PUREPOINT™
LASER

OPERATOR'S MANUAL

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Directive 93/42/EEC

8065751131 Rev. P3.5, CATALOG NUMBER
905-5620-001 Rev. P3.5, TEXT ONLY

PurePoint™ Operator's
8065751131
MANUAL REVISION RECORD

DATE	REVISION	ECN NUMBER AND DESCRIPTION

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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.

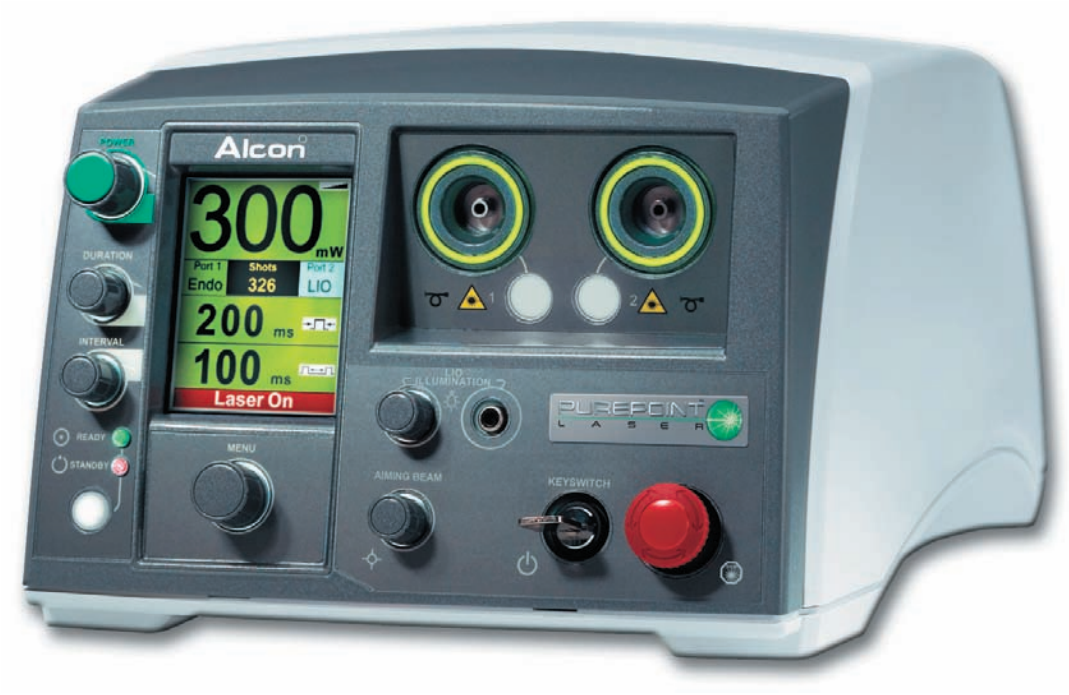


Figure 1-1 The Alcon *PurePoint™* Laser

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.

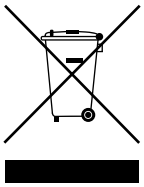
The use of flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen should be avoided. Some materials - for example cotton wool when saturated with oxygen - may be ignited by the high temperatures produced in normal use of the laser equipment. The solvents of adhesives and flammable 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

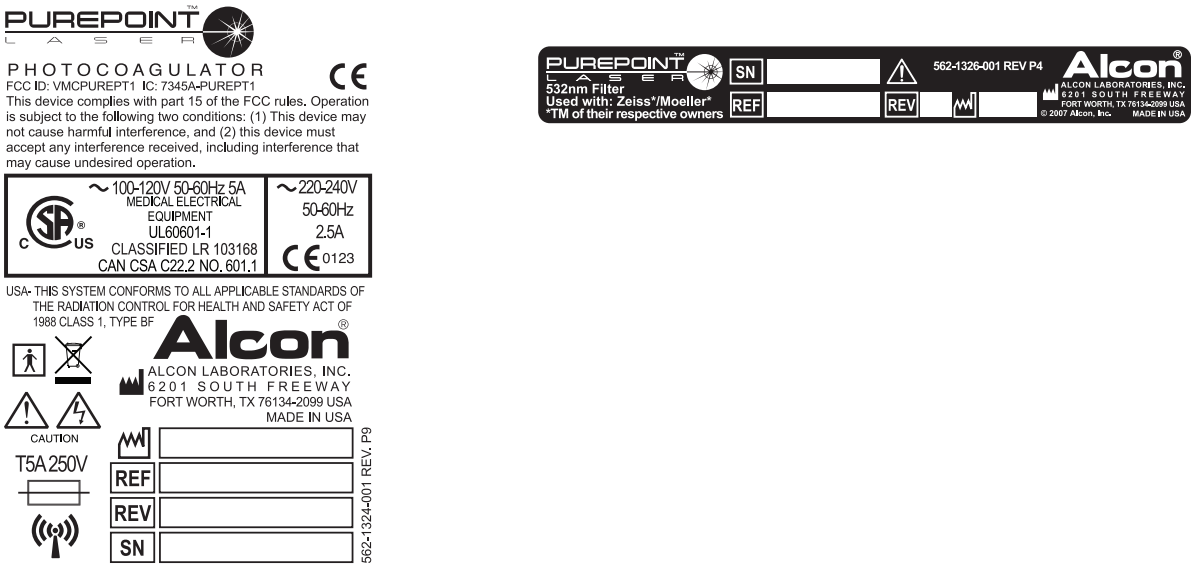
This device complies with the Australian/New Zealand Standard AS/NZS 4268: 2003 Radio Equipment and Systems – Short Range Devices – Limits and methods measurement.

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.)

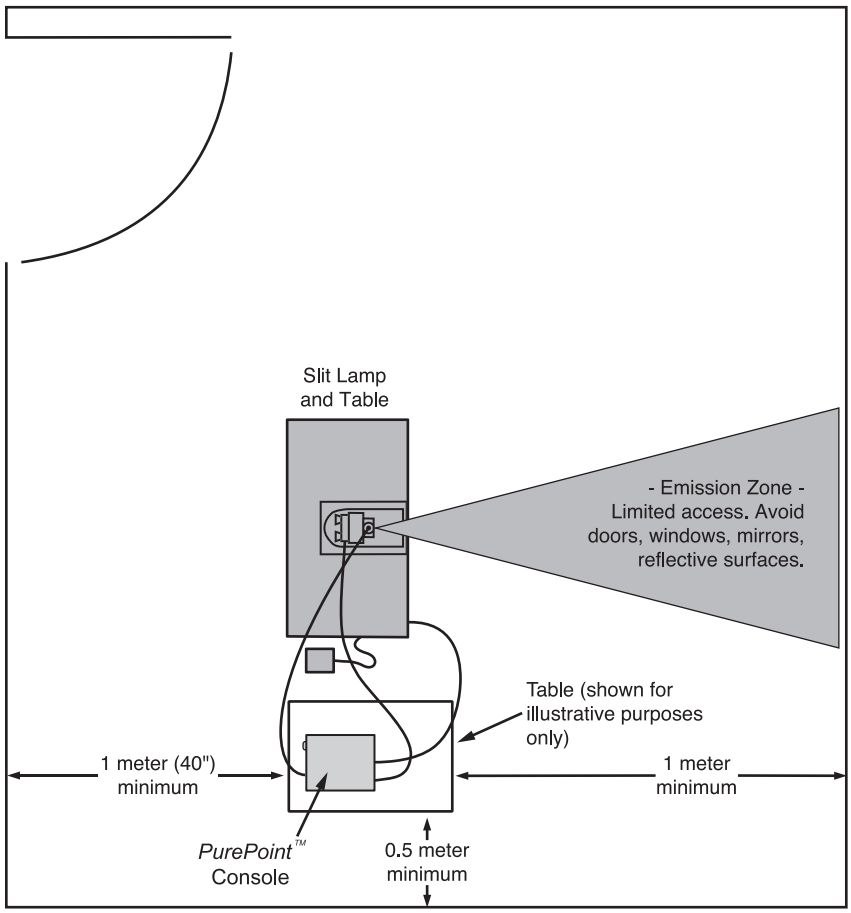


Figure 1-4 Recommended Laser Room Layout (Overhead View)

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.

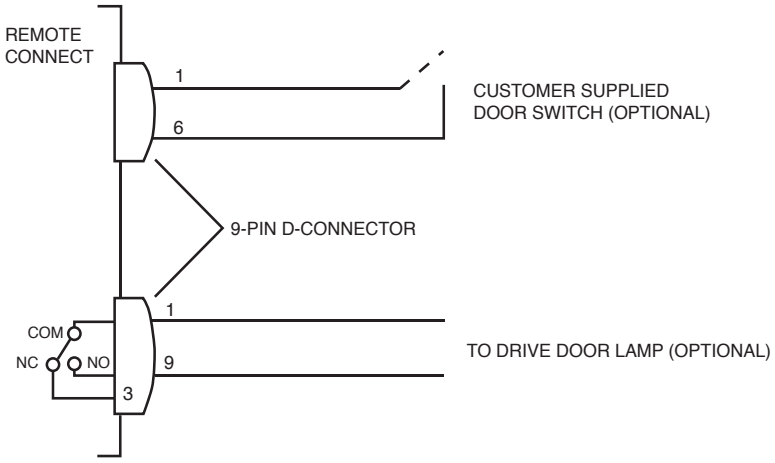


Figure 1-5 Remote Connector/Door Lamp Circuit Diagram

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.