PUREPOINT™
LASER

OPERATOR'S MANUAL

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PurePoint™ Operator's
8065751131
MANUAL REVISION RECORD

DATE	REVISION	ECN NUMBER AND DESCRIPTION

TABLE OF CONTENTS

LIST OF ILLUSTRATIONS

LIST OF ILLUSTRATIONS

LIST OF TABLES

FOREWORD

This Operator's Manual is designed to acquaint the operator and operating room personnel with the *Next Generation* Laser. The manual presents an organized summary of the operating principles, main components, safety features, and instructions for care and use of the instrument.

The information in this manual should be supplemented with reference works on laser theory and the interaction of laser energy with biologic tissues. No attempt is made in this manual to answer all the questions that arise during the use of the instrument in medical procedures.

Questions concerning technique, safety and effectiveness should be referred to pertinent publications or recognized medical experts in laser surgery. Physicians should not attempt to treat patients with this instrument if not thoroughly familiar with its operation, or if in doubt as to its safe operation. All personnel authorized to use this instrument should be required to be thoroughly familiar with this manual.

Please contact Alcon for complete technical support and service if you have questions concerning any aspect of this instrument's operation or if it fails to perform satisfactorily.

To order supplies in U.S.A.:
800-862-5266
FAX: 800-241-0677

Outside U.S.A.: Contact your local Alcon representative for supplies.

IMPORTANT NOTICE

Equipment improvement is an on-going process and, as such, changes may be made to the equipment after this manual is printed.

Pay close attention to WARNINGS and CAUTIONS in this manual. WARNINGS are written to protect individuals from bodily harm. CAUTIONS are written to protect the instrument from damage. Illustrations contained in this manual are for reference only.

It is recommended that maintenance be performed by a qualified Alcon Field Engineer.

Alcon Surgical shall not be liable for any damage resulting from failure to comply with the enclosed instructions.

Alcon reserves the right to change specifications without further notice.

CAUTION

U.S. Federal Law restricts this device to sale by or on the order of a physician only.

WARNINGS!

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

A qualified technician must perform a visual inspection of the following components every twelve months. In case of a deficiency, do not use the system; call Alcon Technical Services.

- **Warning Labels**
- **Power Cord**
- **Fuses**

A qualified technician must check ground continuity and both polarities for leakage current every twelve months to ensure they are within the applicable standard (for example: EN 60601-1/IEC 601-1). Values must be recorded, and if they are above the applicable standard, or 50% above your first measurement, do not use the system; call Alcon Technical Services.

WARNING!

Use of accessories and cables other than those provided may result in increased emissions or decreased immunity of the system. Portable and mobile RF communications equipment can affect this medical electrical equipment.

Comments or corrections concerning this manual should be addressed to:

Alcon
Technical Services Group
PO BOX 19587
Irvine, CA, USA 92623

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SECTION ONE
GENERAL INFORMATION

INTRODUCTION

The Alcon *PurePoint™* Laser provides an exceptional combination of performance, solid-state reliability, versatility, and portability all in one system. It is a diode-pumped solid-state type laser designed for ophthalmic use. This laser delivers a visible 532 nm green treatment beam, and a visible 635 nm Diode Laser aiming beam (635 nm is an approximate value between 630-640 nm).

The system is also supported by a wide range of high quality laser probes, a laser indirect ophthalmoscope (LIO), and is compatible with a wide variety of slit lamps.

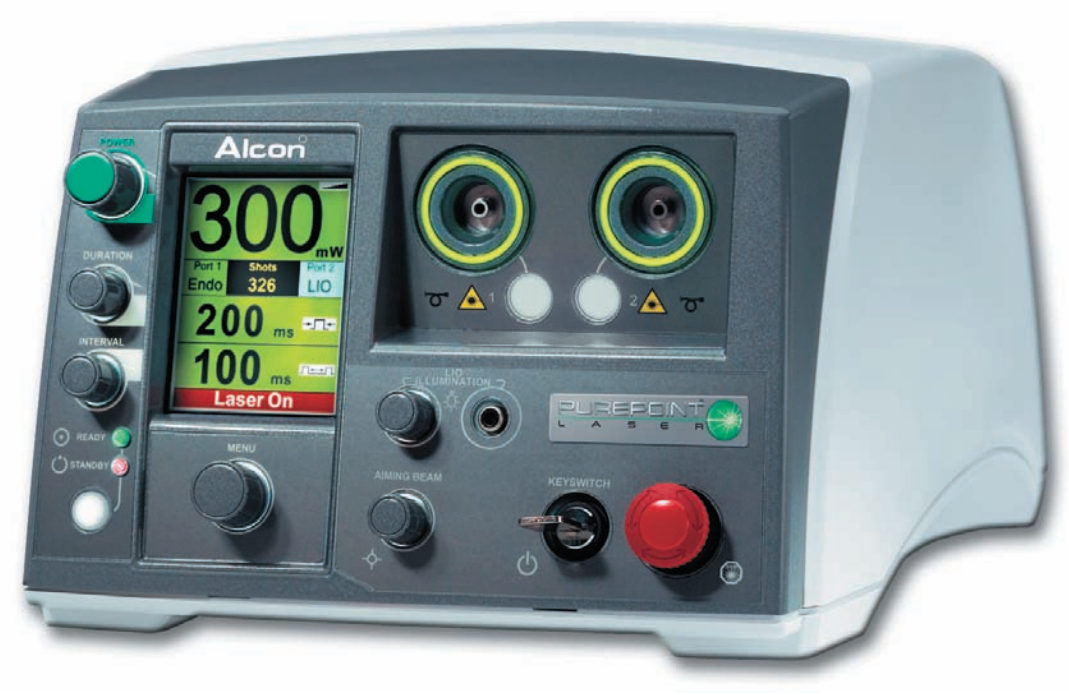


Figure 1-1 The Alcon *PurePoint™* Laser

Table 1-1
Technical Specifications

CATEGORY	SPECIFICATION
Approximate Dimensions	Width: 0.23 m (9.00 inches) Depth: 0.34 m (13.50 inches) Height: 0.18 m (7.00 inches)
Approximate Weight	10.4 kg (23 lbs)
Electrical Characteristics	Voltage: 100-120 VAC@ 5 A (max current) 220-240 VAC @ 2.5 A (max current) Frequency: 50/60 Hz Fuse rating: 250V,Single Phase T5 Amps Insulation class: Class I, type BF,
Environmental Limitations	Operating: Temperature: 10°C ≤ T°≤ 35°C Relative Humity: 10% to 90% with no condensation Storage: Temperature: -40°C ≤ T°≤ 70°C Relative Humity: 10% to 95% with no condensation
Miscellaneous	*PurePoint* Laser complies with CE MDD requirements. Not suitable for use in the presence of flammable anesthetic, oxygen or nitrous oxide. System not protected against the ingress of water. Leakage current per IEC 60601-1 is below 500 micro amps at 264 VAC. Leakage current per IEC 60601-1 is below 300 micro amps at 132 VAC. Ground continuity per IEC 60601-1 is below 0.1 ohm.

Table 1-2
Laser Characteristics

CATEGORY	TREATMENT LASER BEAM	AIMING LASER BEAM
Laser Class	IV	II
Laser Power	• 30 mW to 200 mW in 10 mW steps • 200 mW to 500 mW in 20 mW steps with additional steps at: 250, 350, 450 • 500 mW to 950 mW in 50 mW steps • 1000 mW to 2000 mW in 100 mW steps	Less than 1 mW; adjustable by operator
Laser Wavelength	532 nm	635 nm +/- 5 nm

WARNINGS!

There are potential hazards when inserting, steeply bending, or improperly securing the fiber optic. Not following the recommendations of the manufacturer may lead to damage to the fiber or delivery system and/or harm to the patient or user.

Since the aiming beam passes down the same delivery system as the treatment beam, it provides a good method of checking the integrity of the delivery system. If the aiming beam spot is not present at the distal end of the delivery system, or its intensity is reduced or it looks diffused, this a possible indication of a damaged or not properly working delivery system. If there is any doubt, contact Alcon Technical Services.

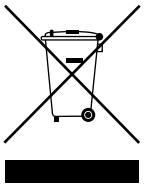
The use of flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen should be avoided. Some materials - for example cotton wool when saturated with oxygen - may be ignited by the high temperatures produced in normal use of the laser equipment. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. There is also danger of ignition of endogenous gases.

NOTE: To eliminate power consumed when the key switch is off, turn off the main power switch on the rear panel.

Environmental Considerations

The equipment that you have purchased requires the use of natural resources for its production. This equipment may also contain hazardous substances which could have potential effect on the environment and human health if disposed of improperly.

In order to avoid the entry of any such substances into our environment and to promote natural resource conservation, we encourage you to use the appropriate take-back systems. Such take-back systems reuse or recycle many of the materials in your end-of-life equipment in a beneficial way. Please contact your local Alcon office for assistance in take-back options through Alcon or other providers.



The crossed-bin symbol located on this equipment reminds you to use take-back systems, while also emphasizing the requirement to collect waste equipment separately, and not dispose of it as unsorted municipal waste.

If you need more information on the collection, reuse, or recycle systems available to you, please contact your local or regional waste administration, or contact your local Alcon office for more information.

Universal Precautions

Universal precautions shall be observed by all people who come in contact with the instrument and/or accessories to help prevent their exposure to blood-borne pathogens and/or other potentially infectious materials. In any circumstance, wherein the exact status of blood or body fluids/tissues encountered are unknown, it shall be uniformly considered potentially infectious and handled in accordance with OSHA guidelines.

EMC Statement

It is important to install and use the equipment in accordance with the instructions in order to prevent harmful interference with other devices in the vicinity. If this equipment causes harmful interference to other devices (determined by turning the equipment off and on), the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the other device(s).
- Increase the distance between the equipment.
- Connect this equipment into an outlet on a circuit different from that to which the other device(s) is connected.
- Consult the manufacturer or your Alcon field service engineer for help.

Table 1-3 Guidance and Manufacturer's Declaration - Electromagnetic Emissions - The *PurePoint*™ Laser is intended for use in the electromagnetic environment specified below. The customer or the user of the *PurePoint*™ Laser should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment-Guidance
RF emissions CISPR 11	Group 1	The *PurePoint*™ Laser 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	Based on extensive field experience the *PurePoint*™ Laser is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes. The EMC Statement provides guidance on steps to take in case of electromagnetic interference.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Table 1-4 Guidance and Manufacturer's Declaration - Electromagnetic Immunity - The *PurePoint*™ Laser is intended for use in the electromagnetic environment specified below. The customer or the user of the Next Generation Laser should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	• ±6 kV contact • ±8 kV air	• ±6 kV contact • ±8 kV air	Floors should be wood, concrete, or ceramic tile. Do not use around floors that are covered with synthetic material to avoid laser stoppage due to ESD.
Electrical fast transient/burst IEC 61000-4-4	• ±2 kV for power supply lines • ±1 kV for input/output lines	• ±2 kV for power supply lines • ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment. To avoid laser stoppage due to fast transients avoid powering the *PurePoint*™ Laser on the same branch circuit with sources that can generate fast transients (inductive switching; e.g., high current motors).
Surge IEC 61000-4-5	• ±1 kV differential mode • ±2 kV common mode	• ±1 kV differential mode • ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment. To avoid laser stoppage due to power-line surges consider powering the *PurePoint*™ Laser through branch circuit that has surge suppressor for protection against lightning surges (e.g., at power panel to surgical/office suite).
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	• <5% U_T (>95% dip in U_T) for 0.5 cycle • 40% U_T (60% dip in U_T) for 5 cycles • 70% (30% dip in U_T) for 25 cycles • <5% (>95% dip in U_T) for 5 sec	• <5% U_T (>95% dip in U_T) for 0.5 cycle • 40% U_T (60% dip in U_T) for 5 cycles • 70% (30% dip in U_T) for 25 cycles • <5% (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the uses of the *PurePoint*™ Laser require continued operation during power mains interruptions, it is recommended that the *PurePoint*™ Laser be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the *PurePoint*™ Laser, including cables, than the recommended separation distance calculated from the equation applicable to the frequency to the transmitter. **Recommended separation distance:** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating to the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strength 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 following symbol. 

Table 1-5 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the *PurePoint*™ Laser - The *PurePoint*™ Laser is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *PurePoint*™ Laser can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *PurePoint*™ Laser as recommended below, according to the maximum output power of the communications equipment.

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

For transmitters rates 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.

FCC and IC Compliance Statement

Equipment contains Radio Frequency Identification (RFID) device.

Operating Frequency: 13.56 MHz
Type of modulation: Amplitude Shift Keying (ASK)
Output power (e.i.r.p): 703 nW

This device complies with Part 15 of the FCC Rules and with Industry Canada Radio Standards Specification RS-210.

Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

CAUTIONS

Change or modifications made to this equipment not expressly approved by Alcon may void the FCC authorization to operate this equipment.

To ensure that the RFID transmitter complies with current FCC regulations limiting both maximum output RF power and human exposure to radio frequency radiation, a separate distance of at least 20 cm must be maintained between the unit's antenna and the body of the user and any nearby persons at all times and in all applications and uses.

This device complies with the RF exposure limits for humans as called out in RSS-102.

Europe - R&TTE Directive 99/5/EC

This device complies with the requirements of the Council Directive 99/5/EC (R&TTE).

Australia and New Zealand

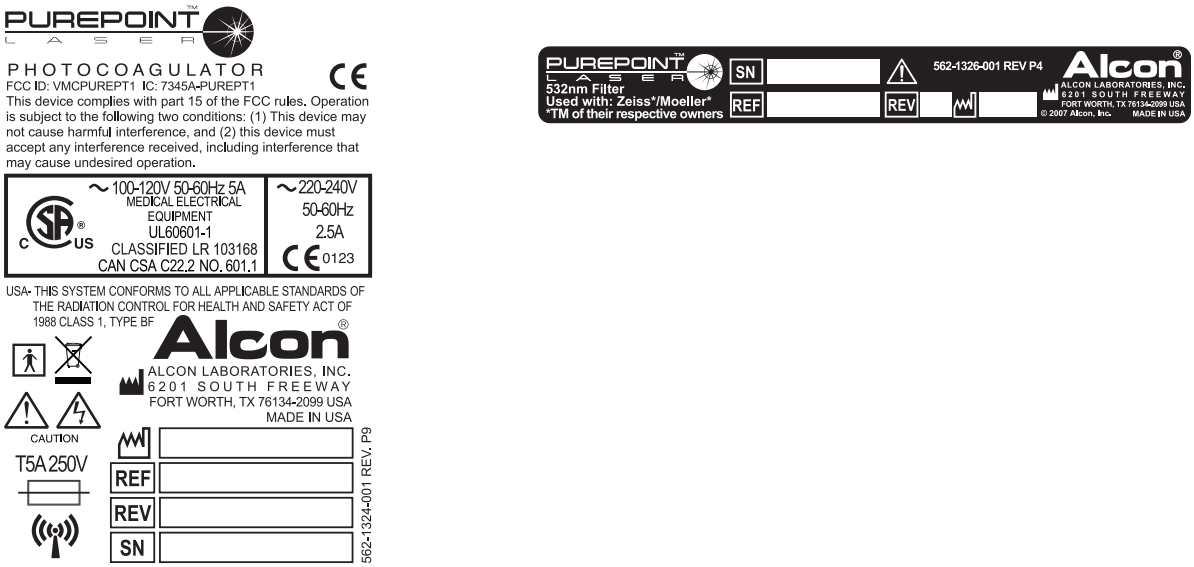
This device complies with the Australian/New Zealand Standard AS/NZS 4268: 2003 Radio Equipment and Systems – Short Range Devices – Limits and methods measurement.

Canada

This ISM device complies with Canadian ICES-001.
(Cet appareil ISM est conforme a la norme NMB-001 du Canada.)

LABELING

Figure 1-2 shows the labeling found on the *PurePoint™* Laser.



Alternating Current

Aiming Beam

Dangerous Voltage

Equipotentiality

Footswitch

Fuse

Illumination

Keyswitch

Laser Connection

Laser Emergency Stop Switch

Laser Port

Off

On

Consult Operator's Manual, or System Error or Advisory

Ready

Standby State

System Fault

System Information

Type BF Equipment

USB Connector

Use appropriate take-back system (see Environmental Considerations in this manual).

Figure 1-2 Labels and Icons on *PurePoint™* Laser Console

Figure 1-4 The *PurePoint*™ Carrying Case

Carrying Case

The carrying case shown in Figure 1-4 is included with the system and intended to be used as an aid to carrying the system.

CAUTION

The carrying case should not be used for shipping the system.

PREPARING FOR INSTALLATION

The *PurePoint™* Laser system was thoroughly inspected and carefully packaged for shipping. If the container is damaged, leave system in original container with packaging and request inspection by the carrier within 3 days of delivery.

Included as part of the packaging is the carry box for the *PurePoint™* Laser. This container is intended to protect the system when moving it from one location to another. Use the carry box whenever the system must be moved.

Initial installation must be performed by an Alcon representative. Prepare the facility for installation of the *PurePoint™* Laser as follows:

General Laser Room Layout

The *PurePoint™* Laser must be installed in a dust free room, and positioned so the laser beam cannot be directed toward a door, window, mirror, or reflective area. To reduce dust, avoid installing the instrument in a carpeted room. An example of a typical laser room layout is shown in Figure 1-4.

Approximate Dimensions of the *PurePoint™* Laser console:

- Width (overall) = 0.23 m (9 inches)
- Length (overall) = 0.35 m (13.5 inches)
- Maximum height (overall) = 0.18 m (7 inches)
- Weight = <13.6 Kilos (30 lbs.)

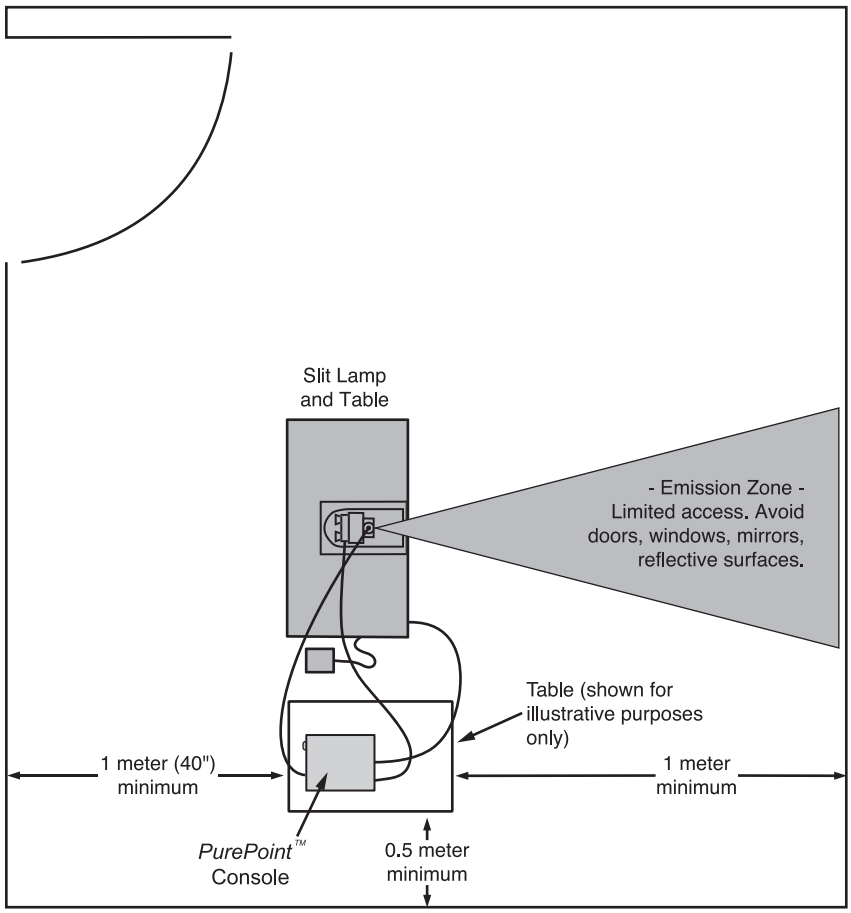


Figure 1-4 Recommended Laser Room Layout (Overhead View)

NOTE: The accessory equipment connected to or used with this equipment must be certified according to the respective IEC standard; e.g., IEC 950 for data processing equipment (data processing equipment must not be used during patient treatment) and IEC 601-1 for medical equipment. Additionally, all configurations shall comply with the system standard IEC 601-1-1. Anyone connecting additional equipment or otherwise causing a different system configuration than provided by Alcon, is responsible for continued compliance to the requirements of the System Standard IEC 601-1-1. If in doubt, consult the Technical Services department of your local Alcon representative.

It is recommended not to use a power strip to plug in accessory equipment. Each accessory should be plugged into a wall unit.

General Safety Precautions (Refer to IEC 825-1 or ANSI Z136.1)

- A laser safety officer should be appointed to supervise the installation and use of the system.
- Install an indicator light outside the laser room warning of instrument operation.
- Position the instrument so that the laser beam is never directed toward a door, window or reflective surface.
- Use non-reflective matte finish wall paint.
- Avoid covering laser room floor and walls with carpet or any other dust generating material. This will minimize the possibility of excess grime and dust on the instrument optics, and interference with equipment cooling.
- The instrument requires a minimum of 0.5 meter of open space on all sides for proper cooling ventilation. Therefore, the system should be set flat, resting on the legs provided on the bottom of the console.
- Unauthorized use of this laser should be prevented by removing the On/Off key.
- Entrances to areas or protective enclosures containing Class IV lasers should be posted with appropriate warning signs.
- Appropriate eye protection must be used in all hazard areas. Use eye protection with OD 4 or above at 532 nm.

Nominal Ocular Hazard Distance (NOHD)

Accessory	Beam Divergence (NOHD)
LIO	0.024 radians (20 meters)
Slit Lamp	0.011 radians (40 meters)
Endoprobe	0.23 radians (3 meters)

- A qualified technician must verify that the power plug used is properly grounded.
- The remote interlock connector should be connected to an emergency master disconnect interlock or to room/door/fixture interlocks. Please refer to figure 1-5.
- The footswitch, the endoprobe, LIO, and the slit lamp adaptation/slit lamp should be placed within 2 meters of the *PurePoint™* Laser console.

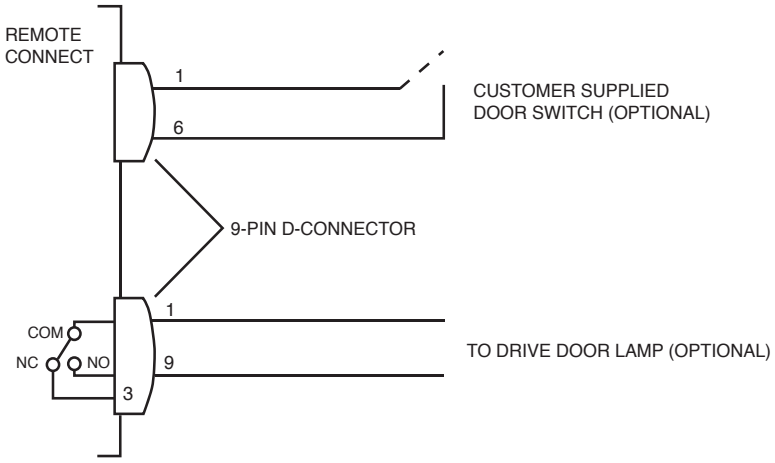


Figure 1-5 Remote Connector/Door Lamp Circuit Diagram

Utility Requirements

Electrical requirement: The *PurePoint™* Laser has a power supply that operates at 100-120 V and 220-240 V input ranges at 50/60 Hz. A properly grounded, standard plug is the only requirement.

Electrical Connections

CAUTION

Before turning the instrument ON for the first time after receipt of the system, wait one hour for the components and optics to normalize to avoid possible condensation that may have occurred during shipping.

Use only <HAR> power cord with a minimum of 10 Amp rating.

Before connecting the main plug verify that:

- The Main Switch on the back panel is in the OFF (O) position.
- The key is in the off (vertical) position, or has been removed.
- The Remote Plug or the interlock cable is connected on the rear panel.

Optical Connections

Optical connections vary in relation to the procedure to be performed. Different peripherals can be connected to the output ports. These peripherals are:

- Slit Lamp adaptation
- Laser Indirect Ophthalmoscope (LIO)
- Endoprobe/Aspirating Endoprobe/Illuminated Endoprobe

The procedures for connecting these peripherals are contained in Section Three: Operating Instructions.

PUREPOINT™ LASER SAFETY FEATURES

The *PurePoint™* Laser is designed for the highest degree of reliability and maximum safety for both the operator and the patient. Any misuse of this laser system may be dangerous. Before using the laser system, the operator must be familiar with the commands and the manipulation of this type of instrument.

The *PurePoint™* Laser is fitted with the following safety systems which must be understood by every operator:

- A protective housing covers the laser source so that no harmful laser radiation will be emitted. No part of this protective housing should be removed by the operator. The laser system must not be used if the protective housing has been damaged or removed.
- A remote connection (interlock) is located on the rear panel and permits the installation of an external switch. Refer to Figure 1-4 for remote switch connections. This switch can be installed on the laser room door and cuts off all laser emissions in case the door is opened during operation. There is also a relay connector for connection to an internal relay to activate a door warning lamp if desired.
- A key switch controls the laser power supply. Laser operation is not possible if the key has been removed. Access to the key should be limited to authorized and knowledgeable personnel. The key should not be left on or near the instrument when not in use.
- During operation, laser status can be determined by visually checking the LCD display. The background colors change to indicate the laser's status for Standby or Ready modes.
- A green background display indicates that the system is in Ready mode. In addition, the system will emit a tone to indicate the mode change. The power and time settings can be set or changed, but not while the laser is being fired.
- A gray background on the LCD indicates that the system is in Standby mode and the laser's default parameters can be altered.
- Under normal Standby, non-firing situations, the background display will be grey.
- An emergency switch is mounted on the front panel. Pushing this switch will cut off all laser emissions (treatment and aiming beam) at any time. The switch must be pulled out to the initial position to restore power. The laser will always restart in Standby mode.
- Laser firing commands are microprocessor controlled and firings are prevented should any malfunction be detected in the instrument electronics. The instrument will only fire when all conditions are correct.
- Output power of the laser beam is continuously monitored and controlled. In case an unusual power condition is detected, firing stops and the treatment laser emission is cut off.

PROFESSIONAL OPERATOR'S INFORMATION

The following information is given to provide the operator with specific information regarding the *PurePoint™* Laser ophthalmic laser.

Indications

The *PurePoint™* Laser is indicated for use in photocoagulation of both anterior and posterior segments of the eye including:

- Retinal Photocoagulation, panretinal photocoagulation and intravitreal endophotocoagulation of vascular and structural abnormalities of the retina and choroid including:
  - Proliferative and nonproliferative retinopathy (including diabetic)
  - AMD; Wet or Dry to include Macular degeneration
  - Retinal tears and detachments
  - Macular Edema
  - Macular photocoagulation; including grid, focal, Laser Drusen scatter (panretinal)
  - Transcleral Cyclophotocoagulation
  - Retinopathy of prematurity;
  - Choroidal neovascularization;
  - Leaking microaneurysms.

- Iridotomy, Iridectomy & Trabeculoplasty for treatment of Chronic/Primary Open Angle Glaucoma (COAG,POAG), Acute Angle Closure Glaucoma (AACG), and Refractory Glaucoma.

- And other laser treatments including:
  - Internal sclerostomy
  - Lattice degeneration
  - Intra-Ocular Tumors; to include Choroidal Hemangioma, Choroidal Melanoma, Retinoblastoma; Central and Branch Retinal Vein Occlusion
  - Suturelysis
  - Vascular and pigmented skin lesions.
  - Otosclerotic Hearing Loss

Effects

The laser beam is primarily absorbed by pigmented tissues within the eye. These primary pigments are hemoglobin/oxy-hemoglobin and melanin. In the case of macular treatment, xanthophyll pigment is involved. The surgeon controls the power, spot size, and exposure time of the delivered laser beam to the targeted tissue. It is the combination of these effects that results in the thermal action of the laser beam upon tissue. One or all of the adjustable parameters can be changed. However, in normal clinical practice, power is usually varied, and spot size and exposure time are preset as a function of the application.

The 532 nm green laser beam has similar absorption characteristics to the 577 nm dye yellow laser beam[7]. This means that the absorption effects of the 532 nm wavelength are considerably higher in hemoglobin and melanin, and less in xanthophyll. In all cases, it is necessary to perform titrations until the desired treatment results are obtained. The 532 wavelength also requires less power than that required with the argon laser to obtain similar results. Therefore, you should begin your titration levels with lower power than required for similar procedures with the argon laser.

WARNING!

Failure to titrate delivered energy may result in patient injury.

Use of this medical laser, as with any other instrument, requires training and experience to obtain maximum clinical performance. Titrating the dosage is recommended by initiating a lesion formation in an area of normal retina with intact pigment epithelium. Power and exposure duration should be varied incrementally until the desired lesion is produced.

WARNING!

If unsure which settings are required, select low power, short duration, and large spot size. Failure to do so may result in patient injury.

Delivery of Laser Energy

The laser beam is delivered to tissue via a Slit Lamp, Endoprobe, Illuminated Endoprobe, aspirating Endoprobe or Laser Indirect Ophthalmoscope (LIO). When using a Slit Lamp, the laser beam is often used in combination with various contact lenses to aid in treatment of particular targets such as the fundus. These contact lenses enable the laser beam to be directed to different sections of the eye.

WARNING!

Some contact lenses, generally classified as wide field or pan fundus lenses, magnify the laser spot incident upon them. For example, a pan retinal photocoagulation procedure is normally done with a spot size setting of 500 microns when using a three mirror lens. If a wide field lens were used, and the laser spot size setting remained at 500 microns, the actual spot in the eye would be larger than the indicated spot size setting. Normal increases in spot size in the eye range between 1.3 and 2 times the spot size as selected at the Slit Lamp zoom. These effects and resultant changes in power density must be considered when using wide field lenses.

Reaction to applied laser energy by the eye is a function of many variables. The pigmentation of the eye, technique or procedure used, laser settings, and pre-existing condition of the eye, such as cataract, will have an effect on the selected laser parameters and the results obtained. Therefore, it is very important to consider all the existing clinical conditions and titrate until the desired results are obtained.

Always use minimal illumination from the Slit Lamp while maintaining good visualization in order to reduce reflections and discomfort for the patient. Likewise, the aiming beam should be used at a minimum setting while maintaining proper targeting of the selected tissue. This will also minimize excessive reflections and scattering, particularly at smaller spot sizes.

Doctor Protection Filter

The *PurePoint™* Laser system can only be fired when appropriate steps are taken to ensure that a doctor's filter is placed in the viewing device (e.g. slit lamp, surgical microscope, etc.). The *PurePoint™* Laser supports three types of doctor filters:

- Non-tethered with fixed filter in viewing path.
- Tethered with fixed filter in viewing path.
- Tethered with manual switch to place filters in and out of the viewing path.

The Doctor Protection Filter must remain in the beam path during treatment, enabling the targeted tissue to be seen with complete protection for the operator. The filter has virtually no effect on visualization (colored** view only).

Rotation of the tethered filter with manual switch in or out of the beam path is accomplished by means of a lever located on the right side of the filter. Note that if the Doctor Protection Filter is in the open position in the Slit Lamp or Endo modes, the laser will not fire and the message "Please Engage Dr. Filter" will appear. Rotate the filter lever clockwise until the Doctor Protection Filter is in the beam path and the

message clears. If using a non-tethered fixed filter, and the system is switched from Standby to Ready mode, the message "Verify appropriate Dr. Filters are installed in all viewing devices" appears and the user must verify before the laser can switch to Ready mode.

If two tethered filters are in place (see rear panel description), both filters must be switched into the beam path before the laser will operate. Switching either filter out of the beam path while the laser is in Ready mode switches the laser to Standby mode immediately. Inserting a filter tether into the machine while it is in Ready mode switches the machine back to Standby mode until all tethered filters have been verified to be in place.

Figure 1-6
Dr. Filter Message

WARNING!

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

NOTE: The aiming beam passes down the same delivery system as the working beam; this provides a good method of checking the integrity of the delivery system. If the aiming beam spot is not present at the distal end of the delivery system, if its intensity is reduced, or if it looks diffused these are possible indications of a damaged or not properly working delivery system.

Treatment Hazards

A single treatment exposure will typically cause a blanching of target tissue. Exposure duration can be adjusted from 0.01 seconds to 2.0 seconds to result in the desired effect. A continuous treatment beam can also be selected.

NOTE: In CW, depending on the thermal load of the system, the system may shut down in safety mode prior to the footswitch being released.

Excessive combinations of power and exposure can cause undesirable tissue vaporization and charring. Reports 1-6 (listed as footnotes at the end of this section) indicate these hazards are no different from adverse effects from continuous wave argon lasers used at these same settings. No evidence of non-thermal effects has been observed.

Contra Indications

Patients with a condition that prevents visualization of target tissue (cloudy cornea, or extreme haze of the aqueous humor of the anterior chamber or vitreous humor) are poor candidates for Slit Lamp or LIO delivered laser treatment.

Side Effects

Corneal burns, inflammation, loss of best-corrected visual acuity, loss of visual field, and transient elevations in intraocular pressure can occur as a result of ophthalmic laser treatment. Unintentional retinal burns can occur if excessive treatment beam power or duration is used.

Laser Safety

Back scattered radiation is of low intensity and is not harmful when viewed through a protective filter. All personnel in the treatment room must wear protective eyewear, OD 4 or above at 532 nm, when the system is in Standby/Ready mode as well as during treatment. The Doctor Protection Filter is an OD greater than 4 at 532 nm.

WARNING!

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

CAUTION

Federal (USA) law restricts this device to sale by, or on the order of, a physician.

1 Ludwig, K.; Lasser, T.; Sakowski, H.; Abramwoski, H.; Worz, G. (Augenklinik, Universitat Munchen) "Photocoagulation in the edematous and non-edematous retina with the cw-laser of different wavelengths." Ophthalmologe (GERMANY), December 1994, Volume 91, No. 6, p783-788.

2 Roider, J.; Schiller, M.; el Hifnawi, E.S.; Birngruber, R. (Augenklinik, Medizinische Universitat zu Lubeck) "Retinal photocoagulation with a pulsed, frequency-doubled Nd: YAG laser (532 nm)." Ophthalmologe (GERMANY), December 1994, Vol. 91 No. 6, p777-782.

3 Wyman, D.; Wilson, B.; Adams, K. (Medical Physics Department, Hamilton Regional Cancer Centre, Ontario, Canada) "Dependence of laser photocoagulation on interstitial delivery parameters." Lasers Surgical Medical (UNITED STATES), 1994, Vol. 14 No. 1, p59-64.

4 Obana, A.; Miki, T.; Matsumoto, M.; Ohtsuka, H.; Moriwaki, M.; Kamo, M.; Mii, T.; Kijima, M. (Department of Ophthalmology, Osaka City University, Medical School, Japan) "An experimental and clinical study of chorioretinal photocoagulation using a frequency-doubled Nd: YAG laser." Nippon Ganka Gakkai Zasshi (JAPAN), September 1993, Vol. 97 No. 9, p1040-1046.

5 Mordon, S.; Beacco, C.; Rotteleur, G.; Brunetaud, J.M. (INSERM - National Institute of Health and Medical Research - Lille, France) "Relation between skin surface temperature and minimal blanching during argon, Nd-YAG 532, and CW dye 585 laser therapy of port-wine stains." Lasers Surg Med (UNITED STATES) 1993, Vol. 13 No. 1, p124-126.

6 Jalkh, A.E.; Pflibsen, K.; Pomerantzeff, O.; Trempe, C.L.; Schepens, C.L. (Eye Research Institute of Retina Foundation, Boston, MA 02114) "A new solid-state, frequency-doubled neodymium-YAG photocoagulation system." Arch Ophthalmol (UNITED STATES) June 1988, Vol. 106 No. 6, p 847-849.

7 Wavelengths, Opthamology, July 1986, Volume 93, Number 7, Page 956.

PRODUCT SERVICE

For product service, please contact Alcon's Technical Services Department at the number provided below.

Operators experiencing problems with the system should refer to the Operating Instructions and Troubleshooting sections of this manual. A problem which persists should be referred to the Alcon Technical Services Department or your local authorized service representative.

For optimum performance, it is the user's responsibility to schedule preventive maintenance service on the system and its accessories one time each year. Alcon's Field Service Engineers are trained and equipped to provide the highest quality of workmanship.

Safety performance should be verified by the user (e.g., qualified service personnel) at least twice a year. Ground resistance must be under 0.1 ohms. Leakage current must be under 500 μA.

To avoid unnecessary shipping, please contact your Alcon Technical Services Department prior to return of any system or accessories. If return of the equipment is deemed necessary, a Return Material Authorization will be issued with appropriate shipping instructions.

Alcon Laboratories, Inc.
Technical Services Department
15800 Alton Parkway
Irvine, California 926183818
(949) 753-1393
(800) 832-7827

LIMITED WARRANTY

Alcon Laboratories, Inc., will repair or replace at its option, any system or accompanying accessories (excluding the optical fiber) found to be defective in material and/or workmanship for a period of one (1) year from the date of initial installation. This warranty applies to the original purchaser of the system, when said system is properly installed, maintained, and operated in accordance with published instructions.

Alcon Laboratories shall not be obligated to provide services under this warranty for damage to or destruction of systems covered where such damage or destruction is (i) a result of or caused by fire or explosion of any origin, riot, civil commotion, aircraft, war, or any Act of God including, but not limited to lightning, windstorm, hail, flood, earthquake, or (ii) caused by customer's misuse or improper servicing of said systems.

The express warranty above is the sole warranty obligation of Alcon, and the remedy provided above is in lieu of any and all other remedies. There are no other agreements, guarantees, or warranties, oral or written, express or implied, including without limitation warranty of merchantability or fitness for a particular purpose. Alcon shall have no liability whatsoever for any incidental or consequential damages arising out of any defect, improper use, or unauthorized service or repair.

WARNING!

The disposables used in conjunction with Alcon instrument products constitute a complete surgical system. Use of disposables and handpieces other than those manufactured by Alcon may affect system performance and create potential hazards. If it is determined that disposables or handpieces not manufactured by Alcon have contributed to the malfunction of the equipment during warranty period, service will be provided at prevailing hourly rates.

SECTION TWO
DESCRIPTION

INTRODUCTION

This section contains descriptions of the front panel, rear panel, and screens that are displayed on the PurePoint Laser.

WARNINGS!

Use of controls, making adjustments, or performance of procedures other than specified in this manual may result in hazardous laser radiation exposure.

Possible explosion hazard if used in the presence of flammable anesthetics or other gas mixtures.

FRONT PANEL DESCRIPTION

The front panel, shown in figure 2-1, allows the operator to control, change settings, and monitor the PurePoint Laser. Changes to the current system setup are confirmed by a system tone or voice confirmation. For example: if the port selection or power is changed, the system will emit a tone. The liquid crystal display (LCD) shows laser parameters, operational prompts, and operator messages.

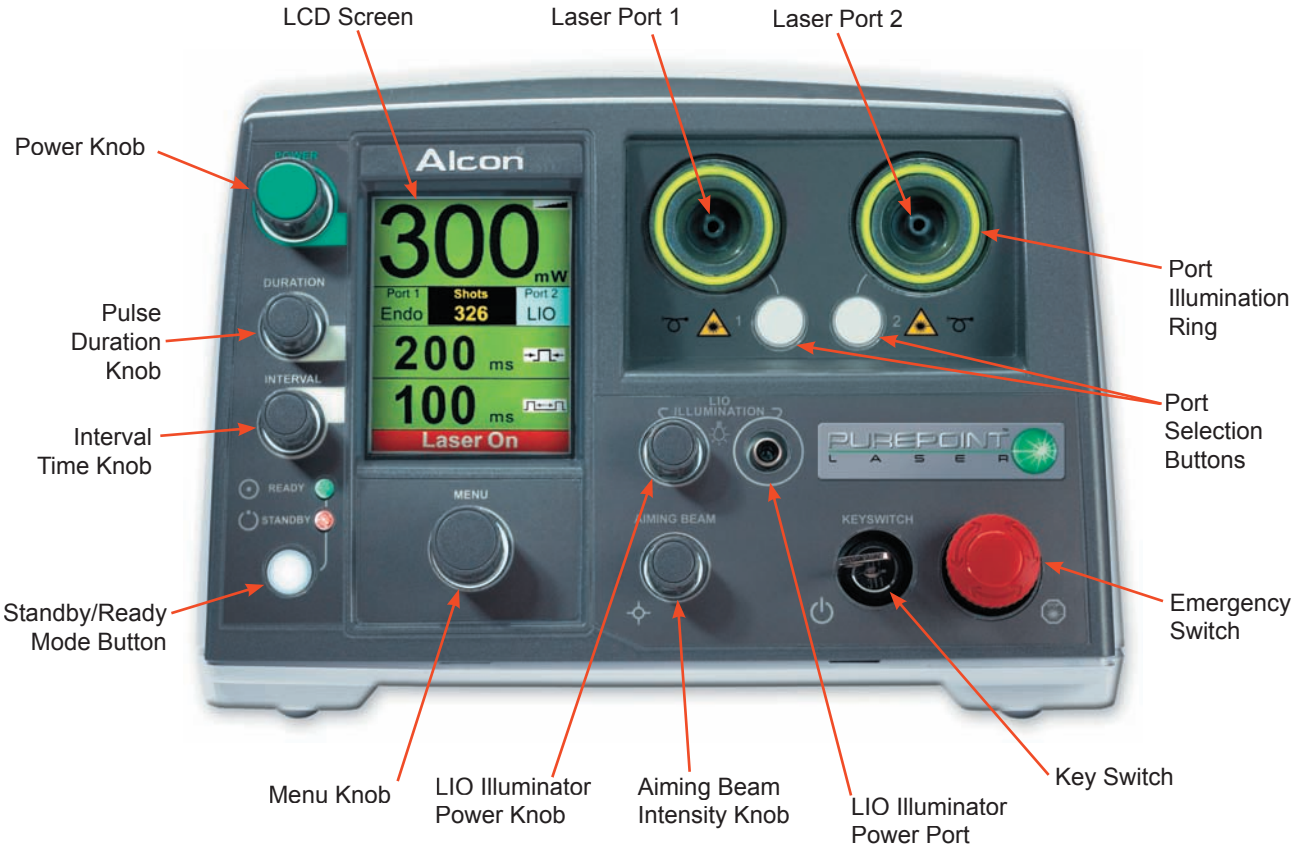


Figure 2-1 The PurePoint Laser Front Panel

LCD Screen

The LCD screen is the communication interface between the surgeon and the system. It provides the surgeon with system status and parameters by displaying text and icons relevant to the current operating state. The background color of this screen is gray when the system is in the Standby state and green when is in the Ready state. When the laser is fired, "Laser On" is display in a red box at the bottom of the screen.

Figure 2-2 shows a typical screen that may be displayed on the LCD. Each screen displayed by the system is described in detail later in this section. System messages (advisories, errors, and warnings) are listed in the Troubleshooting section of this manual.

Figure 2-2
Typical *PurePoint*® Screen

Laser Ports 1 and 2

Dual SMA connectors are provided on the front panel to connect the *PurePoint™* Laser to the desired delivery system; i.e., Slit Lamp adaptation, Laser Indirect Ophthalmoscope (LIO), or Endoprobe/Aspirating probe. Each port has an Radio Frequency Identification (RFID) reader that can identify Alcon RFID enabled probes and automatically set up the default power and time parameters for the specific probe. Laser fibers without RFID must be identified by the operator when prompted on the display.

Port Illumination Ring

The Laser Ports are surrounded by a ring of LED's that provide background illumination for the port and enable the user to visually verify the following items:

- Indicates that the port is selected.
- Indicates that an unidentified probe has been inserted into the port.
- Indicates that a fault has been detected on the port and the port is no longer available.

Port Available Illumination Color: **BLUE**

If no probe is connected to a port, the Port Illumination Ring is illuminated in the color blue.

Selected Port Illumination Color: **GREEN**

If an identified probe is inserted into the port and the port is selected, the Port Illumination Ring is illuminated in the color green.

Unidentified Probe Indication Color: **ORANGE**

If a probe is inserted into the port and is unidentifiable by the system, the Port Illumination Ring is illuminated in the color orange, indicating that the probe must be identified before it can be used.

A message is displayed as shown in Figure 2-3 prompting the user to identify the probe as one of three instruments displayed in the menu options.

After the user has identified the probe:

- The Port Illumination Ring is illuminated in the color green if the port is the only port with an identified probe.
- The Port Illumination Ring is not lighted if the other port already contains an identified probe. The port with the newly-identified probe is not the selected port. The Port Selection Button must be pushed for the probe to be selected.

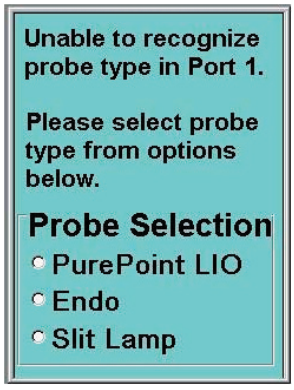


Figure 2-3 Unidentifiable Probe Selection Screen

Disabled Port Indication Color: **RED**

If the *PurePoint™* software determines a port cannot be used due to a mechanical or software fault, the Port Illumination Ring is illuminated in the color red.

Port Selection Buttons

When each port has an identified probe, pressing one of the Port Selection Buttons selects the associated port. The Port Selection Buttons are active only when there are identified probes in each port. In all other cases (such as an unidentified probe in one port, only one port being used, no identified probes in a port, etc.) the *PurePoint™* software will take the correct action.

When a selection is made, the LED surrounding the desired port illuminates green. If selecting a port for the first time after starting the system with an identified endoprobe or slit lamp attachment, a screen is displayed asking the user to confirm that the Dr. Filter is in place.

Emergency Switch

Pressing the Emergency Switch turns off the laser system immediately. To restore power, pull the Emergency Switch to the out position. The system will return to the Standby mode.

Keyswitch

The Keyswitch is a two position switch where the key can be removed only in OFF position. In the OFF position, the power to the laser is shut off. Switching to the ON position turns the laser system on and the system will display the Standby screen.

LIO Illumination Power Knob

The LIO Illumination Power knob adjusts the brightness of the LIO illumination beam (if an LIO power cable is plugged into the LIO Power Port port, a LIO fiber is connected to a laser port, and the port is selected). Turning the knob right makes the LIO illumination beam brighter and turning the knob left makes the beam dimmer.

When the LIO illumination beam reaches its maximum brightness, continuing to turn the knob to the right has no effect. Similarly, when the LIO illumination beam reaches its minimum brightness level, continuing to turn the knob to the left has no effect.

Aiming Beam Intensity Knob

The Aiming Beam Intensity knob adjusts the intensity of the the red laser aiming beam. The system saves the intensity setting for each port. Therefore, when a laser port is selected, the aiming beam intensity setting is the same as the last time the port was selected. In addition, when the laser system has completed initialization, the aiming beam intensity for the selected port is the same as the last time the system was turned on.

- Turning the Aiming Beam Intensity knob clockwise increases the intensity towords the maximum (under 1 mW).
- Turning the knob counter-clockwise decreases the power until it effectively turns off.
- Turning the knob further in either direction has no effect on the power of the aiming beam.

LIO Illumination Power Port

The LIO illumination power cable connector is inserted into this port.

Menu Knob

The Menu knob allows the user to highlight and select a menu item shown on the display. The knob rotates to move the highlighted field on the display, and the highlighted item is selected by pressing the knob.

- Turning the Menu knob clockwise moves the highlighted field to the right (or down).
- Turning the Menu knob counter-clockwise moves the highlighted field to the left (or up).
- Continuing to turn the knob after highlighting the last menu item has no effect.
- On menus in which several choices are required, turning the knob highlights the space, but the knob must be pushed in to make a selection. A choice must be made in each line or column.
- For menu items containing values that can be modified, turning the knob right increases the value and turning the knob left decreases the value. Once the maximum or minimum value for a setting has been reached, turning the knob in that direction has no further effect.

Standby/Ready Button

The Standby/Ready button switches the system between Standby and Ready modes. The screen background changes color for each mode (gray for Standby, green for Ready mode). In addition, each mode has an associated LED that illuminates when that mode is active.

> ***WARNING!***
>
> **In Ready mode, pressing the footswitch will fire the laser.**

To transition the system from Standby to Ready mode, press the Standby/Ready button once. The transition proceeds as follows:

- The LCD background color flashes between gray and green for the 2 seconds.
- During those same 2 seconds, the Standby LED turns off, and the Ready LED flashes on/off.
- After the transition, the LCD background color remains green and the Ready LED stays on indicating that the system is in Ready mode.

Various conditions prevent the system from transitioning to Ready mode including the following:

- Footswitch disconnected
- No identified probe connected
- Remote interlock open
- Tethered Dr. Filter disengaged
- The LCD is displaying a menu screen

Pressing the Standby/Ready button while the system is in Ready mode, immediately returns the system to Standby mode.

The Interval Time Knob

The Interval Time is the time between treatment shots when the treatment mode is set for Repeat mode. The Interval Time knob can adjust the interval time to the following values:

- 30 ms to 100ms in 10 ms steps
- 100 ms to 300 ms in 50 ms steps
- 300 ms up to 1 second duration in 100 ms steps.

The Interval Time Knob functions as follows:

- Turning the knob clockwise increases the amount of time between pulses (interval).
- Turning the know counter-clockwise decreases the amount of time between pulses.
- Turning the knob counter-clockwise from the maximum interval time (1000 ms) places the laser in Single Shot mode. Afterwards, turning the knob clockwise has no effect.
- Turning the knob clockwise from Single Shot mode will place the laser into Repeat mode with the interval time set to 1000 ms.
- Pressing the Interval Time knob sets the laser to Single Shot. Pressing the knob again returns the system to Repeat mode using the previous Interval time. In CW mode, turning or pressing the Interval Time knob has no effect.

NOTE: In Continuous Wave (CW) mode, the Interval Time knob is disabled and interval parameter on the diplay is grayed out.

The Pulse Duration Knob

The Pulse Duration Knob sets the duration (exposure time) of the laser emission and it functions as described below:

- Turning the knob clockwise increases the exposure time up to 2000 ms.
- Turning the knob past the 2000 ms setting or pushing the knob places the system in Continuous Wave (CW) mode. In CW mode, the Interval Time knob is disabled.
- Turning the Pulse Duration knob counter-clockwise from CW mode returns the system to the previous mode: Single Shot or Repeat.
- Turning the knob counter-clockwise decreases the exposure time. The lowest available exposure time is 10 ms.
- The Pulse Duration Knob adjusts the exposure time to the following values in milliseconds:10, 20, 50, 100, 150, 200, 250, 300, 400, 500, 700, 1000, 1500, 2000 ms and Continuous Wave (CW).

NOTE: In CW (Continuous Wave) mode, depending on the thermal load of the system, the system may shut down prior to the footswitch being released, with an indication in the LCD display. It is not recommended to use exposure times longer than 2 seconds in CW mode.

The Power Knob

The Power Knob is used to adjust the treatment laser power and it functions as described below:

Turning the Power Knob clockwise increases the laser power.
Turning the Power Knob counter-clockwise decreases the power power.
The Power Knob adjusts the power setting to the values shown in Table 2-1.

Table 2-1 532 Green Laser Power Values (in milliwatts)

30	40	50	60	70	80	90	100	110	120	130	140
150	160	170	180	190	200	220	240	250	260	280	300
320	340	350	360	380	400	420	440	450	460	480	500
550	600	650	700	750	800	850	900	950	1000	1100	1200
1300	1400	1500	1600	1700	1800	1900	2000				

NOTE: The *PurePoint™* laser determines the 532 green laser maximum available power and limits the user setting to that maximum value if less than 2 W. The maximum selectable power may be less than 2 W (2000 mW) because of the degradation of the laser engine over time.

REAR PANEL DESCRIPTION

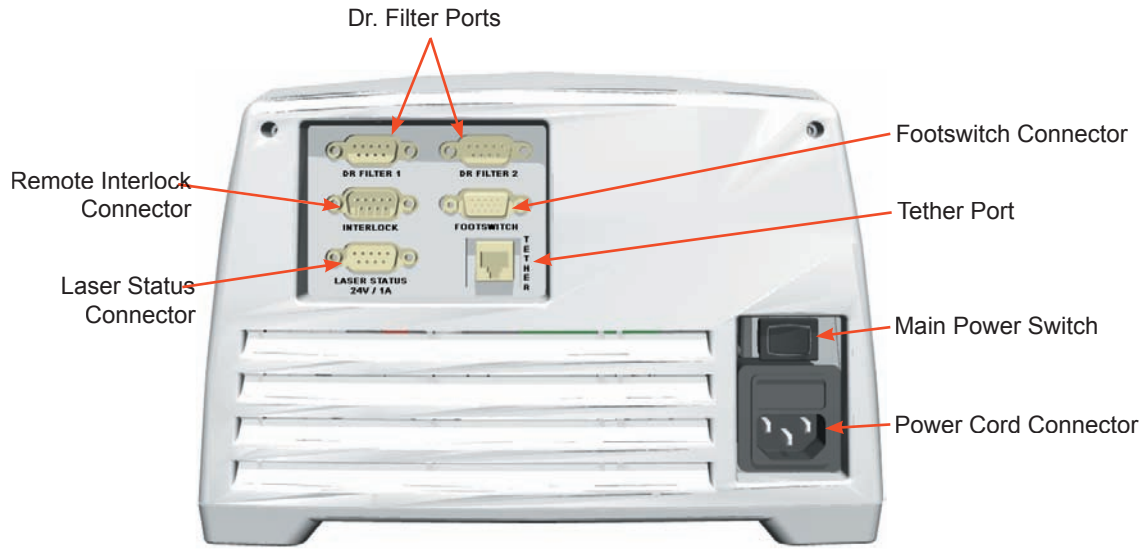


Figure 2-4 The *PurePoint*™ Laser Rear Panel

Doctor Protection Filter Ports

Two ports are provided to connect Doctor's filters. If more than one filter is needed, both ports can be used at the same time. There is no direct correspondence between the laser ports and Dr. Filter ports.

If the Doctor Protection Filter is not engaged, the warning message “Please Engage Dr. Filter” is displayed on the LCD. This message is displayed every time a port with a slit lamp or endoprobe fiber connected is selected. Acknowledging the prompt removes the warning message and allows normal operation to continue.

WARNINGS!

The operator may have a colored view through the Doctor Protection Filter due to blocking of the 532 nm wavelength (green). Newer filters are more transparent and provide a less-discolored view.

The operator must be careful to avoid potential secondary reflections. Therefore, the treatment room should be approved by a qualified laser safety officer.

Footswitch Connection

Either a standard footswitch or a multi-function footswitch is connected to the system through this port. The multi-function footswitch provides additional controls to change laser power and switch between Standby and Ready modes.

Power Cord Connector and Main Power Switch

The power cable for the system is connected in this module and the power switch is located above the power connection. If the Emergency Switch is pressed, the power to the system is shut off even if the Main Power Switch is ON.

Tether Port

This port is used by authorized service personnel to connect a service computer to the system. A password is required to gain access to the system and this procedure can only be performed by authorized service personnel.

Remote Interlock Port

The Remote Interlock Connection permits the facility to connect a door activated switch and/or door warning lamp to the *PurePoint™* system (see Section One for details).

When the Remote Interlock is activated and the connected door is opened:

- when the system is in Standby mode, a message is displayed that prompts the user to close the door prior to continuing.
- when the system is in Ready mode, the system immediately goes to Standby mode, and a message is displayed that prompts the user to close the door prior to continuing.
- when the system is in Firing mode, the laser is turned off, system goes to Standby mode, and a message is displayed that prompts the user to close the door prior to continuing.

Laser Status Connector

A lighted warning sign can be mounted at the entrance of the laser room and connected to the system through this port. When connected, the system will turn the warning sign on during Ready mode, and turn the sign off during Standby mode. The port will drive a bulb with a max rating of 24 Vdc, 1A.

FOOTSWITCH

The multi-function footswitch shown in Figure 2-5 has a depressible pedal to fire the laser and side switches that can be configured via the Footswitch Settings screen to perform other functions. The footswitch is lit by LED's to make it easy to find in a dark operating environment.

The side switches, located on the right and left side of the footswitch enclosure, are either enabled or disabled according to the selection in the Footswitch Settings screen (see the Footswitch Settings screen description later in this section of the manual). When enabled, they can be configured to control laser power or the transition between Standby and Ready modes.

When changing the laser power, holding a side switch depressed does not auto-increment or auto-decrement. The power value on the LCD is updated when a side switch is released. Therefore, each change of value requires a separate press and release.

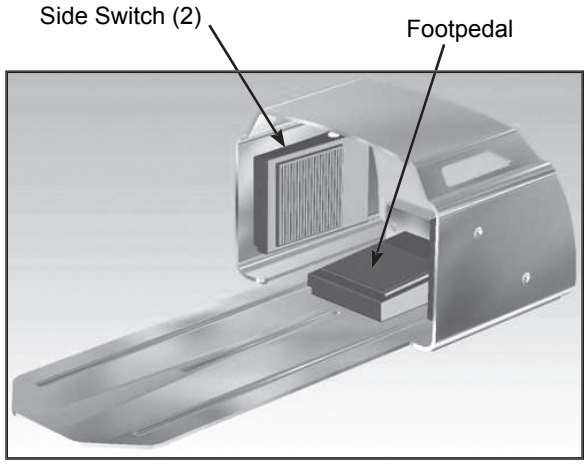


Figure 2-5
***PurePoint™* Multi-Function Footswitch**

SYSTEM MODES

The *PurePoint™* system has three modes describe the different operational states of the system.

Standby Mode

The system starts in this mode after initialization. It also falls back to this mode in response to various events. Settings can be adjusted in this mode, but the system cannot deliver treatment laser energy.

Ready Mode

This mode is initiated when the Standby/Ready button is pushed while the system is in Standby mode. After the button is pushed, the system pauses for 2 seconds, flashes the parameters section of the LCD display, then the system transitions into Ready mode. The system is now prepared to deliver treatment laser energy.

Firing Mode

Pressing the footswitch in Ready mode causes the system to deliver laser treatment energy.

TREATMENT MODES

The system has three treatment modes that determine how the treatment laser shots are delivered.

Repeat Mode

In this mode, pressing and holding down the footswitch pedal causes the laser to fire repeatedly, in a sequence. The individual shots have a duration set by the value in the Pulse Duration field of the display. The time interval between the shots is set by the value in the Interval field of the Display. Lifting the footswitch pedal stops the firing sequence.

Single Shot Mode

In this mode, one treatment shot is delivered per each press of the footswitch pedal. Continuing to hold down the footswitch pedal in this mode after the treatment shot has been delivered shall have no effect. The Treatment Shot duration is set by the value in the Pulse Duration field of the display. Lifting the footswitch pedal stops the firing sequence.

Continuous Mode

In this mode, pressing and holding down the footswitch pedal causes the laser to fire continuously as long as the footswitch pedal is depressed. Lifting the footswitch pedal stops the firing sequence.

SCREEN DESCRIPTIONS

Figure 2-6 shows the hierarchy of screens displayed as you operate the system. Navigation through the screens is accomplished by turning the Menu Knob to highlight the desired selection, then pushing the knob in to activate the selection. When available, pressing "Done" returns the system to the Standby screen, while pressing "Back" takes the system back to the previous screen.

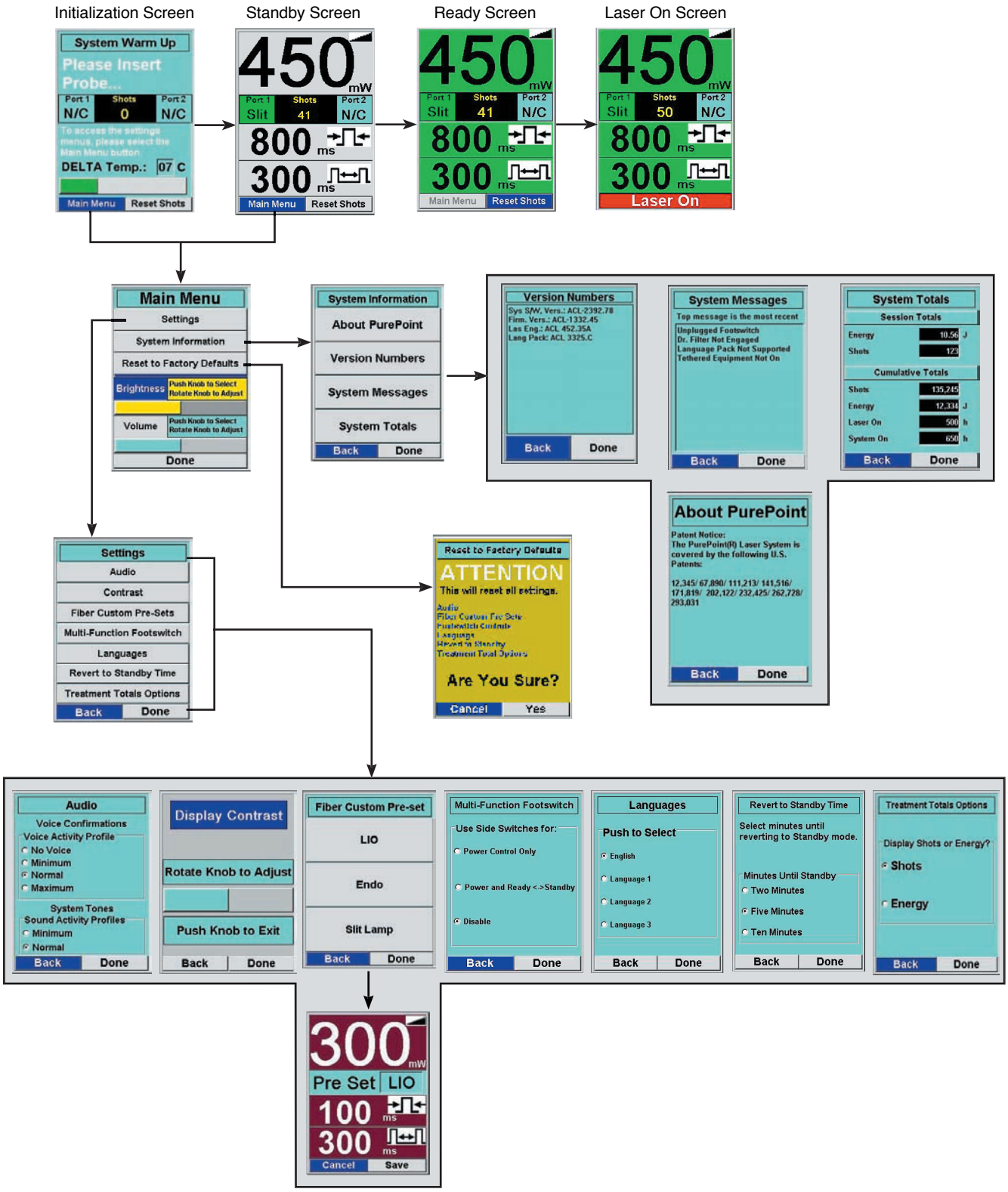


Figure 2-6 Screens Displayed on the *PurePoint*™ LCD

INITIALIZATION SCREEN

The Initialization screen is displayed when the system is powered on. 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: connect probes, connect LIO illumination power, set laser parameters if an identified probe is connected, and view or change system settings.

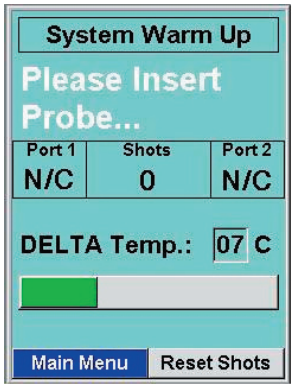


Figure 2-7
Initialization Screen

STANDBY SCREEN

The Standby screen is displayed after the system has initialized and can be identified by its gray background as shown in Figure 2-8.

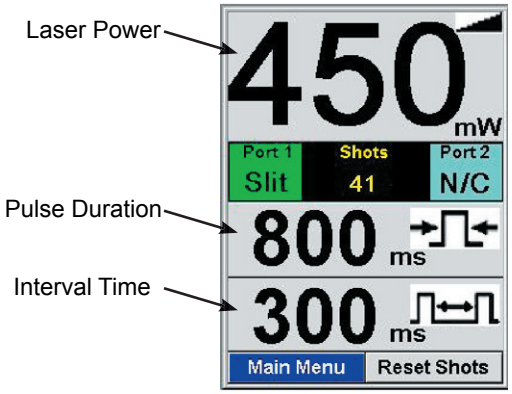


Figure 2-8
Operating Display-
Standby Screen

Laser Power

This field shows the current setting for laser power. The units are shown in milliwatts (mW) for values from 30 to 980, and in watts for values greater than 980. Adjustments are made using the Power knob.

Pulse Duration

This field shows the current setting for duration of the laser emission. The units are shown in milliseconds (ms) for values from 10 to 700, and in seconds for values greater than 700. Settings greater than 2 seconds causes the system to enter Continuous Wave (CW) mode.

Interval Time

The Interval Time field shows the time between treatment shots when Repeat mode is selected. The units are shown in milliseconds (ms) for values from 30 to 900, and in seconds for values greater than 900. Settings greater than 1 second causes the system to enter Single Shot mode.

Port 1 and 2 Status Indicator

Port status is displayed in these fields with one of the following entries:

- N/C - No fiber connected
- Endo- Endoprobe connected
- Slit - Slit lamp fiber connected
- LIO - LIO fiber attached
- ? - Fiber connected but not identified
- Ø - Port is disabled

Shots/Energy

This field displays the number of shots fired since the unit was powered up or since the user re-set the shot count. Through the Treatment Totals Options menu, the user can set the system to display the energy (in Joules (J)) since the unit was powered up or since the user re-set the value.

READY SCREEN

The Ready screen shown in Figure 2-9 indicates that the system is ready to fire. It is displayed when the user presses the Standby/Ready mode button while the system is in Standby. The screen is essentially the same as the Standby screen except that the background is green and the Main Menu button is inactive. Actions permited in this screen include: adjusting the displayed parameters, resetting the shot count, and connecting fibers to the ports.

Figure 2-9
Ready Screen

LASER ON SCREEN

The Laser On screen shown in Figure 2-10 indicates that footpedal has been depressed and the system is firing the laser. In this screen the displayed parameters can be adjusted. Releasing the footpedal sends the system back to the Ready screen.

Figure 2-10
Laser On Screen

MAIN MENU

The Main Menu is displayed by selecting "Main Menu" from either the Initialization screen or the Standby screen. The selection is made by rotating the Menu Knob until "Main Menu" is highlighted, then pressing the knob to activate the selection. The Main Menu, shown in Figure 2-11, allows the user to access screens that change system settings and view system information. Each selection is defined as follows:

- Settings - System settings that can be adjusted by the user.
- System Information - Read-only system values provided for the user's information.
- Reset to Factory Defaults - Allows the user to quickly reset the system to its default settings.

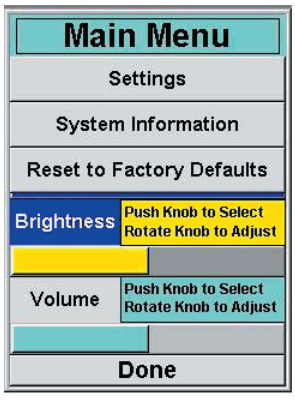


Figure 2-11
Main Menu

- Brightness - This selection allows the user to control the brightness of the LCD display and the front panel control illumination.
- Volume - Controls the volume of system tones and voice confirmation phrases. **NOTE: The volume of tones associated with errors and warnings is adjustable through the Volume Level settings only to the levels specified in Federal regulations.**

SETTINGS

Selecting "Settings" from the Main Menu displays the system settings selections as shown in Figure 2-12. Each setting may be changed according to the requirements of the user.

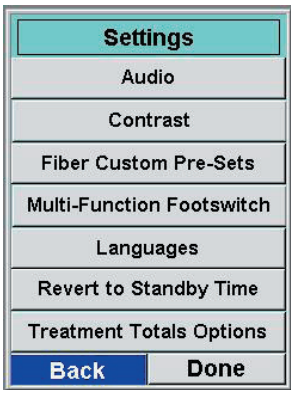


Figure 2-12
Settings Menu

Audio Settings

This menu allows the user to set the audio activity profiles for Voice Confirmations and System Tones. Figure 2-13 shows the available selections for each profile.

NOTE: Voice confirmation is only available when Alcon RFID probes are used.

Figure 2-13
Audio Settings

Voice Confirmations:

- No Voice - Turns off all voice confirmations completely.
- Minimum - Allows the system to emit a minimum number of voice confirmation phrases.
- Normal - Allows the system to emit a moderate number of voice confirmation phrases.
- Maximum - Allows the system to emit all available voice confirmation phrases.

System Tones:

- Minimum - Allows the system to emit only the mandatory system tones.
- Normal - Causes the system to emit all available system tones.

Contrast

The Contrast menu allows the user to change the contrast setting of the displays. When selected, the screen shown in Figure 2-14 is displayed and rotating the Menu knob adjusts the screen contrast. After the display has been adjusted to the desired contrast, pressing the Menu button returns the display back to the Settings screen.

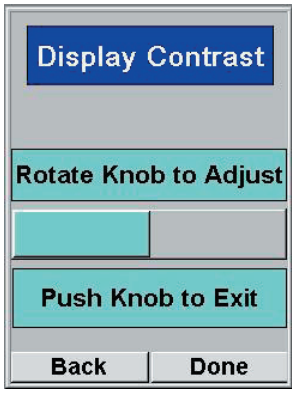


Figure 2-14
Contrast Settings

Fiber Custom Settings

The Fiber Custom Settings menu allows the user to set and save the Power, Pulse Duration, and Inter-Pulse Time parameters as pre-sets for the three instruments used with the system. To select an instrument, rotate the Menu Knob until the desired instrument is highlighted, then push the knob. The selected instrument's Pre-Set screen appears as shown in Figure 2-15 where LIO was selected.

To pre-set an instrument parameter value, rotate the Power, Pulse Duration, and Inter-Pulse Time Knobs to the desired values for the selected instrument. After the settings have been changed, the user can select "Save" to save the changes and go to the operating display or "Cancel" to revert back to the last saved pre-set.

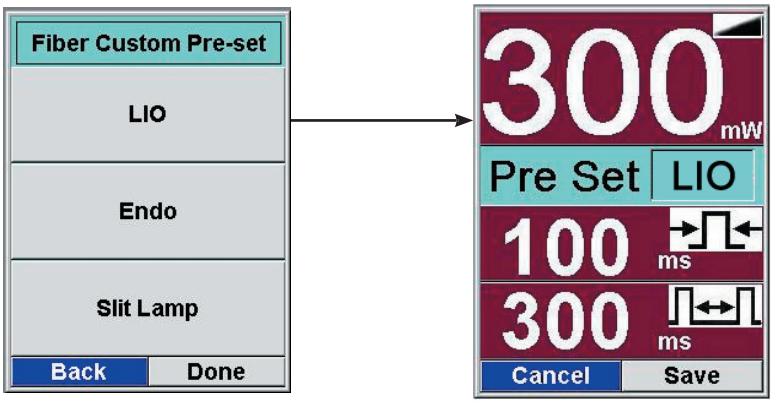


Figure 2-15 Fiber Custom Pre-Sets Screen

Footswitch Settings

Selecting the Footswitch Settings menu item from the Settings menu displays the Settings - Footswitch menu as shown in Figure 2-16. This menu provides three settings that allow the user to select the functionality of the side switches.

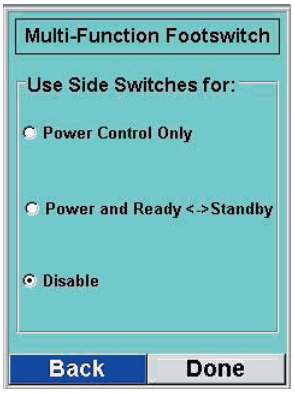


Figure 2-16
Footswitch Settings

NOTE: If the footswitch is not a multi-function footswitch, the only functional setting is "Disable."

Power Control Only
This selection allows the side switches to increment (left switch) or decrement (right switch) the treatment laser power.

Power And Ready <-> Standby
When this selection is enabled, the user can transition from Standby to Ready by pressing and holding the right side switch longer than 1.5 seconds until a tone sounds. Similarly, pressing and holding the left side switch longer than 1.5 seconds (until a tone sounds) will transition the system from Ready back to Standby.

Pressing the side switches for intervals shorter than 1.5 seconds will increase or decrease treatment laser power.

Disable
This setting disables the side switches entirely so the footswitch can only be used for firing the laser. When this setting is selected, power control and switching from Standby to Ready mode can only be done from the front panel of the system.

Selecting Back returns the system to the Settings Menu, while selecting Done returns the system to the operation display.

Languages

Selecting the Languages Setting displays the languages available to the user for displaying the information on the screen. To select a language, rotate the Menu knob until the desired language is chosen, then press the Menu knob to select the highlighted item. Select Back to return to the Settings Menu or Done to return to the operating display. The text displayed on the LCD will reflect the new language setting.

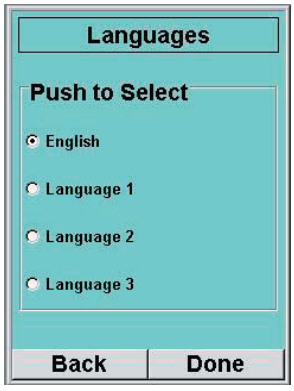


Figure 2-17
Language Settings

Revert To Standby

Selecting the Revert to Standby Time menu item in the Settings Menu displays the Revert to Standby menu as shown in Figure 2-18. This setting determines the time period of inactivity, in minutes, after which the system will revert to the Standby mode of operation. Inactivity is defined as no footswitch activation during the time period. The setting can be adjusted to two, five or ten minutes.

To change the setting, rotate the Menu knob until the desired number of minutes is highlighted, then push the Menu knob to select the value. Selecting Back returns the system to the Settings Menu, while selecting Done returns the system to the operation display.

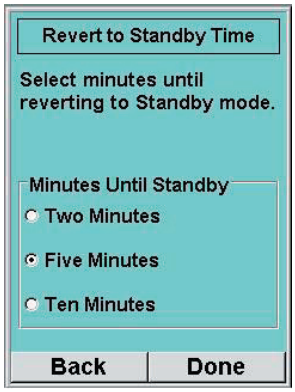


Figure 2-18 Revert to Standby Settings

Treatment Totals Options

Selecting the Treatment Totals Options menu item in the Settings menu displays the Treatment Totals Display menu as shown in Figure 2-19.

The selection in this menu determines whether the Shot Count or the Total Energy Delivered value is displayed in the status section of the operating display. These values pertain to Treatment Totals only, as defined by either total shots or treatment energy delivered from the time the System was powered up, or since the user has re-set the count for this field, whichever is later.

Figure 2-19 Treatment Totals Settings

To make a selection in the Treatment Totals Display menu, rotate the Menu knob until the desired menu item is highlighted, then select the setting by pushing the Menu knob. Selecting Back returns the system to the Settings Menu, while selecting Done returns the system to the operation display.

SYSTEM INFORMATION

The System Information screen, shown Figure 2-20, is displayed by selecting System Information from the Main Menu. System Information includes read-only displays of patents, various system constants, message histories, and treatment totals.

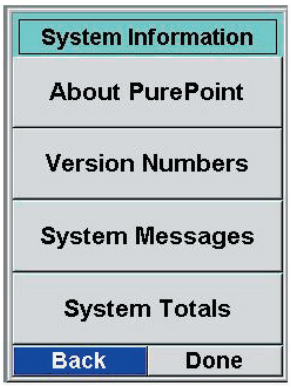


Figure 2-20 System Information Menu

About *PurePoint™*

Selecting the About *PurePoint™* item in the System Information menu displays information about the *PurePoint™* system such as the patent numbers that apply to it as shown in Figure 2-21.

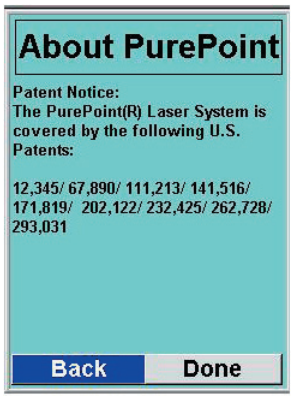


Figure 2-21 About *Purepoint™* Screen

Version Numbers

Selecting Version Numbers from the System Information menu displays the Version Numbers display as shown in Figure 2-22.

The Version Numbers display is a list of system-related version numbers that includes the currently installed versions of system software, firmware, laser engine, and language translation package. This is a read only screen where the only available functions are the Back and Done buttons at the bottom of the display.

Figure 2-22 Version Numbers Information

System Messages

The System Messages display shown in Figure 2-23 contains a scrolling list of system messages that have been logged since the system delivered from the factory or was last factory serviced and a new laser engine installed. System Messages are defined as error, warning, or informational messages that have been displayed to the user. The latest message is displayed at the top of the list and the remaining are listed in descending order.

Figure 2-23
System Messages

System Totals

The System Totals display consists of two information items, Session Totals and Cumulative Totals as shown in Figure 2-24.

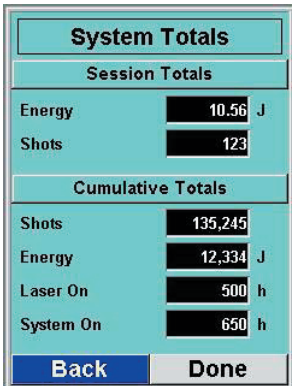


Figure 2-24
System Totals

Session Totals

Session Totals is the number of shots and the amount of Total Energy delivered since the system was powered up.

Cumulative Totals

The Cumulative Totals displays the cumulative totals of the listed treatment values. "Laser On" is the total time that the laser engine has been powered up. This is equivalent to the cumulative time the system has been in Ready mode. "System On" is the total time the laser system has been powered up since it was manufactured.

RESET TO FACTORY DEFAULTS

Selecting Reset to Factory Defaults from the Main Menu displays the screen shown Figure 2-25. This screen allows the user to re-set the system to the factory default settings. Since this action changes many of the settings, the user is prompted with an “Are you sure?” message before the default settings take effect.

Selecting “Yes” will reset all factory settings to the original settings and return the user to the Main Menu. “Cancel” will cancel the operation and return to the Main Menu with the settings unchanged.

Figure 2-25
Reset to Factory Defaults Display

BRIGHTNESS LEVEL

Selecting the Brightness menu item in the Main Menu allows the user to adjust the brightness levels of the LCD display along with the front panel indicator lights. When Brightness Level is selected, rotate the Menu knob until the desired brightness level is achieved. The Indicator Bar provides a visual gauge for the brightness level. When finished, push the Menu knob to save the Brightness Level changes.

VOLUME LEVEL:

Selecting Volume Level from the main menu allows the user to adjust the volume of the system tones and voice confirmations. The system provides a sample sound or voice when a setting is changed. When Volume level is selected, rotate the Menu knob until the desired volume level is achieved. The Indicator Bar provides a visual gauge for the volume level. When finished, push the Menu knob to save the volume level.

NOTES: The mandatory warning sounds cannot be adjusted above or below the levels allowed by regulatory limits.

Voice confirmation is only available when Alcon RFID probes are used.

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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.

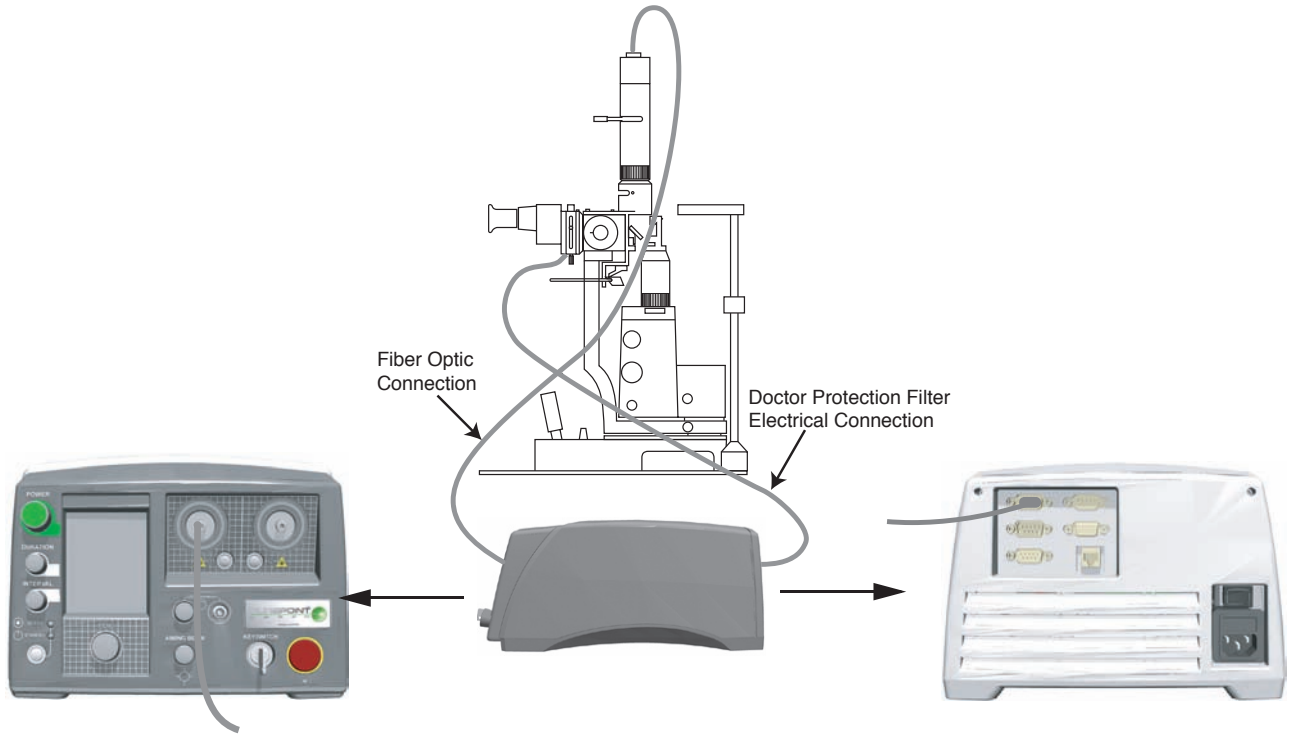

Figure 3-1 Slit Lamp Connections

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 ."

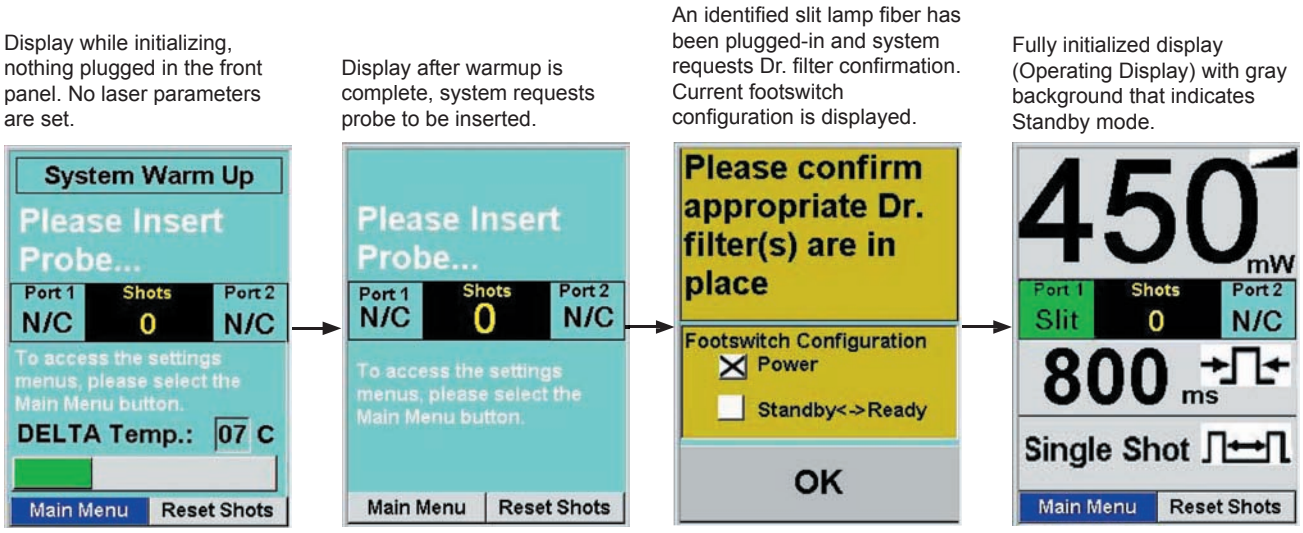

Figure 3-2 Display During Initialization

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.

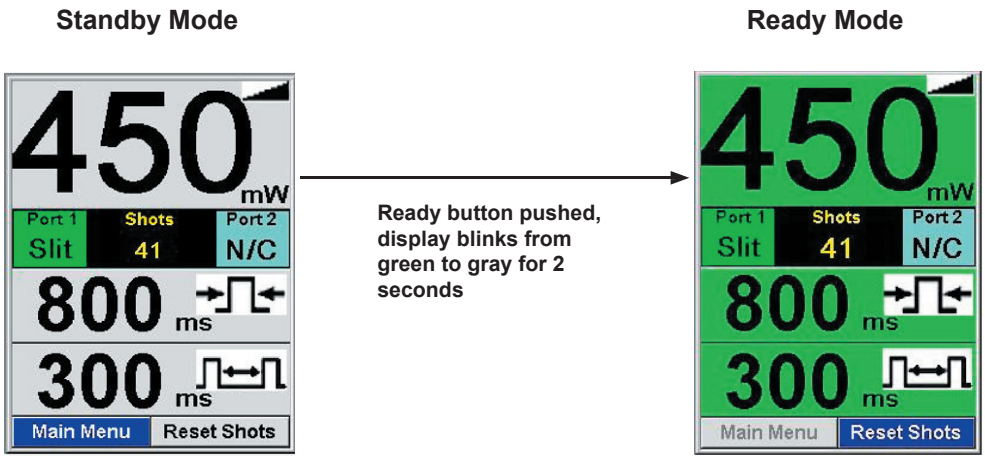

Figure 3-3 Transition from Standby to Ready Mode

> ***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.

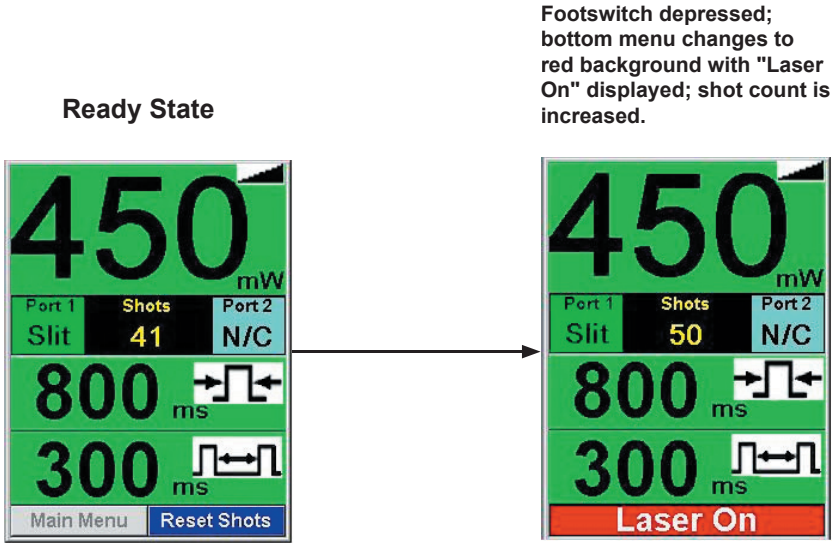

Figure 3-4 Transition from Ready State to Laser On

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.

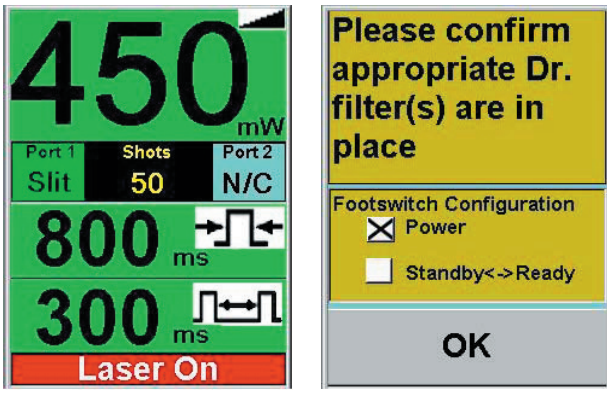

Figure 3-5 Transition from Laser On to Standby because of a Warning

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.

6.1 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.

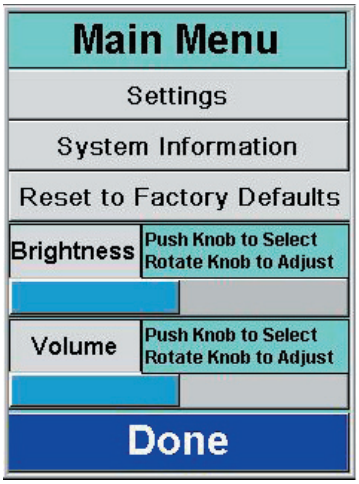

Figure 3-6 Main Menu

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.

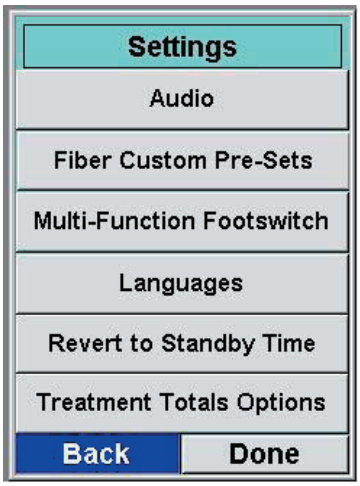

Figure 3-7 Settings Menu

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).

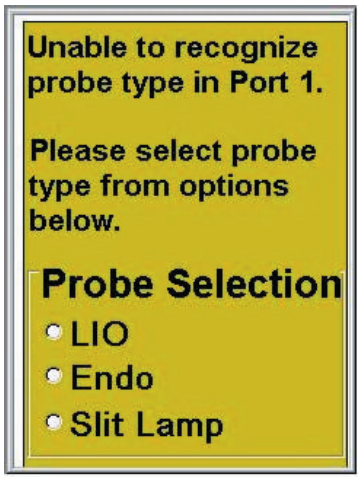

Figure 3-8 Unidentifiable Probe Display

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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SECTION FOUR
CARE AND MAINTENANCE

INTRODUCTION

This section of the manual is designed to inform the operator of basic care and maintenance of the instrument. It is recommended to verify the calibration annually. In the event that recalibration is required, it is also recommended that the procedure to recalibrate the system be performed by Alcon Technical Services personnel. If a problem occurs on the instrument, call the Alcon Technical Services department and give details of the circumstances and effects. From these elements, a specialized technician will evaluate the problem and determine the maintenance requirements.

WARNINGS!

Maintenance on any part of the laser system must be performed with the laser off and the main power plug disconnected.

When keyswitch power is on, all individuals in the laser room must wear laser protective eyewear, OD 4 or above at 532 nm.

CAUTION

There are no operator replaceable parts other than the fuse. Contact Alcon Technical Services for all servicing issues.

Care and Cleaning

WARNING!

A qualified technician must perform a visual inspection of the following components every twelve months:

- **Warning labels (see Section One)**
- **Power Cord**
- **Fuses**

In case of a deficiency, do not use the system; call Alcon Technical Services.

A qualified technician must check ground continuity and both polarities for leakage current every twelve months to ensure they are within the applicable standards (for example: EN60601-1/IEC601-1). Values must be recorded. If they are above the applicable standards, or 50% above initial measurement, do not use the system; call Alcon Technical Services.

The following tips are recommended for proper care of the *PurePoint™* Laser system:

- Turn off the system correctly after each use with the rear panel switch.
- Cover the slit lamp with the plastic cover.
- Cover the fiber optic connector with the dust cover.
- Cover the fiber port with the dust cover.
- Clean the exterior portion of the equipment with a dry, lint-free cloth or tissue. No other products can be used.
- Use care not to damage or scratch the laser apertures or fiber optic connector.
- Place the system into its traveling case when moving to another location.

- Inspect fibers to ensure that they have not been compromised, i.e., chips, cracks, or loose connectors.

The condition of the following system hardware components must be checked periodically to identify any fault that may affect system operation:

- Chassis appearance.
- Operation of controls and indicators.
- State of the fibers and connecting cables.

Damaged hardware must be replaced to ensure safe operation. Call Alcon Technical Services for assistance.

Mirror and Lens Cleaning

The mirrors and lenses of the LIO headpiece and Slit Lamp adaptation must be kept clean and unscratched. Cleaning them requires special care and the following materials:

- Standard lens cleaning paper
- Methanol of spectrographic quality.

The following tips will aid you in cleaning the optics:

- Use each piece of cleaning paper only once.
- Move the cleaning paper across the optic surface from one end to the other in one continuous motion. Discard the cleaning paper and use a new piece for the next cleaning pass.
- Do not use a back and forth rubbing motion on the optic surface.

CAUTION

Care and cleaning operations must be performed with the instrument turned off and power cord disconnected. Use only optical quality paper and spectroscopic quality methanol when cleaning the mirrors and lenses, otherwise the optics could be scratched and their coatings destroyed.

FUSE REPLACEMENT PROCEDURE

NOTE: Use only the recommended fuses for the *PurePoint*™ Laser as listed on the fuse label.

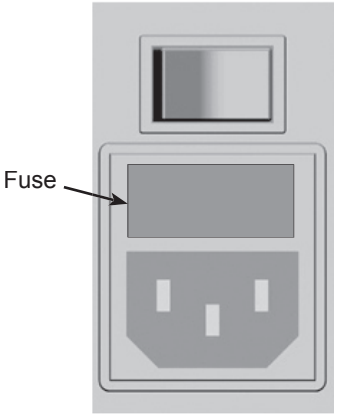
1 Turn system power off and disconnect power cord from the PurePoint™ Laser before changing fuses.

2 Remove the fuse clip from the fuse holder using a small screwdriver.

3 Inspect fuses in holder for damage or a burnt connection.

4 Place new fuses in each side of holder in fuse clip (replace with fuses rated T5A/250V or contact your local Alcon representative).

5 Replace fuse clip into the fuse holder. Close fuse holder.



CALIBRATION VERIFICATION

Calibration verification must be performed at least every twelve months to verify that the laser output is within tolerance and calibration is not required. It is recommended to call Alcon Technical Services before conducting the calibration verification procedure.

CAUTION

Serious damage to the instrument may occur if these procedures are not performed by qualified personnel.

SPECIAL TOOLS

- Computer, with browser software; MS Internet Explorer or equivalent
- Custom service ethernet cable (Alcon p/n 023-100)
- Power Meter, Thermopile type (Coherent FieldMaster w/ LM-10 head or equivalent)
- Laser Safety Goggles (OD4 or above, at 532 nm wavelength)
- Optics cleaning kit, including spectroscopic grade methanol, lens paper and air blower
- Light Meter (Labsphere HLMS 200P or equivalent) - A power meter may be used instead, using the following conversion factors:
  - Ophir Nova with PD300-SH head
    (use conversion factor 2.5mW=1 Lumen; divide meter reading by 2.5)
  - Newport 840-C with 818SL
    (use conversion factor 1.9mW=1 Lumen; divide meter reading by 1.9)
  - Coherent Field Master w/LM-10 head
    (use conversion factor 2.9mW=1 Lumen; divide meter reading by 2.9)

WARNING!

Laser light emitted from the fiber and laser head is powerful enough to cause serious eye or skin damage. Maintenance should be performed only by properly trained personnel, following established guidelines for laser safety. The use of protective eye wear is mandatory.

1 Exposure Time Verification

1.1 Setup the system as shown in Figure 4-1. (Where slit lamp is not used, connect a test fiber or endoprobe and direct the distal output into the photo cell.)

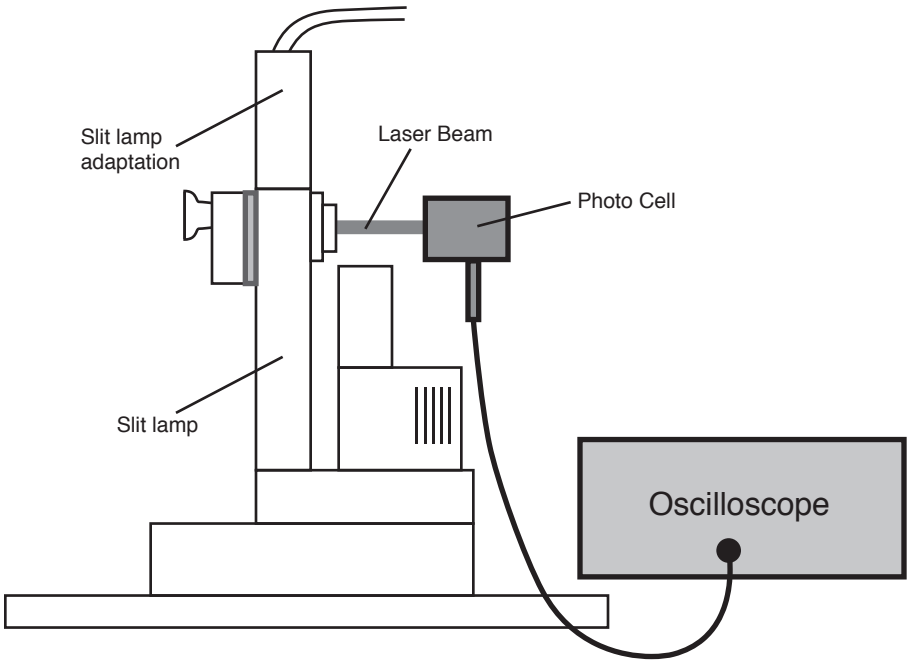


Figure 4-1 Exposure Time Test Configuration (shown for slit lamp)

1.2 Set spot size to 250 microns on the zoom. Adjust the distance between the slit lamp and photo cell to obtain a beam size of 2mm or more on the photo cell. Use aiming beam to determine spot size on the photo cell.

1.3 Set the exposure time to 0.1s and treatment beam power to minimum then select READY mode.

1.4 Fire the laser and record the exposure time as determined from the oscilloscope.

1.5 Repeat steps 1.3 and 1.4 for each time value listed in Table 4-1.

2 Slit Lamp Power Verification

2.1 Setup the system as shown in Figure 4-2.

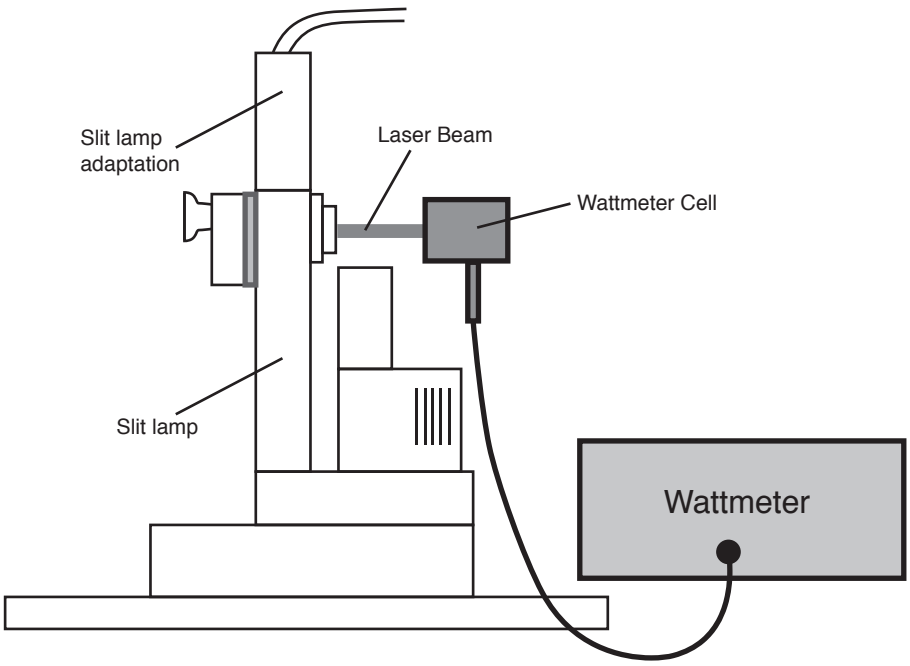


Figure 4-2 Power Test Configuration (shown for Slit Lamp)

2.2 Set the exposure time to CW.

2.3 Set spot size to 250 microns on the zoom. Adjust the distance between the slit lamp and wattmeter cell to obtain a beam size of 2mm or more on the wattmeter cell. Use aiming beam to determine spot size on the wattmeter cell.

2.4 Set the treatment power to 0.10 W then press the Standby/Ready key.

2.5 Fire the laser and record the wattmeter power reading into Table 4-1.

2.6 Repeat steps 2.4 and 2.5 for each value listed in the Slit Lamp section of Table 4-1.

3 Endoprobe Power Verification

3.1 Setup the system in a similar configuration as shown in Figure 4-2, to direct the endoprobe distal output beam into the wattmeter cell.

3.2 Set the exposure time to CW.

3.3 Set the treatment power to 0.10 W then press the Standby/Ready key.

3.4 Fire the laser and record the power reading as determined from the Wattmeter.

3.5 Repeat steps 3.3 and 3.4 for each value listed in the Endoprobe section of Table 4-1.

4 LIO Power Verification

4.1 Setup the system in a similar configuration as shown in Figure 4-2, to direct the LIO distal output beam into the wattmeter cell.

4.2 Set the exposure time to CW.

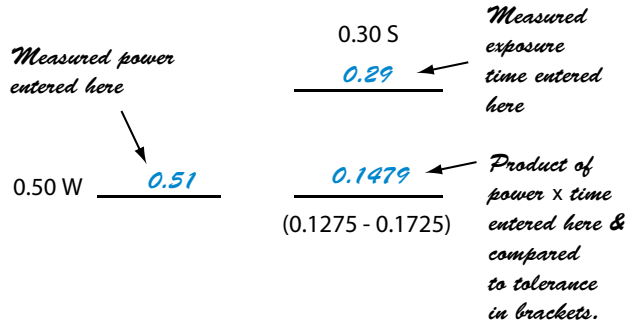
4.3 Set the treatment power to 0.10 W then press the Standby/Ready key.

4.4 Fire the laser and record the power reading as determined from the Wattmeter.

4.5 Repeat steps 4.3 and 4.4 for each value listed in the LIO section of Table 4-1.

5 Energy Matrix Completion

5.1 Complete the matrix by multiplying actual power by actual exposure time and recording the result, as shown in the example below.



5.2 Ensure that all calculated results are within the values listed in each matrix cell. The listed values are ±15% of the set energy.

- If all calculated energy values are within the specified limits, the system calibration is OK.
- If any of the calculated energy results are not within the specified limits, the Terminal Efficiencies will need to be adjusted. Perform the Setting the Terminal Efficiencies procedure following Table 4-1 or call Alcon Technical Services.

	Power v	Exposure Time >	0.10 S	0.30 S	0.50 S
SLIT LAMP	0.10 W		(0.0085 - 0.0115)	(0.0255 - 0.0345)	(0.0425 - 0.0575)
	0.50 W		(0.0425 - 0.0575)	(0.1275 - 0.1725)	(0.2125 - 0.2875)
	1.00 W		(0.0850 - 0.1150)	(0.255 - 0.3450)	(0.4250 - 0.5750)
ENDOPROBE	0.10 W		(0.0085 - 0.0115)	(0.0255 - 0.0345)	(0.0425 - 0.0575)
	0.30 W		(0.0255 - 0.0345)	(0.0765 - 0.1035)	(0.1275 - 0.1725)
	0.70 W		(0.0595 - 0.0805)	(0.1785 - 0.2415)	(0.2975 - 0.4025)
INDIRECT O-SCOPE	0.10 W		(0.0085 - 0.0115)	(0.0255 - 0.0345)	(0.0425 - 0.0575)
	0.30 W		(0.0255 - 0.0345)	(0.0765 - 0.1035)	(0.1275 - 0.1725)
	0.70 W		(0.0595 - 0.0805)	(0.1785 - 0.2415)	(0.2975 - 0.4025)

Table 4-1 Energy Matrix

6 Setting the Terminal Efficiencies

If unable to sucessfully complete the Energy Matrix table, use the following procedure to adjust the Terminal Efficiencies, and retest.

6.1 With the unit off, connect the service ethernet cable between the console and service computer. and turn unit ON. Turn the computer ON and start the browser program.

6.2 Type the IP address into the address box: 161.61.112.69, and hit return. When the page loads, enter the password: ngl1

6.3 For slit lamp, endoprobe, and/or LIO, use a power test configuration similar to as shown in Figure 4-1, to direct the distal output beam into the wattmeter cell.

6.5 Set power to 0.50 watts on the console, exposure time to CW, and select READY mode.

6.6 Fire the laser and record the power reading as determined from the wattmeter.

6.7 Calculate the new Terminal Efficiency cooefficient using the following formula:

$$\text{new coefficient} = \frac{\text{(old coefficient) X (measured power in Step 6.6)}}{0.5}$$

6.8 Enter the new value in the Terminal Efficiency window for the respective device, and click the SAVE button.

6.9 Repeat as needed to bring all values within compliance to complete the Energy Matrix Table 4-1, for each delivery device. If unable to sucessfully complete the matrix, the unit will need a System Calibration, as outlined in the following procedure.

SYSTEM CALIBRATION

WARNING!

Laser light emitted from the fiber and laser head is powerful enough to cause serious eye or skin damage. Maintenance should be performed only by properly trained personnel, following established guidelines for laser safety. The use of protective eye wear is mandatory.

1 With the unit off, connect the service ethernet cable between the console and service computer. and turn unit ON. Turn the computer ON and start the browser program.

2 Type the IP address into the address box: 161.61.112.69, and hit return. When the page loads, enter the password: ngl1

3 Enter and save the following values:

3.1 10 ºC for Minimum Diode Temperature value.

3.2 50 ºC for Maximum Diode Temperature value.

3.3 5 ºC for Minimum LBO Temperature value.

3.4 60 ºC for Maximum LBO Temperature value.

4 Enter and save the following values as denoted on the laser engine:

4.1 Diode Temperature

4.2. LBO Temperature

4.3 Maximum Current

5 Wait at least 2 minutes for the engine to come to proper working temperature for the calibration. Select Port 1 on the console.

6 On the computer, set Simmer Value to 11 amps. Be aware the laser engine is now lasing and producing visible output.

7 LBO Temperature Optimization -

1.7.1 On the computer, vary the LBO Temperature Setpoint to maximize the Pmon1 reading. Use the browser refresh button after each change, and allow 5 seconds for adjustment before reading the new Pmon value. Begin with the default value noted in Step 1.4.2, and sequentially change in +/- 1, 0.5, and 0.25 -degree steps, to fine-tune the setpoint for maximum Pmon reading.

8 On the computer, set the Simmer Value to 5 amps.

9 Select Output Calibration on the computer

10 Pmon 1 Low-Power Calibration -

10.1 Select Port 1 on the console.

10.2 Press “Start Pmon Calibration” on computer.

10.3 Set laser in CONTINUOUS mode on the console.

10.4 Set POWER to 100mw on the console.

10.5 Select READY mode on the console.

10.6 Fire the laser and measure output power directly from Port 1.

10.7 Press “Start Calibration” on the computer

10.8 Input 100mW into the Low Power Display field.

10.9 Input the power, as previously measured, into the Actual Power Field, and press Save

10.10 Return to STANDBY mode on the console.

10.11 Repeat the Pmon 1 Low-Power Calibration as needed (2 or 3 times) to bring Displayed/Actual tracking as close as possible.

11 Pmon 1 High-Power Calibration

11.1 Press “Start Pmon Calibration” on computer

11.2 Set laser in CONTINUOUS mode on the console.

11.3 Set POWER to 1 Watt on the console.

11.4 Select READY mode on the console.

11.5 Fire the laser and measure the actual output power directly from Port 1.

11.6 Press “Start Calibration” on the computer

11.7 Input 1 Watt into the Low Power Display field.

11.8 Input the power, as previously measured, into the Actual Power Field, and press Save

11.9 Return to STANDBY mode on the console.

11.10 Repeat the Pmon 1 High-Power Calibration as needed (2 or 3 times) to bring Displayed/Actual tracking as close as possible.

12 Repeat steps 1.10 and 1.11 for Low/High Power Calibration for Pmon 2.

13 Repeat the Delivered Power Calibration, adjusting the Terminal Efficiencies as required, so to sucessfully complete the Energy Matrix for each delivery device.

AIMING BEAM / LIO ILLUMINATION CALIBRATION

1 With the unit off, connect the service ethernet cable between the console and service computer. and turn unit ON. Turn the computer ON and start the browser program.

2 Type the IP address into the address box: 161.61.112.69, and hit return. When the page loads, enter the password: ngl1

3 Aiming Beam Calibration -

3.1 Adjust aiming beam power output for Port 1 to 0.9 - 0.99mW.

3.2 Click “Set Max Value” on the computer.

3.3 Repeat for Port 2.

4. LIO Illumination Calibration -

4.1 Adjust light output to 90 foot-candle.

4.2 Click “Set Max Value”

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SECTION FIVE
TROUBLESHOOTING

SYSTEM MESSAGES

System messages advise the user of a system condition that requires an action and/or a response in order to proceed with the current procedure.

Advisory Messages

Advisory messages (see Table 5-1) are informational messages that help guide the user or bring attention to the laser's condition.

- Advisory messages appear on the same blue-gray background that many labels and prompts appear on.
- Advisory messages can appear when the device is in Standby or Ready mode. They do not appear when the device is in Firing mode.
- Advisory messages will cause the system to switch from Ready to Standby mode.

Warning Messages

Warning messages (see Table 5-2) are precautionary messages displayed on a yellow background to inform the user of a possible safety or procedural problem that may occur in any mode. The following events take place:

- The laser is placed into Standby mode.
- The user is presented with one of two types of display, an Acknowledgement screen or an Operating screen, each of which asks for an action before the user continues with the procedure:

The Acknowledgement Screen presents the user with information that describes the problem. The user must select a response, using the Menu knob, stating that they have seen and acknowledged the message. This acknowledgement is recorded in the laser's system log. The display returns to the regular operating display in Standby mode. Attempting to go to Ready Mode without taking requested action results in the system continuing to display the Acknowledgement Screen.

The Operating display allows the user to perform operational tasks such as adjusting the laser parameters while a warning prompt appears at the top of the screen asking the user to perform an action. After the requested action is performed, the warning prompt is removed and the display returns to the regular operating display in Standby mode. If the user tries to go to Ready mode without performing the requested action, the prompt starts blinking in order to get the attention of the user. The laser will remain in Standby mode until the action is performed.

Error Messages

Errors are major faults in the system that cannot be resolved by either software, hardware, or user action. The following events take place:

- The laser is placed in a safe state (laser engine is turned off and shutter is closed).
- The user is told by an error message and voice confirmation that a fault has taken place.
- The front panel controls are not functional other than the emergency shut-off switch and the On/Off key. The footswitch controls are also not functional.

An error message is usually an indication that the system requires service in order to correct the problem. If restarting the system does not resolve the problem, contact your local Alcon representative to schedule a service call.

Figure 5-1 Error Message

Table 5-1. Advisory Messages		
Message Displayed	**Condition**	**Action**
“Unable to recognize probe type in Port XX. Please select probe type from options below.”	An unidentified fiber is connected to a laser port. The laser fiber may not include a RFID tag or the tag’s data may be corrupted.	User must select a probe type (slit lamp, LIO, or Endo) to clear the message.
“Please Insert Probe. Select the Main Menu button to view or alter settings.”	Unit completes boot-up and no probe has been inserted.	User must connect a fiber to a laser port or select the Main Menu button to clear the message.
“Maximum Power Available: 1.5W” *(any number under 2W will be displayed; in this case it is 1.5W)*	Power available from the laser drops below the maximum level (2 Watts).	User must acknowledge the screen prompt to clear the message.
“Requested Power Not Available”	The operator depresses the footswitch, but the laser is unable to deliver the power value requested.	User must acknowledge the screen prompt to clear the message. User should then reduce laser power.
“Service Engine Soon”	The laser has a significant drop in its maximum power or system detects other potential maintenance need.	User must acknowledge this prompt to clear the message. If the service has not been done, the message repeats with every boot-up.
"Footswitch side switches control power to laser."	Message is displayed at boot up to inform the user that the footswitch side switches are set to adjust power only.	User must acknowledge this prompt to clear the message.
"Footswitch side switches may be used to change from Standby to Ready and back."	Message is displayed at boot up to inform the user that the footswitch side switches have been set to switch between Standby and Ready.	User must acknowledge this prompt to clear the message.
"Footswitch side switches have been de-activated."	Message is displayed at boot up to inform the user that the footswitch side switches have been de-activated.	User must acknowledge this prompt to clear the message.

Table 5-2. Warning Messages		
Message Displayed	**Condition**	**Action**
"Footswitch Configuration 0 Power 0 Standby/Ready"	The first time after system initialization that a multi-function footswitch is connected and not in Disabled mode.	User must acknowledge the message to clear the screen and continue.
"Verify appropriate Dr. Filters are installed in all viewing devices." Acknowledgement Screen	The first time after system initialization that either a slit lamp or endo laser fiber is selected while at least one tethered doctor filter is connected.	User must acknowledge the message to clear the screen and continue.
Verify appropriate Dr. Filters are installed in all viewing devices." Acknowledgement Screen	Either a slit lamp or endo laser fiber is selected and no tethered doctor filter is connected.	User must acknowledge the message to clear the screen and continue.
"Please Engage Dr. Filter" Operating display	A tethered doctor filter is disengaged.	User must engage the doctor filter to clear the message.
"Please Connect Dr. Filter" Operating display	A tethered doctor filter is disconnected while the system is in Ready or Firing mode.	User must connect a tethered doctor filter to clear the message.
"Please Release Footswitch" Operating display	Operator initiates switching from Standby to Ready while the footswitch is depressed.	User must cease pressing footswitch to clear the message.
"Please Connect Footswitch" Operating display	The footswitch is disconnected in any mode.	Footswitch must be re-connected to clear the message.
"Please Close Remote Interlock" Operating display	The remote interlock circuit detects a door is opened or the remote interlock plug is disconnected from the back panel.	Door must be closed or plug re-connected to clear the message.
"Port 1 cannot be used. Please use Port 2." Acknowledgement Screen	A fault exists on one laser port, but the other port is still usable.	User must acknowledge the message and only use the functioning port.

SECTION SIX
ACCESSORIES AND PARTS

This section of the manual contains the various accessories that are available for use with the *PurePoint*™ Laser (see Table 6-1). If additional information is required for setup and use of the accessory, the Notes column of Table 6-1 provides references to that information.

TABLE 6-1. *PUREPOINT*™ LASER ACCESSORIES

Description	Catalog Number	Notes
Endo Ocular Laser Probe, Straight, 20 Gauge	8065678610	
Endo Ocular Laser Probe, Curved, 20 Gauge	8065010203	
Endo Ocular Laser Probe, Straight, 20 Gauge	8065010219	
Endo Ocular Laser Probe, Straight, 23 Gauge	8065750803	
Endo Ocular Laser Probe, Straight, 25 Gauge	8065750133	
Endo Ocular Laser Probe, Curved, 20 Gauge, W/RFID	8065750989	
Endo Ocular Laser Probe, Straight, 20 Gauge, W/RFID	8065750990	
Endo Ocular Laser Probe, Straight, 25 Gauge, W/RFID	8065750978	
Endo Ocular Laser Probe, Straight, 23 Gauge, W/RFID	8065750991	
Chang Aspirating Laser Probe, Curved, 20 Gauge	8065010703	
Chang Aspirating Laser Probe, Straight, 20 Gauge	8065010719	
Chang Aspirating Laser Probe, Soft Tip, 20 Gauge	8065010739	
Chang Aspirating Laser Probe, Curved, 20 Gauge, W/RFID	8065750979	
Chang Aspirating Laser Probe, Straight, 20 Gauge, W/RFID	8065750980	
Chang Aspirating Laser Probe, Soft Tip, 20 Gauge, W/RFID	8065750981	
Illuminated Endo Ocular Laser Probe, Curved, 20 Gauge	8065010403	
Illuminated Endo Ocular Laser Probe, Curved, 20 Gauge	8065010404	
Illuminated Endo Ocular Laser Probe, Straight, 20 Gauge	8065010419	
Illuminated Endo Ocular Laser Probe, Straight, 20 Gauge	8065010420	
Illuminated Endo Ocular Laser Probe, Curved, 20 Gauge, W/RFID	8065750982	
Illuminated Endo Ocular Laser Probe, Straight, 20 Gauge, W/RFID	8065750983	
Slit Lamp Front Actuating Doctor Protection Filter	8065750260	
Microscope Front Actuating Doctor Protection Filter	8065750448	
PurePoint™ Passive Dr. Filter	8065751051	
Slit Lamp: Alcon® SL 1000 (CSO Table) Adaptation Fiber Strain Relief	8065740982 8065741019 8065750256	See pages 6-2 & 6-5
Slit Lamp: Zeiss 30SL (Topcon Table) Adaptation Fiber Strain Relief	 8065-5010-01 8065750256	See pages 6-2 & 6-5
Slit Lamp: Haag-Streit 900 BM (Haag-Streit Table) Adaptation Fiber Strain Relief	 8065-5011-01 8065750256	See page 6-3
Laser Indirect Ophthalmoscope	8065751050	See page 6-10

SLIT LAMPS WITH DOCTOR PROTECTION FILTERS AND ADAPTATIONS

A slit lamp assembly is typically used to deliver the *PurePoint*™ laser treatment beam to the patient's eye. An adaptation, mounted on the slit lamp, is required to interface the slit lamp to the *PurePoint*™ laser.

The adaptation consists of a zoom assembly with micromanipulator and a Doctor Protection Filter. The Doctor Protection Filter provides eye protection for the physician. The parfocal zoom assembly is used to set the spot size of the aiming and treatment beams, and a micromanipulator is provided for fine adjustment of the beam position.

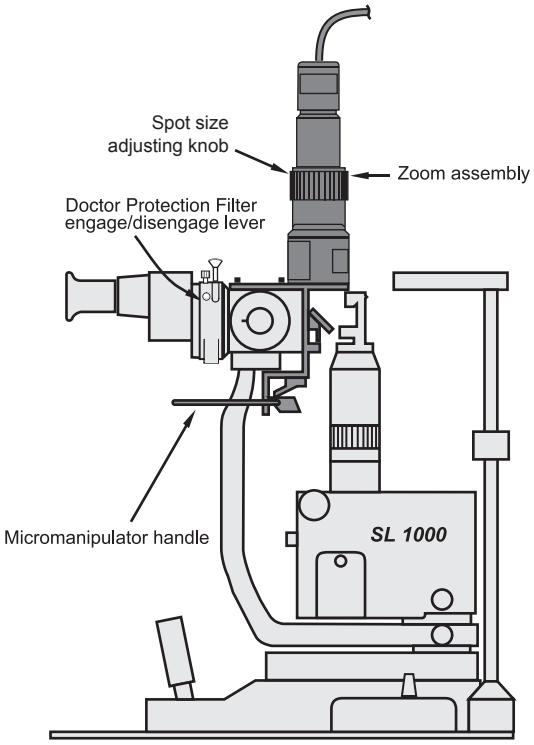


Figure 6-1 Alcon SL1000 Slit Lamp

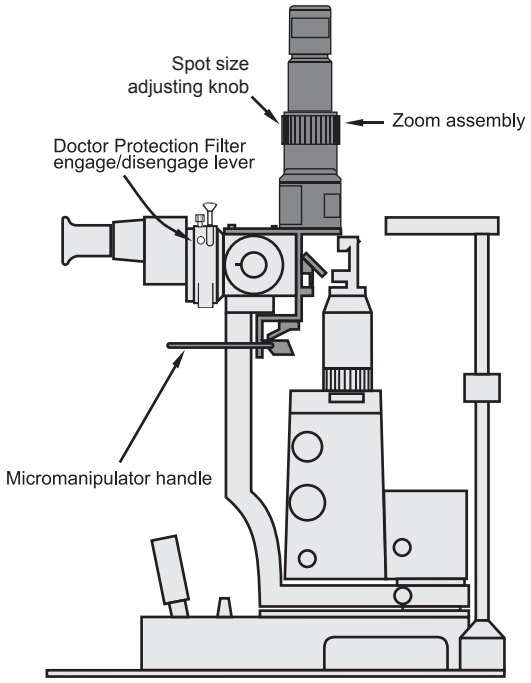


Figure 6-2 Zeiss 30SL

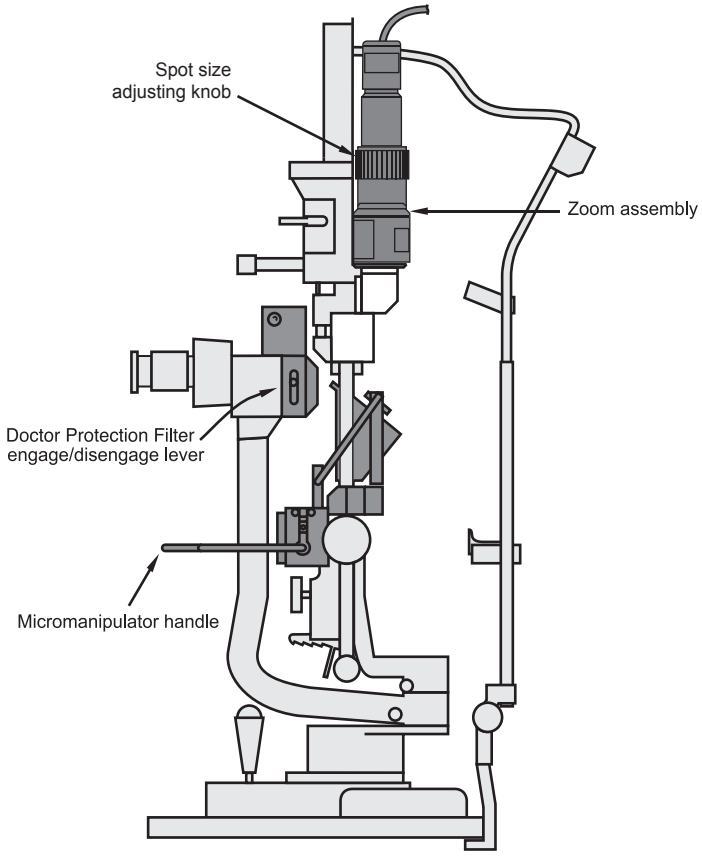


Figure 6-3 Haag-Streit 900 BM

POSITIONING THE DOCTOR PROTECTION FILTER

The Doctor Protection Filter is used to protect the surgeon from harmful laser radiation that could damage his eyes. The Doctor Protection Filter is inserted between the binoculars and the slit lamp or microscope.

WARNINGS!

It is the operator's responsibility to properly install the Doctor Protection Filter and verify operation. Using the instrument with a Doctor Protection Filter that is improperly installed could result in operator injury. Alcon shall not be held liable for problems caused by improper installation of the Doctor Protection Filter. Defeat of the Doctor Protection Filter interlock switches and/or incorrect installation of the Doctor Protection Filter to the microscope could result in ocular hazards to the surgeon.

Operator will have a colored view through the Doctor Protection Filter due to blocking of the 532nm wavelength (green).**

Operator must be careful to avoid potential secondary reflections; therefore, the room used to treat the patient should be approved by a qualified laser safety officer.

1. Loosen thumbscrew on slit lamp assembly (or microscope) and remove binoculars (see Figure below).

2. Place Doctor Protection Filter into position on the slit lamp assembly and secure with thumbscrew.

3. Place binoculars into position on the Doctor Protection Filter and secure with thumbscrew.

4. Connect electrical cable connector to the Doctor Protection Filter port on the *PurePoint*™ rear panel.

5. Perform the System Power Up instructions for the *PurePoint*™ Laser in Section Three of this manual. Move the Doctor Protection Filter lever to disengage the filter and verify proper function; the message "Engage Dr. Filter" should appear. **If the message does not appear, do not use the instrument; call Alcon Technical Services.**

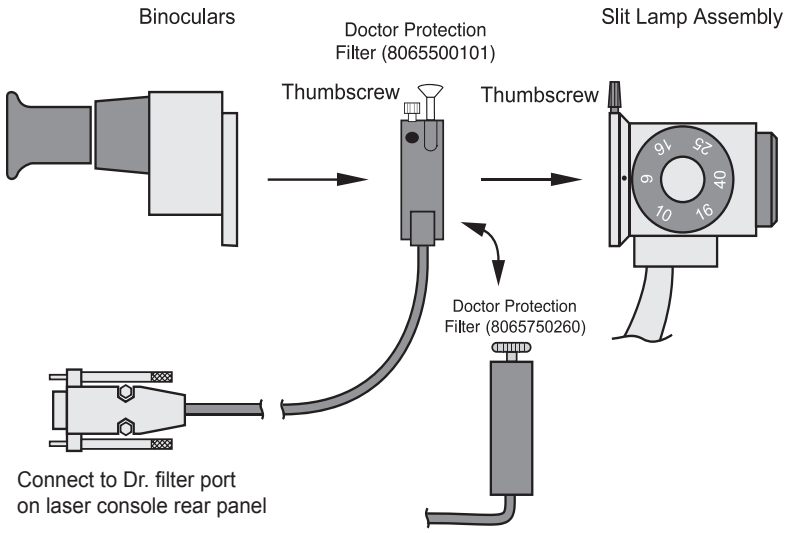


Figure 6-4
Doctor Protection Filter Mounted Between Binoculars and Slit Lamp Assembly

** Newer Doctor Protection Filters will have less tint than older ones.

ALCON SL 1000 AND *ZEISS* 30SL ADAPTATION

Introduction

The Doctor Protection Filter, fiber optic cable, mechanical micromanipulator with zoom, and beam splitter/accessories in combination with the Alcon SL 1000 Slit Lamp (or *Zeiss* 30SL) are designed exclusively for use with the *PurePoint*™ laser system. This instrument combination represents a complete ophthalmic unit. Please refer to the Alcon SL 1000 (or *Zeiss* 30SL) Operator's Manual for information not included in this manual.

The micromanipulator with zoom provides interface between the *PurePoint*™ laser system and the patient. The laser spot is focused and traversed in the X and Y direction by means of the slit lamp joystick. The micromanipulator control lever provides additional positioning of the laser spot. The micromanipulator with integral zoom is used to adjust the laser spot size.

The mandatory Doctor Protection Filter provides protection from the 532nm laser radiation for the attending physician. The safety circuit of the *PurePoint*™ laser is designed to insure the safety filters are engaged (moved into place) prior to the treatment laser being operational.

WARNINGS!

Ensure that the terminal selection on the *PurePoint*™ front panel is SLIT LAMP. Verify that the selection is correctly confirmed. It is the responsibility of the operator to connect and confirm the selected terminal.

Operator will have a colored view through the Doctor Protection Filter due to blocking of the 532nm (green) wavelength.**

To avoid potential secondary reflections, the room used to treat the patient must be approved by a qualified laser safety officer.

All personnel in the treatment room must wear protective eyewear (OD 4 or above at 532nm) when the system is in Standby or Ready modes.

Installation of the complete instrument system or retrofitting an existing SL 1000 slit lamp with a micromanipulator with zoom, a beam splitter/accessories, a fiber optic cable, and a Doctor Protection Filter should only be done by Alcon Service Personnel or persons authorized by Alcon.

A qualified technician must perform a visual inspection of the following components every twelve months: warning labels, power cords, fuses. In case of a deficiency, do not use the system; contact Alcon Technical Services.

Before each use, ensure the Doctor Protection Filter assembly, the micromanipulator with zoom, and the fiber optic cable are firmly attached to the slit lamp. The user must also check the Doctor Protection Filter elements for scratches, breaks, or alterations. If scratched, damaged, or loosely attached, discontinue use of device immediately and contact Alcon Technical Services.

When using beam splitter accessories, the binoculars 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.

** Newer Doctor Protection Filters will have less tint than older ones.

WARNINGS!

Verify that the label marking the laser exit aperture is in place. Refer to the figure below for the location of labels on the Alcon SL 1000.

Never treat a patient when the *PurePoint™* Laser is connected to a service computer.

Defeat of the Doctor Protection Filter switches and/or incorrect installation of the Doctor Protection Filter assembly could result in ocular hazards to the surgeon.

Please refer to the *PurePoint*™ Operating Instructions in section three for further warnings.

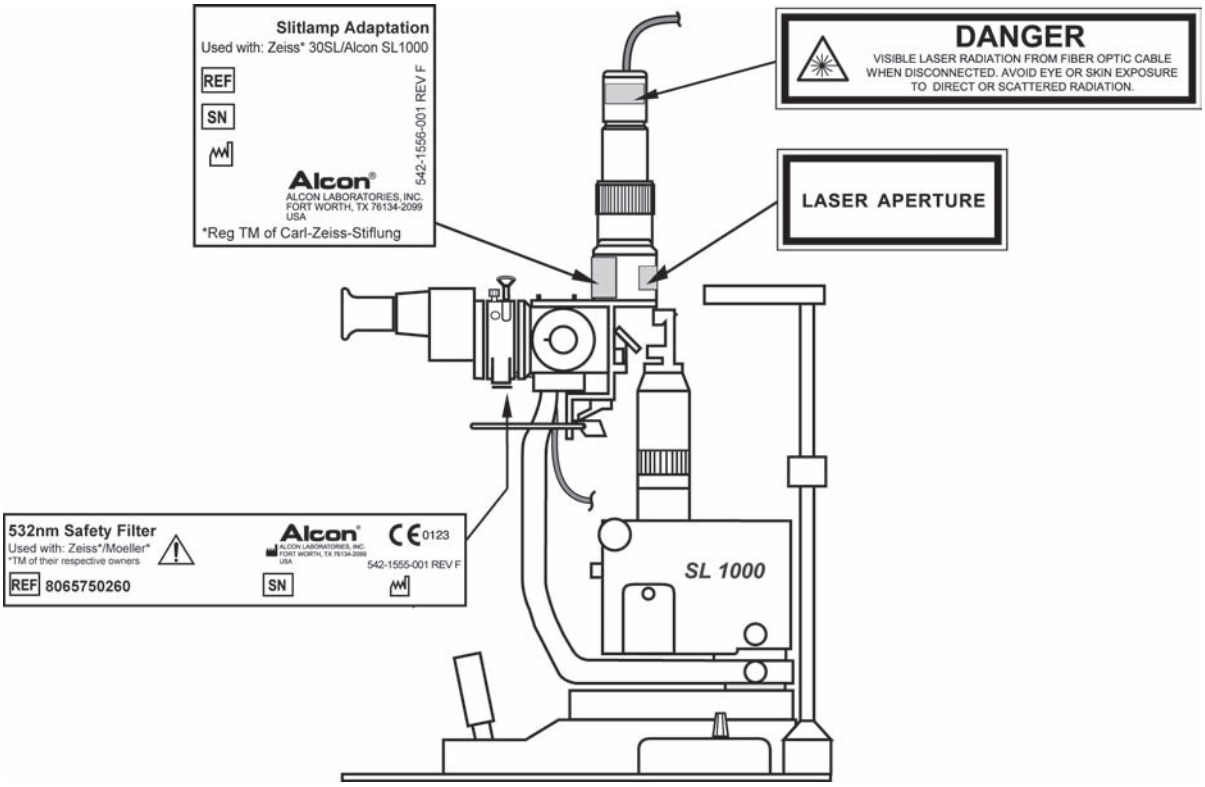


Figure 6-5
Label Location Diagram on Adaptation - Alcon SL 1000 shown

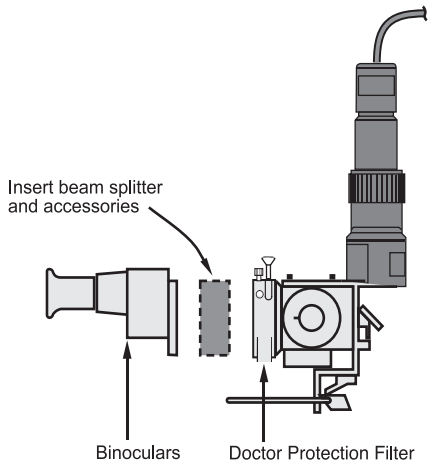


Figure 6-6
To avoid injury, the beam splitter/accessories must be placed between the binoculars and Doctor Protection Filter (Alcon SL 1000 shown)

Adaptation Controls

Laser Spot Size Indicator - Indicates diameter of laser spot in the microscope focal plane.

Laser Spot Size Adjustment Lever - Used to adjust the laser spot size.

Micromanipulator Control Lever - Used to position the laser spot around the microscope center field of view.

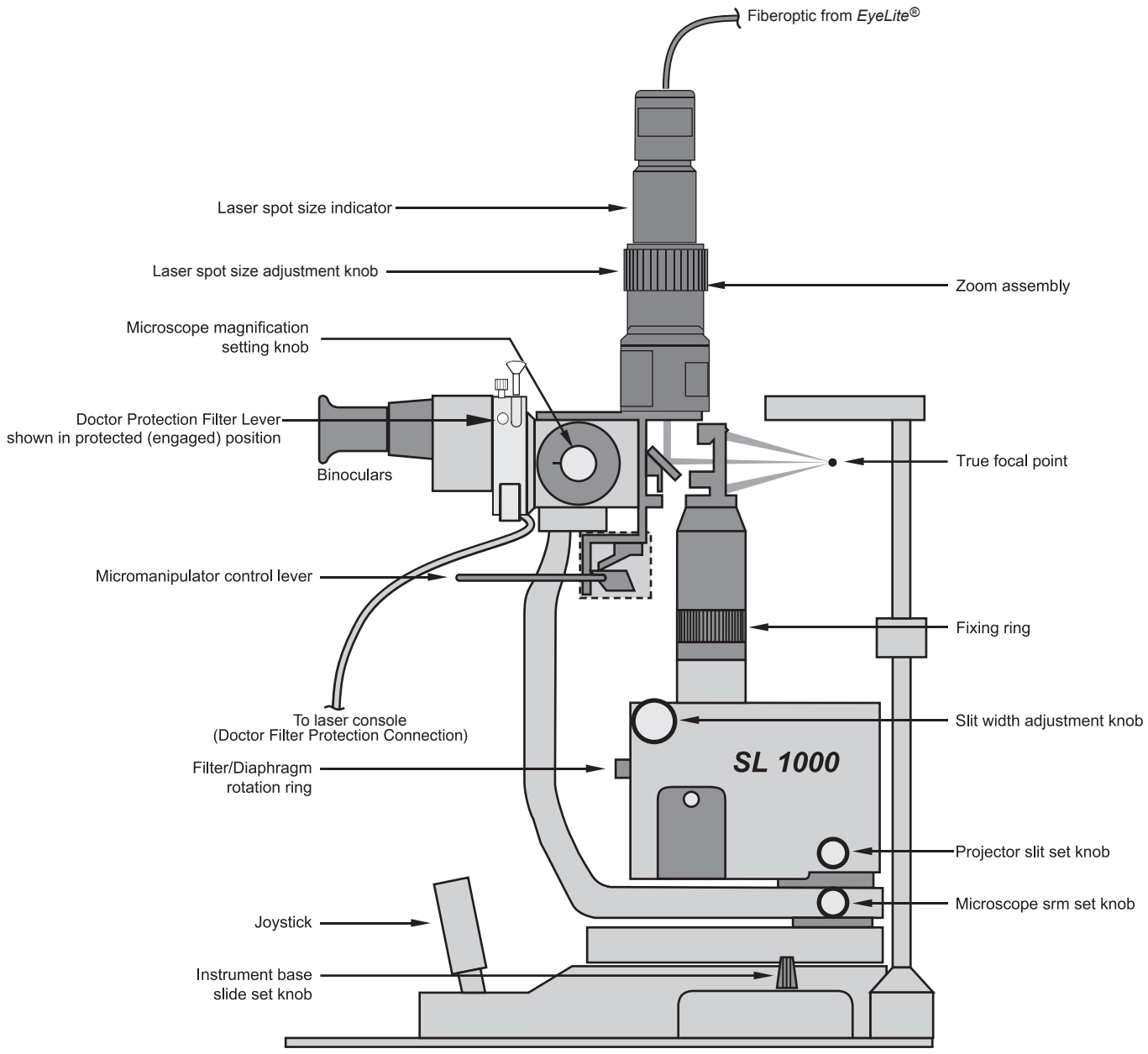


Figure 6-7
Controls on Alcon SL 1000 Slit Lamp with Doctor Protection Filter and Adaptation Installed

Operation

Operation of the Doctor Protection Filter

- Before operating the slit lamp, the Doctor Protection Filter cable must be plugged in and firmly attached to the rear panel of the *PurePoint*™ laser system.

- The Doctor Protection Filter is operated by moving the lever from the unprotected position to the filter protected (engaged) position. The 532nm laser treatment beam is not operational until the filter lever is in the engaged position.

- When using beam splitter accessories, the binoculars 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 (see Figure 6-9).

Positioning and Focusing the Laser Beam

1. Move the joystick left and right to horizontally position the laser spot and illumination slits.

2. Rotate the joystick to vertically position the laser spot.

3. Move the joystick forward and backward to focus the laser spot.

Adjusting the Laser Position and Spot Size

1. Following customary methods, position patient and place the contact lens on patient's eye.

2. Using the joystick control on instrument base, bring the selected area of treatment into position/focus. If desired, lock instrument base in position with instrument base slide set knob.

3. To position the laser spot, choose one or a combination of the following methods:

    3.1 Using the joystick control, position the laser spot on the selected treatment area.

    3.2 Using the micromanipulator, position the laser spot around the microscope center field of view.

    3.3 Tilt the contact lens.

4. Use the laser spot size adjustment lever to set the laser spot size.

Laser Treatment of the Eye

1. The Doctor Protection Filter must be connected and in working order. To protect the user's eyes, the filter must be in the engaged position prior to firing the treatment laser.

2. For laser spot sizes ranging from 50 µm to 500 µm, the focus is parfocal; i.e., the focus of the laser spot lies in the focal plane of the microscope (see Figure 6-11). For laser spots greater than 500 µm, the laser spot sizes are set by defocusing the laser; i.e., the laser focus will not lie in the focal plane of the microscope).

3. If the diopter adjustment(s) of the microscope eyepieces are not accurate, the object and the laser focal point will not be in the same plane (for values between 50 µm and 500 µm). Consequently, the laser spot size on the fundus will be larger than the values set on the zoom.

4. To position the laser spot, use the procedures outlined in the previous section.

5. Activate the treatment laser only if the target area has been clearly localized and irradiation by a treatment laser is warranted. Follow the operating instructions for the *PurePoint*™ laser to operate the laser control console and activate the laser treatment beam.

WARNING!

If the red aiming beam is not operating, do not use the system; contact Alcon Technical Services.

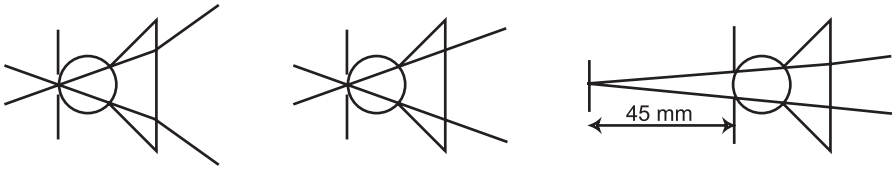


Figure 6-8 Laser Spot Focus

Troubleshooting

The table below is provided as an aid in troubleshooting. Normal care should be used during the troubleshooting process to prevent the introduction of additional problems.

Table 6-2 Adaptation Troubleshooting

SYMPTOM	PROBABLE CAUSE	CORRECTIVE ACTION
No Aiming Beam (red)	Laser not switched on.	Turn on Laser.
	Aiming beam set too low.	Turn up intensity.
	Fiber optic cable not connected.	Connect fiber.
	Aiming beam inoperative.	Contact Technical Services.
No Treatment Beam (532nm - green)	Laser not switched on.	Turn on Laser .
	Doctor Protection Filter not properly connected to Laser.	Connect filter cable to back panel of Laser.
	Filters not engaged.	Properly engage filters.
	Fiber optic cable not connected.	Connect fiber.
Laser spot cannot be positioned	Zero position lock knob in locked position.	Release zero position lock knob.

Introduction

The Alcon Laser Indirect Ophthalmoscope - Advanced Technology (LIO-AT) is an accessory for use exclusively with the *PurePoint*™ Laser. The Alcon LIO-AT is composed of a *Heine* diagnostic headset with integral laser delivery adaptation and an illumination power supply. The treatment laser beam and the aiming beam are both provided by the *PurePoint*™ Laser.

The LIO-AT is connected to the *PurePoint*™ Laser via a fiber optic cable. The LIO-AT headset illuminator is powered by a standard desktop power supply. Prior to connecting the primary power supply, ensure the voltage indicated on the power supply label is the same as the main power outlet. The illumination light is adjustable from approximately 0 to 1000 lux using the illumination control knob on the power supply.

A permanent Doctor Protection Filter protects the surgeon against incidental laser beam reflections. The operator will have a colored** view through the Doctor Protection Filter due to blocking of the 532 nm wavelength (green).

Figure 6-9 The Alcon Laser Indirect Ophthalmoscope-Advanced Technology

WARNINGS!

The head-worn Laser Indirect Ophthalmoscope (LIO-AT) is designed solely for examination and treatment of the eye, particularly the retina.

Use only the illumination power supply provided with LIO-AT. It is specially designed for medical applications.

Insure that the selection on the *PurePoint™* front panel is LIO. It is the responsibility of the operator to verify that the selection is correctly confirmed.

The operator will have a colored (pink) view through the Doctor Protection Filter due to blocking of the 532 nm wavelength (green).**

The operator must be careful to avoid potential secondary reflections; therefore the room used to treat the patient should be approved by a qualified laser safety officer.

All personnel in the treatment room must wear protective eyewear (OD 4 or above at 532 nm) when the system is in "Standby" or "Ready" modes.

The laser delivery system is an integral part of the Alcon LIO-AT and is not designed to be used with an observer. Never use a teaching or observation system in conjunction with the LIO-AT. There is no eye protection provided for the observer.

Never treat a patient when the *PurePoint™* Laser is connected to a service computer.

Before each use of the headset, the operator must check the permanent Doctor Protection Filter for scratches, breaks, or alterations. If there is any doubt, please call Alcon Technical Services, and discontinue use of device.

There are potential hazards when inserting, steeply bending, or improperly handling of the fiber optic cable. Not following the recommendations of the manufacturer may lead to damage to the fiber or delivery system and/or harm to the patient or user.

Since the aiming beam passes down the same delivery system as the treatment beam, it provides a good method of checking the integrity of the delivery system. If the aiming beam spot is not present at the distal end of the delivery system, or its intensity is reduced or it looks diffused, this a possible indication of a damaged or not properly working delivery system. If there is any doubt, contact Alcon Technical Services.

The use of flammable anesthetics or oxydizing gases such as nitrous oxide (N_2O) and oxygen should be avoided. Some materials - for example cotton wool when saturated with oxygen - may be ignited by the high temperatures produced in normal use of the laser equipment. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. There is also danger of ignition of endogenous gases.

A qualified technician must perform a visual inspection of the following components every twelve months: warning labels, power cords, and fuses. In case of a deficiency, do not use the system; call Alcon Technical Services.

A qualified technician must verify the LIO-AT performance by performing an LIO-AT calibration, power output, and energy matrix test every twelve months to ensure the LIO-AT is operating within specifications. See Section Four of this operator's manual for instructions. If the LIO-AT is not operating within specifications, do not use the system; call Alcon Technical Services.

A qualified technician must check and record ground continuity and both polarities for leakage current every twelve months to ensure they are within the applicable standards (for example: EN60601-1/IEC601-1). If they are above the applicable standards, or 50% above initial measurement, do not use the system; call Alcon Technical Services.

Alcon LIO-AT Icons and Labels

The labels and icons shown in Figure 6-10 are found on the Alcon LIO-AT and are defined as indicated.

Refer to Operator's Manual

Laser Radiation

Laser Aperture

Use appropriate take-back system (See Environmental Considerations in this manual)

No Continuous Use of LIO-AT; 10 Minutes ON/20 Minutes OFF.

Manufacture Date

Fragile - Handle Laser Fiber With Care

CE Identification Label

cUL-UL Identification Label

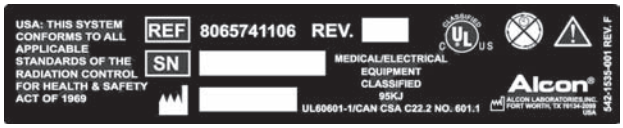


Figure 6-10 Alcon LIO-AT Labeling

Table 6-3 Alcon LIO-AT Technical Specifications

CATEGORY	SPECIFICATION
Dimensions	Width: 22.0 cm (8.7 inches) Length: 24.2 cm (9.5 inches) Height: 20.0 cm (7.9 inches)
Headset Weight	571 g (1.26 lbs.)
Electrical characteristics	See Heine power supply documentation.
Environmental Limitations	Operating: Temperature: 15° C≤ T° ≤ 35° C Relative Humidity: 10% to 90% with no condensation Storage: Temperature: -40° C≤ T° ≤ 70° C Relative Humidity: 10% to 90% with no condensation
Miscellaneous	*EyeLite®* Laser complies with CE MDD requirements (CE 0123). Not suitable for use in the presence of flammable anesthetic, oxygen, or nitrous oxide. System not protected against the ingress of water. Class IIb, IEC 601-1

Alcon LIO-AT Safety Features

- Labels on the instrument warn the operator about laser dangers.
- An On/Off (I/O) switch with indicator light controls the illumination power supply. When the indicator light is ON, the illumination power supply is ON.
- A protective housing covers the laser source completely and the beam will only exit through the LIO-AT exit window.
- A permanent Doctor Protection Filter on the LIO-AT headset protects the operator from incidental reflections of the laser beam. Prior to using the laser system, ensure that the filter is in good condition and that it has not been damaged, displaced, or moved.
- An emergency switch located on the *PurePoint*™ console can be used to shut off power to the laser. After using the emergency switch, pull it back to its initial position to restore power and start the instrument.

General System Precautions

All personnel operating laser systems shall follow each of the general safety precautions listed below.

- Never look into the laser beam.
- Restrict laser room access to people whose presence is required and who are familiar with the laser precautions.
- The laser room should be clearly identified with proper warning signs.
- Never direct the laser beam towards an opening.
- Never place any reflecting object in the path of the laser beam, or direct the laser beam toward objects that may reflect light (such as surgical instruments).
- Turn the *PurePoint*™ Laser OFF when not in use.
- Turn the LIO-AT illumination power supply OFF when not in use.
- Only authorized personnel thoroughly familiar with the recommendations contained in this manual may operate the LIO-AT. Any use of this laser system beyond the design intentions may result in dangerous exposure to laser radiation.
- Familiarity and understanding the use and application of the Indirect Ophthalmoscope is a prerequisite to using the LIO-AT.

Power Supply

For information on the desktop power supply (*Heine* EN 20-1) refer to the documentation provided with the power supply.

Connecting the Alcon LIO-AT to the *PurePoint*™ Laser

1. Connect the fiber from the LIO-AT termination to the Laser Aperture connector on the *PurePoint*™ front panel.
2. Attach the power cord from the LIO-AT to the power supply (see *Heine* EN 20-1 documentation) and switch on illumination.

CAUTION

Do not use the *Heine* standard desktop power supply EXTENSION cable (PN X-00.99.207) on the LIO-AT.

Using the Optics Overband

The pivoting overband allows the laser optics to be pushed up out of the operator's field of view (see Figure 6-11). It is locked in the end position and can only be released by pressing the Overband Adjustment Knob.

To pivot the overband, press the Overband Adjustment Knob with the right hand and pivot the overband into the desired position (up for the “rest” position and down for the “working” position). When the unit is properly adjusted, the overband can be lowered into the same pre-selected working position. Once set, changing the adjustments is required only if another examiner uses the instrument.

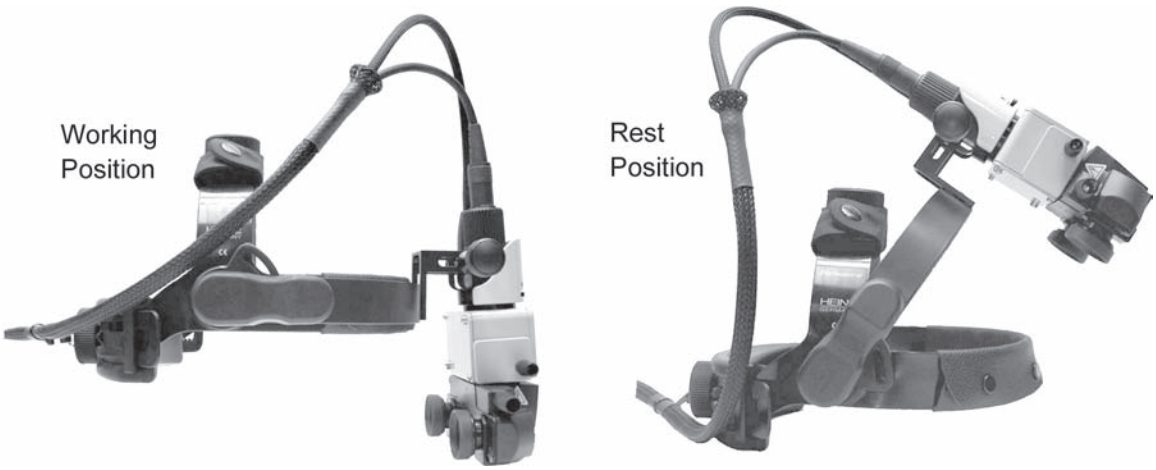


Figure 6-11 Adjusting the LIO-AT Overband

Observation Optics Adjustment

1. Loosen the Observation Optics Adjustment Knob (see Figure 6-36) so that the observation optics are free to move. The Observation Optics Adjustment Knob can be unscrewed and reversed to the other side for left-handed operators. Remove dust cover protecting delivery window.

2. Place the LIO-AT on your head and adjust the circumference and height using the Circumference and Height Adjustment Knobs so that the headband is firmly positioned but comfortable.

3. For convenience, use clothing clip to attach the fiber/cable assembly to clothing.

4. Move the eyepieces as close as possible to your eyes and look at the light spot at a distance of 30 cm. A small object (such as a pencil) held in front of the eyepieces at 30 cm must be clearly focused.

5. Using the Delivery Mirror Control Knob, adjust the optics so that the light spot is centered vertically in your field of view, then tighten the Observation Optics Adjustment Knob.

6. If the light spot is not centered horizontally, adjust the headband left or right accordingly.

7. Adjust the pupil distance setting by viewing the light spot alternately with the left eye then the right eye, and sliding the eyepieces so that the spot is centered within your field of view.

8. Remove the LIO-AT and look at the scale on the eyepieces to insure that the pupil distance is symmetrical. If not, center the headset and readjust the eyepieces. Correct adjustment of the optics is particularly important when examining small pupils.

Once set, changing the adjustments is required only if another examiner uses the instrument.

Controls for Observation and Illumination

The Aperture Lever (see Figure 6-12) allows you to choose between two different-sized illumination fields. The choice of illumination field size depends mainly on the size of the patient's pupil (the small illumination field is the recommended setting). The positions of the Aperture Lever for large and small illumination fields are marked with large and small black dots, respectively.

The Convergence Control Knob provides synchronized adjustment of both examination and illumination beams to suit the patient's pupil size. Wide convergence and parallax selection allows for maximum stereopsis with large pupils. Narrow convergence and parallax selection allows stereoscopic examination for small pupils. **NOTE: Use the small pupil setting and narrowest convergence angle at the small illumination field size setting; otherwise, clipping (shadow) of the illumination field will occur. The Convergence Control Knob adjustment range is limited in the LIO-AT to 50% of the original *Heine* range to accommodate for the laser beam delivery requirements.**

The Delivery Mirror Control Knob can be rotated to move both the illumination beam and the laser beam in the vertical plane.

CAUTION

Do not use the LIO-AT with the illumination power supply set at maximum intensity for more than 10 continuous minutes. The LIO-AT must be allowed to cool down at least 20 minutes between uses. Use as little observation/illumination light as possible and always switch power supply OFF after use.

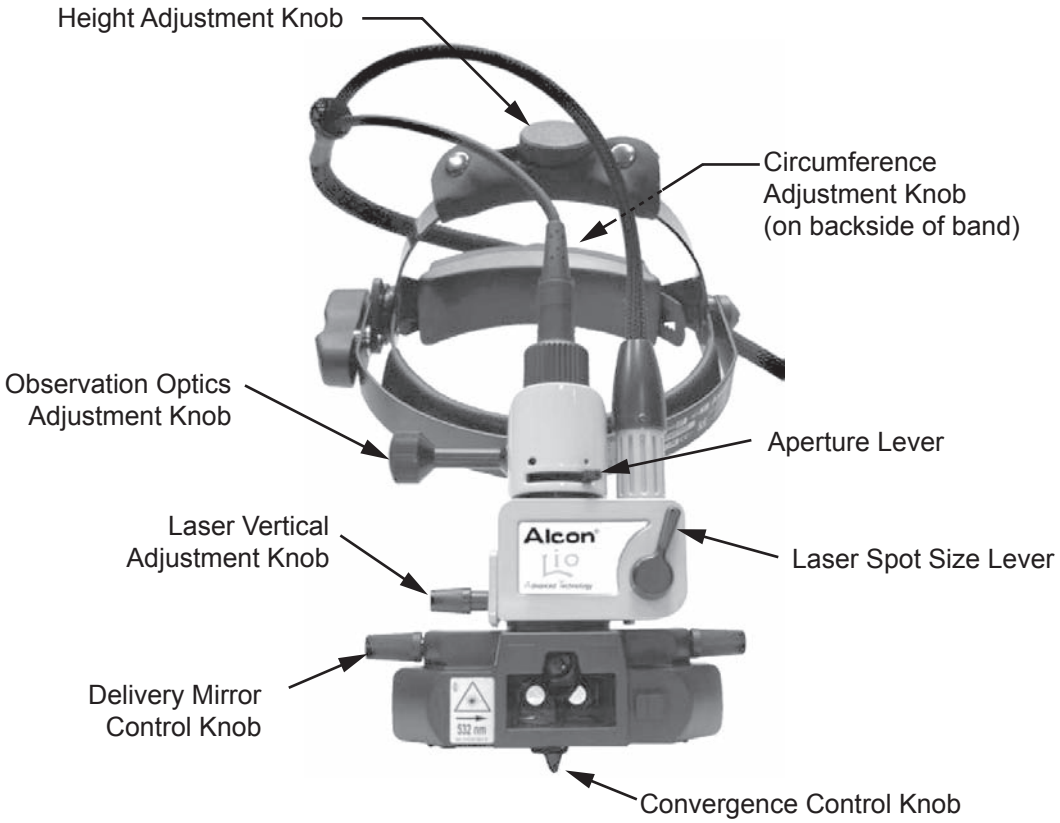


Figure 6-12 LIO-AT Controls and Adjustments

Using the Alcon LIO-AT for Observation

If the LIO-AT is used for illumination purposes only, the laser fiber does not need to be connected to the *PurePoint*™ Laser. **Note: Put dust cover on fiber termination to protect fiber when not connected to *PurePoint*™ Laser.**

1. Turn the illumination power supply on.

2. Adjust the light intensity with the power supply illumination control knob.

Using the Alcon LIO-AT for Laser Treatment

Using the system in this mode enables photocoagulation with the LIO-AT.

WARNING!

All the personnel in the room during the operation must wear protective safety eyewear with a minimum optical density OD 4 to filter 532nm radiation.

Before each use of the headset, the operator must examine the permanent Doctor Protection Filter for scratches, breaks, or alterations by looking through the ocular lens. If there is any doubt, discontinue use of device and please call Alcon Technical Service.

NOTE: The LIO-AT is shipped with +2 diopter ocular lenses installed. These may be changed with 0 (zero) diopter lenses.

1. If desired, change the ocular lenses by unscrewing the eyecup retainer in the counterclockwise direction, change each lens, and replace the eyecup retainers. Ensure that the new lenses are clean, i.e. no fingerprints or debris. Refer to the LIO-AT maintenance section for cleaning instructions.

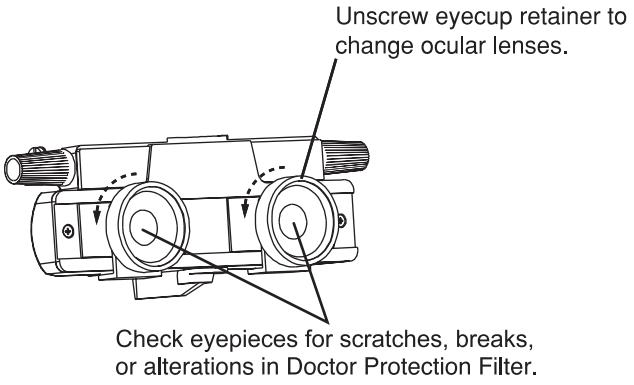


Figure 6-13
Eyecup Retainers and Ocular Lens on the Alcon LIO-AT

2. Turn the *PurePoint*™ console power ON and make the appropriate selections as specified in Operator's Manual.

3. Turn the LIO-AT Illumination power supply ON.

4. Select the appropriate illumination field size by toggling the illumination aperture lever to the desired setting.

5. Adjust the illumination intensity using the power supply illumination control knob.

6. Set the power below the nominal titration level by turning the Power Adjust knob on the *PurePoint*™ console counterclockwise. If the power parameter is not set below the nominal titration level, the message "Set Power < xxxx mW" will appear on the display.

7. If necessary press the Reset key to reset the shot counter to 0.

You can now adjust exposure time, aiming beam power, and treatment beam power.

8. Select exposure time by pressing the Exposure Time Adjustment arrow keys. If Continuous Wave mode is selected, "Mode: Continuous" is displayed.

WARNING!

Verify that all personnel are wearing protective eyewear (OD 4 or above at 532 nm) as soon as the system is in Standby/Ready mode, as well as during treatment.

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.

9. Select the aiming beam intensity by turning the Aiming Beam Intensity knob.

WARNING!

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

10. Turn the Power Adjust knob to set the desired treatment power.

11. Select the laser spot size using the Laser Spot Size Lever (see Figure 6-12). The positions of the Laser Spot Size lever for large (approximately 1mm) and small (approximately 0.5mm) laser spot sizes are marked with large and small black dots on the right side of the box, respectively. The change of laser spot size from large to small results in approximately four times increase in irradiance within the treatment area, provided that laser power was not adjusted.

    It is recommended to adjust laser power each time the Laser Spot Size Control setting is changed. Start with a low power, short duration pulse then increase until the desired coagulation result is achieved.

WARNING!

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

12. Press the Standby/Ready key on the front panel. The green Standby LED turns OFF, and the red Ready LED illuminates.

NOTE: The footswitch must be released to proceed to Ready mode. If the footswitch is depressed during power-up or while in Standby mode, "Release footswitch" is displayed. Release footswitch and proceed.

13. Use the Laser Vertical Adjustment Knob (see Figure 6-12) on the laser delivery adaptation to aim the laser at the desired location within the illumination field.

14. Press the footswitch when ready to fire. The system will emit a 4 millisecond beep each time the laser fires. If the footswitch is not pressed within 2 or 10 minutes starting from entry into "Ready" mode, the system emits one beep and switches to "Standby" mode.

NOTE: The aiming beam is off during treatment beam exposure, except in repeat mode.

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

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

NOTE: You can disable both treatment and aiming lasers by pressing the Laser ON/OFF switch. When turning the switch ON again, the system will default to the last terminal selection used before shutdown with the exception that LIO will default to Endo. Parameters shall be restored to the selected terminal.

Turn Off Sequence

1. Turn the Power Adjust knob to the minimum position.

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

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

3. Place the power switch on the rear of the system in the OFF (O) position.

NOTE: Between patients you can use the LASER ON/OFF switch to disable the treatment and aiming beams. The cooling system remains active in this mode.

4. Place the illumination power switch to the OFF (O) position.

ALCON LIO-AT MAINTENANCE

This section contains information for basic care and maintenance of the instrument. If a problem occurs on the instrument, call the Alcon Technical Services department and give details of the breakdown circumstances and effects. From these elements, a technician will evaluate the problem and determine the maintenance requirements.

WARNING!

Maintenance on any part of the laser system must be performed with the laser off and the main power plug disconnected.

Checking System Appearance

The condition of the system hardware components must be checked periodically to identify any fault which might cause incorrect operation of the system.

- Chassis appearance.
- Operation of controls and indicators.
- State of the fibers and connecting cables.
- Check permanent Doctor Protection Filter for damage; i.e., scratches and cracks.

Any damaged hardware must be replaced. Contact your Alcon Technical Service representative.

CAUTION

Care and cleaning operations must be performed with the instrument turned off and power disconnected.

Headset Care and Maintenance

- The eyepieces and the glass in front of the binocular assembly can be cleaned with a soft cloth (dipped in alcohol if necessary).
- The cushions for forehead and nape can be removed for wiping with soapy water.
- The rest of the instrument can be cleaned with a soft cloth dipped in alcohol. Under no circumstances should cleaning fluids be used.

Storage

The LIO-AT should be stored either on the Headset Stand or in the Storage Case when not in use to prevent inadvertent damage to the headset or cables.

Changing The Illumination Bulb

1. Ensure that power switches on the *PurePoint*™ Laser and illuminator power supply are in the OFF (O) position.

2. Disconnect power cord from power source.

3. Pull the cord socket away from the bulb connector (see Figure 6-14).

4. Unscrew and remove the bulb connector, then pull the bulb out of the socket.

WARNING!
The bulb and bulb connector may be hot, and can burn your fingers.

CAUTION
Do not touch the glass part of the new bulb directly with your fingers. Oil from fingers can dramatically reduce bulb life.

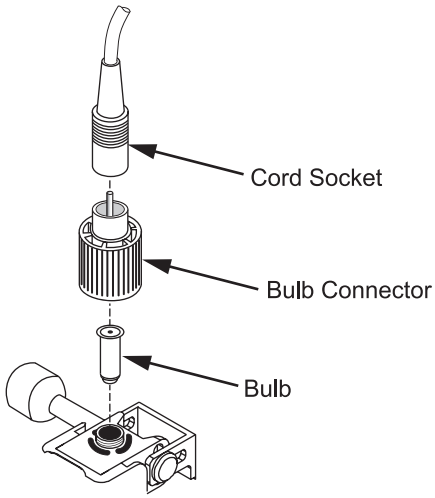
5. Clean the new bulb with a soft, clean cloth.

6. Insert the new bulb so its locating pin engages in the housing slit.

7. Rest the bulb connector on the base of the bulb and firmly screw it in.

8. Re-connect the cord socket.

Figure 6-14
Alcon LIO-AT Bulb Replacement



Calibration
Alcon Surgical recommends that the Laser Indirect Ophthalmoscope be calibrated on an annual basis as an integral part of the laser system with which it is used. Refer to Section Four for calibration information.

ALCON LIO-AT SPARE PARTS AND ACCESSORIES

Bulb 6V	P/N 542-1119-001
Laser Protective Eyewear	P/N 8065750107
28 D Lens	P/N 8065750158
20 D Lens	P/N 8065-6879-01
+2 D Ocular Lens	P/N 301-361
0 D Ocular Lens	P/N 301-362
Headset Stand	P/N 8065750891

SECTION SEVEN
INDEX

TO BE DETERMINED...

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