SECTION THREE
OPERATING INSTRUCTIONS

INTRODUCTION

This section details the recommended setup and operation for the *PurePoint™* Laser. These procedures may be modified to conform to hospital requirements and practices as you become experienced in using the system. However, the operational checks that are performed at various points in the setup procedure to verify instrument operation must be performed exactly as indicated.

> ### *WARNING!*
> **Noncompliance with the instructions contained in this manual may result in operator injury.**

The following procedures (Initial Setup, System Connections, System Power Up, and Operation) cover preparation for laser treatment involving Slit Lamp, Endoprobe/ Aspirating Endoprobe/Illuminated Endoprobes, or LIO usage.

Any questions pertaining to setup and checkout procedures should be directed to your Alcon Technical Services representative.

1   INITIAL SETUP

> ### *WARNING!*
> **To avoid potential secondary reflections, a qualified laser safety officer should approve the room used to treat the patient.**

1.1   Position the instrument for surgeon's comfort and preference. Refer to Section One for "Recommended Laser Room Layout."

1.2   Verify that no combustible materials are adjacent to the laser and its delivery systems.

2   SYSTEM CONNECTIONS

2.1   Connect footswitch to Footswitch connector.

2.2   Connect Remote Interlock to REMOTE Interlock connection.

2.3   Plug in the power cord to the power cord socket and to a properly grounded main power outlet (220-240 VAC, 10A minimum; or 100-120 VAC, 15A minimum).

2.4   Ensure all Doctor/Observer protection filters are installed in the optical path of the slit lamp or microscope, and connected to the Doctor Protection Filter ports on the rear panel (see Figure 3-1).

2.5   Verify that the power switch on the rear panel is in the ON position.

2.6   Insert key into keyswitch on front panel. Leave in the OFF position.

WARNINGS!

The Slit Lamp must be equipped with a special Alcon Slit Lamp adaptation. This adaptation is available for many of the existing Slit Lamps. (Reference section six for list of adaptations to be used with existing slit lamps.) If peripherals are not correctly connected and confirmed by the operator, the operator and patient will be exposed to hazardous radiation.

Refer to Section Six for instructions on installing the Doctor Protection Filter. The operator may have a colored view through the Doctor Protection Filter due to blocking of the green 532 nm wavelength light. Newer filters will have less color blocking. It is the operator's responsibility to properly install the Doctor Protection Filter. Alcon shall not be held liable for problems caused by improper installation of the Doctor Protection Filter.

If a tethered manual Doctor Protection Filter is in the "not engaged" position the prompt on the *PurePoint*™ LCD display must read "Please engage Dr. Filter." If not, the operator must discontinue using the system and notify Alcon Technical Services for assistance.

When using beam splitter accessories, the ocular stereo microscope head must first be attached to the beam splitter (the beam splitter accessories are attached to the beam splitter on the protected side of the Doctor Protection Filter assembly); the beam splitter is then attached to the permanently installed Doctor Protection Filter. Improper installation could cause injury to the operator and/or the patient.

It is the user's responsibility to ensure that non-RFID probes are correctly identified.

Do not use assessories with a fiber or connector that have been compromised.

2.7   *SLIT LAMP CONNECTION:* Connect the fiber optic connection from the slit lamp zoom to a laser fiber port on the front panel (see Figure 3-1)

NOTE: When removing the fiber of a slit lamp terminal or an LIO terminal, be sure to secure the dust cover on the front panel fiber port.

2.8   *LIO CONNECTION:*

    2.8.1   Connect LIO fiber to a laser fiber port on the *PurePoint™* front panel.

    2.8.2   Insert LIO power cord into LIO illuminator power port on front panel.

WARNING!

Endoprobes are for single-use only. Microbial or prion infection may occur if re-used.

2.9   *ENDOPROBE CONNECTION:* Connect fiber to a laser fiber port on the *PurePoint™* front panel.

NOTE: Refer to section six for additional information on setting up and using these accessories.

2.10 Ensure Red Emergency Switch is pulled out. Press only in case of emergency.

> ## *WARNINGS!*
>
> **Performing procedures other than those specified herein may result in hazardous laser radiation exposure.**
>
> **Everyone present in the treatment room must wear protective eyewear O.D. 4 or above at 532 nm when the system is in standby as well as during treatment.**
>
> **Possible explosion hazard if used in the presence of flammable anesthetics or other gas mixtures.**

Fiber Optic Connection

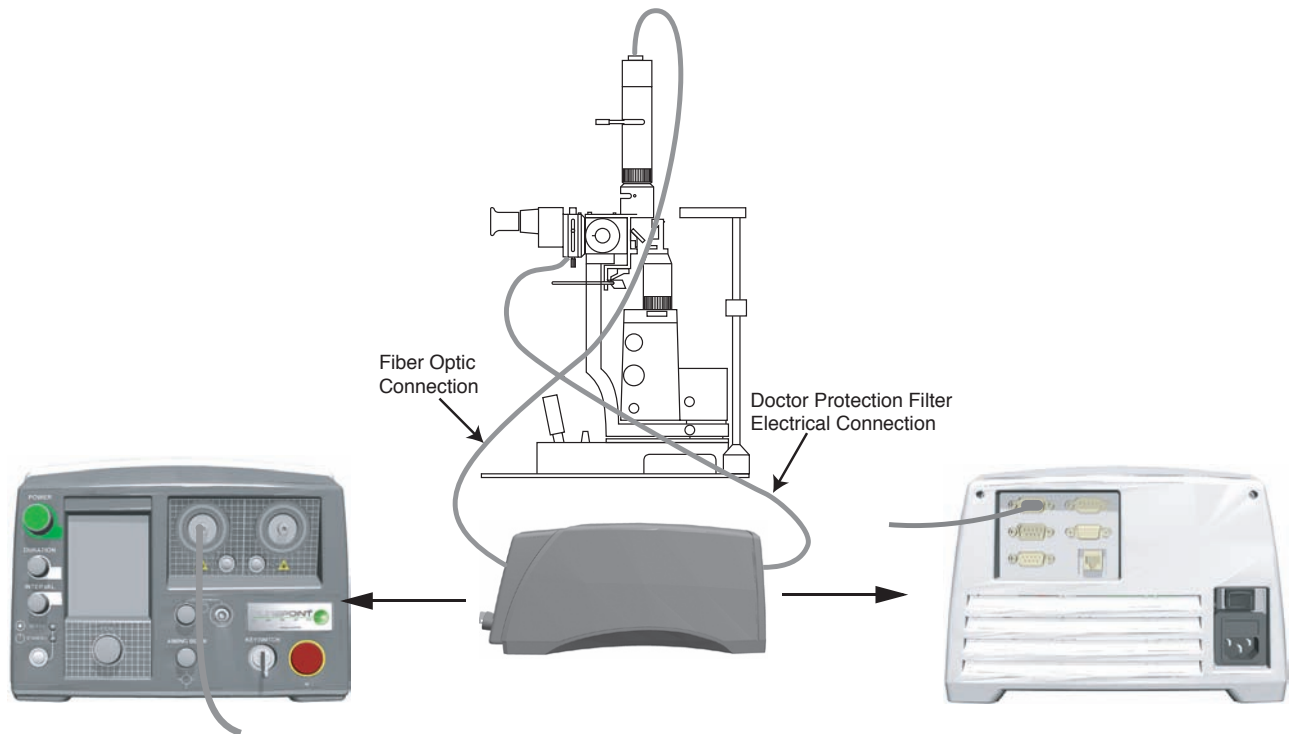Doctor Protection Filter Electrical Connection

Figure 3-1   Slit Lamp Connections

3   SYSTEM POWER UP AND SET UP

NOTE: Be sure to read all prompts on the display.

3.1   Turn the key to the ON (horizontal) position. Figure 3-2 shows the sequence of screens displayed during initialization.

- The front panel display illuminates the background LED's and initializes the LCD screen.

- If no laser fiber is connected to a port, a prompt to insert a probe is displayed until one is connected.

During initialization of the system, the delta between the set point and actual temperature of the laser engine is shown as it approaches nominal operating temperature. The user can perform the following setup operations during initialization: inserting probes, inserting LIO illumination power, set laser parameters if an identified probe is inserted, and view or change system settings.

NOTES: If the optical fiber is not connected, the aiming beam will not turn on and the system will continue to display: "Please Insert Probe ."
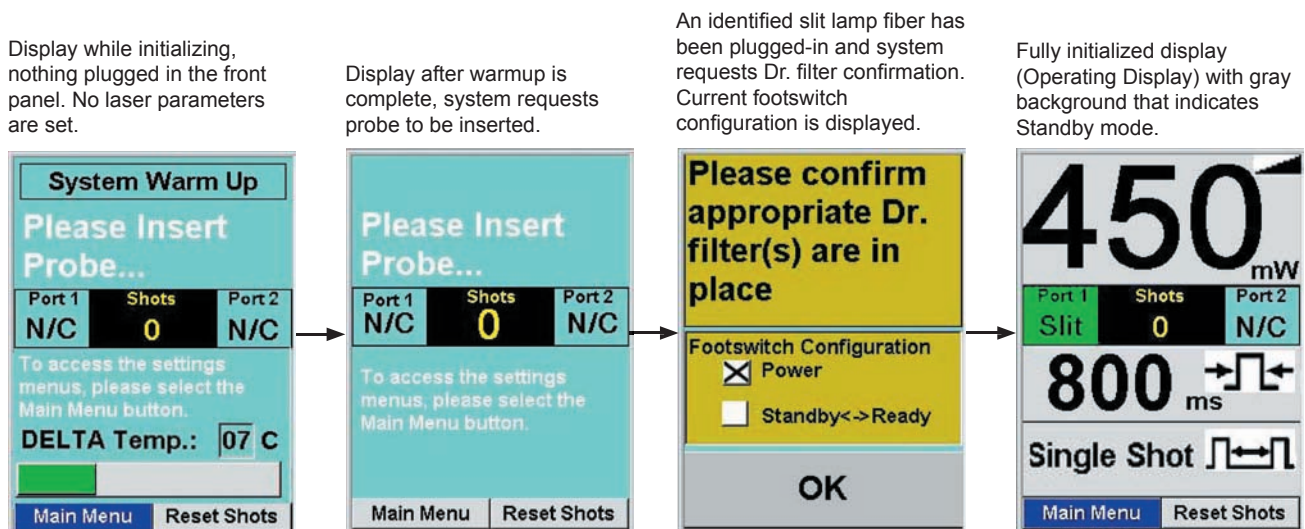
Display while initializing, nothing plugged in the front panel. No laser parameters are set.

Display after warmup is complete, system requests probe to be inserted.

An identified slit lamp fiber has been plugged-in and system requests Dr. filter confirmation. Current footswitch configuration is displayed.

Fully initialized display (Operating Display) with gray background that indicates Standby mode.

Figure 3-2   Display During Initialization

3.2 Verify Presence of Dr. Filter(s). (For slit lamp and endo selections.)

When the message "Verify appropriate Dr. Filters in viewing devices" appears, verify that the appropriate Dr. Filters are placed in all viewing devices.

Next, highlight "Connected" or "Not Connected" by turning the settings knob and press when the desired response is highlighted. If "Not Connected" is selected, the laser cannot be fired.

- If the Doctor Protection Filter is not in place, install it as described in Section Six, and then select "Connected" from the display using the settings knob.

- If a tethered Doctor Protection Filter is in place but not engaged, engage the Doctor Protection Filter by rotating lever clockwise until engaged/stopped.

WARNING!

It is the operator's responsibility to properly install the Doctor Protection Filter. The operator may have a colored view through the Doctor Protection Filter due to blocking of the 532 nm wavelength (green). Newer filters have less color, making the view more true to the actual colors.

NOTE: The default values for the following parameters can be changed as described in Section Two of this manual.

3.3 Set the shot count to zero by turning the Menu knob until "Reset Shots" is selected, then push the knob in to zero the count. To change from Shot Count to Total Energy, go to the Treatment Totals Options screen (Main Menu\Settings\ Treatment Totals Options).

WARNING!

If unsure which settings are required, select a low power, short duration, and large spot size. Failure to titrate delivered energy may lead to patient injury.

3.4 Select the desired port by pressing the associated Port Selection button.

3.5 Set the desired treatment power by turning the Power knob.

3.6 Set the desired pulse duration of the laser shot by turning the Pulse Duration knob. If Continuous Wave mode is selected, the letters CW are displayed instead of a number.

NOTE: It is not recommended to use exposure times longer than 2 seconds in CW(Continuous Wave) mode. Depending on the thermal load, the system may shut down prior to the footswitch being released. A message will appear on the display indicating this condition.

3.7   Set the desired inter-pulse time by turning the Inter-Pulse Time knob to the desired setting in Repeat mode. To select Single Shot mode press the knob in or turn the knob clockwise past the maximum 1 second inter-pulse time. In Single Shot mode, the footswitch must be depressed for each shot. In Repeat mode, the shots are fired in a regular sequence while the footswitch is depressed and stops when the footswitch is released.

3.8   Set the aiming beam intensity to the desired level by turning the Aiming Beam Intensity knob.

WARNING!

Do not attempt treatment if aiming beam is not present. Patient injury may occur.

NOTES: The footswitch must be released to proceed to Ready Mode. If the footswitch is depressed during power-up or when switching from Standby to Ready mode, the "Release Footswitch" message is displayed.

4 NORMAL OPERATING PROCEDURE

> ### WARNING!
> **In the event of a system malfunction, press the Emergency Switch to immediately disable the system.**

After completing Power Up and Set Up Sequence, proceed as follows for normal operation.

4.1 Ensure that all personnel are wearing protective eyewear, OD 4 or above at 532nm.

4.2 Slit Lamp and LIO Set Up

- If using a Slit Lamp, adjust the intra-pupillary distance and the biomicroscope oculars focus so that the image is clear. Have the patient sit in front of the Slit Lamp with his chin and forehead on the head rest. Target the red aiming beam on the area to be treated and select the beam diameter for the treatment.

- If using the LIO, adjust the intra-pupillary distance on the headset so that the image is clear. Target the red aiming beam on the area to be treated.

4.3 Go to Ready mode by pressing the Standby/Ready Mode button on the front panel or, if the multifunction footswitch setting is set to "Power and Ready <-> Standby," press and hold the right side switch until a tone sounds (1.5 seconds).

The Standby LED turns off, and the Ready LED blinks on and off during transition. After 2 seconds, the background of the initialized display turns green, indicating that the laser is ready to fire. Figure 3-3 show the screen transition from Standby to the Ready Mode.

If the multifunction footswitch setting is set to "Power and Ready <-> Standby" or "Power Control Only," then the side switches can be used to increase (left switch) or decrease (right switch) the laser power. In "Power and Ready <-> Standby," the side switches must be pressed less than 1.5 seconds to change power. Pressing the right side switch longer than 1.5 seconds causes the system to go to Ready mode, while pressing the left side switch longer than 1.5 seconds causes the system to go to Standby mode.

> ### WARNINGS!
> **Laser is ready to fire. Ensure the correct port and energy delivery settings are selected each time the system is brought to the Ready mode.**
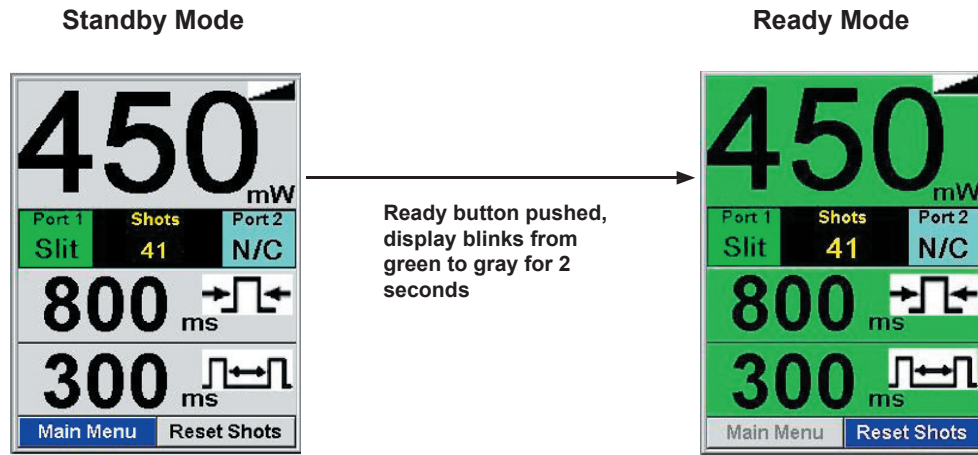
Standby Mode

Ready Mode

Ready button pushed, display blinks from green to gray for 2 seconds

Figure 3-3   Transition from Standby to Ready Mode

WARNING!
Do not proceed if aiming beam does not turn on.

4.4   Press the footswitch when ready to fire. The system emits a tone each time the laser fires. Figure 3-4 shows the display transition from Ready State to Laser On. If the footswitch is not pressed within a period selected by the user from entry into ready mode, the system switches back to Standby mode.

NOTE: The aiming beam turns off when the treatment beam fires, except in Repeat Mode.

Footswitch depressed; bottom menu changes to red background with "Laser On" displayed; shot count is increased.
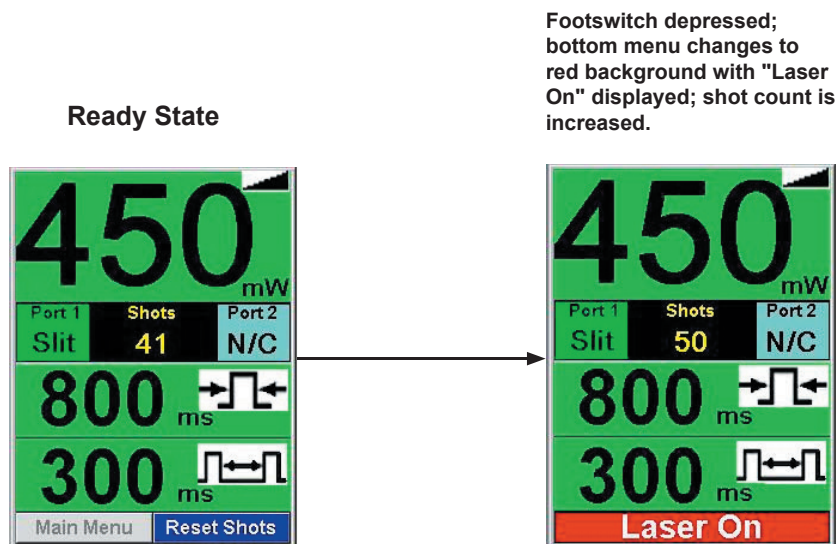
Ready State

Figure 3-4   Transition from Ready State to Laser On

4.5 Repeat the firing procedure as often as necessary, making adjustments to power output and duration as appropriate to complete the treatment session.

If the system transitions back to Standby mode because of a warning condition, the parameters section color is changed and a warning message is displayed as shown in Figure 3-5. This mode change will occur if any of the following events occurs while the laser is firing:

- Standby/Ready button pushed.
- Footswitch unplugged.
- Laser fiber disconnected from selected port.
- Remote Interlock disconnected port.
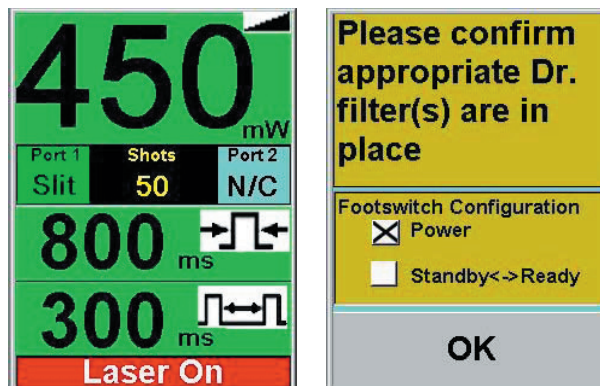- Dr. Filter connected, disconnected, or disengaged.
- System fault.

Figure 3-5   Transition from Laser On to Standby because of a Warning

To resume normal operation, perform the action(s) displayed in the warning message.

4.6 When the treatment is completed, release the footswitch and press the Standby/Ready key. The Standby LED illuminates and the system is placed in standby mode.

5   TURN OFF SEQUENCE

5.1 Turn the key to the OFF (O) position and, for safety reasons, remove the key.

NOTE: **The emergency switch on the front panel should only be used in an emergency. After using the emergency switch, pull it back to its initial position to restore power and start the instrument.**

5.2 Place the power switch on the rear of the system to the OFF (O) position.

6 CHANGING THE SYSTEM SETTINGS

6.1 To access the Settings menu (system must be in Standby mode), turn the Menu knob until "Main Menu" is highlighted then push the Menu knob to select. The Main Menu is displayed as shown in Figure 3-6.
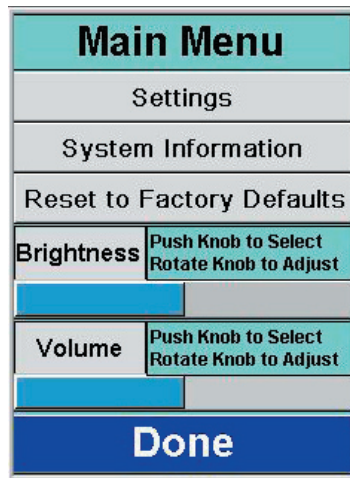

Figure 3-6   Main Menu

6.2 Turn the Menu knob until "Settings" is selected then press the Menu knob. The Settings menu is displayed as shown in Figure 3-7.

Figure 3-7   Settings Menu

6.3 Turn the Menu knob until the desired setting is selected then press the Menu knob. Refer to Section Two for a detailed description of each setting screen.

6.4 When setting changes are complete, select "Back" to return to the Settings menu or "Done" to go back to the Standby screen.

7   IDENTIFYING UNRECOGNIZED PROBES

If a probe without an identifying RFID tag is connected to the system, a message appears stating that the system is unable to recognize the probe and prompts the user to select a probe type (see Figure 3-8).
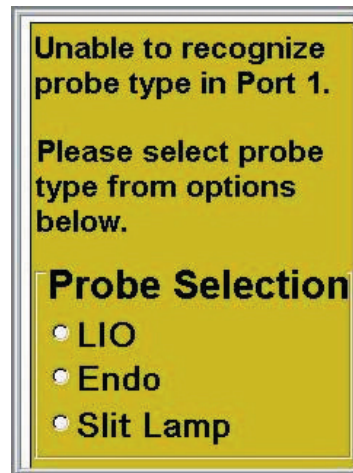

Figure 3-8   Unidentifiable Probe Display

7.1   Using the Menu Knob, select the type of probe connected to the system. The system then applies the factory settings for that type of probe. These settings may be changed in the Fiber Custom Presets display from the Main Menu.

If two unidentified probes are connected when the when the system is turned on, the display appears for Port 1, which is selected by default. The probe in Port 2 will not require identification until the port is selected. If a probe is inserted in Port 2 before one is inserted in Port 1, then the Port 2 probe will be the first selected for identification.

If the laser is in Firing mode and an unidentified probe is connected to the other port, the Unidentified Probe display will not appear until the user has stopped firing the laser and the port is selected.

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