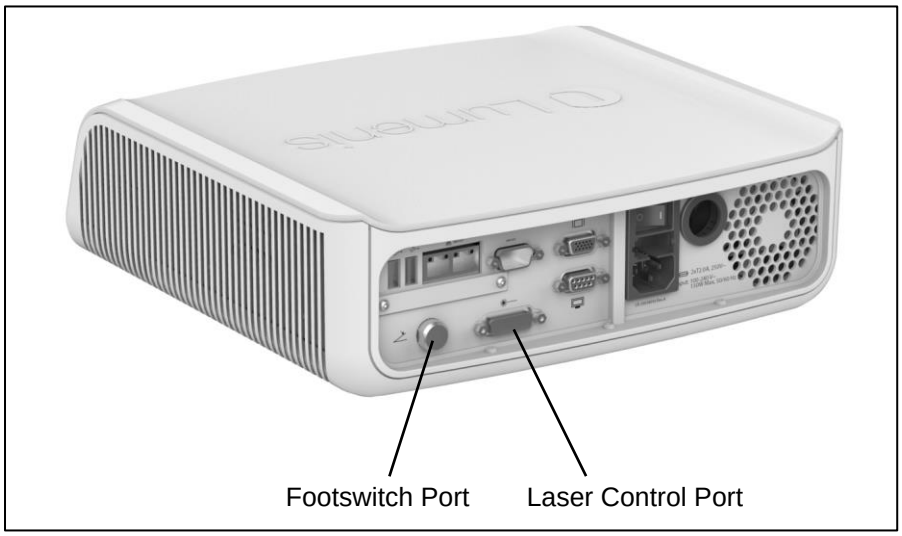

Fig. 4 Console Ports

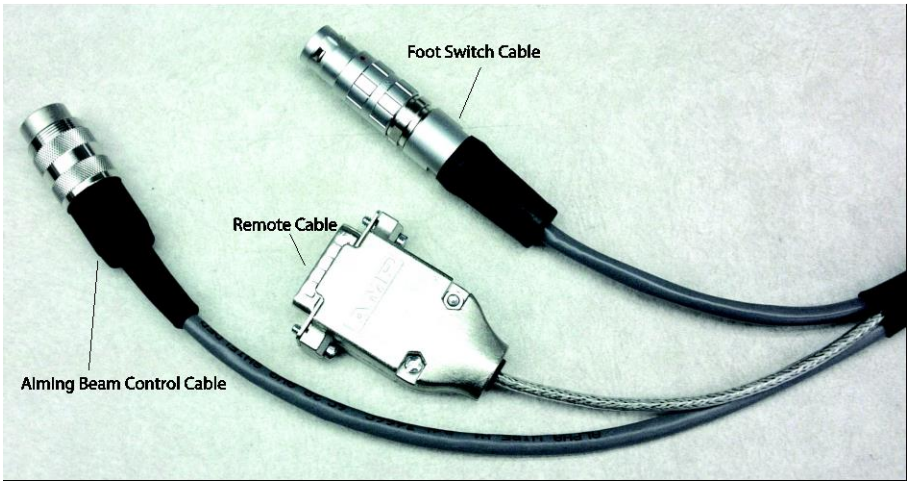

Fig. 5 Cables

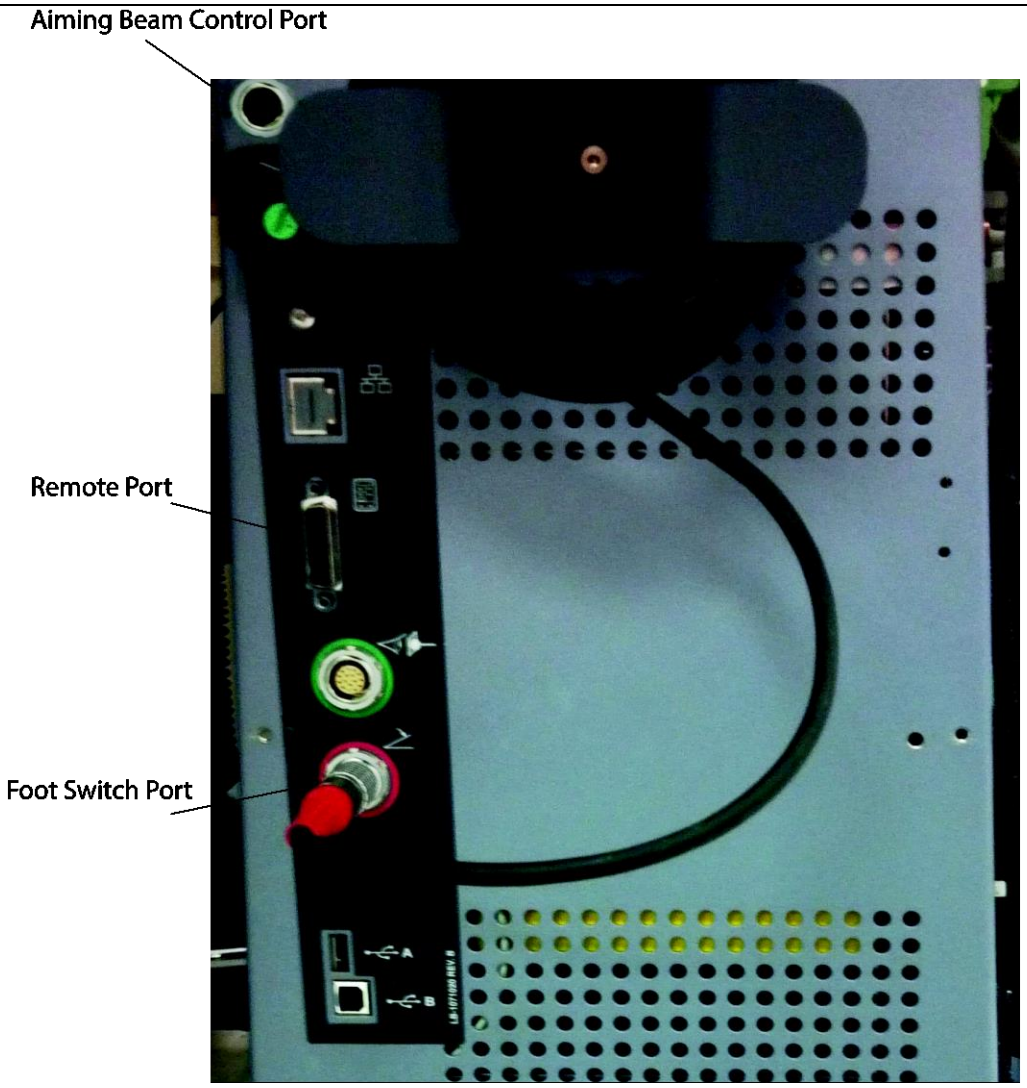

Fig. 6 Laser System Ports

After the Array LaserLink has been set up by a technician, it can be detached and reattached to the laser system by the user. The console cables will only attach one way preventing improper connection.

To detach the Laser System:

- Detach the laser control cables from the laser system. The cables include the aiming beam control cable, remote cable, and foot switch cable.
- Detach the foot switch from the console port and attach it to the laser system.

To attach the laser system:

- Remove the foot switch from the laser system and connect it to the console.
- Attach the laser control cables (foot switch, remote, and aiming beam control) to the laser system.

If the Array Module is removed from the compatible Slit Lamp for any reason, it must be reinstalled by a Lumenis-certified technician.

The Array LaserLink must be installed so that the wall plug is accessible for ease of disconnecting.

CAUTION - Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "Hospital Grade" or "Hospital Only".

Connecting an Eye Safety Filter

The Eye Safety Filter blocks the transmission of laser light, thereby protecting the physician's eyes from laser exposure while looking through the Slit Lamp.

The Eye Safety Filter is a component that is not connected to the Array LaserLink, but is part of the Lumenis Photocoagulator Laser System that is being used in conjunction with the Array LaserLink. Operating and installation instructions for the Eye Safety Filter are located in the Operator's Manual of the Lumenis Photocoagulator Laser System which is being used.

CAUTION - During treatment, the Eye Safety Filter must be attached to the Slit Lamp. Failure to do so could result in serious ocular injury.

CAUTION - Eye safety filters are labeled for laser model or wavelength compatibility. Use only Eye Safety Filters that are labeled for your laser model or wavelength. Use of an incorrect Eye Safety Filter could result in serious ocular injury.

Installing Observation Equipment

Install observation equipment according to the instructions that accompany those accessories.

Array LaserLink Operation

CAUTION - Before each use, inspect the system for dirt, debris, or damage. Check the Eye Safety Filter cable and the Eye Safety Filter extension cable, if applicable, to ensure that they are not frayed or split. Check the optical fiber to ensure that it is not punctured, fractured, or sharply bent.

CAUTION - Check to ensure there is no debris or object in the beam path. If any problems are noticed, do not use the device until unit is in appropriate working condition.

CAUTION - To prevent accidental laser exposure, always turn off the laser, as instructed in your laser operator manual, before connecting the delivery device.

NOTE - Refer to the Connection Instructions section of your laser operator manual, and perform the laser operating instructions in sequence with the instructions outlined in this manual.

1. Turn the laser system on, as instructed in your laser system operator manual.
2. Turn the Array LaserLink delivery device on by pressing the ❙ (on) switch on the Array LaserLink Console rear side and press the On/Off button on the front side.

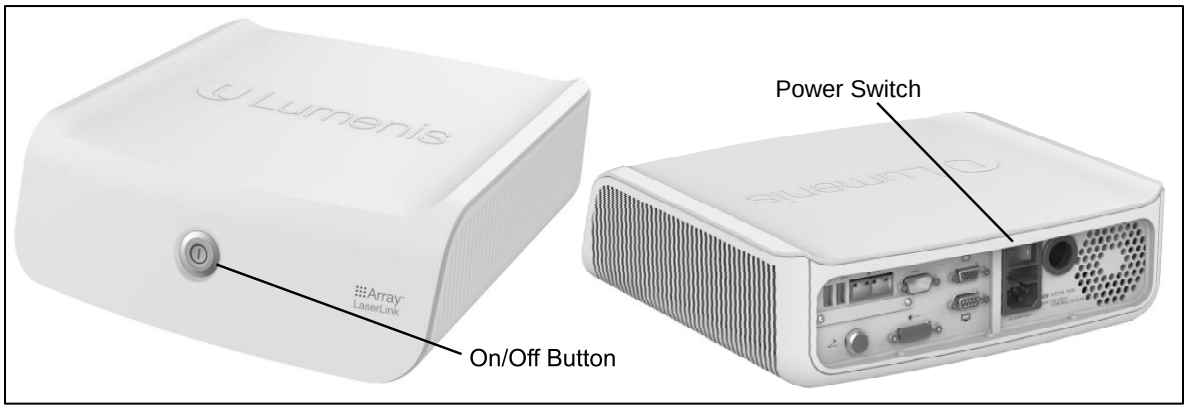

Fig. 7 Power Switch Location

The Treatment Screen

The Array LaserLink provides a touch sensitive graphical user interface for controlling the Array LaserLink delivery device. Most laser treatment parameters are directly adjustable from the treatment screen, as shown in Fig. 8, making it unnecessary to interact with the laser system directly. In fact, it is recommended that you perform all treatment adjustments using the Array LaserLink treatment screen. Some treatment parameters that are adjustable on the treatment screen are also adjustable on the touchpad\3D mouse.

The treatment screen is composed of panels in the upper left corner. One panel is visible at a time and is selected using the tabs at the bottom of the panel.

- **Shape**: The Shape Panel is where you will work during treatment. This panel is used for selecting the shape and setting the number of spots in the selected shape.
- **Options**: The Options Panel is used for setting up your preferred system settings.
- **Presets**: The Presets Panel allows up to 5 doctors to customize their personal treatment settings.
- **Report**: The Report Panel generates treatment reports.

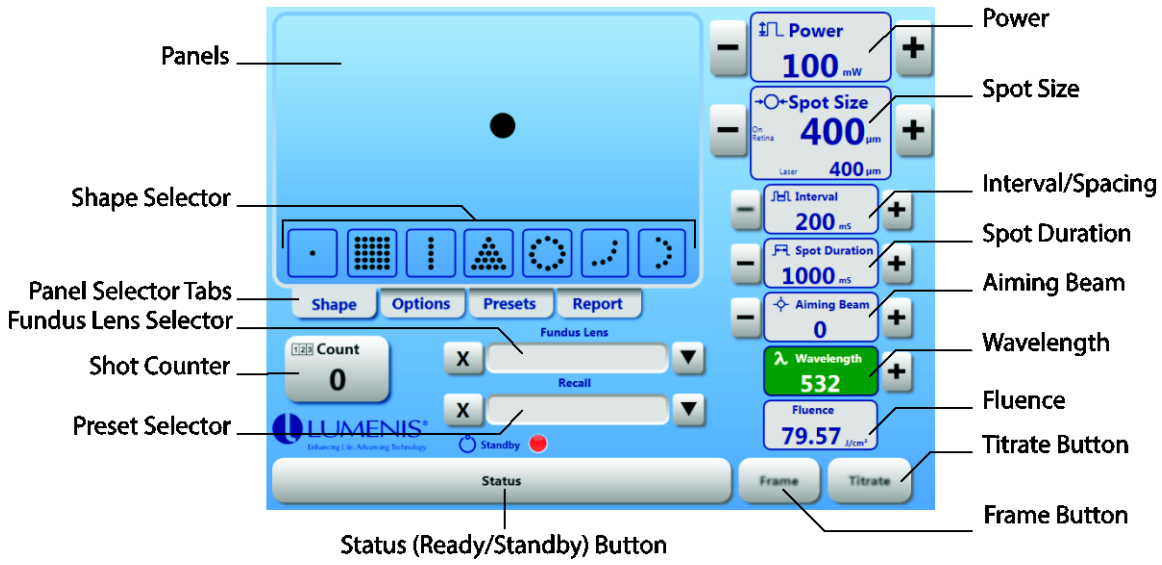

Fig. 8 The Array LaserLink Touchscreen

Touchpad

Fig. 9 shows the Array LaserLink touchpad. This touchpad facilitates making adjustments without having to remove your eyes from the binoculars. It also allows you to rotate the shape and perform fine positional adjustments (micromanipulation). In addition to the touch sensitive surface, the touchpad has two buttons for controlling the power settings and a pair of “middle” buttons which control titrate mode. The setup of the touchpad is covered later in this manual in the **Setting System Options** section.

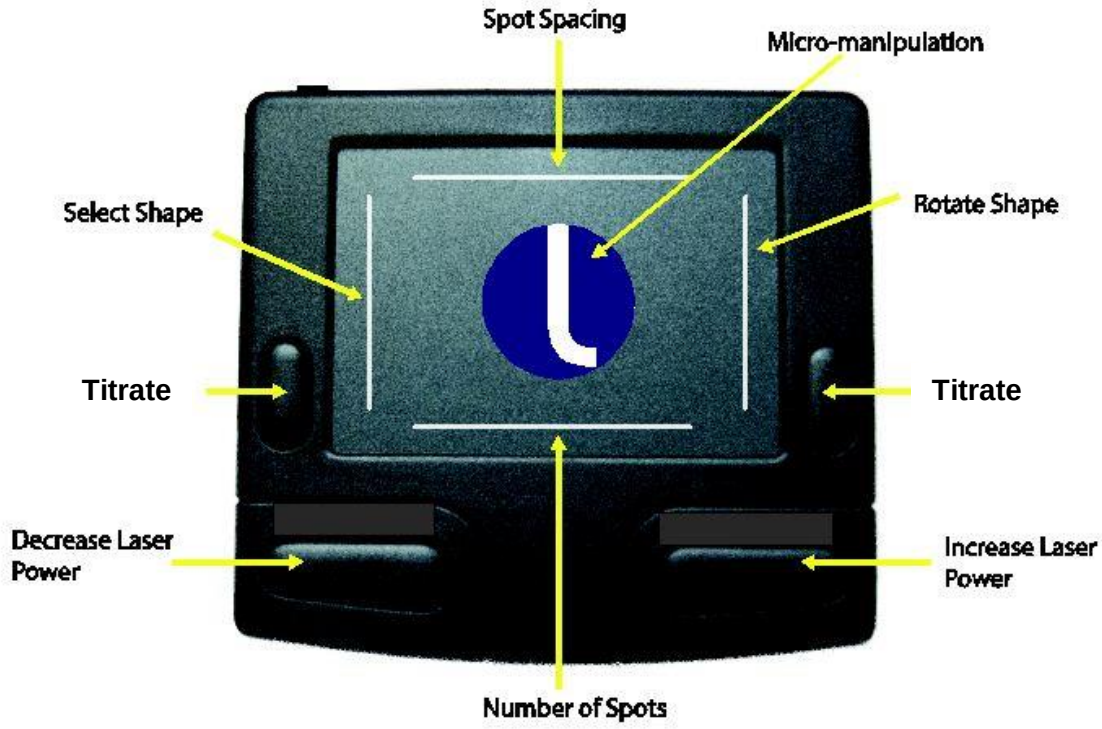

Fig. 9 The Array LaserLink Touchpad

3D mouse

Figure 10 shows the Array LaserLink 3D mouse. This device allows you to perform the following operations:

- Micromanipulation - fine positional adjustments.
- Change laser power settings - The 3D mouse has two buttons for controlling the power settings.
- Control Titrate mode - Pushing the main controller down toggles titrate mode on/off.
- Change number-of-spots - Rotating the main controller clockwise will increase the number of spots. Rotating the main controller counter-clockwise will decrease the number of spots.

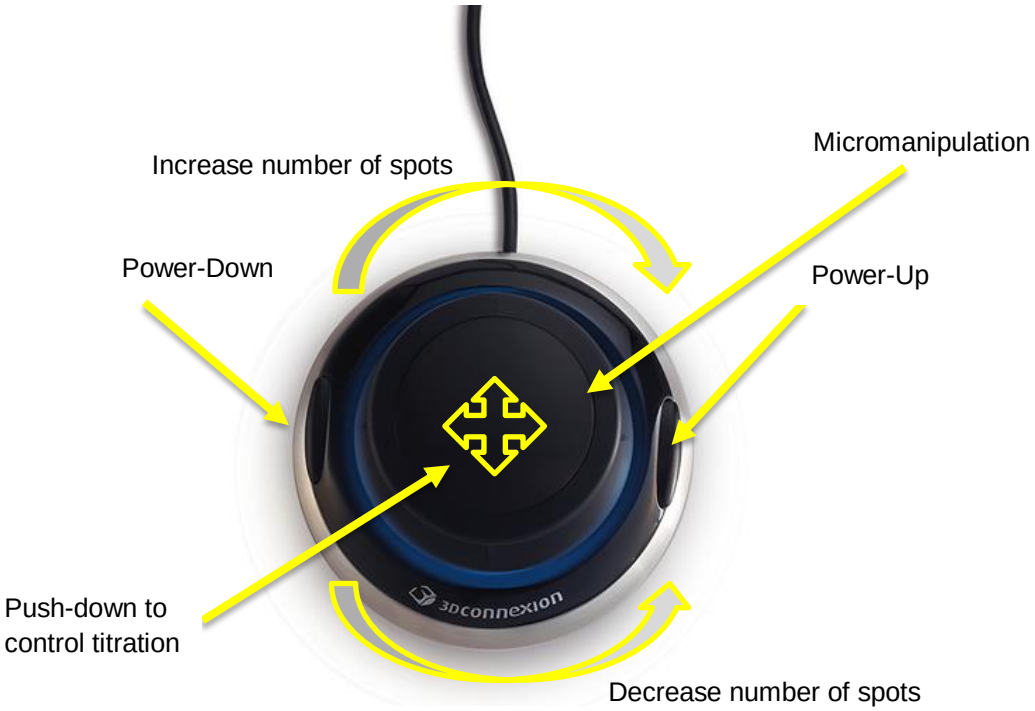

Figure 10 – The Array LaserLink 3D Mouse controls

Setting Treatment Parameters

CAUTION - Always verify that the desired treatment parameters are displayed on the touchscreen before initiating treatment.

CAUTION - If there is no change in display when you interact with the touchscreen or touchpad\3D mouse, or if the touchscreen appears otherwise erratic, do not use the laser. Contact your local Lumenis Representative.

Selecting the Shape

Seven shapes are available: single spot, square, line, triangle, circle, quarter circle and half circle. Select the desired shape by pressing the corresponding shape selector; the shape appears in the Shape Panel as seen in Fig. 11 and is traced by the aiming beam on the retina.

Press the − and + buttons on each side of the **Spot Size** display to increase or decrease the range of spots; the total number of spots is shown in the **Total Spots** display.

You may also use the Touchpad to select the shape by sliding your finger along the left edge as shown in Fig. 9 on the previous page.

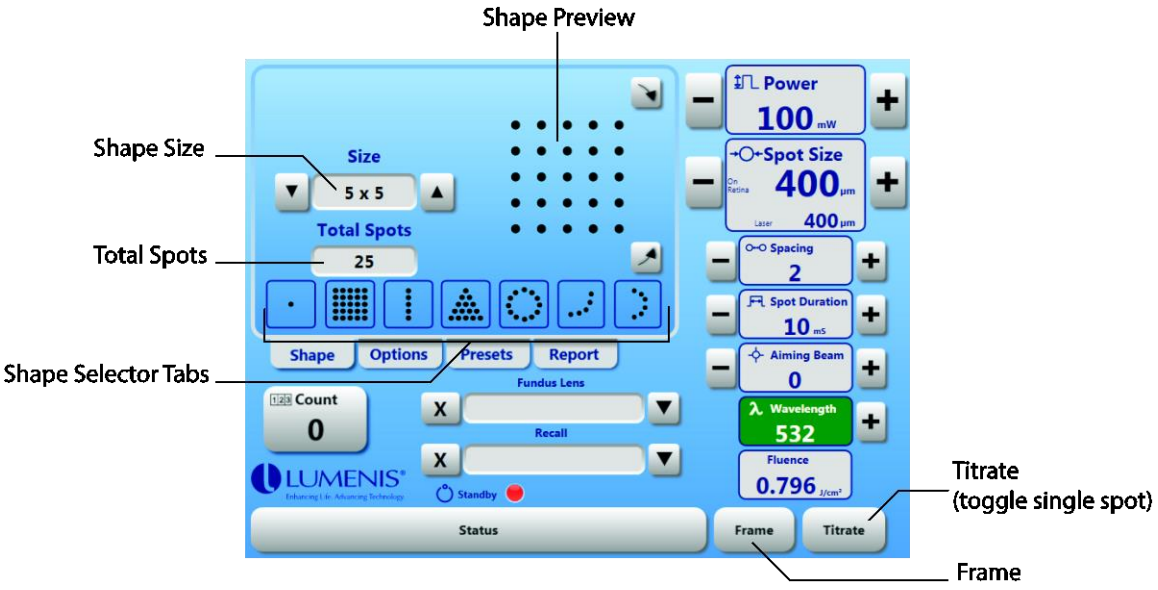

Fig. 11 The Shape Panel

Titrating

The Array LaserLink provides a shortcut to simplify titrating. After you have selected a shape, you can instantly switch to a single spot for making adjustments to power level and spot size, etc. Press the **Titrate** button to activate the single spot. In titrate mode, the treatment screen shows the dimmed pattern with a single spot in the center as shown in Fig. 12. On the retina, only the single spot will be visible. To return back to the orginal shape, press the **Titrate** button again.

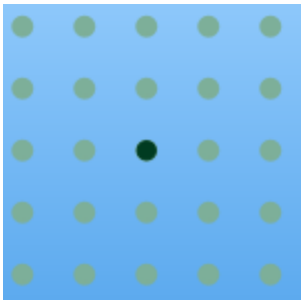

Fig. 12 Titrate Preview

Frame Mode

Press the **Frame** button to display only an outline of the shape for a less obstructed visualization of the target. When frame mode is selected, the treatment screen displays the selected shape in a bounding frame as seen in Fig. 13.

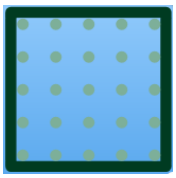

Fig. 13 Frame Mode Preview

The screen shows the spots that will be delivered during treatment. On the retina, only the outline will be visible.

NOTE – Treatment *cannot* be delivered in Frame Mode. User must go back to normal aim beam mode to treat.

Rotating a Shape

The Array LaserLink allows you to rotate any shape, with the exception of single spot. A pair of buttons in the upper and lower right corner of the Shape panel (see Fig. 14) lets you rotate the shape in either direction in 15 degree increments.

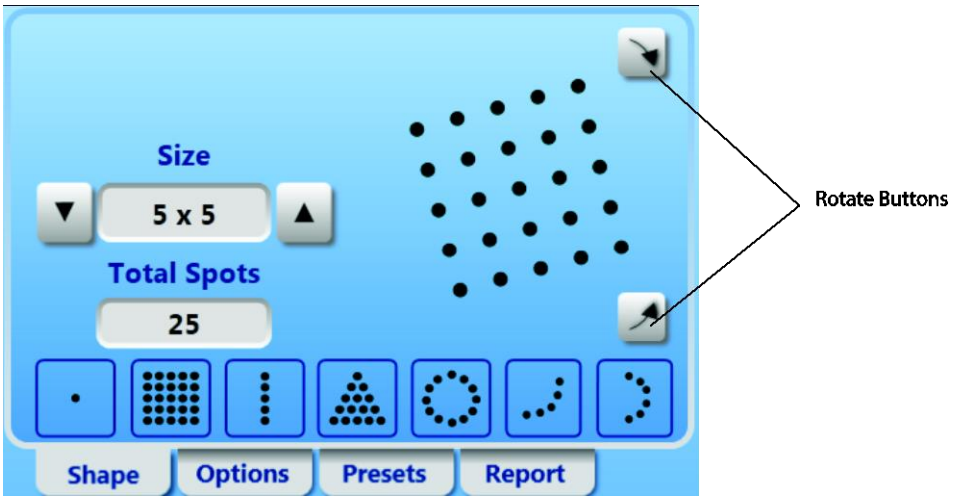

Fig. 14 Rotation Buttons

You can also use the touchpad to rotate the shape. Rotating is performed by sliding your finger along the right edge of the touchpad as shown in Fig. 15.

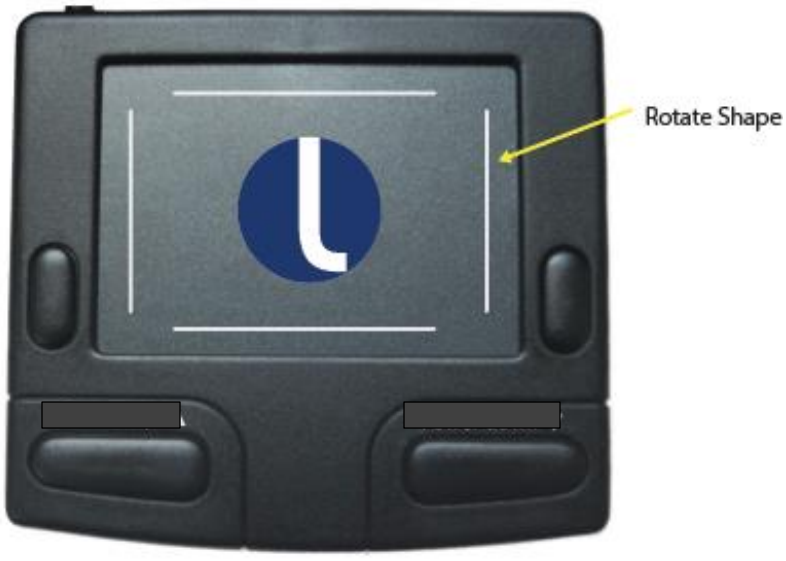

Fig. 15 Rotation Zone

Micromanipulation

The Array LaserLink features an electronic micromanipulation feature. By using the touchpad\3D mouse you can perform fine adjustments on the location of the treatment. The middle section of the touchpad\3D mouse as shown in Fig. 16 can be used to move the pattern in any direction. The amount of movement is limited by the optical range of the Array LaserLink. Unlike the rotate feature, micromanipulation is not rendered on the treatment screen. This can only be witnessed on the retina.

Fig. 16 Micromanipulation area

Adjusting the Spacing between Spots

Press the − and + buttons in the **Spacing** field (Fig. 17) to adjust the spacing between spots. The **Spacing** field is only applicable when a non-single spot shape is selected.

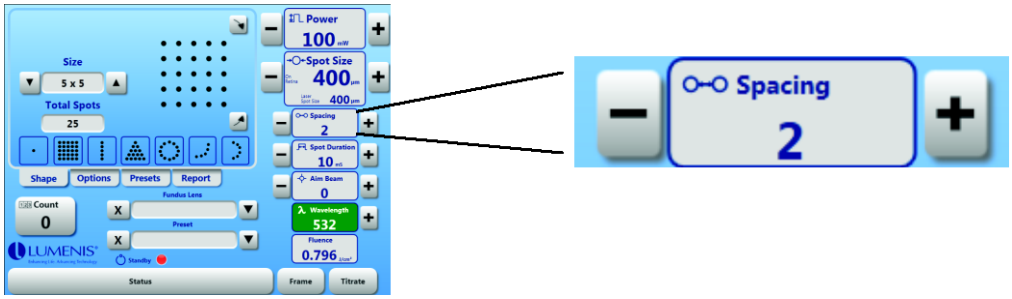

Fig. 17 Spacing

To adjust the spacing using the touchpad, slide your finger horizontally along the top edge of the touchpad until the desired spacing is reached (Fig. 18).

Fig. 18 Spacing Zone

Setting the Laser Power

To set the power from the touchscreen, press the − and + buttons in the **Power** field (Fig. 19) until the desired setting is reached. Whenever the power is changed, the new value will be temporarily displayed on the retina on a heads-up display.

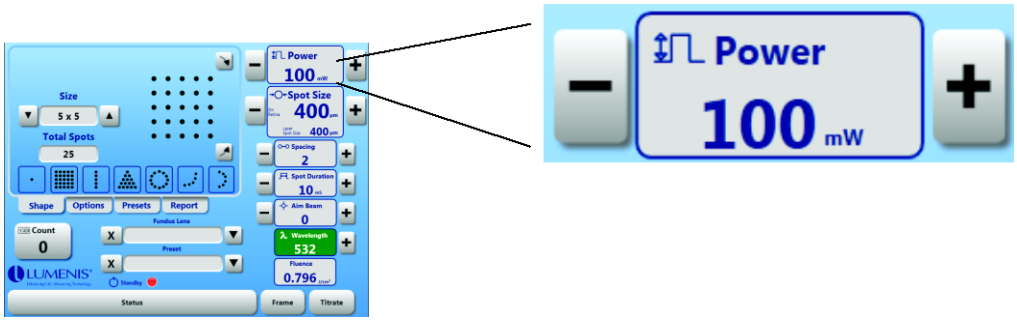

Fig. 19 Power

To set the power from the touchpad, press increase laser power and decrease laser power buttons on the touchpad\3D mouse. Fig. 20 shows the location of these buttons.

Fig. 20 Power Buttons

NOTE: A single spot titration of laser power (with repeat mode off) should occur prior to initiation of a multi-spot pattern. If uncertain of expected clinical response, users should start with conservative settings and increase laser power and/or duration settings in small steps.

Setting the Spot Size

The Array LaserLink touchscreen controls the laser spot size. Spot sizes of 50 (single spot) to 1000 µm are available. During scanning the minimum spot is 100 µm and the maximum spot size is 500 µm.

To set the spot size from the touchscreen, press − and + buttons in the →○← **Spot Size** field (until desired setting is shown is Fig 21).

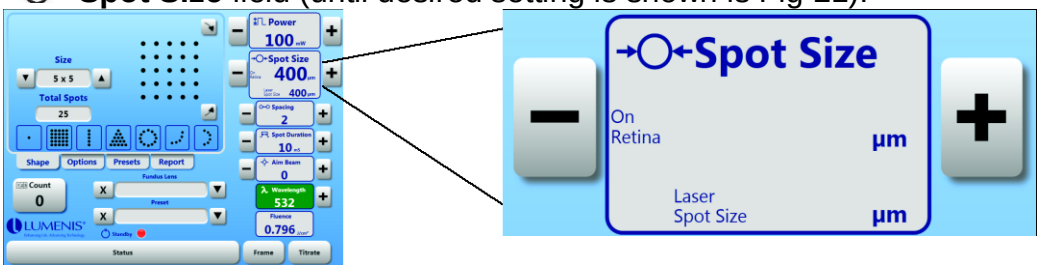

Fig. 21 Spot Size

NOTE – The spot size range is affected by the choice of Fundus lens. In single spot mode, the normal range for spot size with no Fundus lens is 50 µm to 1000 µm. However when a Fundus lens is used, that range changes depending on the magnification of the lens.

At the lower end, the minimum On-Retina spot size is limited by the 50 µm laser spot size limit. So with a lens having a magnification less than 1.0, an On-Retina spot size less than 50 µm can be obtained. With a lens magnification greater than 1.0, the On-Retina spot size will be something larger than 50 µm.

At the upper end,. the Array LaserLink limits the On-Retina spot size to 1000 µm for single spot mode, and 500 µm for any other shape.

NOTE – The Array LaserLink should always be used in conjunction with a Fundus lens. The Array LaserLink gives the user the option to have the actual spot size on the retina be calculated by the system by selecting the appropriate lens from the drop down menu, or do the calculation manually by selecting no lens and setting the spot size directly.

Minimum time interval between spots with single spot mode is 0.05s.

Average time between successive treatment spots in multi-spot mode is 1.5ms. This time will vary by as much as ±.1ms depending on the number of spots, spot size, and spot spacing parameters used in the pattern.

NOTE: Human reaction time can exceed the rate of treatment spot delivery in either single spot repeat or multi-spot pattern mode. This can result in delivery of laser applications after intended release of the footswitch prior to completion of a pattern.

About Spot Size and Fluence

Fluence at the treatment site largely determines the degree of interaction of the laser beam with tissue. Fluence is defined as laser power divided by the area of the spot size. Fluence can be increased by increasing the laser power or by decreasing the spot size.

WARNING - The relationship between spot size and fluence is not linear. Reducing the spot size by 50% will quadruple the fluence. The laser clinician must understand the relationships between spot size, laser power, fluence, and thermal interaction of the laser beam with living tissue before using the laser and delivery device.

The following table shows how the fluence at the treatment site changes with increasing or decreasing laser beam spot sizes. The figures in this table should not be used to set treatment parameters; they are intended as a guide to the relationships between laser power, laser beam spot size, and laser beam fluence at the treatment site.

Spot Size	Laser Power Level (watts)			
	0.1	0.5	1.0	1.5
50 µm	5,093	25,465	50,930	76,394
100 µm	1,273	6,366	12,732	19,099
200 µm	318	1,592	3,183	4,775
500 µm	51	255	509	764
1000 µm (single spot only)	13	64	127	191

Laser Fluence table (watts/centimeter^2)

Setting the Aiming Beam Intensity

To set the aiming beam intensity, press − and + buttons in the **Aiming Beam** field (Fig. 22) until the desired intensity is shown.

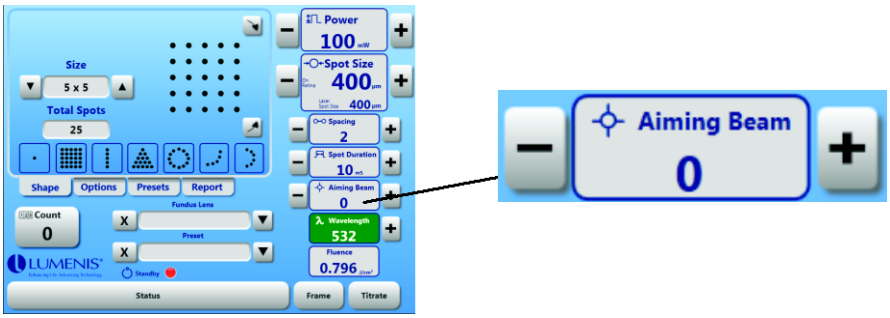

Fig. 22 Aiming Beam

Setting the Duration

To set the treatment duration, press the − and + buttons in the **Duration** field (Fig. 23) until the desired setting is shown. The duration refers to the treatment time for each spot. Except for single spot shapes, the allowed settings are 10, 20 and 30 milliseconds. For single spot, the duration range is determined by the laser system.

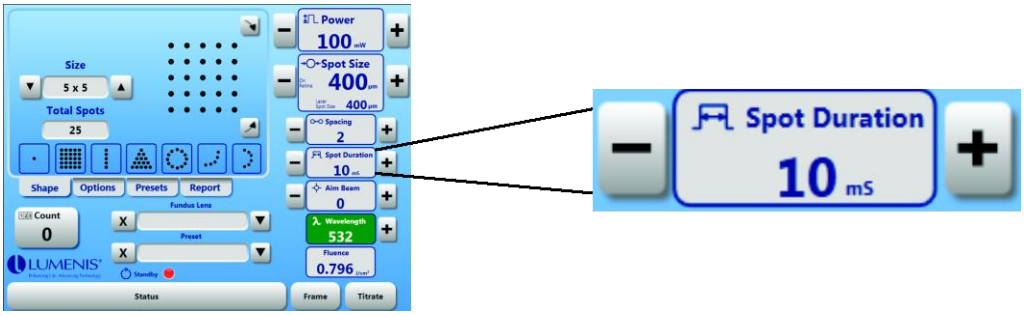

Fig. 23 Duration

NOTE: The minimum interval between treatment spots in scanning mode is 1.5ms. This interval is significantly shorter than the minimum treatment pulse duration available in single spot mode, which is 5ms.

Setting the Interval

To set the interval, press the + button in the **Interval** field (Fig. 24) until the desired setting is shown. This Interval field is only visible when Single Spot is selected.

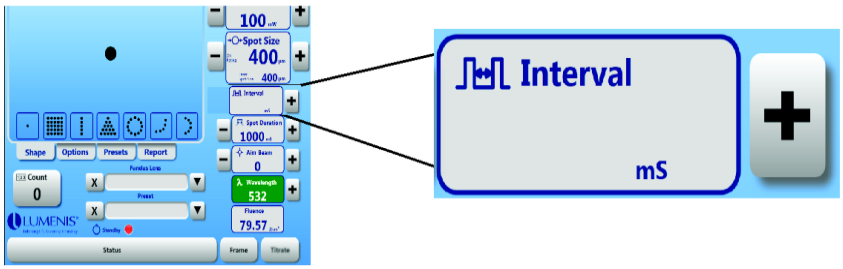

Fig. 24 Interval

NOTE – In single spot mode, the decrement button does not appear in the Interval field. This is due to a limitation of the laser systems.

To obtain an Interval setting, press the + button repeatedly until the desired value is displayed.

When a non-single spot shape is selected, the Interval field becomes the Spacing field, in which case the decrement button is functional.

Setting the Treatment Beam Wavelength

If using a laser system with multiple treatment wavelengths, press the + selector to the right of the λ **Wavelength** field (Fig. 25) repeatedly until the desired wavelength is selected.

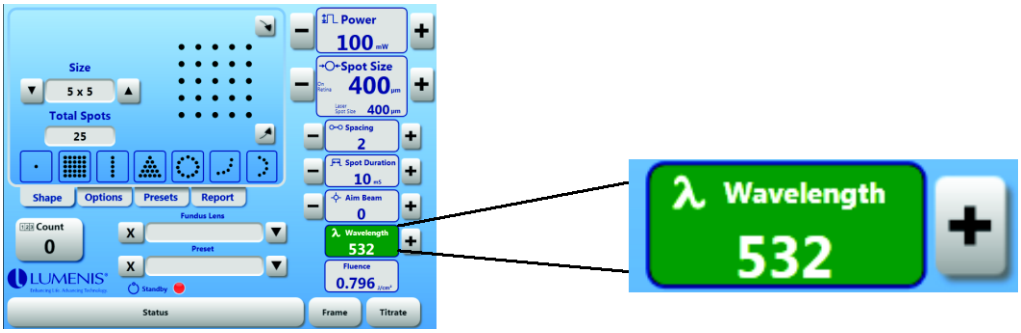

Fig. 25 Wavelength

NOTE – The Array LaserLink will not allow scanning with a red laser. A red laser can only be used with a single spot pattern. Because of this, selecting a red laser will cause the Array LaserLink to automatically switch to the Single Spot shape if you currently have any other shape selected.

When you switch from a red laser to a different wavelength, the Array LaserLink will switch back to the previous shape if you did not change any settings while the red laser was selected. If, however, you changed any settings while the red laser was selected, the Array LaserLink will remain in Single Spot shape after switching to the new wavelength.

Resetting the Shot Counter

The shot counter displays the total number of treatment pulses delivered during a treatment session, or since the 123 **Count** Button (Fig. 26) was last pressed. The current pulse count is maintained across shutdowns. To reset the pulse counter from the treatment screen, press the **Count** Button.

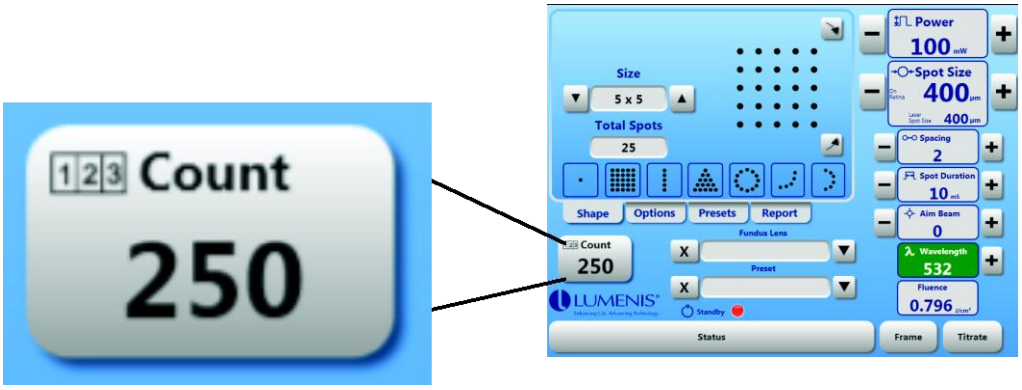

Fig. 26 Shot Count Button

Selecting the Fundus Lens

Press the ▼ button in the **Fundus Lens** field (Fig. 27) to display a list of Fundus lenses.

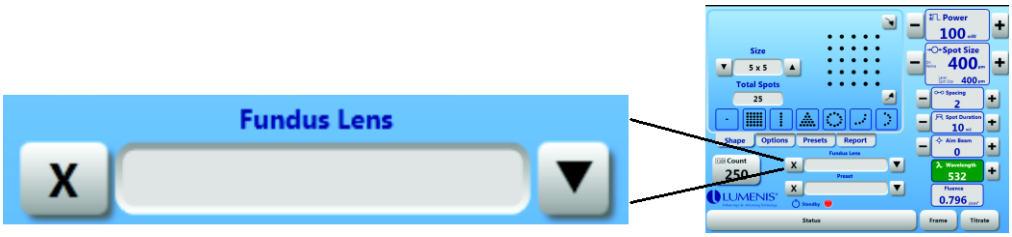

Fig. 27 Fundus Lens Selector

When the window is first displayed, it shows your Favorites list, as seen in Fig. 28. This provides you with a short list of lenses to select from so you don't have to search the full list of lenses.

Fig. 28 Fundus Lens Window Displaying Favorites List

Select the lens by touching the item in the list followed by pressing the OK button.

To create or customize your Favorites list, select the All Lenses tab at the top of the window. This view shows all of the Fundus lenses recognized by the Array LaserLink. Yellow stars indicate which lenses will be displayed in the Favorites list. To add or remove a lens from the Favorites list, touch the star next to the lens.

You can scroll through the list using the up and down buttons on the right of the list. You may also sort the list by magnification or by name. This will make it quicker to find a particular lens.

Using a Fundus lens affects the size of the spot on the retina. The Spot Size field displays both the Laser Spot Size before the Fundus lens and the On-Retina Spot Size.

To de-select the Fundus lens, press the  button at the left of the Fundus Lens field.

CAUTION - The correctness of the On-Retina Spot Size is dependent of the selection of the correct Fundus lens. Using a Fundus lens with a magnification different than the selected lens will produce a spot size that does not match the size displayed on the touchscreen.

Selecting the Laser Status

Press the **Status** button to toggle the laser system between READY and STANDBY modes. The current mode is displayed above the **Status** button. The laser system should be in STANDBY mode *except* during actual treatment. The **Status** button and **Status Indicator** are shown in Fig. 29.

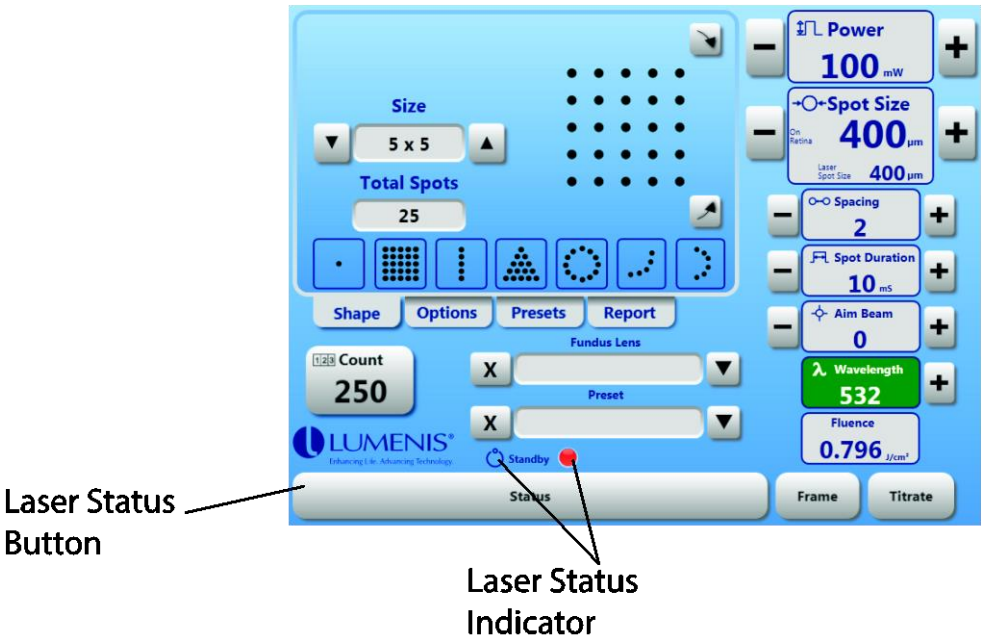

Fig. 29 Laser Status Button and Indicator

WARNING – Inadvertent laser emission can cause serious tissue damage. Therefore, it is recommended that the laser system is kept in STANDBY mode *except* during actual treatment.

Setting System Options

Press the **Options** tab to display the system options. The **Options** are displayed within three forms. To navigate the forms, use the **Back** and **Forward** buttons.

Options Form 1

Fig. 30 Options - Form 1

Form 1 lets you set:

- The Date & Time
- Speaker Volume
- Standby Backlight Level
- Ready Backlight Level

Setting the Date & Time

The date and time are displayed in the reports created by the Array LaserLink. To ensure that the date and time in the reports are correct, use the **Date & Time** fields to set the current date and time.

Setting Time Format

Time can be displayed in 12-hour or 24-hour format. By pressing the time format button you can switch between the two modes. The time format button's label will show 12H or 24H depending on which mode you have chosen.

Setting Date Format

The date can be displayed in one of four different formats. The Date format button label shows the selected format. To set the format, press the Date format button until the desired format is displayed. The possible formats are:

- **DD/MM/YYYY** *(31/01/2014)*
- **DD MMM YYYY** *(31 Jan 2014)*
- **MM/DD/YYYY** *(01/31/2014)*
- **MMM DD YYYY** *(Jan 31 2014)*

Adjusting Date & Time

To adjust the date and time press the field select button  . This will select which part of the date and time you are setting. After one press, the Hour field will be highlighted in red. After the second press, the Minutes field will be highlighted, and so on. Select the field you wish to adjust, then use the decrease and increase buttons  to change the value. When you are finished setting the date and time, press the field select button until none of the fields are highlighted.

Setting the Speaker Volume

The **Volume** setting controls the sound level of sounds produced by the system.

Standby Backlight and Ready Backlight

The **Standby Backlight** level controls the touchscreen brightness while the system is in Standby mode. Conversely, the **Ready Backlight** level controls the touchscreen brightness while the system is in Ready mode. Separate levels are provided so you can dim the touchscreen during treatment when the room lights are dimmed.

When setting these levels, set the system to the appropriate mode Ready or Standby) and have the room lights set to the corresponding level.

Options Form 2

Fig. 31 Options - Form 2

Form 2 lets you:

- Enable or disable the speaker sound.
- Display or hide the fluence value on the treatment screen.
- Auto-Center the shape when switching to a different shape. This resets any micromanipulation or rotation that has been applied to the shape.
- Enable the displaying of On-Retina Text.

Controlling Sound

The **Enable Sound** checkbox is used to control whether speaker is enabled. To mute the speaker, un-check the **Enable Sound** checkbox. Otherwise, leave it checked.

Displaying Fluence

The fluence value on the treatment screen can be hidden by un-checking the **Show Fluence** checkbox. If you prefer to have fluence displayed, leave the checkbox checked.

Resetting Rotation and Micromanipulation

You may or may not want to have any rotation or micromanipulation that you have applied to be reset when switching shapes. If you wish to retain these settings when switching to a new shape, then un-check the **Auto-Center Shape** checkbox. If you wish to clear the micromanipulation and rotation, then leave the **Auto-Center Shape** button checked.

Enabling the On-Retina Text

When enabled, changes to some parameters such as power and duration etc. will be displayed on the retina for a short period.

Options Form 3

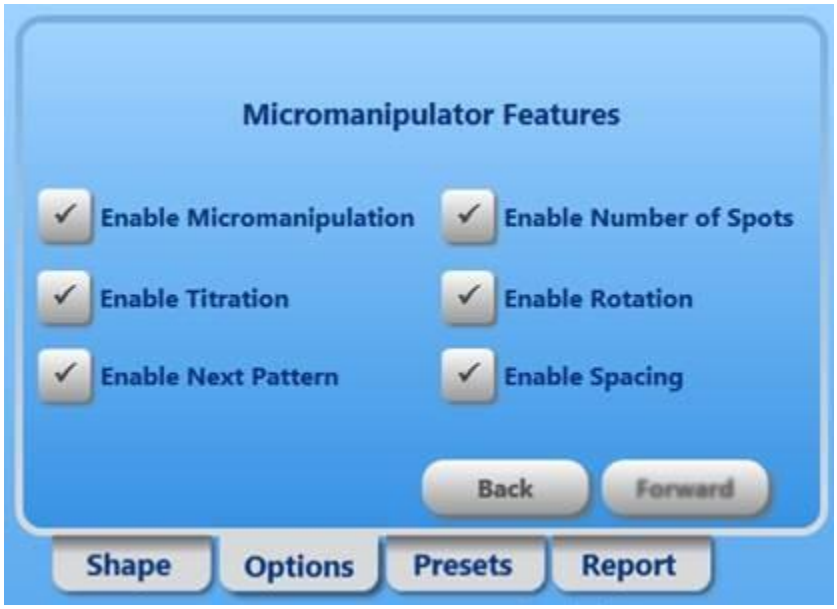

Fig. 32 Options - Form 3

Form 3, as shown in Fig. 32, lets you set the feature level of the touchpad\3D mouse.

The Touchpad\3D mouse Features choices are:

- Enable Micromanipulation.
- Enable Spacing (Does not exist with 3D mouse).
- Enable Next Pattern. (Does not exist with 3D mouse).
- Enable Number of Spots.
- Enable Rotation (Does not exist with 3D mouse).

Enable Manipulation

This button lets you enable or display the Micromanipulation feature.

Enable Spacing

This button lets you enable or display the Spacing control feature.

Enable Next Pattern

This button lets you enable or display the Next Pattern feature.

Enable Number of Spots

This button lets you enable or display the Number of Spots control feature.

Enable Rotation

This button lets you enable or display the Rotation control feature.

Saving and Retrieving Treatment Presets

The Preset Panel

The **Presets** panel lets you view and manage the five user definable presets. To access the **Presets** panel, select the Presets Panel tab.

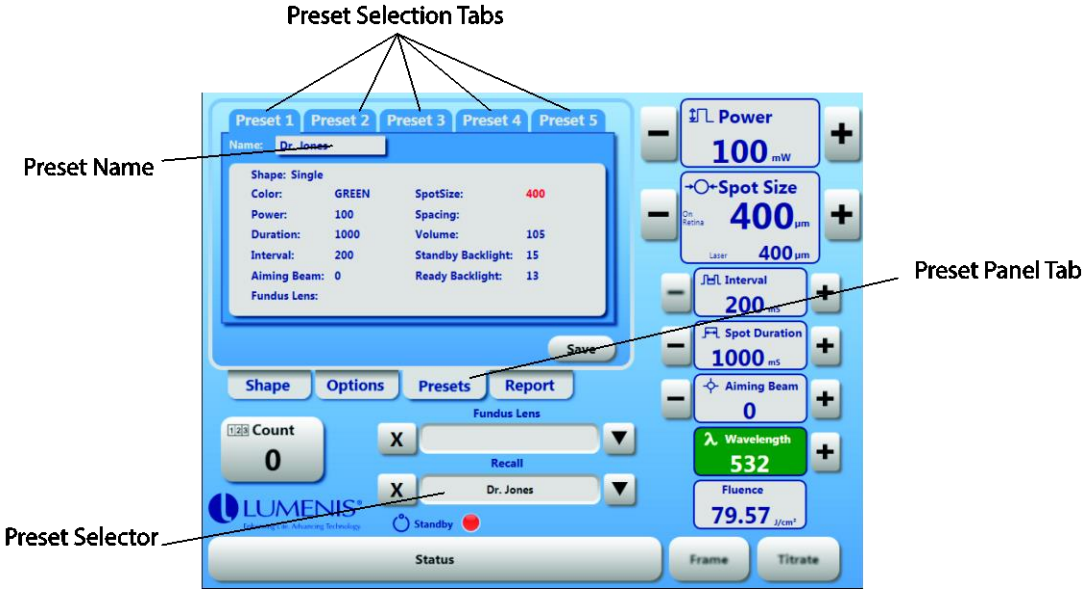

Fig. 33 Presets Panel

Five presets are available for saving laser treatment settings. Each preset is displayed in a separate tab labeled Preset 1 through 5 at the top of the Preset panel. The panel displays all of the treatment settings that are stored in a preset. Any treatment setting that currently doesn't match what is stored in the preset will be shown in red. The parts of the **Preset Panel** are shown in Fig. 33.

Saving a Preset

Choose a preset you want to save by selecting one of the Preset selection tabs. Each preset must be assigned a name which is used when recalling the preset settings.

Touch the **Name** field to assign a name to your preset using the on-screen keyboard. The on-screen keyboard will pop up. Type in a name and press the **Enter** or **Done** key when finished. Press the **Save** button to save the preset.

Recalling a Preset

Press the ▼ button in the **Recall** selector (Fig. 34) to display the list of saved presets; from the Preset Selection Dialog Box, select the desired preset name (Fig. 35). The saved name you gave the preset will be displayed in the **Recall** field.

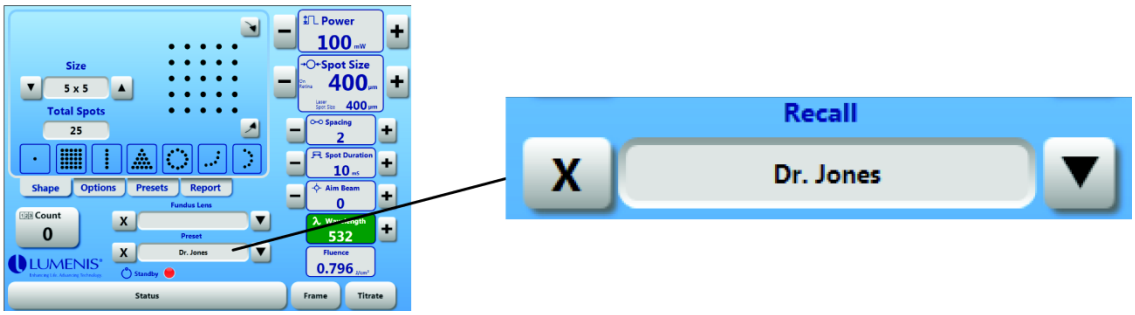

Fig. 34 Preset Selector

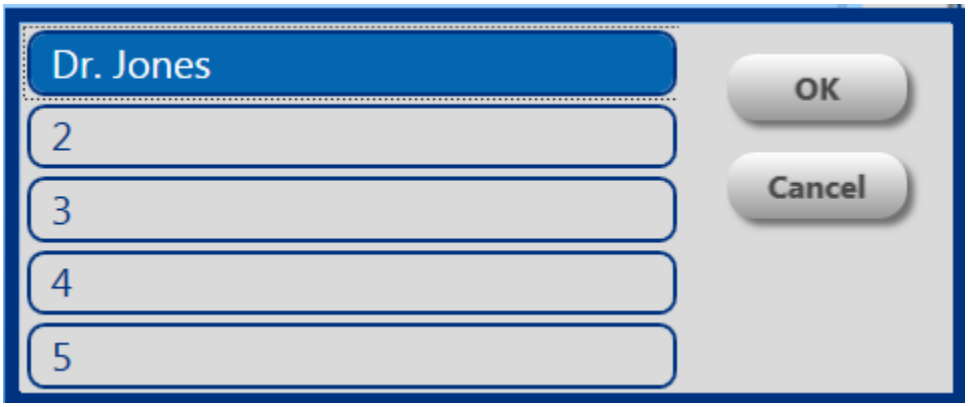

Fig. 35 Preset Selection Dialog Box

Updating a Preset

After selecting a preset with the Preset selector, any changes made to the treatment settings will be reflected in the Preset screen for the selected preset. For instance, select a preset using the Preset selector. Now change the Power setting. If you view the corresponding preset in the Preset panel, you will see the Power value displayed in red. This means that the current setting doesn't match the preset. If you wish to update the preset with the new power setting, simply press the **Save** button in the preset panel.

You can also restore all settings back to the preset settings by cycling through the presets repeatedly pressing the **Preset** selector until you reach the desired preset.

Exporting and Printing Reports

The Array LaserLink lets you create reports that record many of the details of a treatment session. The report may be saved to a USB thumb drive, or other USB storage device, as a PDF or text file.

The **Report** information is input within five forms: **Patient Information** form, **Diagnostic** form, **Pattern** form, **Location** form, and a final form which provides fields for entering the estimated number of spots fired and for listing the names of the surgeons. To navigate the five forms, use the **Back** and **Forward** buttons at the top of the Report Panel as seen in Fig. 36.

The **File Name** and **Eye** fields are required. All other fields are optional. Any field that is left empty or un-selected can be filled in by hand after the report is printed.

Information that is supplied to the Report forms will be included in the saved report file. Also, information provided by the Array LaserLink, such as power, shape, spot size etc. will be included in the report automatically.

Fig. 36 Report Panel Displaying the Patient Information Form

Using the Report Panel

1. Press the **Report** tab to view the report forms. The first form is the Patient Information form.

2. Touch the **File Name** field to enter a file name for the report. The name may only contain letters and numbers. Upon touching the **File Name** field, a keyboard will pop up at the bottom of the screen as seen in Fig. 37. Using the touchscreen keyboard, type in a file name for the report and press either the **Enter** key or the **Done** key when you are finished.

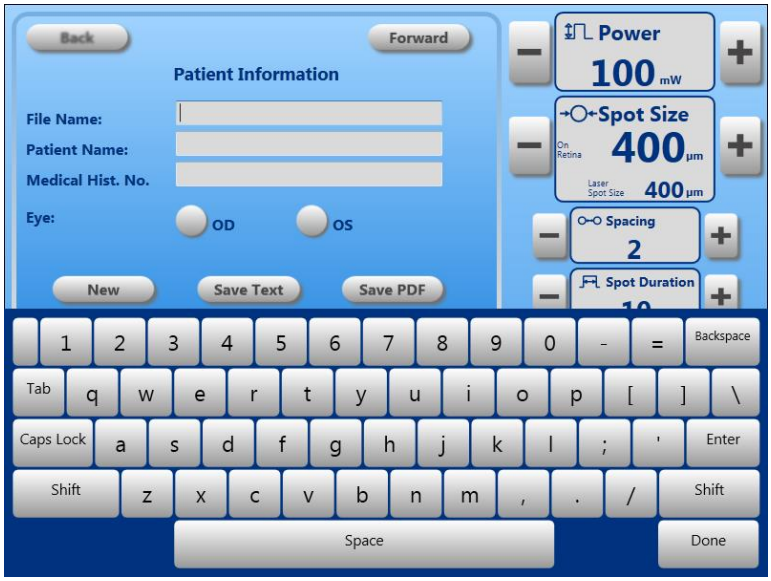

Fig. 37 Popup Keyboard

3. You may repeat the same process to enter the patient's name and medical history number. If you prefer, as mentioned earlier, you can leave these fields blank and write them in after the report is printed.

4. Select either **OD** (right eye) or **OS** (left eye).

5. If you wish to write in the remaining information later, skip down to step 13 below to save the report.

6. Press the **Forward** button to continue to the **Diagnosis** form (Fig. 38).

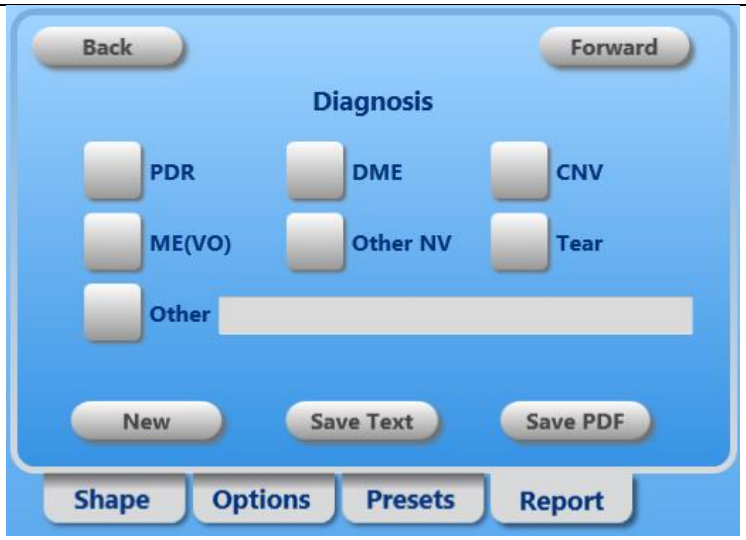

Fig. 38 Diagnosis Form

7. Press the appropriate checkboxes to record the diagnosis. The **Other** option is provided for specifying a diagnosis that is not listed in this form.
8. Press the **Forward** button to proceed to the **Pattern** form (Fig. 39).

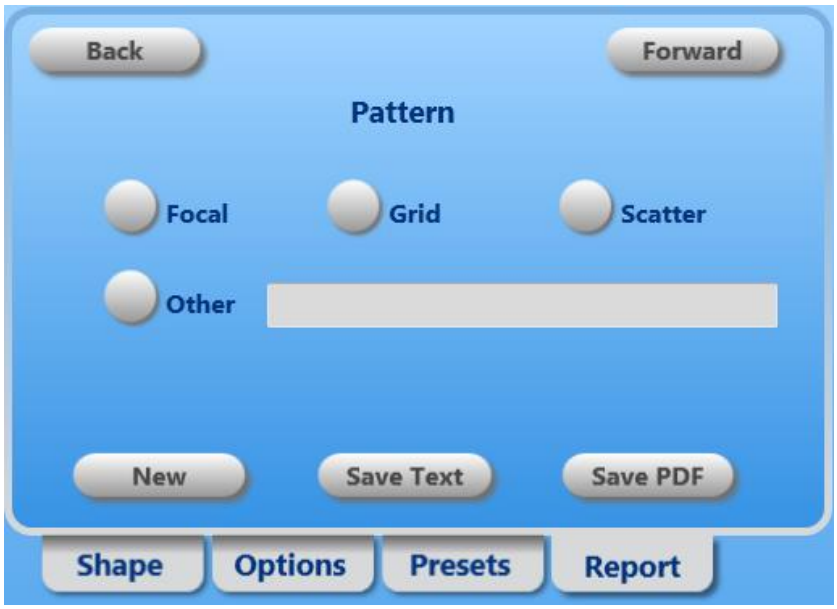

Fig. 39 Pattern Form

9. Select the appropriate pattern button. If the pattern is not listed, select the **Other** field and type in the pattern in the provided field.
10. Press the **Forward** button to continue to the **Location** form (Fig. 40).

Fig. 40 Location Form

11. Select the appropriate button(s) on the Location form to indicate the treatment location on the macula and/or periphery: Superior temporal (ST), superior nasal (SN), inferior temporal (IT), or inferior nasal (IN). Then, press the **Forward** button to continue.

12. The final form provides fields for entering the estimated number of spots fired. The actual number counted by the Array LaserLink will also appear in the report. The remaining fields on the form are for entering the names of the surgeons.

13. If you have skipped here from Step 5, or you have completed filling out all the forms, and you want to save the report, insert a USB thumb drive into the USB port on the side of the Array LaserLink control unit. Press the **Save Text** or **Save PDF** button to save the report to the thumb drive. You will see a message window once the file is saved. You can remove the USB thumb drive now.

14. Once the session is complete, press the **New** button. This will clear all of the session information in the report and, optionally, clear the shot counter.

Preoperative Instructions

WARNING – Do not put any body part or reflective object in the beam path. This action could cause severe burns to the user, patient, or bystanders. Turn off laser system before inspecting any attached delivery device or laser components.

1. Turn on the laser, as instructed in your laser operator manual.
2. Turn on the Array LaserLink Console, as instructed in this operator manual.
3. Ensure that the laser system is in STANDBY mode to prevent inadvertent treatment beam emission.
4. Ensure that the correct Eye Safety Filter and the Array LaserLink are properly connected to the laser system.
5. If used, post a “Laser in Use” warning sign outside the treatment room door.
6. Verify that all persons in the treatment room are wearing the appropriate laser safety eyewear. Refer to the Safety and Regulatory section of this manual and your laser operator manual for additional information.
7. If using an automatic Eye Safety Filter, select the desired Eye Safety Filter mode.
8. For dual port laser systems, select the appropriate fiber receptacle.

Intraoperative Instructions

1. As directed in your laser operator manual, prepare the treatment room and verify that the laser is turned on and in STANDBY mode.
2. Position the patient in a sitting position in front of the Slit Lamp.
3. Select the desired spot size, as instructed in the Spot Size Selection section of this chapter.
4. Select the desired treatment parameters, as instructed in your laser operator manual.

CAUTION – Exercise caution while setting multi-spot parameters (pulse duration and the number of spots per pattern) when continuous wave laser burns are to be delivered in the macula; with longer grid completion times, the possibility of patient movement increases the risk of treatment of unintended targets.

WARNING - Incorrect treatment settings can cause serious tissue damage. Therefore, it is recommended that you use the lowest acceptable treatment settings until you are familiar with the instrument's capabilities. Use extreme caution until you thoroughly understand the biological interaction between the laser energy and tissue.

5. If used, place the contact lens up to the patient's eye.

CAUTION – Use caution when using a multiple mirror contact lens with multi-spot patterns. Prior to activating the laser, ensure that you have visualization of the complete pattern and the area to be treated. Adjust the pattern if necessary so that it does not overfill the mirror.

6. Adjust the Slit Lamp if necessary.
7. Position the aiming beam on the target tissue using the touchpad\3D mouse or the Slit Lamp micromanipulator.

CAUTION – If a blurry or partial aiming pattern is noticed, the system is out of focus or alignment. Stop use and contact your Lumenis Service Representative.

CAUTION – If the pattern or aiming beam spot size that is visualized through the Slit Lamp is not the same as what is displayed on the control panel or was requested by operator, stop treatment and contact your Lumenis Service Representative.

8. If using the co-observation tube, lift the sleeve to the desired viewing angle; rotate the image adjustment ring to achieve an upright image.
9. Place the laser in READY mode.
10. Depress the laser footswitch to deliver the treatment beam to the target site.

CAUTION – In scanning pattern mode when the footswitch is depressed, a multi-spot pattern will be delivered. If the footswitch is released during application of the pattern, the laser will stop and the full pattern will not be delivered.

NOTE – In single spot repeat mode, when the footswitch is depressed, the laser system will continue to deliver single laser shots at the selected duration and interval until the footswitch is released. Repeat mode is not available for multi-spot patterns.

Postoperative Instructions

1. Place the laser in STANDBY mode.
2. Turn the key switch to the OFF position. Remove the key to prevent unauthorized use of the laser.
3. Turn off the Array LaserLink console using the On/Off switch on the front and the On/Off switch on the rear.

Maintenance

Troubleshooting Guide

If the instrument fails to operate properly, this troubleshooting guide will help you to locate and correct the malfunction. First, please check for the following items:

Electrical power source

Verify that the electrical disconnect switch (the circuit breaker) is turned on.

Laser console electrical

Verify that the laser is on and properly connected to an electrical service outlet.

Delivery device connections

Verify that the delivery device is properly connected.

External door interlock

If the external door interlock is used in conjunction with a remote switch, verify that the external door interlock plug is inserted in the external door interlock receptacle. Close the interlocked door.

Problem	Probable Cause	Solution
Inadequate Slit Lamp illumination.	The illuminator intensity is not in the proper position, or the illuminator bulb is burned out.	→ Refer to your Slit Lamp operator manual.
	Slit adjustments are needed.	→ Refer to your Slit Lamp operator manual.
Inadequate aiming beam or no aiming beam.	The aiming beam is set to the lowest intensity.	→ Refer to the Operation section of this manual and your laser operator manual, and check the intensity settings.
	The laser and delivery device components are not properly connected.	→ Refer to the Operation section of this manual and your laser operator manual, and check the connections.
	The laser is in standby mode.	→ Place the laser in ready mode.
	The wrong fiber is selected on lasers with dual fiber configurations.	→ Check, and if appropriate, select the correct fiber.
	The Array LaserLink laser connector is damaged.	→ Contact your local Lumenis Representative.
Blurry or partial aiming beam	The delivery device and Slit Lamp are out of focus or alignment.	→ Contact your local Lumenis Representative.
Pattern seen through Slit Lamp is inconsistent with display screen	The delivery device software is not working correctly and will display Error code.	→ Contact your local Lumenis Representative.

Problem	Probable Cause	Solution
No treatment beam is delivered when the footswitch is depressed, or the beam is of poor quality.	The laser is in standby mode.	→ Place the laser in ready mode.
	The laser and delivery device components are not properly connected.	→ Refer to the Operation section of this manual and your laser operator manual, and check the connections.
	The laser optics are dirty or out of alignment.	→ Contact your local Lumenis Representative.
	No Eye Safety Filter is connected to the laser, the filter is improperly connected, or the filter is not operating.	→ Refer to the Operation section of this manual, and check the Eye Safety Filter connections. If properly connected, contact your local Lumenis Representative.
	The wrong fiber is selected on lasers with dual fiber configurations.	→ Check, and if appropriate, select the correct fiber.
	The Array LaserLink laser connector is damaged.	→ Contact your local Lumenis Representative.
Bright flashes occur when the footswitch is depressed.	The filter is improperly connected; or the filter is not operating.	→ Refer to the Operation section of the laser and Eye Safety Filter manuals, and check the Eye Safety Filter connections. If properly connected, contact your local Lumenis Representative. Do not use the delivery device unless advised to do so by the Lumenis Representative.

Problem	Probable Cause		Solution
The fiber error message, as defined in your laser operator manual, displays on the control panel or remote control.	The Array LaserLink is not connected or is improperly connected to the laser console.	→	Contact your local Lumenis Representative.
	The wrong fiber is selected on lasers with dual fiber configurations.	→	Check, and if appropriate, select the correct fiber.
The Eye Safety Filter error message, as defined in your laser operator manual, displays on the control panel or remote control.	No Eye Safety Filter is connected to the laser; the filter is improperly connected; or the filter is not operating.	→	Refer to the Operation section of the laser and Eye Safety Filter manuals, and check the Eye Safety Filter connections. If properly connected, contact your local Lumenis Representative. Do not use the delivery device unless advised to do so by the Lumenis Representative.
	When using the dual filter extension cable, both receptacles on the extension cable require connectors.	→	Refer to the Operation section of the laser and Eye Safety Filter manuals, and check the Eye Safety Filter connections. If using only one automatic Eye Safety Filter with the dual filter extension cable, insert the emulation plug that is tethered to the extension cable into the vacant receptacle.

Error Messages

Error Number	Error Description	Corrective Action
2	Fire @ Aim Off	Turn on the aiming beam before attempting to fire.
101	GUI Comm	Restart the device; if the message persists, contact your local Lumenis Representative.
102	GUI Version	Contact your local Lumenis Representative.
103	FPGA Comm	Restart the device; if the message persists, contact your local Lumenis Representative.
104	FPGA Version	Contact your local Lumenis Representative.
111	Invalid Clock	Set the date and time under the Options tab, as described in this operator manual.
112	Shutter	Restart the device; if the message persists, contact your local Lumenis Representative.
113	FPGA Watchdog	
120	FPGA Checksum	
121	Aim Bm Not Cal	Contact your local Lumenis Representative.
125	CPU Temperature	Restart the device; if the message persists, contact your local Lumenis Representative.
302	No Footswitch	Insert the footswitch plug into the footswitch receptacle.
401	Laser Comm	Restart the device; if the message persists, contact your local Lumenis Representative.
402	Head Mismatch	Contact your local Lumenis Representative.
403	Scope Not Cal	
404	Galvos Not Cal	
405	Galvo X Pos	Restart the device; if the message persists, contact your local Lumenis Representative. *When firing the laser, hold down the footswitch for the entirety of the pattern; If lifted before the pattern finishes, the 409 error will occur. Contact your local Lumenis Representative if error persists.
406	Galvo Y Pos	
407	PhotoDiode	
408	Timing	
409	Short Pattern*	
410	PID Calc	
411	Scope Fail	
412	EEPROM Fail	

User Maintenance

Inspecting the Delivery Device Components

Before and after each use, inspect the delivery device components for dirt, debris, or damage.

WARNING - Never look directly into the device while it is connected to the laser. Accidental laser exposure can cause severe eye damage

Do not touch any optical lens; finger oils may damage the delicate coatings.

Clean the External Surface of the Delivery Device

To clean the external surface, first disconnect the delivery device from the laser. Wipe using a cloth dampened with a normal commercial cleaner/disisfectant. Dry with a clean cloth.

Do not spray or pour cleaning agents directly on the device, and do not wipe the inside surface.

Annual Maintenance

Preventative maintenance (for cleaning of exposed optics), safety, power, and calibration checks should be performed annually by a Lumenis-certified service engineer to ensure proper device performance.

The software part numbers and revisions shall be displayed on the service screen for service personnel reference; however, if the screen is not functioning, the software version can be identified by referencing the PCB part number and revision.

Lumenis shall provide a service manual containing circuit diagrams, component parts list, calibration instructions, or other information which will assist the service engineer in maintaining the Array LaserLink which is expected to have a five (5) to seven (7) year service life.

Changing the Console Fuses

1. Turn off the system.
2. Remove the power plug from the wall receptacle and unplug the cord from the system's main power receptacle.

WARNING - Failure to unplug the machine during any type of maintenance could result in electrical shock.

3. Locate the electrical input module, which is adjacent to the main power receptacle.
4. Unlock the electrical input module cover by inserting a small flathead screwdriver into the slot. Gently push against the locking tab until the lock releases. Remove the fuse cover (Fig. 41).

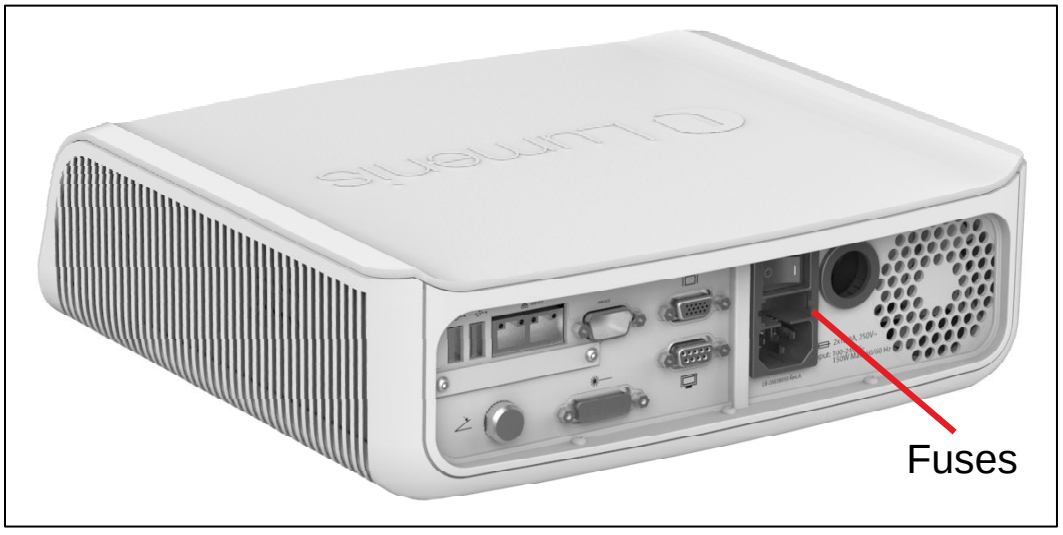

Fig. 41 Changing the Fuses

5. Replace the two 5 millimeters by 20 millimeters fuses with the appropriate replacement fuses as indicated below:

Voltage Configuration	Fuse Rating
250 VAC	2.0 A

Fuse table

6. Place the cover back onto the module. Gently push against the cover until the locking tab latches.

Electromagnetic Compatibility

The Array LaserLink has been designed and tested to comply with IEC 60601-1-2 requirements for EMC with other Lumenis devices.

WARNING - Do not use cables or accessories other than those provided with the Array LaserLink delivery device, as this may result in increased electromagnetic emissions or decreased immunity to such emissions.

WARNING – The Array LaserLink has been tested and approved for both stacked and adjacent placement with a secondary device and not have any interferance or negative impact on either device.

Essential Performance

The essential performance for the Array LaserLink has been determined to require that during scanning operation, the preset scan pattern shall appear without distortion. Any pattern distortion could result in unacceptable risk. If the expected pattern is distorted or not displayed as expected, immediately cease treatment and use of the device.

The essential performance for the Array LaserLink has been determined to require the LaserLink to be securely mounted as instructed to the listed compatible lasers and Slit Lamps. Improper mounting could result in unacceptable risk.

Specifications

Array LaserLink Specifications	
Compatible lasers	
Vision One	532 nm (green); 577 nm (yellow); 659 nm (red)
Power	532 nm = 50-2000 mW, adjustable in variable increments 577 nm = 50-1500 mW, adjustable in variable increments 659 nm = 50-800 mW (single spot only), adjustable in variable increments
Novus Spectra / Spectra DP	532 nm (green)
Power	532 nm = 50-2000 mW, adjustable in variable increments
Patterns	Single spot, square, line, triangle, circle, half circle, quarter circle
Spot Size	50, 100, 125, 150, 175, 200, 250, 300, 400, 500 µm 3-ring half or quarter circle: 100 µm and 200 µm
Spot Spacing	0 for single- circle only. All patterns: 0.25, 0.50, 0.75, 1.00, 1.50, 2.00, 2.50, 3.00
Spot Duration	10, 20, 30, 40, 50 ms
Laser beam spot size thru Slit Lamp	
Off axis Slit Lamp	Single Spot 50 to 1000 µm Scanning 100 to 500 µm
Eye Safety Filter optical density	> OD5 (Refer to the Laser Safety Eyewear sections of this manual and your laser operator manual for detailed laser safety eyewear information.)
Compatible Slit Lamps	
Off Axis Illumination Slit Lamps	Lumenis 980, Zeiss 30SL, Zeiss SL130
Electrical requirements	100 - 240 VAC, 50/60 Hz, 150 W max.

General Specifications	
Weight Console Array LaserLink Module	 3.5 kg or 8 lbs. 5 kg or 11 lbs.
Dimensions Console Array LaserLink Module	 313 mm x 300 mm x 100 mm 270 mm x 190 mm x 75 mm
Equipment classification	Class II
IP Rating	IPX0
Mode of Operation	Continuous
Operating Conditions	+15°C to +30°C Relative Humidity: 30% to 75% non-condensing
Environmental, Shipping, and Storage Conditions	-10°C to +55°C Relative Humidity 90% at +55°C non-condensing

Warranty Information

For specific and detailed warranty information for this instrument, please refer to the first page of your purchase “Agreement” and the last page of the “Terms and Conditions of Sale.”

Safety and Regulatory

Introduction

Users must take precautions to prevent exposure of laser energy to the eyes and skin from either direct or diffusely reflected laser beams, except as a therapeutic application. Additional precautions must be taken to prevent fire, electrical injury, and explosion.

Lumenis does not make recommendations regarding the practice of medicine. Laser treatment parameters are provided as a guide. Individual treatment should be based on clinical training, clinical observation of laser-tissue interaction, and appropriate clinical endpoints.

See the American National Standard (ANSI) publications Z136.3, ANSI Z136.1, and EN 207 for recommendations on the safe use of lasers in health care facilities.

Laser Safety Eyewear

Laser safety eyewear is routinely required with most lasers. When using the laser system, the Laser Safety Officer should determine the need for safety eyewear based on the Maximum Permissible Exposure (MPE), Nominal Hazard Zone (NHZ), the Nominal Ocular Hazard Distance (NOHD), and the optical density (OD) for each of the available laser emissions and the configuration of the treatment room (usually within the controlled area). For additional information, refer to ANSI Z136.1, ANSI Z136.3, or International Standard IEC 60825-1.

The following formula (Fig. 42) was used to calculate the worst case NOHD for Vision One, Novus Spectra, Novus Spectra DP, and compatible delivery systems. Therefore, the values specified here meet or exceed the laser safety eyewear requirements for the Lumenis Array LaserLink delivery systems.

$$NOHD = Z + \frac{1}{\theta}\sqrt{\frac{4}{\pi}\frac{\Phi}{MPE}\,Pf - a^2}$$

Fig. 42 Formula for NOHD

where,

Z	=	the distance of the beam waist from the laser system;
a	=	the beam waist diameter (1/e² of axial irradiance for Gaussian beam);
θ	=	minimum full angle beam divergence (1/e² of axial irradiance for Gaussian beam);
e	≈	2.7182818285, the base of natural logarithms;
Φ	=	maximum energy of one laser pulse or maximum CW laser power;
Pf	=	the profile correction factor (1 for uniform profile or 2 for Gaussian Irradiance Profile);
MPE	=	Maximum Permissible Exposure, in energy density units (energy per unit area), þ or fluence units (power per unit area);
NOHD	=	the Nominal Ocular Hazard Distance (measured from laser aperture); and the distance required to reduce the energy density or fluence to the MPE.

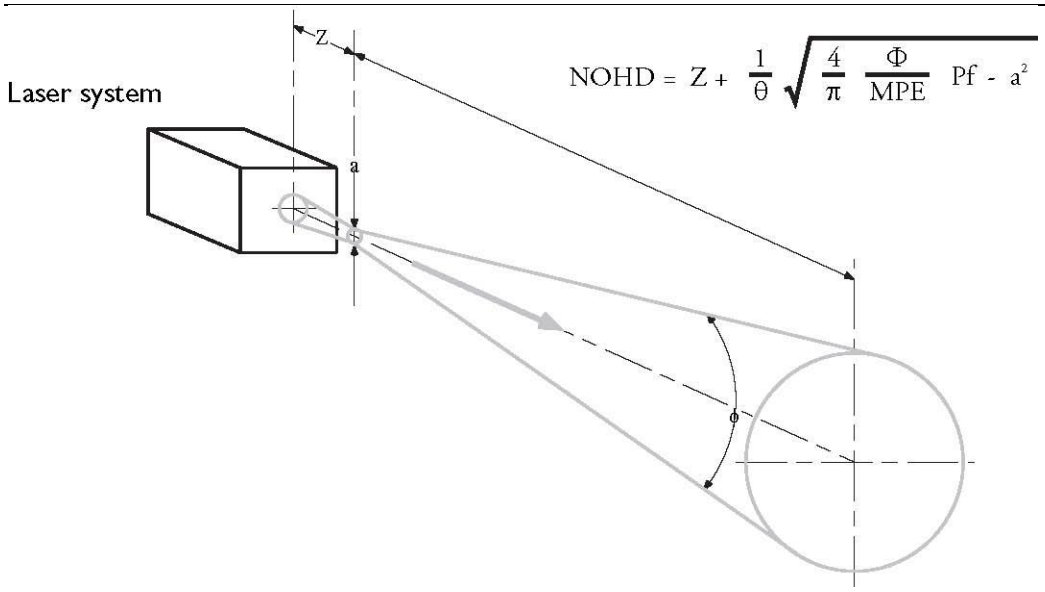

Fig. 43 Approach for deriving formula values

Using this approach in Fig. 43, we derive the following values:

Laser System	θ (rad)	Φ (W)	**MPE** (W/cm2)	**Pf**	**a** (cm)	**Z** (cm)
Vision One	0.010	2.0	0.00255	1	0.100	9.8
Novus Spectra and Spectra DP	0.010	2.5	0.00255	1	0.100	9.8

which results in a worst case NOHD of:

Laser System	**NOHD**
Vision One	31 m
Novus Spectra and Spectra DP	35 m

All personnel who are within the NOHD are considered to be within the controlled area and shall wear eye protection with a minimum optical density (OD) of:

Laser System	**OD**
Vision One	3.3
Novus Spectra and Spectra DP	3.41

Laser safety eyewear must also be resistant to physical damage or photo-bleaching resulting from laser exposure as per ANSI Z136.1. For users who must comply with EN 207 and IEC 60825-1, the safety eyewear must have a protection class of L5.

In addition to providing the required laser safety eyewear, take the following steps to secure the treatment room, or the controlled area:

1. To alert personnel before they enter the controlled area, place a warning sign on the outside of the treatment room door when the laser is in use.
2. Close the treatment room door before operation of the laser.
3. External door interlocks that automatically disable the laser when the treatment room door is opened may be installed.

A blocking barrier, screen, or curtain capable of blocking or filtering the laser beam could be placed to create a controlled area inside a large treatment room. The barrier should be made of material that can withstand the power of the treatment beam for the maximum exposure time, relative to the configuration of the controlled area and the treatment parameters for the specific medical application.

Additional Ocular Protection

WARNING - Always verify that the delivery device is properly connected to the laser. An improper connection may result in an inadvertent secondary laser beam. Severe eye or tissue damage could occur.

WARNING - Severe and irreversible eye damage and scarring may occur from direct or indirect exposure to the treatment beam. The predominant ocular structures at risk are dependent on the laser wavelength in use. In general, visible and near-infrared wavelengths are most damaging to the retina, while ultraviolet or infrared wavelengths are most damaging to the cornea and sclera. Severity of injury depends on how concentrated or diffused the treatment beam is and the length of exposure. A thorough understanding of the specific ocular risks and safety precautions for each laser wavelength is necessary to ensure the safety of the patient and operating personnel.

WARNING - Never look directly into any optical lens, except for therapeutic purposes, nor any optical fiber, probe, or laser system aperture while the laser is energized. Severe eye damage could occur. Turn off the laser before inspecting any delivery system or laser components.

Additional Safety Considerations

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

CAUTION - US law restricts this device to sale by or on the order of a physician.

CAUTION - Lumenis medical lasers and laser delivery systems are intended solely for physicians trained in the use of these instruments.

CAUTION – Lumenis medical laser aiming beams should be used at the lowest possible setting while maintaining effectiveness.

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

CAUTION – The laser system should always be in STANDBY mode except during actual treatment.

Electrical Hazards

WARNING - Never open the console protective covers. Opening the covers will expose the user to hazardous voltages. Only Lumenis-certified service technicians shall work inside the console.

WARNING - The area around the console and footswitch should 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 Lumenis manufacturer's recommendations and institutional standards.

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

WARNING - No modification of this equipment is allowed.

Regulatory Compliance

Lumenis lasers systems comply with 21 CFR 1040.10 & 1040.11, except for deviations pursuant to Laser Notice 50, dated June 24, 2007, as administered by the Center for Devices and Radiological Health of the US Food and Drug Administration (FDA).

Eye Safety Filter

Lumenis delivery devices have specially designed Eye Safety Filters that guard the operator from exposure to laser radiation. The protective filter ensures that all laser radiation returned to the operator's eyes is below the Class I limit.

Location of Controls

Operation and adjustment controls are located so that the user need not be exposed to laser radiation during laser operation or adjustment.

Location of Regulatory and other System Labels

As required by national and international regulatory agencies, appropriate warning labels have been mounted in specified locations.

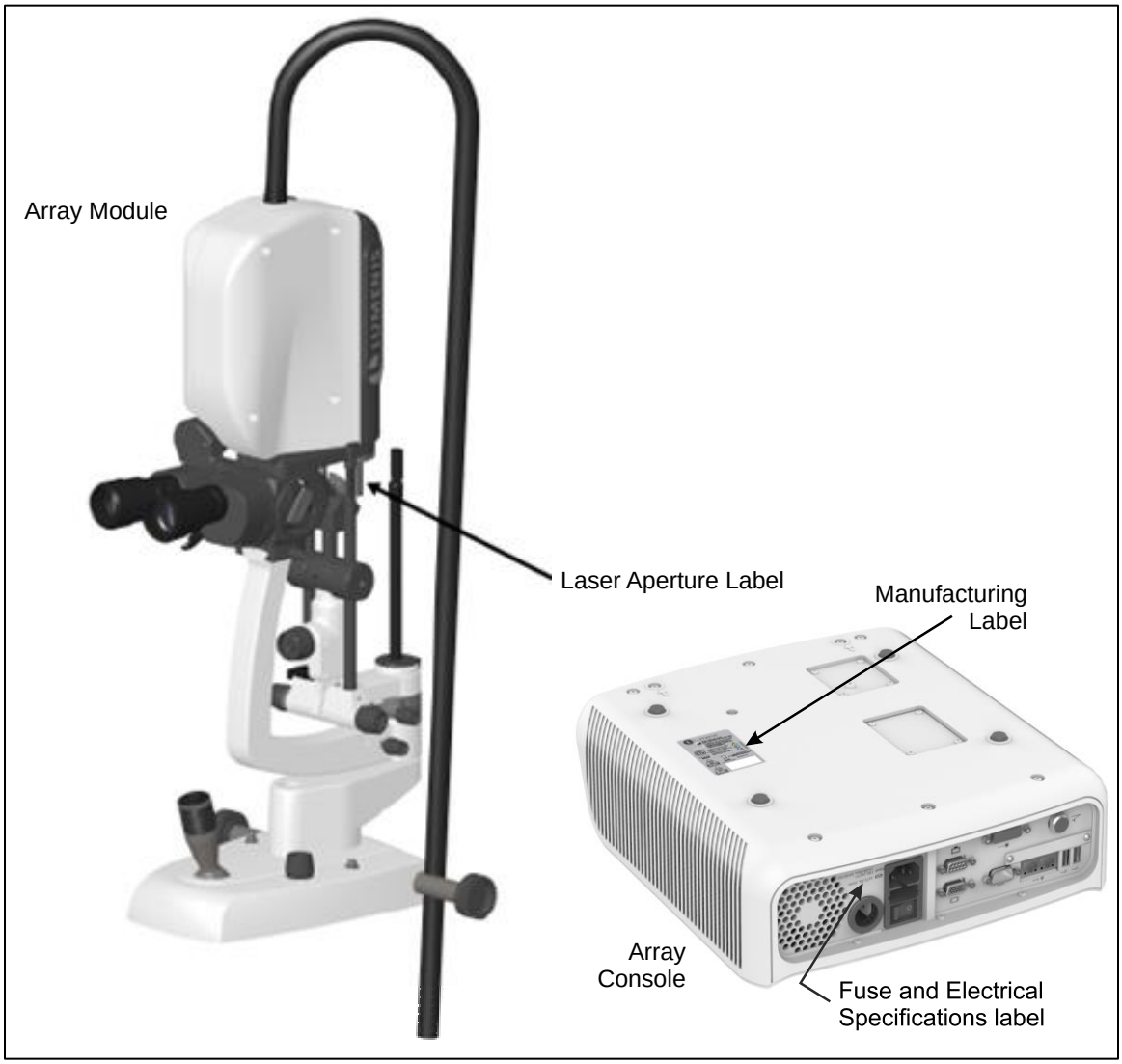

Fig. 44 Location of regulatory compliance labels

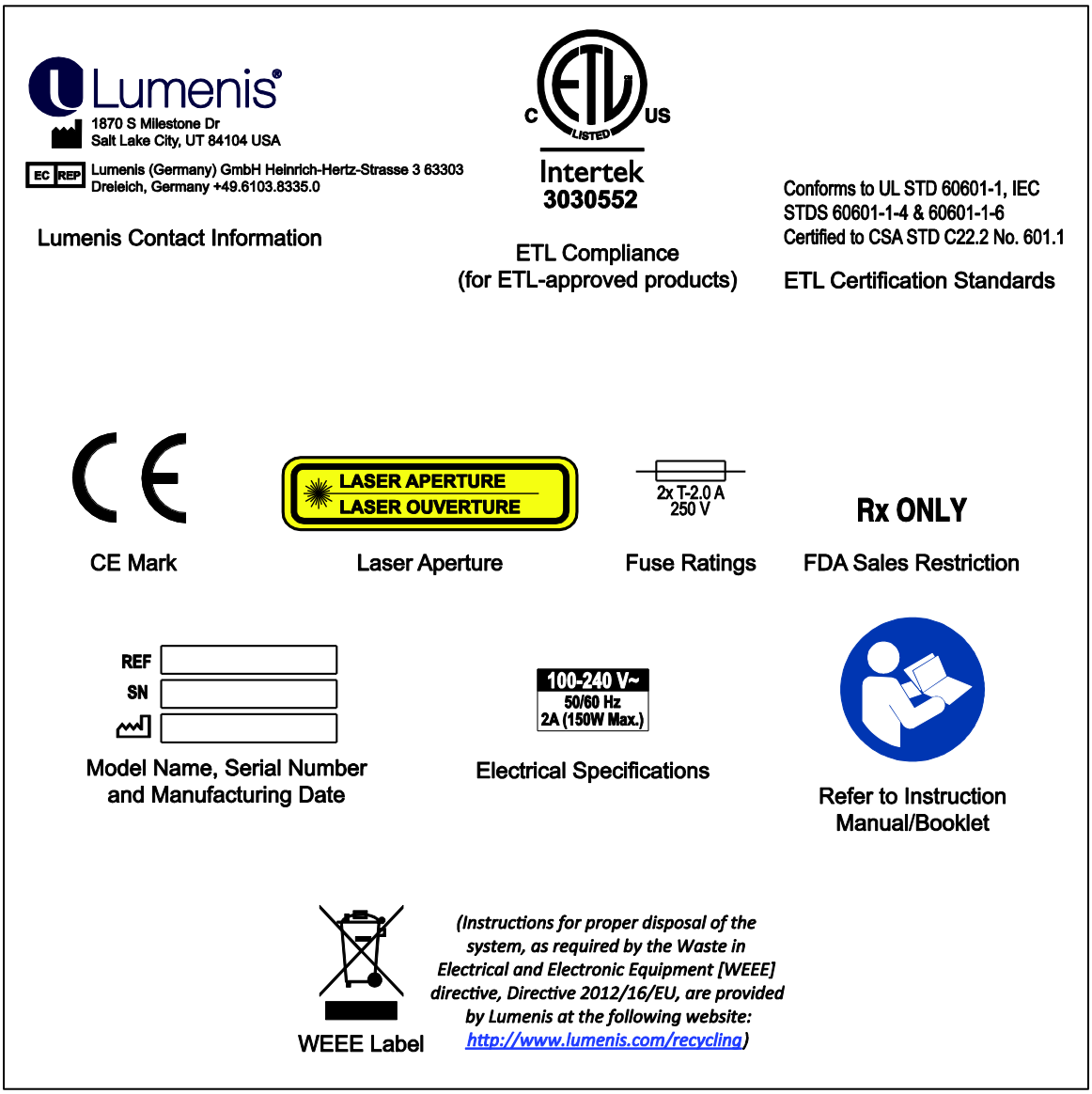

Fig. 45 Regulatory Compliance Labels

Indications for Use

Indications for Use

Device Name: Lumenis® Array™ LaserLink™

Indications for Use:

The Lumenis® Array™ LaserLink™ device is a laser system accessory intended for use in the treatment of ocular pathology.

- For the posterior segment, the Lumenis® Array™ LaserLink™ device is indicated for use in retinal photocoagulation and panretinal photocoagulation of vascular and structural abnormalities of the retina and choroid including:
  - Proliferative and severe and very severe non-proliferative diabetic retinopathy
  - Macular edema associated with proliferative or non-proliferative diabetic retinopathy
  - Choroidal neovascularization
  - Retinal neovascularization associated with retinal occlusive disease (Branch retinal vein occlusion; Central retinal vein occlusion)
  - Macular edema associated with Branch retinal vein occlusion
  - Retinal tears and detachments
- And anterior segments as follows:
  - Iridotomy in closed angle glaucoma
  - Trabeculoplasty in open angle glaucoma

The Lumenis Laser Systems compatible for connection with the Lumenis® Array™ LaserLink™ device are:

- Novus Spectra™ Laser System (K022327)(532nm)
- Novus Spectra™ Dual Port Laser System (K022327) (532nm)
- Vision One™ Laser System (K111213) (532nm, 577nm, 659nm)

Table 1 Pattern Indications for Use

Condition	Treatment	Pattern Selection Option	Specific Pattern
Posterior segment: Retina			
Proliferative Diabetic Retinopathy	Panretinal Photocoagulation	Yes	All patterns except circle/half circle arc
Severe and Very Severe Non-Proliferative Diabetic Retinopathy	Panretinal Photocoagulation	Yes	All patterns except circle/half circle arc
Macular Edema associated with Proliferative or Non-Proliferative Diabetic Retinopathy	Focal Photocoagulation	No	Single Spot (no pattern)
	Grid Photocoagulation	Yes	Square, arc, line
Retinal neovascularization associated with Retinal Occlusive Disease (Branch Retinal Vein Occlusion; Central Retinal Vein Occlusion)	Panretinal Photocoagulation	Yes	All patterns except circle/half circle arc
Macular Edema associated with Branch Retinal Vein Occlusion	Grid Photocoagulation	Yes	Square, arc, line
Retinal Tears and Detachments	Laser Retinopexy	Yes	Circle, half circle, quarter circle
Choroidal Neovascularization	Focal Laser	No	Single Spot (no pattern)
Anterior Segment: Glaucoma			
Primary Open-Angle Glaucoma	Trabeculoplasty	No	Single Spot (no pattern)
Closed Angle Glaucoma	Iridotomy	No	Single Spot (no pattern)

Contraindications in Ophthalmology

Laser surgery with the Array LaserLink attached to a laser system is contraindicated when an appropriate procedure cannot be performed safely. This occurs when target tissue cannot be visualized properly. Corneal opacities, cataract formation and vitreous hemorrhage can all interfere with the laser surgeon's view of appropriate target structures and important tissue structure adjacent to the target tissue might be photocoagulated inadvertently. Under such circumstances treatment should be delayed until the ocular media problem resolves or is corrected.

NOTE: If insufficient energy is delivered to the patient, under treatment could occur. This could require the patient to undergo further treatment potentially causing over treatment of the treatment area.

CAUTION – Misaiming the laser, movement of the patient, uncontrolled eye movement or nystagmus may result in unintentional damage to tissue adjacent to the target tissue.

Retinal Pigmentation

Pigmentation of the target tissue will determine the absorption of the laser energy and affect the result of photocoagulation. Dark pigmented eyes will require lower energy to obtain equivalent results as compared to light pigmented eyes. In treating eyes with no pigmentation, such as with albinism, laser photocoagulation should not be used as photocoagulation requires pigment in the retinal pigment epithelial cells for adequate absorption of laser energy.

For proper treatment, the user should consider variation in pigmentation and adjust laser power accordingly. Laser treatment patterns should be confined to areas where the pigmentation is homogeneous.

Potential Side Effects or Complications

Potential complications of retinal photocoagulation include:

- permanent central scotoma from inadvertent foveal burns
- paracentral scotomas from treatment burns close to the fovea, especially large or confluent burns
- initial decrease in central vision loss from macular edema
- peripheral visual field constrictions with poor dark adaptation
- vitreous hemorrhage if neovascularization is present
- loss of accommodation
- optic neuritis from treatment directly or adjacent to the disc
- rupture of Bruch's membrane from application of high fluence burns, which may cause hemorrhage or lead to vascular ingrowth
- ciliary body and choroidal detachment
- subretinal fibrosis
- progressive enlargement of photocoagulation scars
- choroidal neovascularization
- exudative retinal detachment
- pupillary abnormalities from damage to the ciliary nerves

Potential complications of laser iridotomy include:

- acute increase in IOP
- iritis
- neovascularization
- bleeding (hyphema)
- infection
- cataract
- visual symptoms (transient blurring, glare, ghost images)
- retinal detachment (rarely)

Potential complications of laser trabeculoplasty include:

- increased interocular pressure
- cataract
- iritis
- progression of visual field loss
- transient corneal endothelial changes

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Appendix 1

EMC Guidance and Manufacturer's Declarations

Guidance and Manufacturer's Declaration Electromagnetic Emissions		
The Array LaserLink delivery system is for use in the electromagnetic environment specified below. The customer or the user of Array LaserLink deliver system should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic Environment - guidance
RF emissions CISPR 11	Group 1	The Array LaserLink delivery system uses RF energy only for its internal function; therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Array LaserLink delivery system is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning statement is heeded: Warning: This system is intended for use by health care professionals only. This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the system or shielding the location.
Harmonic emissions IEC61000-3-2	Class A	
Voltage Fluctuations/ flicker emissions IEC61000-3-3	Complies	

Guidance and Manufacturer's Declaration Electromagnetic Emissions			
The Array LaserLink delivery system is intended for use in the electromagnetic environment specified below. The customer or the user of Array LaserLink delivery systems 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	±6kV contact ±8kV air	Class A	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	±2kV for power supply lines ±1kV for input/output lines	Class A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1kV line(s) to line(s) ±2kV line(s) to earth	Class A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec.	Class A Class A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Array LaserLink delivery system requires continued operation during power mains interruptions, it is recommended that Array LaserLink delivery systems be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	N/A	Power-frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The Array LaserLink delivery system is intended for use in the electromagnetic environment specified below. The customer or the user of Array LaserLink delivery systems should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Array LaserLink delivery system, including its cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5 GHz	3 V/m	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 Mhz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 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: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Array LaserLink delivery system is used exceeds the applicable RF compliance level above, the Array LaserLink delivery system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Array LaserLink delivery system unit.

(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Array LaserLink Delivery System

The Array LaserLink delivery system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Array LaserLink delivery system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Array LaserLink delivery 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**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.116	0.116	0.233
0.1	0.368	0.368	0.737
1	1.16	1.16	2.33
10	3.66	3.66	7.37
100	11.16	11.16	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Appendix 2

Specifications for Patterns, Spacing, and Spot Size

Pattern Table

Patterns	Square	Line	Triangle	Circle	Half Circle	Quarter Circle
Configurations	Array - 2x2, 3x3, 4x4, 5x5	Array - 1-4 Lines / 2-5 Spots	Array - 6 and 15 Spots	Array - 1 Ring, 800-3500µm Inner Radius	Array - 1 or 3 Rings, 800-3500µm Inner Radius	Array - 1 or 3 Rings, 800-3500µm Inner Radius
Spot Size	Array - 100, 125, 150, 175, 200, 250, 300, 400, 500µm	Array - 100, 125, 150, 175, 200, 250, 300, 400, 500µm	Array - 100, 125, 150, 175, 200, 250, 300, 400, 500µm	Array - 100, 125, 150, 175, 200, 250, 300, 400, 500µm	Array - 100, 125, 150, 175, 200, 250, 300, 400, 500µm (100 and 200µm only for 3 ring)	Array - 100, 125, 150, 175, 200, 250, 300, 400, 500µm (100 and 200µm only for 3 ring)
Spot Spacing (microns)	Array - 0.25, 0.50, 0.75, 1.00, 1.50, 2.00, 2.50, 3.00	Array - 0.25, 0.50, 0.75, 1.00, 1.50, 2.00, 2.50, 3.00	Array - 0.25, 0.50, 0.75, 1.00, 1.50, 2.00, 2.50, 3.00	Array - 0, 0.25, 0.50, 0.75, 1.00, 1.50, 2.00, 2.50, 3.00	Array - 0.25, 0.50, 0.75, 1.00, 1.50, 2.00, 2.50, 3.00	Array - 0.25, 0.50, 0.75, 1.00, 1.50, 2.00, 2.50, 3.00
Spot Duration	Array - 10, 20, 30, 40, 50ms	Array - 10, 20, 30, 40, 50ms	Array - 10, 20, 30, 40, 50ms	Array - 10, 20, 30, 40, 50ms	Array - 10, 20, 30, 40, 50ms	Array - 10, 20, 30, 40, 50ms
Power 532 (Green)	Array/w 50-2000mW Vision One, 50-2000mW Spectra	Array/w 50-2000mW Vision One, 50-2000mW Spectra	Array/w 50-2000mW Vision One, 50-2000mW Spectra	Array/w 50-2000mW Vision One, 50-2000mW Spectra	Array/w 50-2000mW Vision One, 50-2000mW Spectra	Array/w 50-2000mW Vision One, 50-2000mW Spectra
577 (Yellow)	50-1500mW Vision One	50-1500mW Vision One	50-1500mW Vision One	50-1500mW Vision One	50-1500mW Vision One	50-1500mW Vision One
Total Treatment Time	Array - Limit total treatment time to under .65s for any given single pattern.	Array - Limit total treatment time to under .65s for any given single pattern.	Array - Limit total treatment time to under .65s for any given single pattern.	Array - Limit total treatment time to under .65s for any given single pattern.	Array - Limit total treatment time to under .65s for any given single pattern.	Array - Limit total treatment time to under .65s for any given single pattern.
Maximum No. of Treatment Spots	Array - 25	Array - 20	Array - 15	Array - 56	Array - 56	Array - 56
Minimum Area of Treatment	225µm x 225µm (W x H)	225µm x 100µm (W x H)	350µm x 303µm (Base x Height)	1700µm OD	1700µm OD	1200µm Chord Length
Maximum Area of Treatment	6800µm x 6800µm (W x H)	6800µm x 5000µm (W x H)	6800µm x 5900µm (Base x Height)	7500µm OD	7400µm OD	7400µm Chord Length

Single Spot Parameters, Array LaserLink

Laser System Connected	*Spectra / Spectra Dual Port*	*Vision One*
Spot Size (Microns)	50, 100, 125, 150, 175, 200, 250, 300, 400, 500, 1000	50, 100, 125, 150, 175, 200, 250, 300, 400, 500, 1000
Duration (Seconds)	0.01, 0.02, 0.03, 0.04, 0.05, 0.06, 0.07, 0.10, 0.15, 0.20, 0.30, 0.40, 0.50, 0.70, 1.00, 1.50, 2.00, 3.00	0.01, 0.02, 0.03, 0.04, 0.05, 0.06, 0.07, 0.10, 0.15, 0.20, 0.30, 0.40, 0.50, 0.70, 1.00, 1.50, 2.00, 3.00
Interval (Seconds)	Single (no-repeat mode), 0.05, 0.07, 0.10, 0.15, 0.20, 0.30, 0.40, 0.50, 0.70, 1.00	Single (no-repeat mode), 0.05, 0.07, 0.10, 0.15, 0.20, 0.30, 0.40, 0.50, 0.70, 1.00
Power (mW)	**532 nm:** 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200, 210, 220, 230, 240, 250, 260, 270, 280, 290, 300, 320, 340, 360, 380, 400, 420, 440, 460, 480, 500, 550, 600, 650, 700, 750, 800, 850, 900, 950, 1000, 1100, 1200, 1300, 1400, 1500, 1600, 1700, 1800, 1900, 2000	**532 nm:** 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200, 210, 220, 230, 240, 250, 260, 270, 280, 290, 300, 320, 340, 360, 380, 400, 420, 440, 460, 480, 500, 550, 600, 650, 700, 750, 800, 850, 900, 950, 1000, 1100, 1200, 1300, 1400, 1500, 1600, 1700, 1800, 1900, 2000
		577 nm: 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200, 210, 220, 230, 240, 250, 260, 270, 280, 290, 300, 320, 340, 360, 380, 400, 420, 440, 460, 480, 500, 550, 600, 650, 700, 750, 800, 850, 900, 950, 1000, 1100, 1200, 1300, 1400, 1500
		659 nm: 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200, 210, 220, 230, 240, 250, 260, 270, 280, 290, 300, 320, 340, 360, 380, 400, 420, 440, 460, 480, 500, 550, 600, 650, 700, 750, 800