OPHTHALAS® 532
EyeLite®

OPERATOR'S MANUAL

CE 0123

Directive 93/42/EEC

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905-5420-501 R, ASSEMBLY
905-5420-001 R, TEXT ONLY

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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.

Comments or corrections concerning this manual should be addressed to:

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

OPHTHALAS® 532 EYELITE®

MANUAL REVISION RECORD

DATE	REVISION	REVISED PAGE NUMBERS
8/96	A	Initial Release.
4/97	B	i, iv thru vii, 3-8, 6-1, 6-16 thru 6-19, 7-1, 7-2
6/97	C	as required, and to add Zeiss SL130 adaptation (i, iv, vi, vii, 1-4, 2-5, 3-2, 3-3, 3-8, 6-1, 6-4, 6-6, 6-12, 6-19 thru 6-26, 7-1, 7-2)
7/97	D	i, iv, vi, 6-20, 6-26
12/97	E	Added Bridge part numbers: i, iv, 6-1
3/98	F	i, iii thru viii, 1-1, 2-8, 3-8, 4-7, 4-8, 6-1, 6-3, 6-9, 6-12, 6-13, 6-16 thru 6-39, Index 1, Index 2, all remaining pages changed to update trademark on EyeLite®.
7/98	G	Title, iv, vi, vii, 1-3, 4-7 thru 4-9, 6-1 thru 6-29 (deleted information on pages 6-2 thru 6-12 and all pages were renumbered), 7-1 and 7-2.
3/99	H	Title, iv, 2-2, 6-16, 6-17, 6-19, 6-22, 6-23.
4/99	J	Title, iv, 6-1, 6-23
6/99	K	ECN 99200493 - i, iv, vi, 1-3, 6-1, 6-3
6/99	L	ECN 99200574 - i, iv, vi, 1-7, 2-4, 3-1, 3-3, 6-1, 6-3, 7-1
11/99	M	ECN 99201028 - i, iv, 1-8, 3-7, 6-26
4/2000	N	ECN 20002490 - i, iv, 1-4, 1-6, 1-7, 2-5, 2-8 (changed remote interlock icon; added nominal ocular hazard distance info. to warnings)
6/2000	R	ECN 20002714 - i, iv,1-9, 6-1

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* Zeiss is a registered ™ of Carl-Zeiss-Stiflung.

LIST OF ILLUSTRATIONS

FOREWORD

This Operator's Manual is designed to acquaint the operator and operating room personnel with the Ophthalas® 532 EyeLite®. 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 Surgical 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.

Domestic Customer Service to order supplies:
800-862-5266
FAX: 800-241-0677

Domestic Service:
800-832-7827
FAX: 714-753-6614

International: Contact your local Alcon representative for service and supplies.

SECTION ONE
GENERAL INFORMATION

INTRODUCTION

The OPHTHALAS® 532 EyeLite® (EyeLite®) is a Neodymium-doped Yttrium Aluminum Garnet (ND: YAG) type laser which has been designed for ophthalmic use. LASER is an acronym for "Light Amplification by Stimulated Emission of Radiation." This laser delivers a visible 532 nm green laser beam (frequency doubled), and a visible 670 nm Diode Laser aiming beam (670 nm is an approximate value between 660-680 nm).

Figure 1-1
The OPHTHALAS® 532 EyeLite® Laser

EyeLite® Laser Generation Principle

The EyeLite® laser beam is generated when a laser diode beam excites the Neodymium atoms in the rod material. When one atom which has been excited by the beam returns to its initial stable level, the energy difference between the two states is emitted as radiation in the form of a photon. When this photon meets another excited atom, emission of a second photon occurs. The second photon has the same phase, wavelength, and direction as the first photon. The light emitted in this manner oscillates between two mirrors. The light is amplified by this stimulated emission process and a 1064 nm output laser beam is produced.

The frequency doubling process of the 1064 nm wavelength results when the infrared beam goes through a second harmonic crystal. The crystal is an optical dielectric that exhibits a non-linear optical response. The 532 nm wavelength is produced by harmonic generation of the 1064 nm laser beam.

Table 1-1
Technical Specifications

CATEGORY	SPECIFICATION
Approximate Dimensions	Width: 0.38 m (15.30 inches) Length: 0.45 m (17.75 inches) Height: 0.23 m (9.10 inches)
Approximate Weight	16.4 Kilos (36 lbs.)
Electrical Characteristics	Voltage: 100-120 VAC/220-240 VAC Frequency: 50/60 Hz Fuse rating: 250V,Single Phase 6.3 Amps Insulation class: Class I, type BF, ⍓ Intermittent use: 50% Duty cycle
Environmental Limitations	Operating: Temperature: 15°C ≤ T°≤ 35°C Relative Humity: 10% to 90% with no condensation Storage: Temperature: -40°C ≤ T°≤ 70°C Relative Humity: 10% to 90% with no condensation
Miscellaneous	EyeLite® 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 601-1 is below 500 micro amps. Ground continuity per IEC 601-1 is below 0.1 ohm.

Table 1-2
Laser Characteristics

CATEGORY	TREATMENT LASER BEAM	AIMING LASER BEAM
Laser Class	IV	II
Laser Power	• 30mW to 100mW in 10mW steps • 100mW to 1W in 20mW steps with additional steps at: 0.15, 0.25, 0.35, 0.45, 0.55, 0.65, 0.75, 0.85, 0.95 • 1W to 1.7W (minimum) in 100mW steps	1mW maximum; adjustable by operator
Laser Wavelength	532 nm	approximately 670 nm

CAUTION

Canadian approval requires this supply system to be balanced, single-phase, two-pole system. Leakage exceeds 100 mA in an unbalanced system.

EMC Statement:
This equipment has been tested and found to comply with the limits for medical devices as specified in IEC 601-1-2:1993, EN60601-1-2:1994 and Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

It is important to install and use the equipment in accordance with the instructions to prevent harmful interference to other devices in the surrounding area. You can determine whether or not the device is causing interference by turning it off and checking to see if the problem still exists. If this equipment does cause harmful interference to other devices, the user is encouraged to correct the interference by one or more of the following measures:

- Reorient or relocate the other device(s).
- Increase the separation between the equipment
- Connect this equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manu facturer or authorized field service technician for help.

Environmental Issues:
Follow local governing ordinances and recycling plans regarding disposal or recycling of device components.

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 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.

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.

WARNING LABELS

Refer to Figure 1-2 for the location of warning labels on the EyeLite® console.

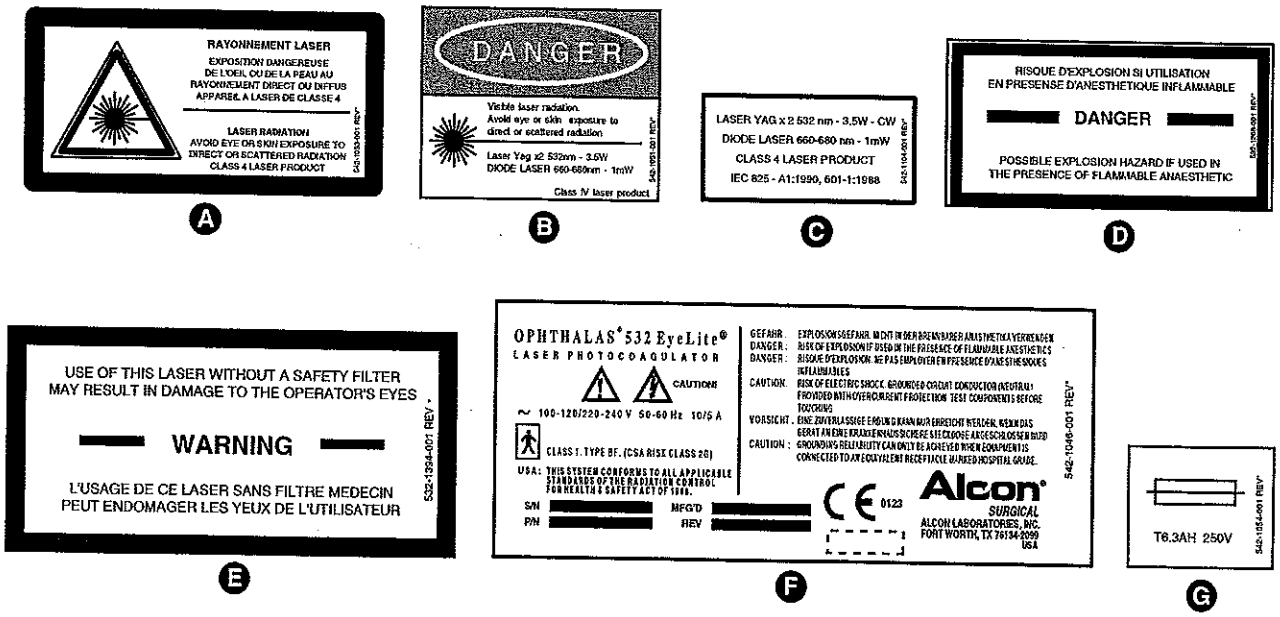


Figure 1-2
Warning Label Location Diagram

PREPARING FOR INSTALLATION

Your OPHTHALAS® 532 EyeLite® 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.

Initial installation must be performed by an Alcon Surgical representative. The following information will enable you to prepare the facility for installation of the EyeLite®.

General Laser Room Layout

The EyeLite® 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 1-3.

Approximate dimensions of the EyeLite® console:

Width (overall) = 0.38 m (15.30 inches)
Length (overall) = 0.45 m (17.75 inches)
Maximum height (overall) = 0.23 m (9.10 inches)
Weight = 16.4 Kilos (36 lbs.)

Approximate dimensions of the Slit Lamp table:

Width (overall) = 0.74 m (29 inches)
Length (overall) = 0.40 m (15.5 inches)
Maximum height (overall) = 0.88 m (34.5 inches)

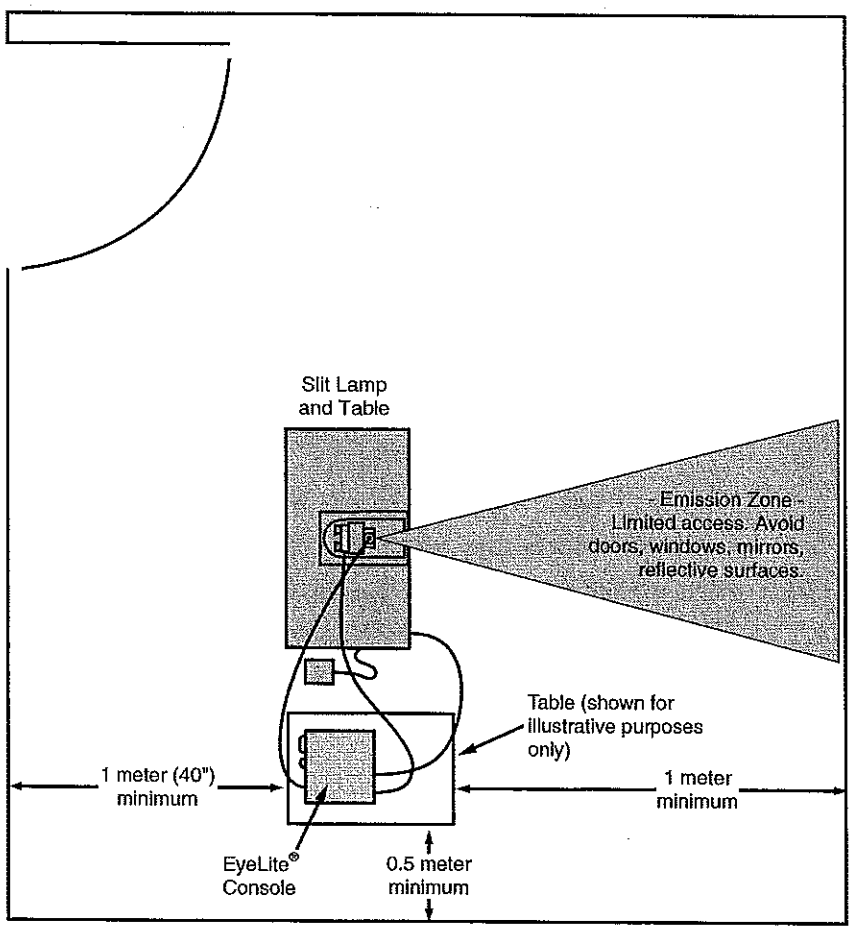


Figure 1-3
Recommended Laser Room Layout (Overhead View)

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.

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 a 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 key removal.
- 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 1-4.

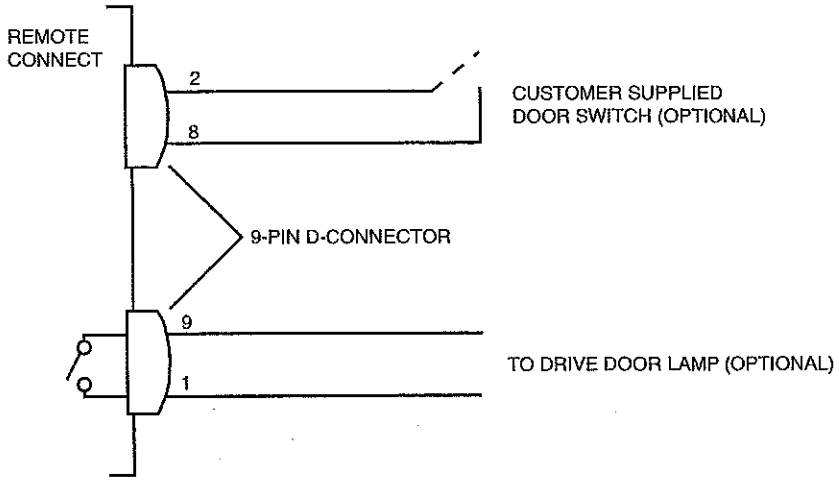


Figure 1-4
Remote Connector/Door Lamp Circuit Diagram

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 accordingly. This is in accordance with OSHA guidelines.

Utility Requirements:

Electrical requirement: The EyeLite® has an auto-ranging power supply which 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 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 port. These peripherals are:

- Slit Lamp adaptation
- Laser Indirect Ophthalmoscope
- Endoprobe/Aspirating Endoprobe/Illuminated Endoprobe

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

EYELITE® SAFETY FEATURES

The EyeLite® is designed for the highest degree of reliability and maximum safety for both the operator and the patient. Any abuse 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 EyeLite® 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. Do not leave key on or near instrument when not in use.
- Laser status can be determined by visually checking the Ready and Standby LEDs. The green LED indicates that the system is in Standby mode. The red LED indicates that the system is in Ready mode and the laser is ready to fire. In addition, the system will emit a 4 millisecond beep each time the laser fires.
- An emergency stop push button is mounted on the front panel. This button will cut off all laser emissions (treatment and aiming beam) at any time. The button must be pulled out to the initial position to restore power.
- 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 is inhibited and treatment laser emission is cut off.

PROFESSIONAL OPERATOR'S INFORMATION

The following information is given to supplement the operator with specific information regarding the EyeLite® Ophthalmic Laser.

Indications

The EyeLite® is designed for use in the treatment of ophthalmic conditions including: Proliferative Diabetic Retinopathy, Macular Degeneration, and Retinal Detachment.

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 titrate laser parameters 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's Safety Filter

The wavelength of the green treatment beam is 532 nm, and 660 nm - 680 nm for the red aiming beam. The doctor's filter remains 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). However, under certain conditions it may be desirable to remove the doctor's safety filter from the beam path for pre- or post-operative observation. Rotation of the filter in or out of the beam path is accomplished by means of a lever located on the right side of the filter. Note that the laser will not fire with the filter out of the beam path.

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] 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, 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 are 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 goggles, OD 4 or above at 532 nm, when the system is in Standby/Ready mode as well as during treatment. The Doctor's 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.

SECTION TWO
DESCRIPTION

This section contains descriptions of the front panel, rear panel, and messages that appear on the display.

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 EyeLite®. Changes to the current system setup are acknowledged by a beep. For example: if the terminal selection or power are changed, the system will beep. A liquid crystal display shows operational prompts and error messages.

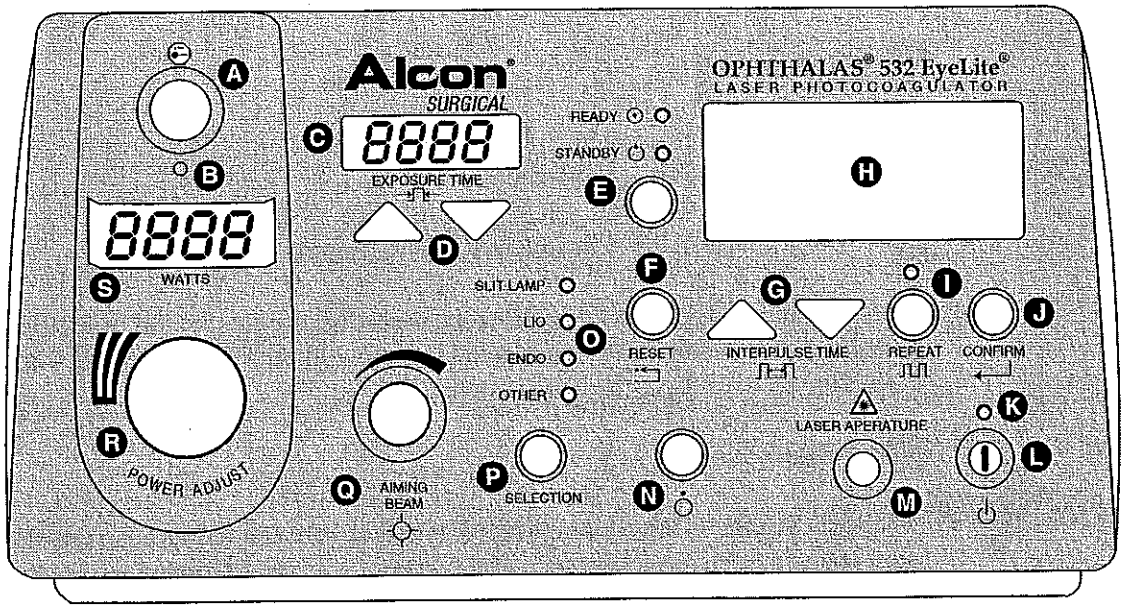


Figure 2-1
EyeLite® Front Panel

A Emergency Switch

Pushing the Emergency Switch causes all functions, including the laser power supply, to shut down. To restore power, pull the Emergency Switch to the out position.

B Emergency Switch Indicator LED

This indicator illuminates to warn the surgeon when the Emergency Switch has been depressed to shutdown the system. Pulling the Emergency Switch to the out position extinguishes this LED.

C Exposure Time Display

An arrangement of four, 7-segment LEDs that displays the selected exposure time in seconds. The exposure time is adjusted by the Exposure Time Adjustment Keys. In Continuous Wave mode, all displays show dots (...).

D Exposure Time Adjustment Keys

These up and down arrow keys allow the user to adjust the duration of the exposure time. The default setting for exposure time is 0.2 s. The exposure time can be adjusted to the following values by these two keys:

0.01 - 0.02 - 0.05 - 0.1 - 0.15 - 0.2 - 0.25 - 0.3 - 0.4 - 0.5 - 0.7 - 1 - 1.5 - 2.0 - 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 the indication in the LCD display. It is not recommended to use exposure times longer than 2 seconds in CW mode.

E Standby/Ready Switch

The Standby/Ready Switch allows the user to select either Standby or Ready mode. Each mode has a corresponding LED - Green for Standby and Red for Ready - to indicate the current selection. The Ready mode must be selected in order for laser treatment to proceed.

F Reset Key

Pressing the Reset Key resets the laser exposure counter displayed on the LCD back to 0. The maximum number is 9999 shots.

G Interpulse Time Adjustment Keys For Repeat Mode

These up and down arrow keys allow the user to adjust the interval time between exposure times in repeat mode. The default value is set to 300 ms and is adjusted by these two keys from 100 ms to 1000 ms in 100 ms steps.

H LCD Display

The LCD display is the communication interface between the surgeon and the system. It advises the surgeon as to the state of the system with the following information: the terminal selected, the repeat mode configuration, the number of shots, and error messages.

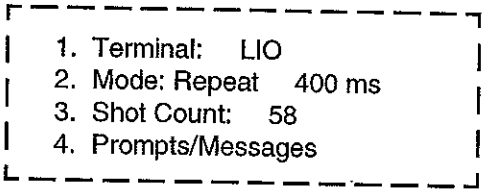


Figure 2-2
EyeLite® Display

1. Terminal selected corresponds with the selection made by the operator using the Terminal Selection key.
2. Indicates single shot or repeat mode selection with the interpulse time.
3. Counter contains the number of shots.

4. Each prompt must be confirmed by depressing the Confirm key. Each message informs the operator of the current system status.

WARNINGS!

It is the operator's responsibility to confirm correctly any questions asked by the system. Alcon shall not be held liable for problems caused by wrong response given by the user.

It is the operator's responsibility to properly select and confirm the terminal used. Alcon shall not be held liable for problems caused by a mis-selection or mis-confirmation of the terminal used. Failure to comply may cause the patient and users to be exposed to hazardous laser radiation.

I Repeat Mode Selection Key

Repeat mode is selected by pressing the Repeat Mode Selection Key for at least two seconds. The two second delay serves to avoid any non-intentional setup. The LED above this key illuminates when the system is in repeat mode. The interval time between each shot in repeat mode is displayed on the LCD.

A single press of the Repeat key returns the system to single shot mode (one exposure time per footswitch depression determined by the exposure time selection).

J Confirm Key

The Confirm Key allows the surgeon to respond to a system prompt which is displayed on the LCD during a procedure. Pressing the Confirm key represents a positive reply to a prompt. The system stays in the pending mode until a confirmation is given by the operator.

K Key Indicator

The Key Indicator illuminates when the key is turned to the ON position.

L Keyswitch

The keyswitch is a two position switch where the key can be removed only in OFF position. In the OFF position, the main power to the system is shut off. In the ON position, an orange LED is illuminated.

M Laser Aperture

An SMA connector with a fiber safety connection is provided to connect the EyeLite® to the desired delivery system (terminal); i.e., Slit Lamp adaptation, Laser Indirect Ophthalmoscope (LIO), or Endoprobe/Aspirating probe. When the fiber is disconnected, a message is displayed on the LCD.

N Laser ON/OFF Switch

- The system powers up with this switch ON. In this position the laser could be operational depending upon the next keystroke(s).
- When the switch is OFF, both lasers are OFF, the cooling system is powered, and the LCD alerts the surgeon that the system is in this mode.
- When the switch is turned ON again, the system goes back to the default value, and the terminal selection is the Slit Lamp.

O Terminal Selection LEDs

When the desired terminal is selected, the LED that corresponds to the selected terminal illuminates.

P Terminal Selection Key

The Terminal Selection Key allows the user to select one of the following terminals for operation: Slit Lamp Adaptation, Laser Indirect Ophthalmoscope (LIO) or Endoprobe/ Aspirating Endoprobe/Illuminated Endoprobe. The selection "OTHER" is not enabled.

A selection is made by pressing and holding the Terminal Selection Key until the LED representing the desired terminal illuminates. When switching from one terminal to another, a prompt is displayed on the LCD which requires confirmation by pressing the Confirm key.

Q Aiming Beam Intensity Knob

This knob is attached to a potentiometer which adjusts the intensity of the aiming beam. The computer adjusts the intensity limits depending upon the delivery system selected; therefore, at a given position the output intensity could be different from one delivery system selection to another.

The knob travels through 270° of rotation with minimum output in the farthest counterclockwise position and maximum output in the farthest clockwise position.

R Power Adjust Knob

The power is adjusted by turning this knob which is attached to a three turn potentiometer. If the potentiometer is not in the minimum position after the initial setup time, a warning message prompting the user to turn it to the minimum position is displayed on the LCD. The following power settings are available for the listed delivery systems:

0.03W - 1.7W (minimum) Slit Lamp
0.10W - 1.7W (minimum) LIO
0.05W - 1.7W (minimum) Endo/Aspirating/Illuminated Endoprobe

If the operator turns this knob too fast, a safety shutdown occurs as the system detects an invalid control command and displays the following message: "Potentiometer Fault".

S Power Indicator

The Power Indicator is an arrangement of four, 7-segment LEDs that shows the output power (in Watts) at the cornea.

REAR PANEL DESCRIPTION

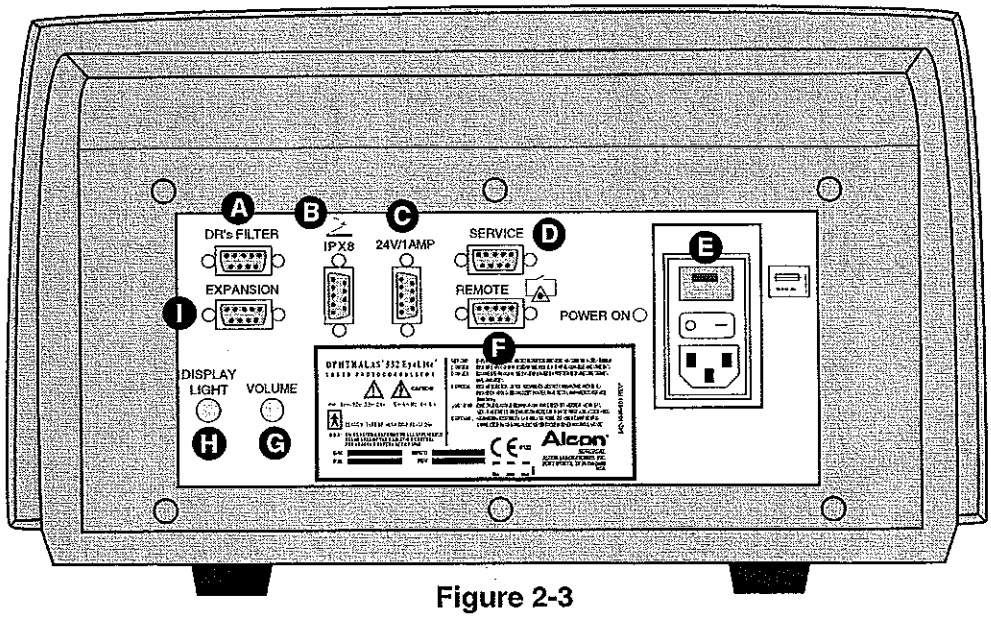


Figure 2-3
Rear Panel

A Doctor's Filter Connection

The Doctor's Filter (for Slit Lamp and Endoprobe) is connected to this port. If the Doctor's Filter is not engaged, firing cannot occur and the message "Engage Dr's filter" is displayed on the LCD.

WARNINGS!

The operator will have a colored view through the doctors filter due to blocking of the 532 nm wavelength (green).

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

B Footswitch Connection

The footswitch controls delivery of the treatment laser beam and is connected to the system through this port.

C Relay Contact

A relay closure rated at 24 VDC, 1 amp is provided to comply with CE regulations.

D Service Connector

The Alcon Field Engineer can access the system by connecting a laptop computer to this port. A password is required to gain access to the system and this procedure can only be performed by qualified personnel.

WARNING!

Never use the EyeLite® for treatment when connected to a computer or any other device.

E Power Entry Module

The main power cord is connected to the plug connector on the device with the necessary fuse to comply with electrical regulations. When the main power cord is connected and the power switch is turned on, an LED on the back panel illuminates.

F Remote Interlock Connection

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

When the Remote Interlock is activated, the surgeon is warned by a message displayed on the LCD (Laser Fault 07) and the lasers are turned off. Clear the Remote Interlock and reset the system by turning the key OFF then ON.

G Volume Adjustment Knob

Provision for future applications.

H Display Light Adjustment Knob

The LCD backlighting intensity is adjusted by turning this knob.

I Expansion Connector

Provision for future connections.

ICONS

The following icons are used on the front and rear panels of the EyeLite® console to aid the operator in determining the function of each button, knob, connector, etc.

Emergency Laser Off

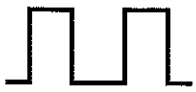
Main Power On

Main Power Off

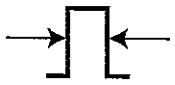
Standby Mode

Ready Mode

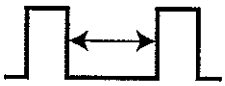
Laser Off



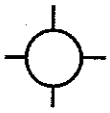
Repeat Exposure Mode



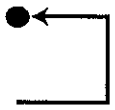
Exposure Time (Duration)



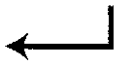
Interpulse Time (Exposure Interval)



Aiming Beam



Reset (Reset Shot Counter)

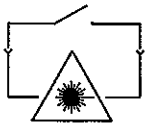


Confirm (Confirm Key)

Key Switch; OFF in vertical position, ON in horizontal position

Power Adjust (Treatment Power Adjustment)

Power Adjust (Aiming Beam Power Adjustment)



Remote Interlock Connection

Refer to Operator's Manual

Caution! High Voltage

Alternating Current

BF Type Applied Part

Footswitch Connection: To Watertight (IPX8) Footswitch

Laser Radiation

Fuse

Protective Ground (Internal Label)

Laser Aperture

INFORMATIVE MESSAGES

The messages listed in Table 2-1 are displayed on the LCD display to inform the operator of system status.

Table 2-1
EyeLite® Messages

MESSAGE	DESCRIPTION
Alcon 532 EyeLite XX	Represents the version of software in the system.
Please Wait	During the initial warm-up sequence, the LEDs flash for 8 seconds.
System Start-up	Start-up procedure.
Mode: Single Shot	When the system is in Ready mode with the Single Shot selection, an action on the footswitch delivers one shot per exposure time selected. If the footswitch is released prior to the termination of the exposure time, the treatment beam is interrupted.
Mode: Continuous	When the system is in Ready mode with the Continuous selection, an action on the footswitch delivers the beam until the footswitch is released.
Mode: Repeat XXX ms	XXX represents the interval time which can be selected. The range is 100ms to 1000ms in 100ms increments (default is 300ms).
Shot Count: XXXX	XXXX represents the number of shots. This can be reset to 0 by pressing the reset key.
Lasers OFF	When the OFF key is pressed, both lasers shut-down.
Terminal Slit Lamp	The operator has selected and confirmed the Slit Lamp terminal.
Terminal LIO	The operator has selected and confirmed the LIO terminal.
Terminal Endo	The operator has selected and confirmed the Endo terminal.
LIO Term Selected	This message flashes for 3 seconds to alert the operator that this selection has been made.
Power not in range	Power is not within ±20% before treatment.
OFF Condition	Treatment has been interrupted since the power is not within ±20%.

The prompts listed in Table 2-2 are displayed on the LCD display when action is required by the operator.

Table 2-2
EyeLite® Prompts

PROMPT	DESCRIPTION
Connect Fiber	The system has detected that the fiber is not connected to the Laser Aperature SMA connector on the front panel. The system will stay in this mode until the connection is made.
Set power to minimum	The system has detected that the treatment power is not set to the minimum setting. For safety reasons, the system will stay in this mode until the Power Adjust knob is turned fully counterclockwise to the minimum setting.
Release Footswitch	The system has detected that the footswitch is depressed during warm-up or while in standby. In order for the system to proceed, the footswitch must be released.
Engage Dr. Filter	The system has detected that the Dr's Filter is not engaged. The system will remain in standby until the Dr's Filter is engaged.
Check Filter/Bridge	The system detected that either the Dr's Filter or the Bridge (3000LE) has not been connected or properly engaged. The system will remain in Standby mode until the connection is made.
Select Slit Lamp?	The Slit Lamp Terminal is selected. Pressing the confirm key sets the system for use with this terminal.
Select LIO Term?	The LIO Terminal is selected. Pressing the confirm key sets the system for use with this terminal.
Select Endo Term?	The Endo Terminal is selected. Pressing the confirm key sets the system for use with this terminal.
Dr's Filter in place?	The Dr's Filter must be properly in place on the Slit Lamp and Endo terminals to protect the Doctor during treatment.

SECTION THREE
OPERATING INSTRUCTIONS

INTRODUCTION

This section details the recommended setup and operation for the Alcon EyeLite® laser. These procedures may be modified to conform to hospital requirements and practices as you become experienced in using the system. The operational checks; however, which 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.

INITIAL SETUP

WARNING!

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

1 Position the instrument for surgeon's comfort and preference.

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

3 Verify the power switch on the rear panel is in OFF position (O).

4 Insert key and verify the key is in the OFF (vertical) position.

5 Connect the power cord to a properly grounded main power outlet (220-240 VAC, 6.3A; or 100-120 VAC, 6.3A).

SYSTEM CONNECTIONS

Connecting the EyeLite® to a Slit Lamp

WARNINGS!

The Slit Lamp must be equipped with a special Alcon Surgical Slit Lamp adaptation. This adaptation is available for many of the 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's filter. The operator will have a colored view through the Doctor's Filter due to blocking of the green 532 nm wavelength light. It is the operator's responsibility to properly install the Doctor's Filter. Alcon shall not be held liable for problems caused by improper installation of the Doctor's Filter.

If the Doctor's filter is in the "not engaged" position, either

a. without a 3000LE® Bridge adaptation, or

b. with a 3000LE® Bridge adaptation in coagulation mode,

the prompt on the EyeLite® LCD display must read "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 Dr. Filter Assembly); the beam splitter is then attached to the permanently installed Dr. Filter. Improper installation could cause injury to the operator and/or the patient.

1 Connect the fiber optic connection from Slit Lamp Zoom to Laser Aperture SMA connector on the front panel (see Figure 3-1).

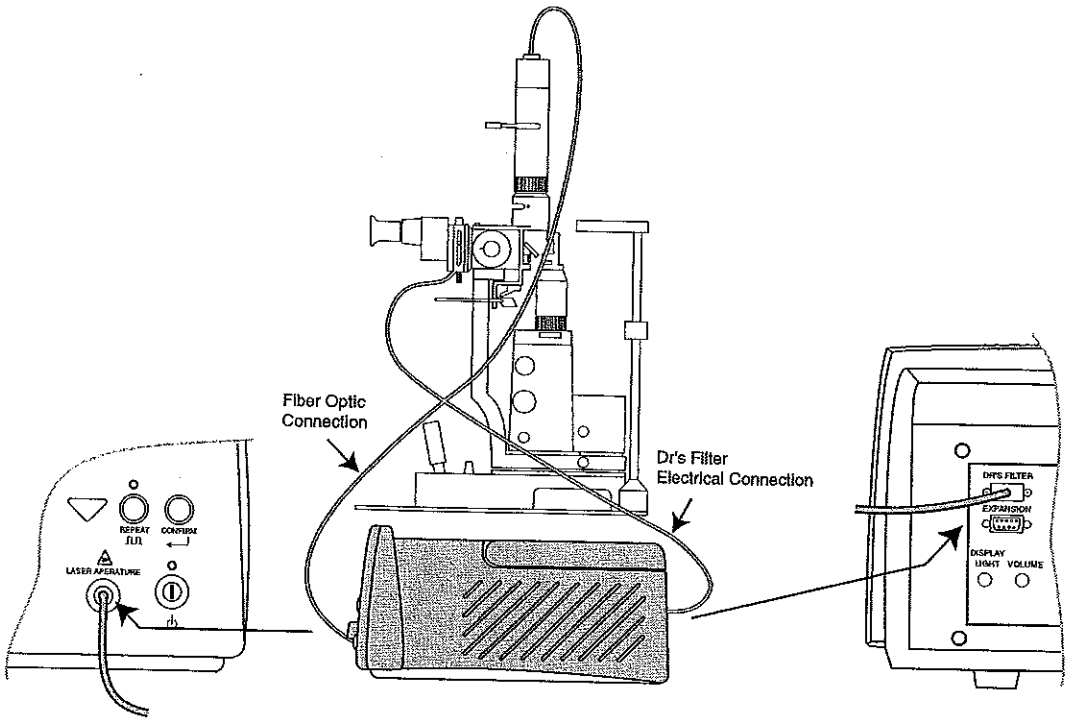


Figure 3-1
Slit Lamp Connections

NOTES: When removing the fiber of Slit Lamp terminal or LIO terminal, connect the dust covers on fibers as well as on the fiber port.

The Endoprobe/Aspirating/Illuminated Endoprobe, the LIO, and the EyeLite® 3000LE® Bridge are accessories for the EyeLite®; refer to Section Six for connection instructions.

2 Connect Dr's Filter electrical connection to Dr's Filter port on rear panel.

SYSTEM POWER UP

This procedure outlines the sequence required to properly turn EyeLite® power ON. See Figure 3-2 for a flowchart of this procedure.

WARNINGS!

Performing procedures other than those specified herein may result in hazardous laser radiation exposure.

Everyone present in the treatment room must wear protective eye goggles 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.

1 Put on protective eye goggles.

2 Place the rear panel power switch in the ON position. The green power indicator on the rear panel illuminates. Verify the Remote Connector is plugged in.

3 Turn the key to the a ON (horizontal) position. The Front Panel display illuminates 0.00 first, then the start-up message is displayed, and all LEDs repeatedly flash the number eight (8). VX.XX reflects the software revision of the system.

WARNING!

If a front panel LED or any segment of an LED does not illuminate during the initial flashing sequence, call Alcon Technical Services.

NOTE: If the optical fiber is not connected, the aiming beam will stay off and the following message will be displayed: "Connect fiber".

4 Select the terminal to be used by pressing the Terminal Selection key. Confirm selection by pressing the Confirm key.

WARNING!

It is the operator's responsibility to properly select and confirm the terminal used. Alcon shall not be held liable for problems caused by a mis-selection or mis-confirmation of the terminal used.

The following laser settings listed in Table 3-1 appear on the front panel as the system comes up in the STANDBY SAFETY position according to your selection:

TABLE 3-1
DEFAULT SETTINGS

	Slit Lamp	Endo Probe	Laser Indirect Ophthalmoscope
Power	0.03 Watt	0.05 Watt	0.1 Watt
Exposure time	0.2 second	0.2 second	0.2 second
Aim Intensity	Potentiometer Selection	Potentiometer Selection	Potentiometer Selection
Firing mode*	Single shot	Single shot	Single shot

* If repeat mode is selected, the default setting for Interval time duration is 300 ms.

5 • For LIO selection, continue to step 5.1.

• For Slit Lamp and Endo selections go to step 6.

5.1 Turn on the LIO Illumination Box.

5.2 Adjust the illumination intensity using the Illumination Intensity Knob.

5.3 Go to step 7.

6 If the Doctor's Filter is in place when the message "Dr's filter in place?" appears on the display, press the Confirm key. If the Doctor's Filter is not in place, put it in place as described in Section Six, then press the Confirm key.

NOTE: When using a bridge with the 3000LE, the message "Check Filter/Bridge" will appear and the aiming beam will not operate if the bridge is not properly connected in Photocoagulation mode. The bridge must be engaged to proceed.

WARNING!
Operator will have a colored view through the Doctor's filter due to blocking of the 532 nm wavelength (green).

7 Set the power to minimum by turning the Power Adjust knob counterclockwise. If the power parameter is not set to the minimum, the message "Set power to minimum" appears on the display.

8 Press the Reset key to reset the shot counter to 0.

NOTE: Shot counter remains set at the value recorded during the last laser operation. The counter is automatically reset to 1 after 9999 shots. The counter can be manually reset to 0 by pressing the Reset key.

You can now adjust power, exposure time, aiming beam power, and select repeat mode if desired.

9 To select Repeat Mode, perform the following steps. Otherwise, go to the Normal Operating Procedure.

9.1 Press the Repeat key for 2-3 seconds. The repeat mode LED illuminates.

9.2 Adjust Interval time by pressing the Interval Adjustment keys (default is 300 ms, minimum is 100 ms and maximum is 1 second). To return to single shot status, depress the Repeat key.

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.**
- **Depress the Laser ON/OFF button to shut down aiming and treatment lasers. Depress again to return to the System Power Up at step 4.**

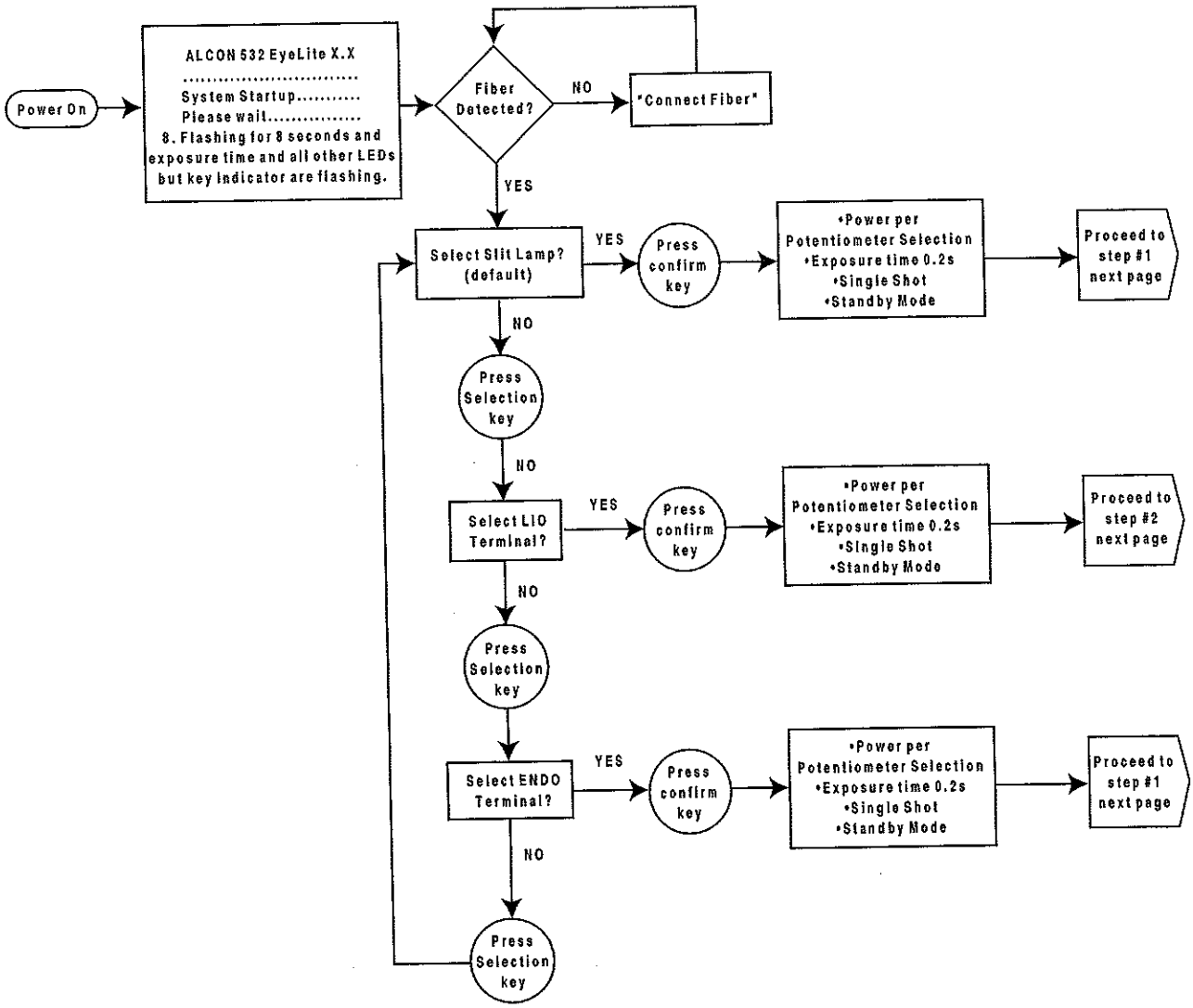


Figure 3-2
Turn On Sequence Flow Chart

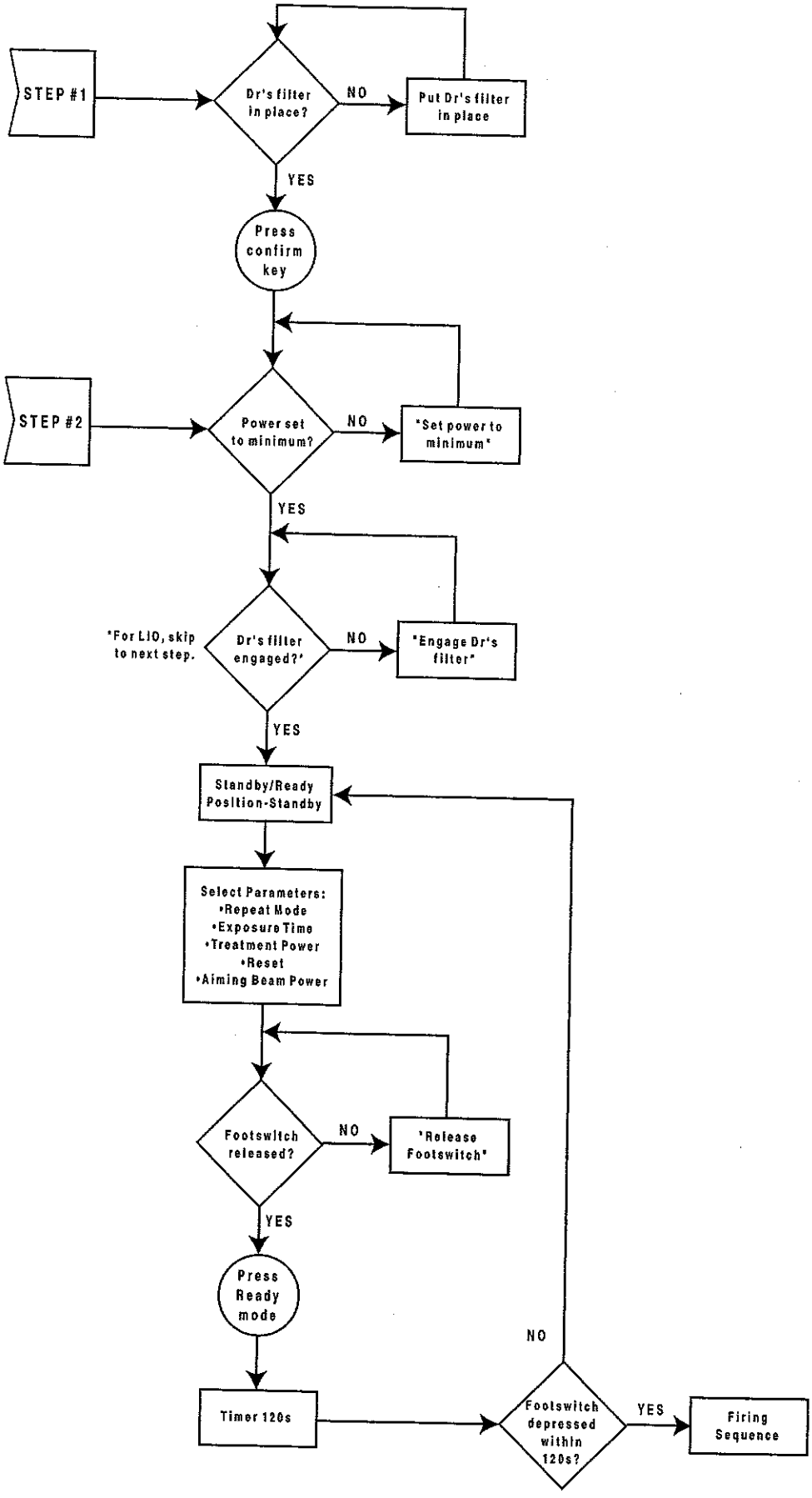


Figure 3-2 (continued)
Turn On Sequence Flow Chart

NORMAL OPERATING PROCEDURE USING A SLIT LAMP

After completing Turn On Sequence, proceed as follows for normal operation.

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

> ***WARNING!***
> **Verify that all personnel are wearing protective goggles, 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.

2 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.**

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

> ***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.**

4
- If using the 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.

5 Press the Standby/Ready key on the front panel. The green Standby LED turns off, and the red READY LED illuminates.

6 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 120 seconds from entry into ready mode, the system emits one beep and switches to standby mode.

NOTE: The aiming beam turns off when the treatment beam fires, except in repeat mode.

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

8 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 lasers by pressing the Laser ON/OFF switch. When turning the switch on again, the system will ask you to select a terminal starting with the Slit Lamp Terminal. All other parameters are set in the default selection.

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 stop button on the front panel should only be used in an emergency. After using the emergency stop button, 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 to 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.

LABELS

Refer to Figure 3-3 for label locations.

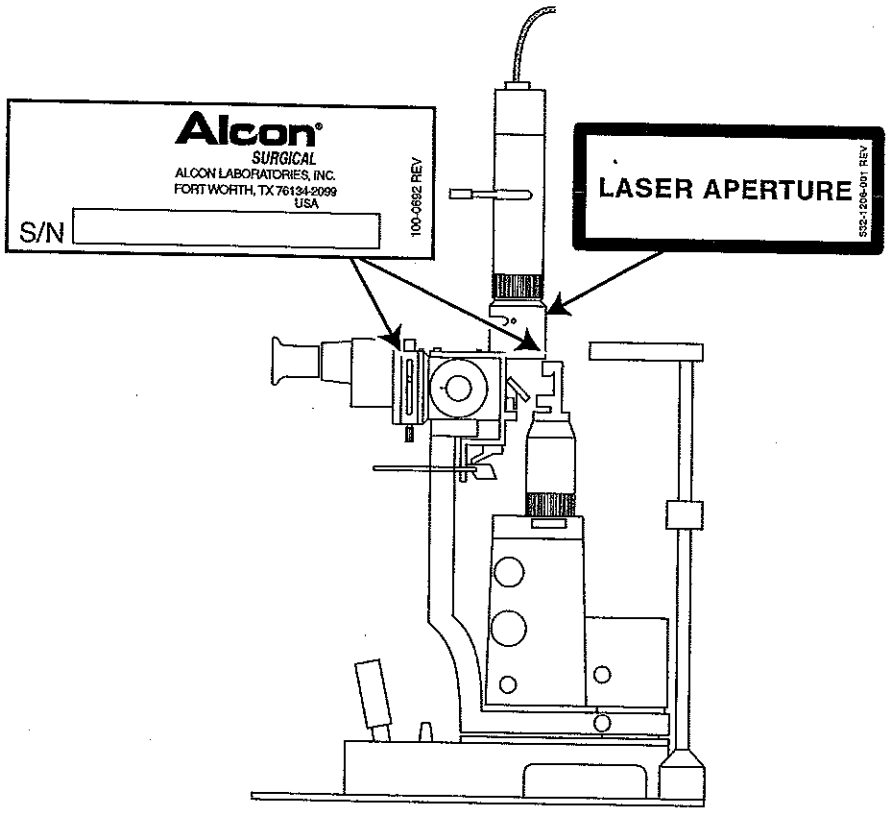


Figure 3-3
Label Location Diagram

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 breakdown circumstances and effects. From these elements, a specialized 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.

When EyeLite® power is on, all individuals in the laser room must wear laser protective goggles, 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, and 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 EyeLite® system:

- Switch off the instrument correctly after each use.
- Cover the slit lamp with the plastic cover provided.
- Cover the fiber optic connector with the dust cover provided.
- Cover the fiber port with the dust cover provided.
- 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 aperture or fiber optic connector.

The condition of the following EyeLite® system hardware components must be checked periodically to identify any fault which might involve incorrect operation of the system:

- 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: Turn system power off and disconnect power cord from the EyeLite® before changing fuses. Use only the recommended fuses for the EyeLite® as listed on the fuse label.

1 Remove the fuse clip from the EyeLite® fuse holder using a small screwdriver. Refer to Figure 4-1 for fuse location.

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

3 Place new fuses in each side of holder in fuse clip (Alcon P/N 130-179, T6.3AH, 250V).

4 Replace fuse clip into the EyeLite® fuse holder. Close fuse holder.

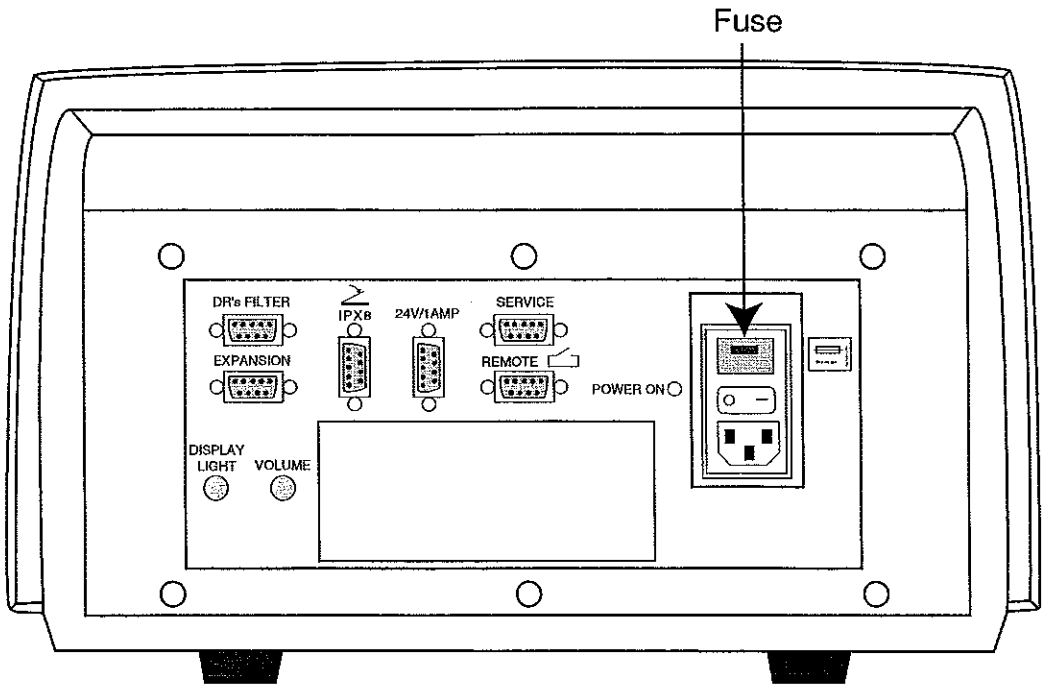


Figure 4-1
Fuse Location on EyeLite® Console

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 Surgical 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.

WARNING!

All personnel in the room during calibration should wear protective goggles, OD 4 or above to filter 532 nm.

Avoid contacting skin and clothing with the laser beam. Severe burns or fire may result.

The following tools are required for the Calibration Verification procedure:

- 1 Wattmeter calibrated to 532 nm wavelength, fast response (Newport 815, Coherent 210 or equivalent).
- 1 Wattmeter cell, fast response.
- 1 Photo cell, fast response (Newport 818SL or equivalent).
- 1 pair of protective goggles (OD 4 or above, at 532 nm wavelength) for each person in the area of the procedure.
- 1 oscilloscope (20 MHz or better).

1.0 SLIT LAMP CALIBRATION VERIFICATION

1.1 Slit Lamp Exposure Time Verification

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

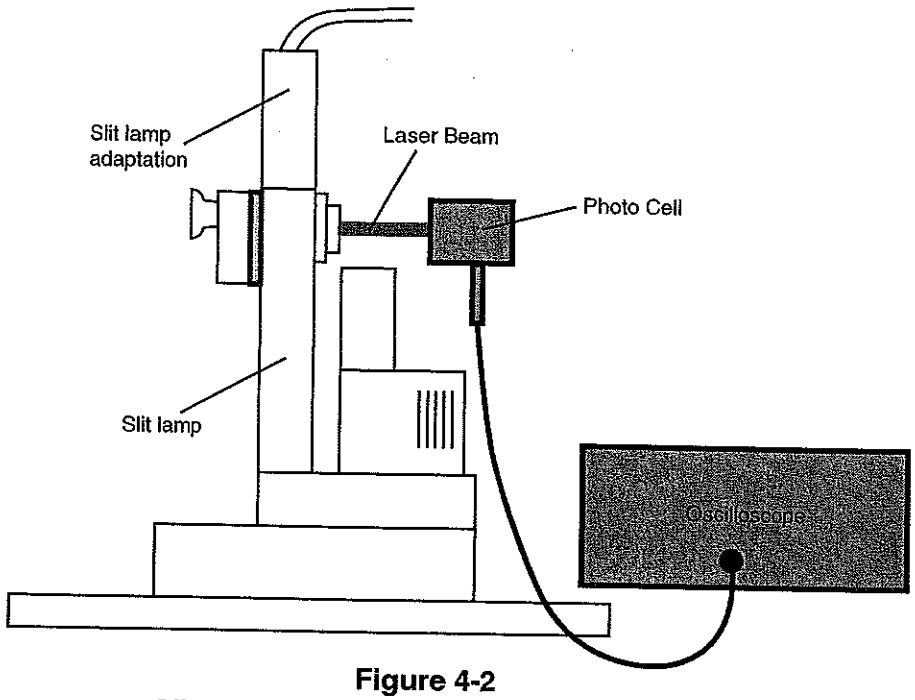


Figure 4-2
Slit Lamp Exposure Time Configuration

1.1.2 Power up the system as detailed in Section Three.

1.1.3 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.

1.1.4 Set the exposure time to 0.05s and treatment beam power to minimum then press the Standby/Ready key.

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

1.1.6 Repeat steps 1.1.4 and 1.1.5 for each value listed in Table 4-1.

Table 4-1
Slit Lamp Exposure Time Verification

EXPOSURE TIME VALUE DISPLAYED ON CONSOLE (seconds)	ACTUAL TIME FROM OSCILLOSCOPE (seconds)
0.05	
0.1	
0.2	
0.3	
0.5	
0.7	
1.0	
1.5	

1.2 Slit Lamp Power Verification

1.2.1 Setup the system as shown in Figure 4-3.

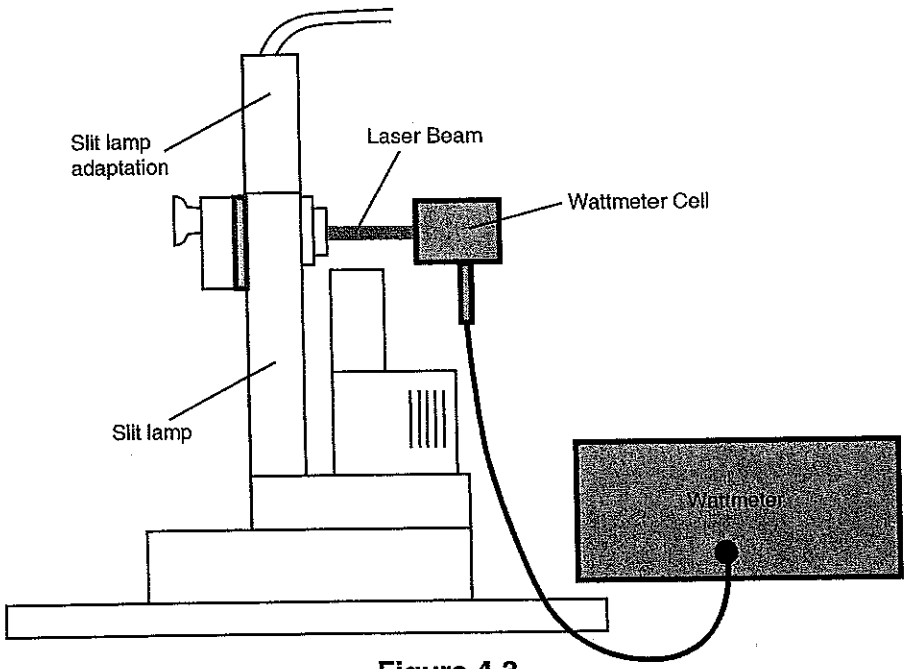


Figure 4-3
Slit Lamp Power Configuration

1.2.2 Set the exposure time to CW.

1.2.3 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.

1.2.4 Set the treatment power to 0.03 then press the Standby/Ready key.

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

1.2.6 Repeat steps 1.2.4 and 1.2.5 for each value listed in Table 4-2.

Table 4-2
Slit Lamp Power Verification

POWER VALUE DISPLAYED ON CONSOLE (Watts)	ACTUAL POWER FROM WATTMETER (Watts)
0.03	
0.2	
0.5	
0.7	
1	
1.5	

1.3 Slit Lamp Energy Matrix

1.3.1 Transfer actual power and time values to Table 4-3. **NOTE: Not all values in Tables 4-1 and 4-2 are entered into Table 4-3.**

Table 4-3
Slit Lamp Energy Matrix

POWER→ (displayed)/actual TIME↓ (displayed)/actual	(0.03)/_____	(0.2)/_____	(0.5)/_____	(1.0)/_____	(1.5)/_____
(0.05)/_____	.001275 .001725	.0085 .0115	.02125 .02875	.0425 .0575	.06375 .08625
(0.1)/_____	.00255 .00345	.017 .023	.0425 .0575	.085 .115	.1275 .1725
(0.3)/_____	.00765 .01035	.051 .069	.1275 .1725	.255 .345	.3825 .5175
(0.7)/_____	.0179 .0242	.119 .161	.2975 .4025	.595 .805	.8925 1.2075
(1.5)/_____	.03825 .05175	.255 .345	.6375 .8625	1.275 1.725	1.9125 2.5875

1.3.2 Complete the matrix by multiplying actual power by actual time and recording the result.

1.3.3 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, perform the calibration procedure or call Alcon Technical Services.

2.0 LIO CALIBRATION VERIFICATION

2.1 LIO Exposure Time Verification

2.1.1 Setup the system as shown in Figure 4-4.

- Position the reflection mirror to 45 degrees; 90 degrees with respect to the headset axis.
- Position the power meter approximately 250 mm ±40 mm from the headset axis.
- The beam must be centered on the surface of the power meter and approximately 1/4 inch in diameter.

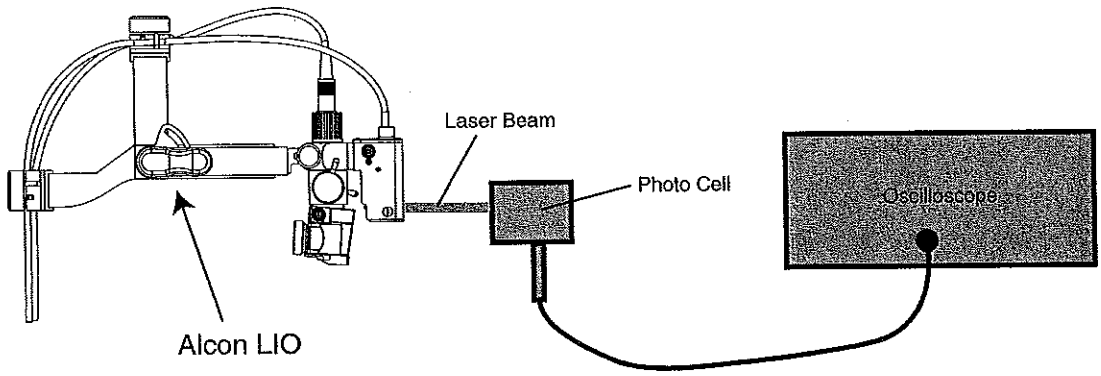


Figure 4-4
LIO Exposure Time Configuration

2.1.2 Use the aiming beam to create an appropriate beam size on the face of the photo cell.

2.1.3 Set the exposure time to 0.05 s and treatment beam power to minimum then press the Standby/Ready key.

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

2.1.5 Repeat steps 2.1.3 and 2.1.4 for each value listed in Table 4-4.

Table 4-4
LIO Exposure Time Verification

EXPOSURE TIME VALUE DISPLAYED ON CONSOLE (seconds)	ACTUAL TIME FROM OSCILLOSCOPE (seconds)
0.01	
0.1	
0.3	
0.7	
1.5	

2.2 LIO Power Verification

2.2.1 Setup the system as shown in Figure 4-5.

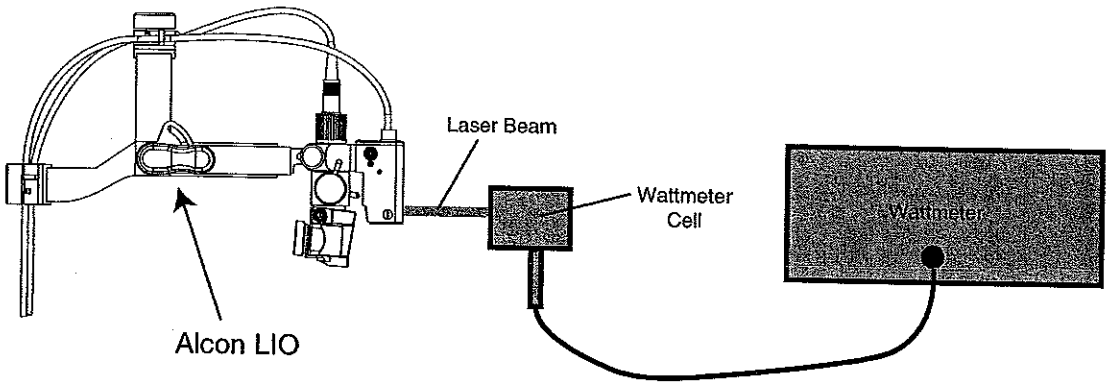


Figure 4-5
LIO Power Configuration

2.2.2 Set the exposure time to CW.

2.2.3 Set the treatment power to 0.1 W then press the Standby/Ready key.

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

2.2.5 Repeat steps 2.2.3 and 2.2.4 for each value listed in Table 4-5.

Table 4-5
LIO Power Verification

POWER VALUE DISPLAYED ON CONSOLE (Watts)	ACTUAL POWER FROM WATTMETER (Watts)
0.1	
0.2	
0.5	
1.0	
1.7	

2.3 LIO Energy Matrix

2.3.1 Transfer actual power and time values to Table 4-6.

Table 4-6
LIO Energy Matrix

POWER ↱ (displayed)/actual TIME ↳ (displayed)/actual	(0.1)/_____	(0.2)/_____	(0.5)/_____	(1.0)/_____	(1.7)/_____
(0.01)/_____	.00085 .00115	.0017 .0023	.00425 .00575	.0085 .0115	.01445 .01955
(0.1)/_____	.0085 .0115	.017 .023	.0425 .0575	.085 .115	.1445 .1955
(0.3)/_____	.0255 .0345	.051 .069	.1275 .1725	.255 .345	.4335 .5865
(0.7)/_____	.0595 .0805	.119 .161	.2975 .4025	.595 .805	.8500 1.3685
(1.5)/_____	.1275 .1725	.255 .345	.6375 .8625	1.275 1.725	2.1675 2.9325

2.3.2 Complete the matrix by multiplying actual power by actual time and recording the result.

2.3.3 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, perform the calibration procedure or call Alcon Technical Services.

3.0 ENDOPROBE CALIBRATION VERIFICATION

3.1 Endoprobe Exposure Time Verification

3.1.1 Setup the system as shown in Figure 4-6.

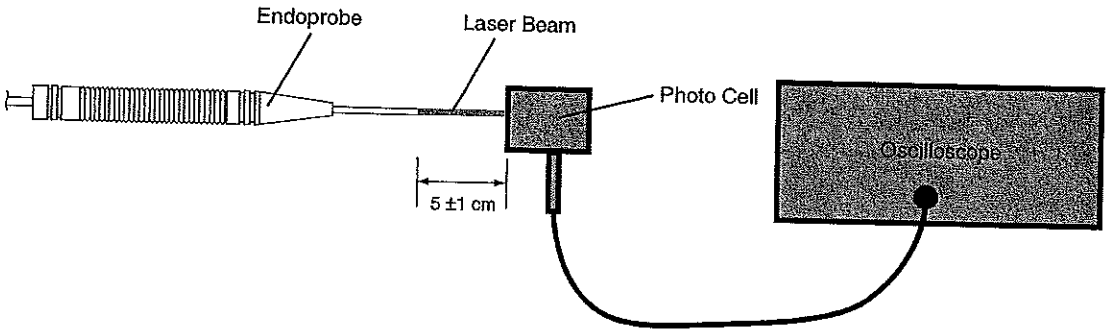


Figure 4-6
Endoprobe Exposure Time Configuration

3.1.2 Use the aiming beam to locate the beam on the face of the photo cell.

3.1.3 Set the exposure time to 0.05 s and treatment beam power to minimum then press the Standby/Ready key.

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

3.1.5 Repeat steps 3.1.3 and 3.1.4 for each value listed in Table 4-7.

Table 4-7
Endoprobe Exposure Time Verification

EXPOSURE TIME VALUE DISPLAYED ON CONSOLE (seconds)	ACTUAL TIME FROM OSCILLOSCOPE (seconds)
0.05	
0.1	
0.3	
0.7	

3.2 Endoprobe Power Verification

3.2.1 Setup the system as shown in Figure 4-7.

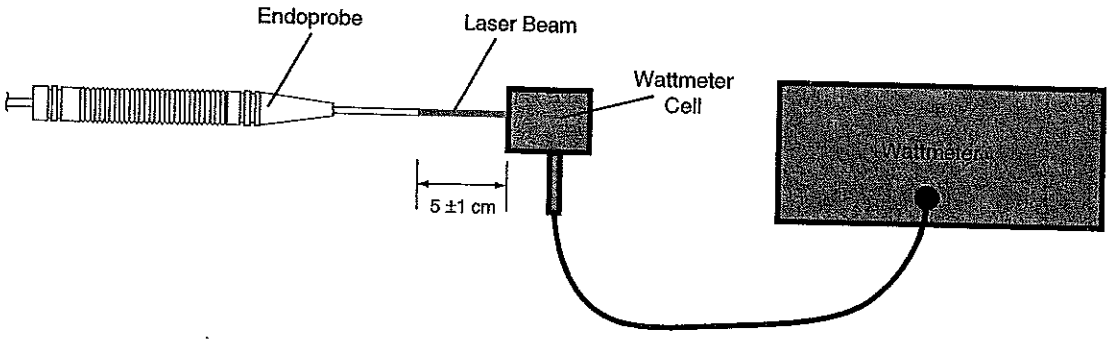


Figure 4-7
Endoprobe Power Configuration

3.2.2 Set the exposure time to CW.

3.2.3 Set the treatment power to 0.05 W then press the Standby/Ready key.

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

3.2.5 Repeat steps 3.2.3 and 3.2.4 for each value listed in Table 4-8.

Table 4-8
Endoprobe Power Verification

POWER VALUE DISPLAYED ON CONSOLE (Watts)	ACTUAL POWER FROM WATTMETER (Watts)
0.05	
0.2	
0.5	
1.0	

3.3 Endoprobe Energy Matrix

3.3.1 Transfer actual power and time values to Table 4-9.

Table 4-9
Endoprobe Energy Matrix

POWER⇨ (displayed)/actual TIME⇩ (displayed)/actual	(0.05)/_____	(0.2)/_____	(0.5)/_____	(1.0)/_____
(0.05)/_____	.002125 .002875	.0085 .0115	.02125 .02875	.0425 .0575
(0.1)/_____	.00425 .00575	.017 .023	.0425 .0575	.085 .115
(0.3)/_____	.01275 .01725	.051 .069	.1275 .1725	.255 .345
(0.7)/_____	.02975 .04025	.119 .161	.2975 .4025	.595 .805

3.3.2 Complete the matrix by multiplying actual power by actual time and recording the result.

3.3.3 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, call Alcon Technical Services.

CALIBRATION PROCEDURE

Calibration requires a software program which is accessible by connecting an ASCII Terminal Service Computer to the EyeLite® with a null modem cable and running a communication program. A password is required to access the program.

Calibration can only be performed for the Slit Lamp and the LIO. It is recommended that all calibration procedures be performed by a trained Alcon Field Service Representative.

Required Tools:

- 1 ASCII Terminal Service Computer - RS232 Connection - communication program.
- 1 NULL MODEM 9-pin connector for terminal.
- 1 Wattmeter calibrated to 532 nm wavelength, fast response.
- 1 pair of protective goggles (OD 4 or above, at 532) nm wavelength for each person in the area of the procedure.
- 1 oscilloscope (20 MHz or better).
- Configuration of RS232 connection:
  - 9600 Baud.
  - No parity bit.
  - 8 data bits.
  - 2 stop bits.

CAUTION

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

WARNINGS!

Most laser safeties are inactive during the calibration procedure; only the Emergency Stop and temperature safeties are active while the program is operating.

Alcon Surgical shall not be liable for any damage or injuries resulting from failure to comply with, or incorrect application of, these instructions.

Never treat a patient when the EyeLite® is connected to a service computer.

If the power is out of tolerance after completing this procedure, contact Alcon Surgical Technical Services and discontinue using the system.

1 Ensure that the EyeLite® and Service Computer are both turned off, and slit lamp fiber or LIO fiber is properly connected to the Laser Aperture SMA connector on the front panel.

2 Connect the Service Computer to the EyeLite® with the null modem cable. The cable connects to the service port on the back panel of the EyeLite®.

3 Turn the Service Computer on.

4 Start the communications program.

5 Turn the EyeLite® on. After approximately 8 seconds, the Service Computer will prompt you for a password.

6 Enter the password: ALCON532

The following warning appears on the computer display.

WARNING!

It is operator's responsibility to comply with the safety regulations and all personnel in the room must wear goggles with an OD 4 or above at 532 nm. By typing the password in the next step, you are agreeing that you have read, understand, and will comply with the procedure.

It is operator's responsibility to strictly follow the calibration procedure. Non-compliance with this procedure could result in a miscalibration of the system and patient injury. Each time a calibration is done, the operator must verify that the system is in compliance with the Energy Matrix provided in the Calibration Verification procedure. If the system still does not comply with the Energy Matrix, the operator must call Alcon Technical Services for assistance and discontinue using the system.

7 If you agree to comply with the warning, enter the password again: ALCON532
The following screen appears on the display:

```
Ophthalas® 532 EyeLite® Main Menu
1 - Display System Parameters
2 - Calibrate The System
X - Exit Service
```

8 Select item 2. The following screen appears:

```
Data Acquisition in progress - Please Wait...
0<**************************************>100%

Data acquisition is completed.
To continue select the terminal to be calibrated.

WARNING!
IT IS THE OPERATOR'S RESPONSIBILITY TO PROPERLY SELECT
THE TERMINAL USED. ALCON SHALL NOT BE HELD LIABLE FOR
PROBLEMS CAUSED BY MIS-SELECTION OF THE TERMINAL
USED. FAILURE TO COMPLY MAY CAUSE PATIENT AND
OPERATORS TO BE EXPOSED TO HAZARDOUS LASER
RADIATION.

1 - Slit Lamp Terminal Calibration
2 - LIO Terminal Calibration
X - Return to Main Menu

Select an item ->
```

9
- Proceed to step 10 for Slit Lamp calibration.
- Proceed to step 11 for LIO calibration.

10 SLIT LAMP CALIBRATION

10.1 Select item 1 to calibrate the Slit Lamp terminal. Follow the steps that appear on the display (shown below).

Step 1: Verify that the power meter is properly positioned at the slit lamp output. Use the 1 Watt range.

WARNING
WHEN THE FOOTSWITCH IS DEPRESSED, THE SYSTEM WILL EMIT 1 WATT AT THE OUTPUT. OBSERVE ALL SAFETY REQUIREMENTS.

Step 2: Depress the footswitch and read the actual output power on the power meter.
Step 3: The power meter reading must be between 550 mW and 800 mW. If the reading is not within this range, stop the calibration procedure, do not use the system, and call Alcon Technical Services.

Press <Enter> key to continue.

Enter your reading->

10.2 Enter the power meter reading. The following message appears (a reading of 800 is used as an example):

Step 4: You entered 800; is this correct? Press "Y" to accept the reading; press "N" to re-enter the reading.

Accept the reading? ->

10.3 • If you pressed "N", the above message will appear again so you can verify the new reading.

• If you pressed "Y", the following screen appears:

Your calibration factor is 80 percent.

WARNING
IT IS THE OPERATOR'S RESPONSIBILITY TO PROPERLY SELECT THE TERMINAL USED. ALCON SHALL NOT BE HELD LIABLE FOR PROBLEMS CAUSED BY MIS-SELECTION OF THE TERMINAL USED. FAILURE TO COMPLY MAY CAUSE PATIENT AND OPERATORS TO BE EXPOSED TO HAZARDOUS LASER RADIATION.

1 - Slit Lamp Terminal Calibration
2 - LIO Terminal Calibration
X - Return to Main Menu

Select an item ->

10.4 Select X to return to the Main Menu. The following screen appears:

```
Ophthalas® 532 EyeLite® Main Menu
1 - Display System Parameters
2 - Calibrate The System
X - Exit Service

Select an item ->
```

10.5 Select X to exit the calibration program.

10.6 Turn the EyeLite OFF.

10.7 • If you want to calibrate the LIO terminal:
- Remove the slit lamp fiber from the EyeLite® SMA connector.
- Connect the LIO fiber to the SMA connector.
- Return to step 5.

• If you want to finish calibration, go to step 13.

11 LIO CALIBRATION

11.1 Select item 2 to calibrate the LIO terminal. Follow the steps that appear on the display (shown below).

```
Step 1: Verify that the power meter is properly positioned at the LIO
output. Use the 1 Watt range.

WARNING: WHEN THE FOOTSWITCH IS DEPRESSED, THE
SYSTEM WILL EMIT 1 WATT AT THE OUTPUT. OBSERVE ALL
SAFETY REQUIREMENTS.

Step 2: Depress the footswitch and read the actual output power on the
power meter.
Step 3: The power meter reading must be between 700 mW and 900
mW. If the reading is not within this range, stop the calibration procedure,
do not use the system, and call Alcon Technical Services.

Press <Enter> key to continue.

Enter your reading->
```

11.2 Enter the power meter reading. The following message appears (a reading of 800 is used as an example):

```
Step 4: You entered 800; is this correct? Press "Y" to accept the reading;
press "N" to re-enter the reading.

Accept the reading? ->
```

11.3 • If you pressed "N", the above message will appear again so you can verify the new reading.

• If you pressed "Y", the following screen appears:

```
Your calibration factor is 80 percent.

WARNING
IT IS THE OPERATOR'S RESPONSIBILITY TO PROPERLY SELECT
THE TERMINAL USED. ALCON SHALL NOT BE HELD LIABLE FOR
PROBLEMS CAUSED BY MIS-SELECTION OF THE TERMINAL
USED. FAILURE TO COMPLY MAY CAUSE PATIENT AND
OPERATORS TO BE EXPOSED TO HAZARDOUS LASER
RADIATION.

1 - Slit Lamp Terminal Calibration
2 - LIO Terminal Calibration
X - Return to Main Menu

Select an item ->
```

11.4 Select X to return to the Main Menu. The following screen appears:

```
Ophthalas® 532 EyeLite® Main Menu
1 - Display System Parameters
2 - Calibrate The System
X - Exit Service

Select an item ->
```

12 Select 1 to display the system parameters or X to exit the calibration program.

NOTE: If you select to display the system parameters, the following screen appears giving you a summary of calibration coeffecients and operational parameters of the laser head. Pressing the Enter key returns you to the Main Menu.

NOTE: Numbers shown in this screen are for illustrative purposes only.

```
EyeLite 532 System Parameters...

Accumulated Shots Count.....74703
Laser Head Serial No.....XXXXX
Pmon 1 Threshold.....3
Pmon 2 Threshold.....3
Power Offset.....4
Conversion Factor.....190
Simmer Value.....736
Language.....English
SLIT_LAMP Terminal Efficiency.....80 Percent
LIO Terminal Efficiency.....80 Percent
ENDO Terminal Efficiency.....90 Percent
Service Required.....0

Press <Enter> key to continue->
```

13 Turn the computer and the EyeLite® off, and remove the null modem cable connecting the EyeLite® to the computer.

14 Restart the EyeLite® and perform the Calibration Verification procedure.

SECTION FIVE
TROUBLESHOOTING

ERROR AND FAULT MESSAGES

Error and fault messages are shown on the display window to warn the operator of a possible failure. Tables 5-1 through 5-4 list the messages that may be displayed. When an error or fault message appears, the operator must turn off the EyeLite® using the key, then restart the system. If the message persists, discontinue use of the system and contact Alcon Technical Services for assistance.

NOTES: Some operating failures detected will allow the surgeon to continue the treatment.

Some operating failures detected will stop the treatment immediately and a system reset will be required.

Some operating failures detected will stop the system completely and a service representative will need to inspect the unit.

Table 5-1
Error Messages

MESSAGE (shown on line four of display)
Footswitch Fault*
Shutter Fault
C3-Detected Fault
Aiming Beam Fault
Exposure Fault
Fiber Fault**
Emergency Shutdown
Laser Fault XX (see Table 5-2)
Software Error XX (see Table 5-3)
Hardware Error XX (see Table 5-4)
Laser Output Fault
Potentiometer Fault***
Service Requested
Calibration Required

* Before turning on the instrument again, verify that the footswitch has been properly connected to the EyeLite® rear panel.

** Before turning on the instrument again, verify that the fiber has been properly and fully connected to the EyeLite® front panel.

*** Do not turn the Power Adjust Knob too fast. This could be interpreted by the system as an error.

Table 5-2
Laser Fault Error

DISPLAYED MESSAGE	FAULT
Laser Fault 01	Over-Current Fault
Laser Fault 02	Over-Voltage Fault
Laser Fault 03	Watchdog Fault
Laser Fault 04	Temperature Fault
Laser Fault 05	OFF Fault
Laser Fault 06	Head Fault
Laser Fault 07	Remote Fault

Table 5-3
Software Fault Error

DISPLAYED MESSAGE	ERROR
Software Error 01	ERROR Process ERROR
Software Error 02	SEND Process ERROR
Software Error 03	POWER Process ERROR
Software Error 04	PULSE Process ERROR
Software Error 05	MAP Process ERROR
Software Error 06	MONITOR Process ERROR
Software Error 07	PEDAL Process ERROR
Software Error 08	RECEIVE Process ERROR
Software Error 09	TIMER Process ERROR
Software Error 10	DATA DUPLICATION ERROR
Software Error 11	MSG QUEUE ERROR
Software Error 12	SEMAPHORE ERROR
Software Error 13	PRIORITY ERROR
Software Error 14	FIBER COEFFICIENT ERROR

Table 5-4
Hardware Fault Error

DISPLAYED MESSAGE	ERROR
Hardware Error 01	CRC ERROR
Hardware Error 02	SERIAL ERROR
Hardware Error 03	PMON ERROR
Hardware Error 04	EPROM ERROR
Hardware Error 05	STARTUP ERROR
Hardware Error 06	DA ERROR
Hardware Error 07	MEMORY ERROR
Hardware Error 08	CPU ERROR
Hardware Error 09	KEYBOARD ERROR
Hardware Error 10	TIMER ERROR
Hardware Error 11	ANALOG ERROR
Hardware Error 12	POWER ERROR

SECTION SIX
ACCESSORIES AND PARTS

This section of the manual contains the various accessories that are available for use with the EyeLite®. The following accessories are described in this section:

* Zeiss is a registered trademark of Carl-Zeiss-Stiflung.

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ENDOPROBE/ASPIRATING ENDOPROBE/ILLUMINATED ENDOPROBE

The Endoprobe, the Aspirating Endoprobe, and the Illuminated Endoprobe are used to perform endophotocoagulation. These probes are sterile medical devices intended for one procedure only. Please refer to the probe container for instructions and warnings regarding the use of these probes.

"Y" CABLE KIT FOR DR. FILTERS

The "Y" Cable Kit for the Zeiss* CS microscope, is used to install two Dr. Filter assemblies. One Dr. Filter is for protecting the surgeon, and the second Dr. Filter is for the observation tube. Please refer to the instructions supplied with the kit for installation. For use see Doctor's Filter (30SL, OPMI 6) on page 6-4.

MEDITEC HAAG-STREIT 900®BQ LINK

Meditec Haag-Streit 900®BQ Link is a slit lamp adaptation for use with the EyeLite® laser for the primary purpose of performing retinal photocoagulation. Please refer to the Link Operator Manual for instructions and warnings regarding the use of the Link.

DOCTOR'S FILTER INSTALLATION FOR SLIT LAMP ZEISS* 30SL AND/OR OPERATING ROOM MICROSCOPE OPMI 6

POSITIONING THE DOCTOR'S FILTER

WARNINGS!

Defeat of the Doctor's Filter interlock switches and/or incorrect installation of the Doctor's Filter to the microscope could result in ocular hazards to the surgeon.

Operator will have a colored view through the doctor's 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.

NOTE: The Dr's Filter is inserted between the binocular and the biomicroscope.

1 Unscrew the binocular setscrew and remove the binocular (see Figure 6-1 for setscrew location).

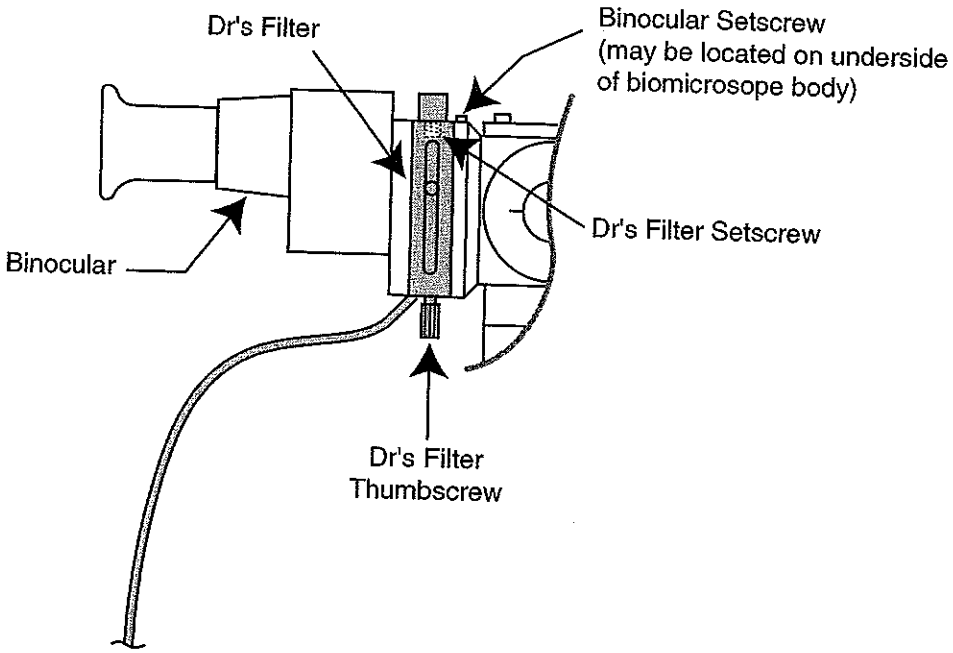


Figure 6-1
Doctor's Filter Mounted on a Biomicroscope

2 Place the Dr's Filter into position on the microscope as indicated in Figure 6-1.

3 Position the binocular in the Dr's Filter and secure using the Dr's Filter thumbscrew.

4 Tighten the Dr's Filter setscrew.

5 Connect the electrical connector to the Dr's Filter port on the EyeLite® rear panel.

6 After installation, go through the start up procedure for the EyeLite® in Section Three. Deactivate the Dr's Filter lever to verify proper function. The message "Engage Dr. Filter" should appear. **If not, do not use the instrument and call Alcon Technical Services.**

WARNING!

It is the operator's responsibility to properly install the Doctor's Filter and verify operation. Using the instrument with a Doctor's 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's Filter.

EYELITE® 3000LE® BRIDGE

INTRODUCTION

The EyeLite® 3000LE® bridge allows both the EyeLite® and 3000LE® lasers to use the same 3000LE® slit lamp for patient treatments. This is done by connecting the EyeLite® laser beam fiber and interconnect cable to the 3000LE® with a special adaptation. When installed, the operator only needs to slide a bridge on the adaptation to the left ("Coagulation" mode) or to the right ("Disruption" mode) to treat the patient with an EyeLite® or 3000LE® laser beam.

WARNINGS!

The EyeLite® 3000LE® Bridge is designed only for 3000LE® systems with version 2.2 software or higher. If necessary, install the proper software prior to installing the Bridge. An inappropriate software version could result in patient injury. This adaptation must be installed by an Alcon trained representative.

SYSTEM CONNECTIONS

Connecting the EyeLite® to a 3000LE® Slit Lamp

WARNINGS!

The 3000LE® Slit Lamp must be equipped with a special Alcon Surgical Slit Lamp adaptation. If peripherals are not correctly connected and confirmed by the operator, the operator and patient will be exposed to hazardous radiation.

Unauthorized installation or removal of the 3000LE® Doctor's Filter from slit lamp may expose the operator to hazardous laser radiation.

The operator will have a colored view through the Doctor's Filter due to blocking of the green 532 nm wavelength light.

1 Connect the fiber optic connection from Slit Lamp Zoom to Laser Aperture SMA connector on the front panel (see Figure 6-2).

NOTE: When removing the fiber of Slit Lamp terminal, connect the dust covers on fibers as well as on the fiber port.

2 Connect Dr's Filter electrical connection to Dr's Filter port on rear panel (see Figure 6-2).

3 Connect Dr's Filter interlock cable to 3000LE® interlock via the bridge cable assembly (see Figure 6-2).

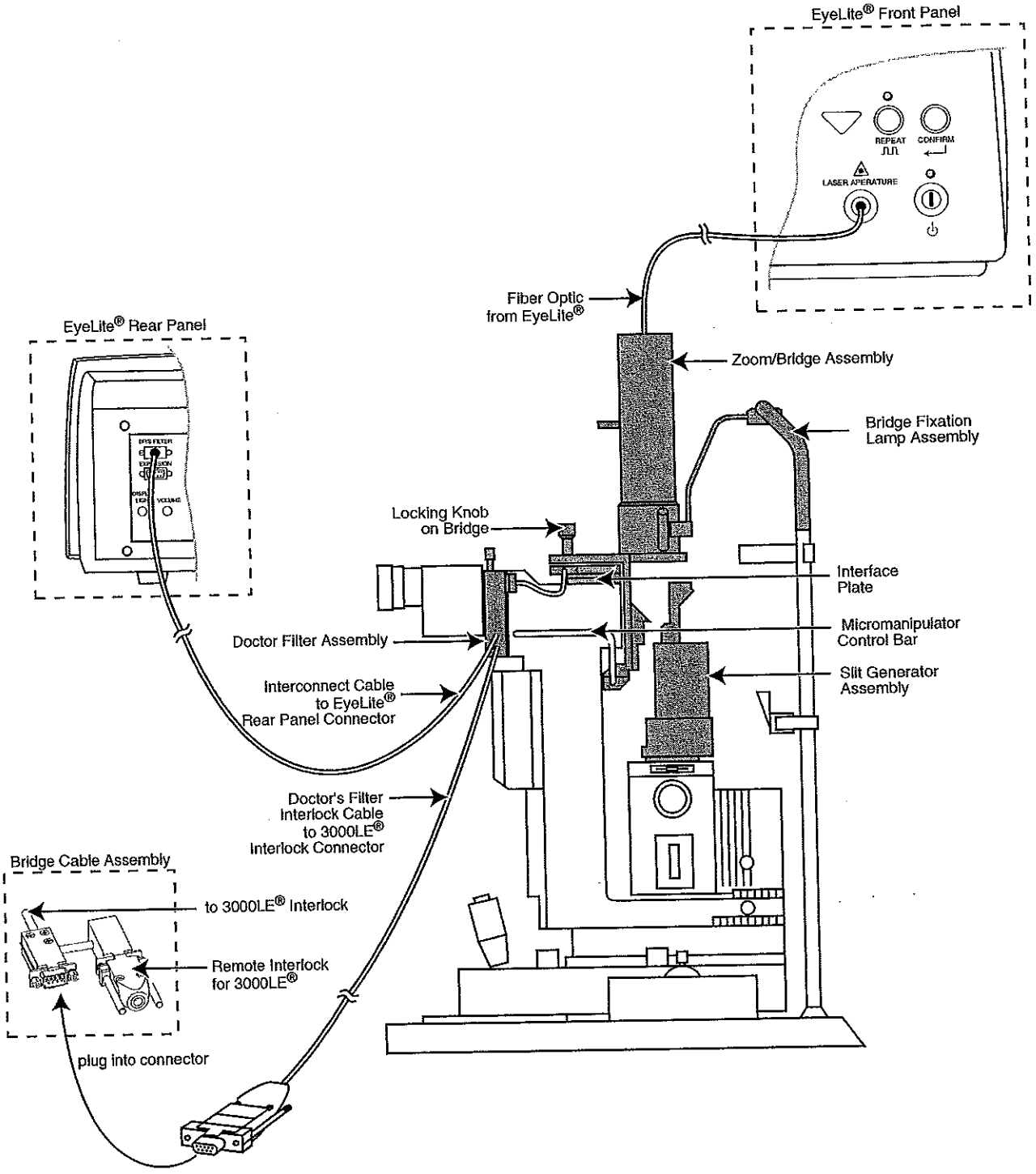


Figure 6-2
EyeLite® 3000LE® Bridge

NOTE: The remote interlock on the 3000LE® bridge cable assembly (see Figure 6-2) should be connected to an emergency master disconnect interlock or to a room/door/ fixture interlock (see Figure 6-3).

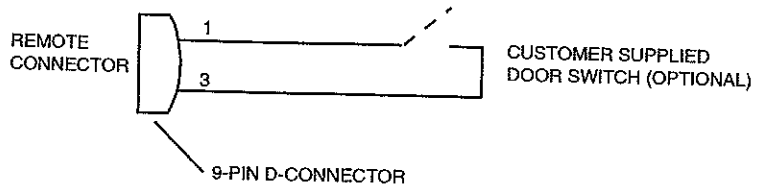


Figure 6-3
Remote Connector/EyeLite® 3000LE® Bridge

To Operate the EyeLite® Laser:

1 Turn the 3000LE® power off.

2 Shift the EyeLite® 3000LE® bridge to the "Coagulation" mode (see Figure 6-4) by pulling up on the bridge locking knob and sliding the zoom assembly to the left. Release the knob and verify that it snaps into its locked position.

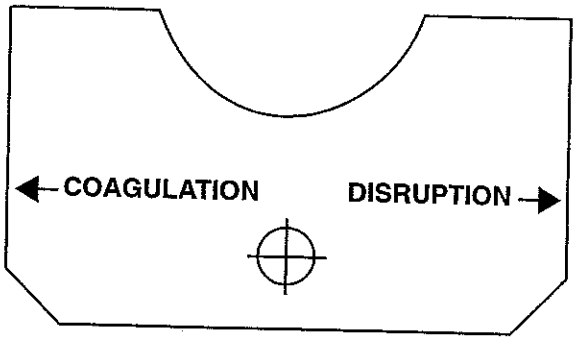


Figure 6-4
Commutation between the EyeLite®
and the 3000LE® Bridge

3 Rotate the slit tower to the center position.

4 Rotate the doctor's filter lever to the engaged position (colored view).

5 Refer to Section 3, Normal Operating Procedure Using a Slit Lamp, for further operating instructions.

To Operate the 3000LE® Laser:

1 Turn the EyeLite® power off (refer to the "Turn Off Sequence" in Section Three of this Operator's Manual).

2 Shift the EyeLite® 3000LE® bridge to the "Disruption" mode (see Figure 6-4) by pulling up on the bridge locking knob and sliding the zoom assembly to the right. Release the knob and verify that it snaps into its locked position.

3 Rotate the slit tower to the right to remove it from the 3000LE® laser beam path.

4 Rotate the doctor's filter lever to the not engaged position (clear view).

5 Turn the 3000LE® power ON and follow instructions in the 3000LE® Operator's Manual.

LABELS

Refer to Figure 6-5 for the location of labels on the 3000LE®:

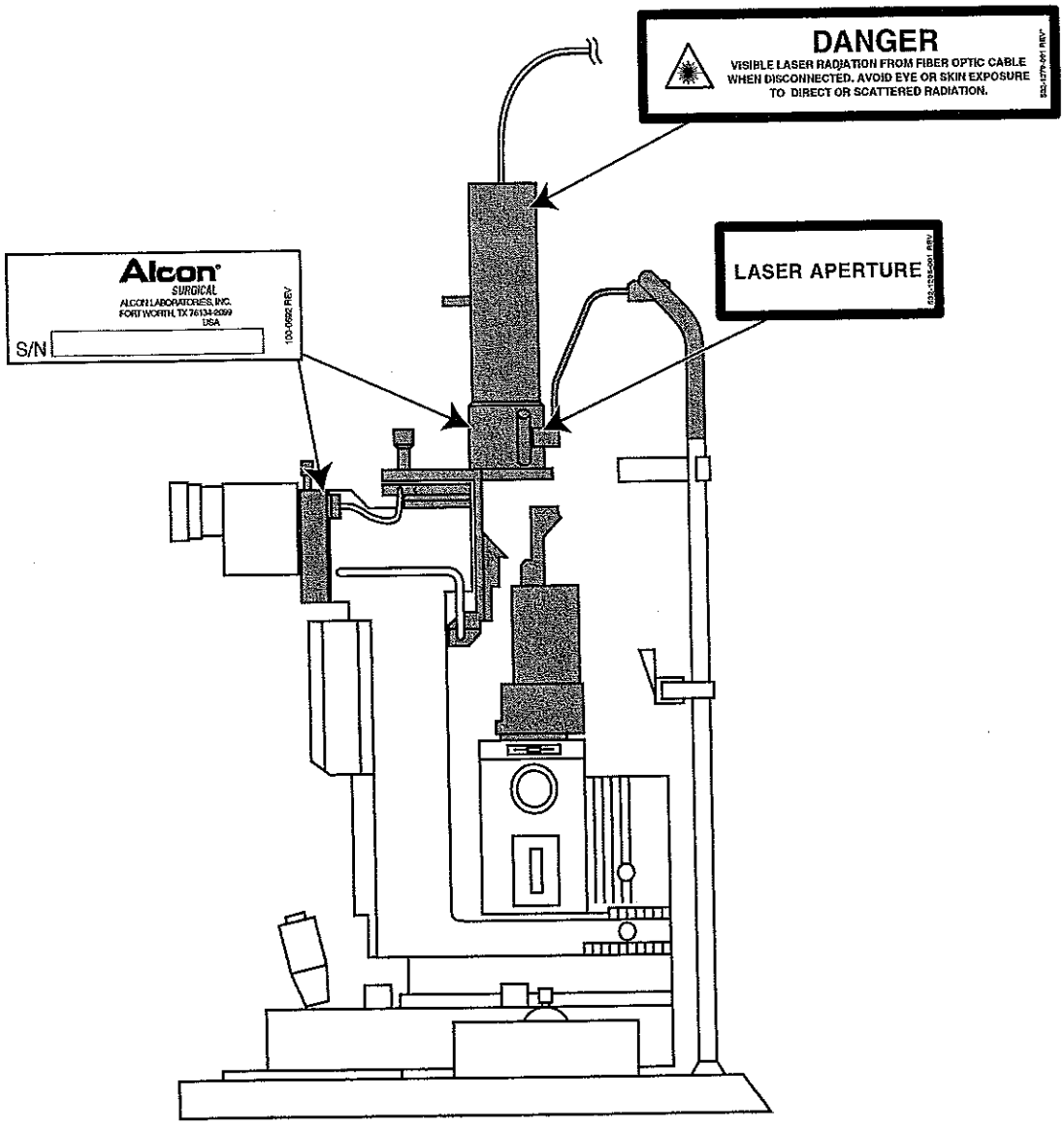


Figure 6-5
Label Location Diagram - 3000LE® Bridge

ZEISS SL130 ADAPTATION

INTRODUCTION

The protective Dr. Filter, fiberoptic cable, mechanical micromanipulator with zoom and stereo microscope extension in combination with the Zeiss* SL130 Slit Lamp are designed exclusively for use with the EyeLite® Laser system. This instrument combination represents a complete ophthalmic unit. Please refer to the Zeiss SL130 Instruction Manual for information not included in this manual.

The micromanipulator with zoom provides interface between the EyeLite® 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 with integral zoom adjusts the laser spot size. The micromanipulator control lever provides additional positioning of the laser spot.

The mandatory protective Dr. Filter provides protection from the 532nm laser radiation for the attending physician. The safety circuit of the EyeLite® 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 EyeLite® 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's 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 goggles (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 SL130 Slit Lamp with a micromanipulator with zoom, a stereo microscope extension, a fiberoptic cable and protective Dr. Filter should only be done by an Alcon Field Service Representative 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 Dr. Filter assembly, the micromanipulator with zoom, and the fiberoptic cable are firmly attached to the slit lamp. The user must also check the Doctor's 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 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 Dr. Filter Assembly); the beam splitter is then attached to the permanently installed Dr. Filter (see Figure 6-7). Improper installation could cause injury to the operator and/or the patient.

WARNINGS!

Verify that the label marking the laser exit aperture is in place. If needed, refer to Figure 6-6 for the location of labels on the Zeiss* SL130.

Never treat a patient when the EyeLite® is connected to a service computer.

Defeat of the Dr's Filter switches and/or incorrect installation of the Dr. Filter assembly could result in ocular hazards to the surgeon.

Please refer to the EyeLite® Operating Instructions in section three for further warnings.

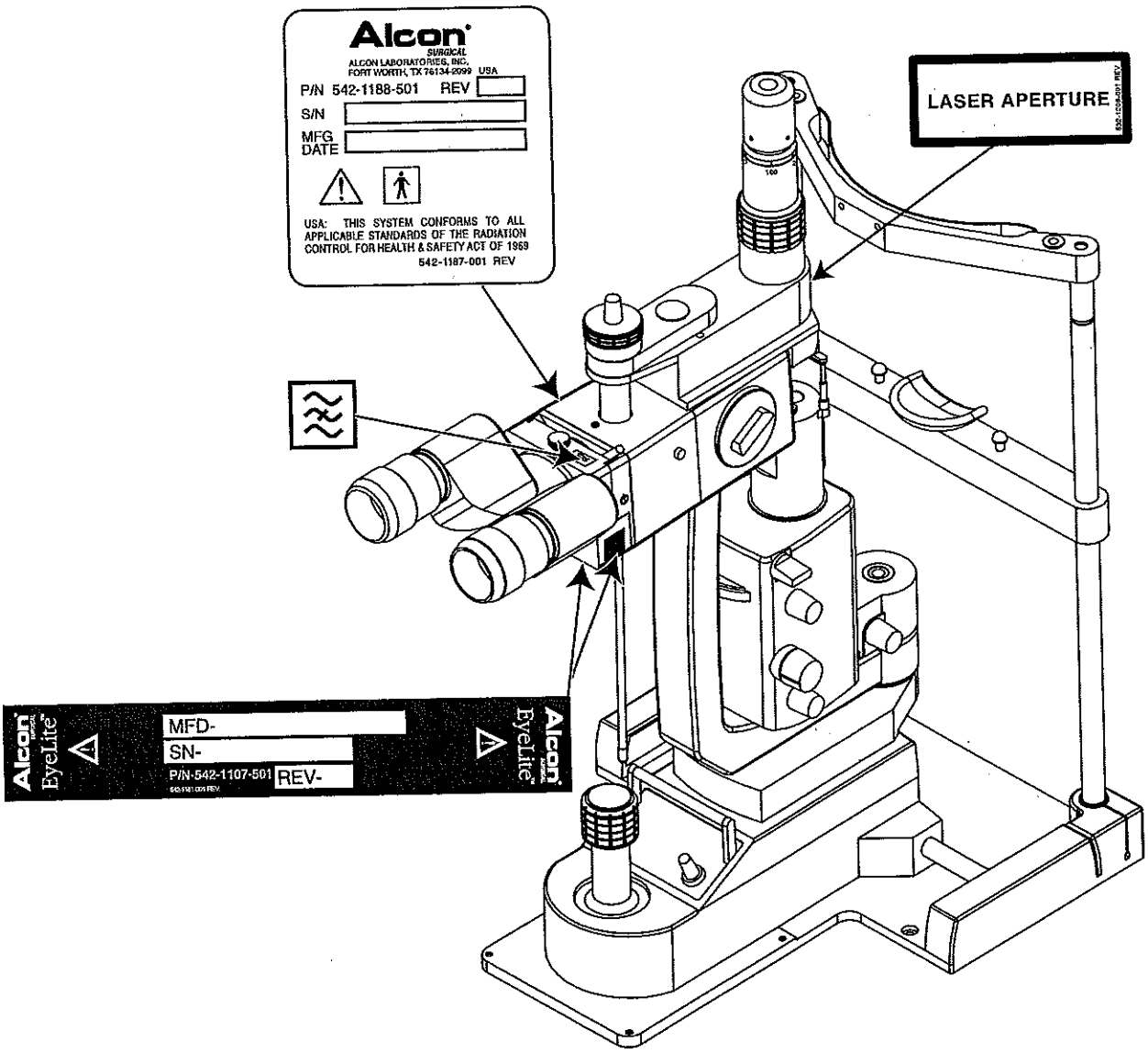


Figure 6-6
Label Location Diagram - Zeiss SL130

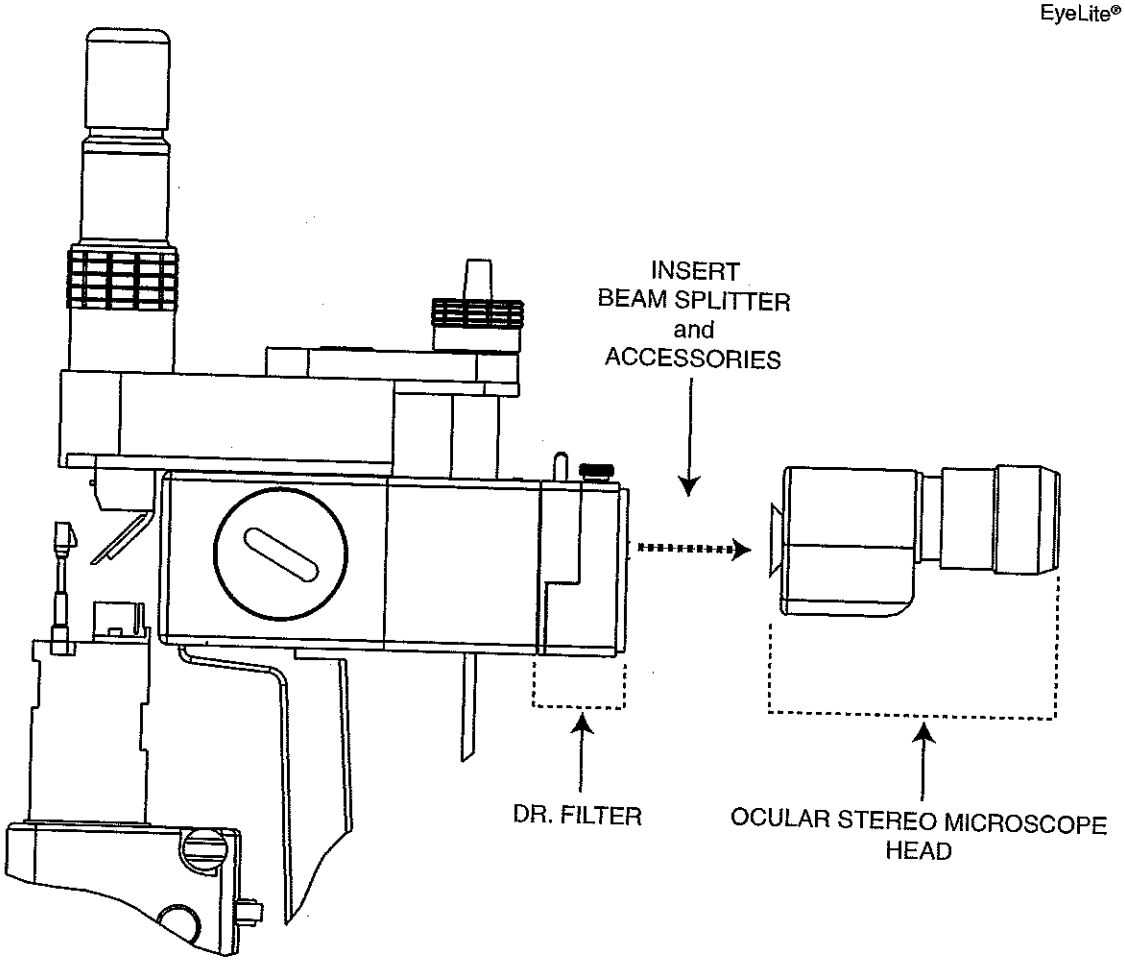


Figure 6-7
Installation of Beam Splitter and Accessories

The following icons are used on the slit lamp adaptation:


Refer to Operator's Manual


532nm Blocking Filter, protected position


Micromanipulator Control Lever, locked position


Micromanipulator Control Lever, free position

CONTROLS

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

Laser Spot Size Adjustment Knob - used to adjust the laser spot size.

Tension Control (for Micromanipulator movement) - used to vary the retracting force of the control lever.

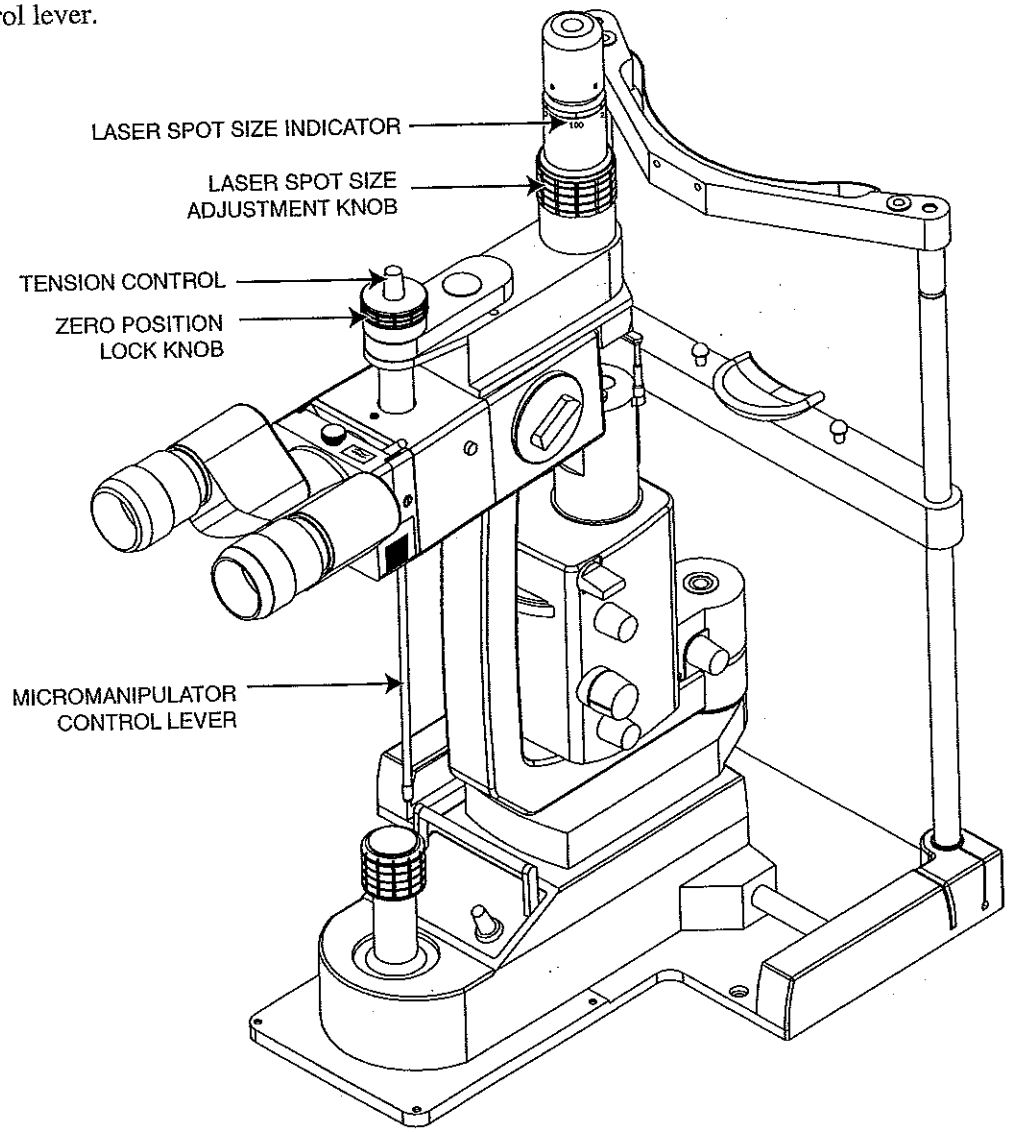


Figure 6-8
Micromanipulator Controls

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

Zero Position Lock Knob - When the lock knob is in the locked position, the laser spot is in the center of the field of view and the micromanipulator control lever is locked at zero. **Inadvertent displacement of the laser is, therefore, mechanically impossible in the zero position.** To reposition the laser spot (i.e., to move the micromanipulator control lever freely) the lock knob must be rotated from the locked position, |●|, to the unrestrained/free position, |●|.

Operation of the Protective Dr. Filter

- Before operating the slit lamp, the Dr. Filter cable must be plugged in and firmly attached to the rear panel of the EyeLite® Laser system (see Figure 6-2).
- The protective Dr. Filter is operated by moving the lever from the unprotected position to the filter engaged (protected) position (see Figure 6-9). The 532nm laser treatment beam is not operational until the filters are in the engaged position.
- 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 Dr. Filter Assembly); the beam splitter is then attached to the permanently installed Dr. Filter (see Figure 6-7).

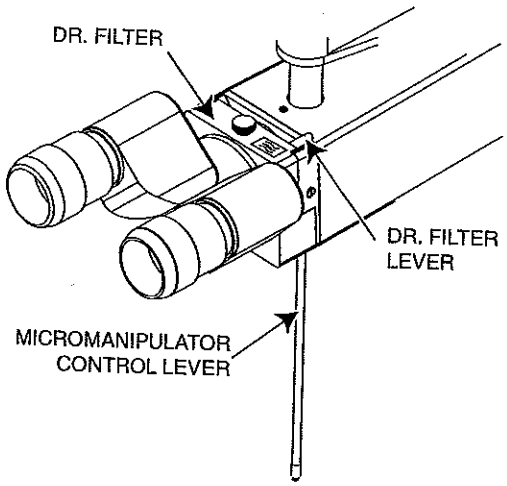


Figure 6-9
Protective Dr. Filter(protected position shown)

Positioning and Focusing the Laser Beam

1 Move the joystick control left to right to horizontally position the laser spot and illumination slits (see Figure 6-10).

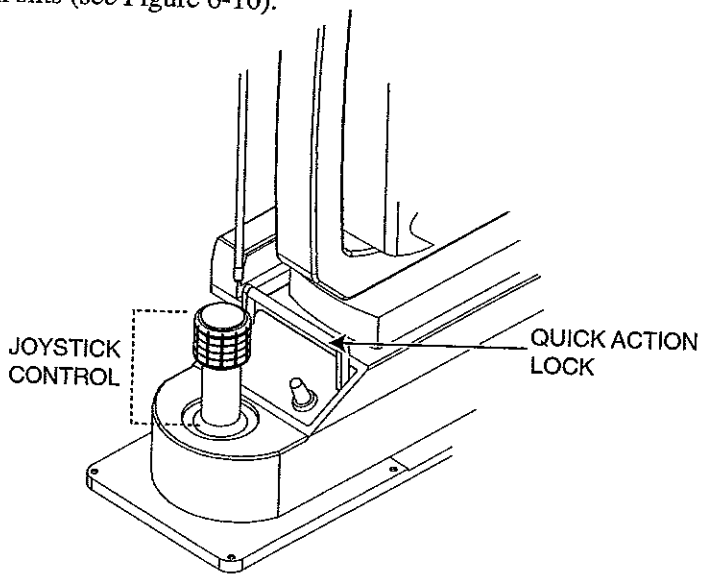


Figure 6-10
Positioning and Focusing the Laser Beam

Positioning and Focusing the Laser Beam (continued)

2 Rotate/twist the knurled area of the joystick control to position the laser spot vertically.

3 Move the joystick control front to back to focus the laser spot.

Adjusting the Laser Position and Spot Size

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

2 To bring the selected area of treatment into position/focus, adjust the joystick control (see Figure 6-10) on the instrument base. If desired, lock the instrument base in position by means of quick action lock.

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

3.1 Using the joystick control shown in Figure 6-10, position the laser spot on the selected treatment area.

3.2 Loosen the micromanipulator zero position lock knob (see Figure 6-8) so that the control lever can be used to position the laser spot around the microscope center field of view.

3.3 Tilt the contact lens.

4 Use the laser spot size adjustment knob (see Figure 6-8) to set the laser spot size.

Laser Treatment of the Eye

1 The protective Dr. Filter must be connected and in working order. To protect the user's eyes, the filters must be in the engaged position prior to the firing of 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).

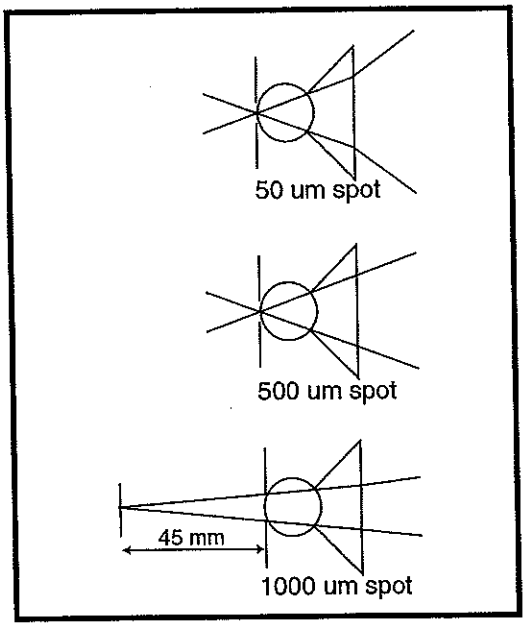


Figure 6-11
Laser Spot Focus

WARNING!

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

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 Release 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 EyeLite® Laser to operate the laser control console and release the laser treatment beam.

TROUBLESHOOTING

Table 6-1 is provided as an aid in troubleshooting. Normal care should be used during the troubleshooting process to prevent the introduction of additional problems.

Table 6-1
SL130 Adaptation Troubleshooting

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

SL 130 Spare Parts Numbers:
Red Blinking Fixation LED (542-1244-001)
6V, 20W Halogen Lamp (143-097)

ALCON LASER INDIRECT OPHTHALMOSCOPE (LIO)

INTRODUCTION

The Alcon Laser Indirect Ophthalmoscope (LIO) is an accessory for use exclusively with the EyeLite®. The Alcon LIO 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 EyeLite®. The operating laser beam output power can be adjusted between 0.10W and 1.7W (minimum).

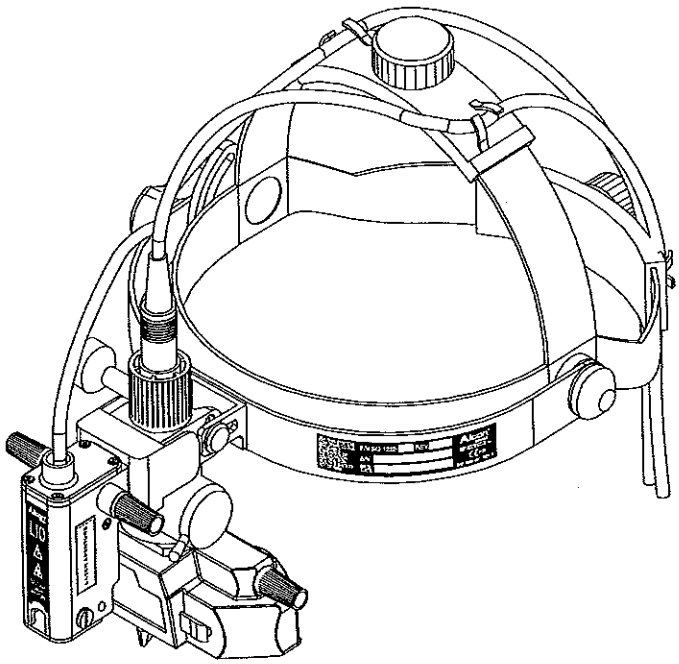


Figure 6-12
The Alcon Laser Indirect Opthalmoscope (CE version shown)

The LIO is connected to the EyeLite® via a fiber optic cable. The LIO headset Illuminator is powered by either a standard desktop power supply or an optional portable battery operated 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 (500 lux for portable) using the illumination control knob on the power supply.

A permanent doctor's filter protects the surgeon against incidental laser beam reflections. The operator will have a colored view through the doctor's filter due to blocking of the 532 nm wavelength (green).

WARNINGS!

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

Use only the illumination power supplies provided with LIO. These are specially designed for medical applications.

Insure that the selection on the EyeLite® 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 view through the doctor's 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 goggles (OD 4 or above at 532 nm) when the system is in "Standby" or "Ready" modes.

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

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 performance by performing an LIO calibration, power output, and energy matrix test every twelve months to ensure the LIO is operating within specifications. See Section Four of this operator's manual for instructions. If the LIO 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.

Never treat a patient when the EyeLite® is connected to a service computer.

Before each use of the headset, the operator must check the permanent doctor's filter shown in Figure 6-17 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 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 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.

ALCON LIO ICONS AND LABELS

The following icons are found on the Alcon LIO and are defined as follows:

Refer to Operator's Manual

Laser Radiation

Laser Aperture

Labeling for the Alcon LIO is shown in Figure 6-13.

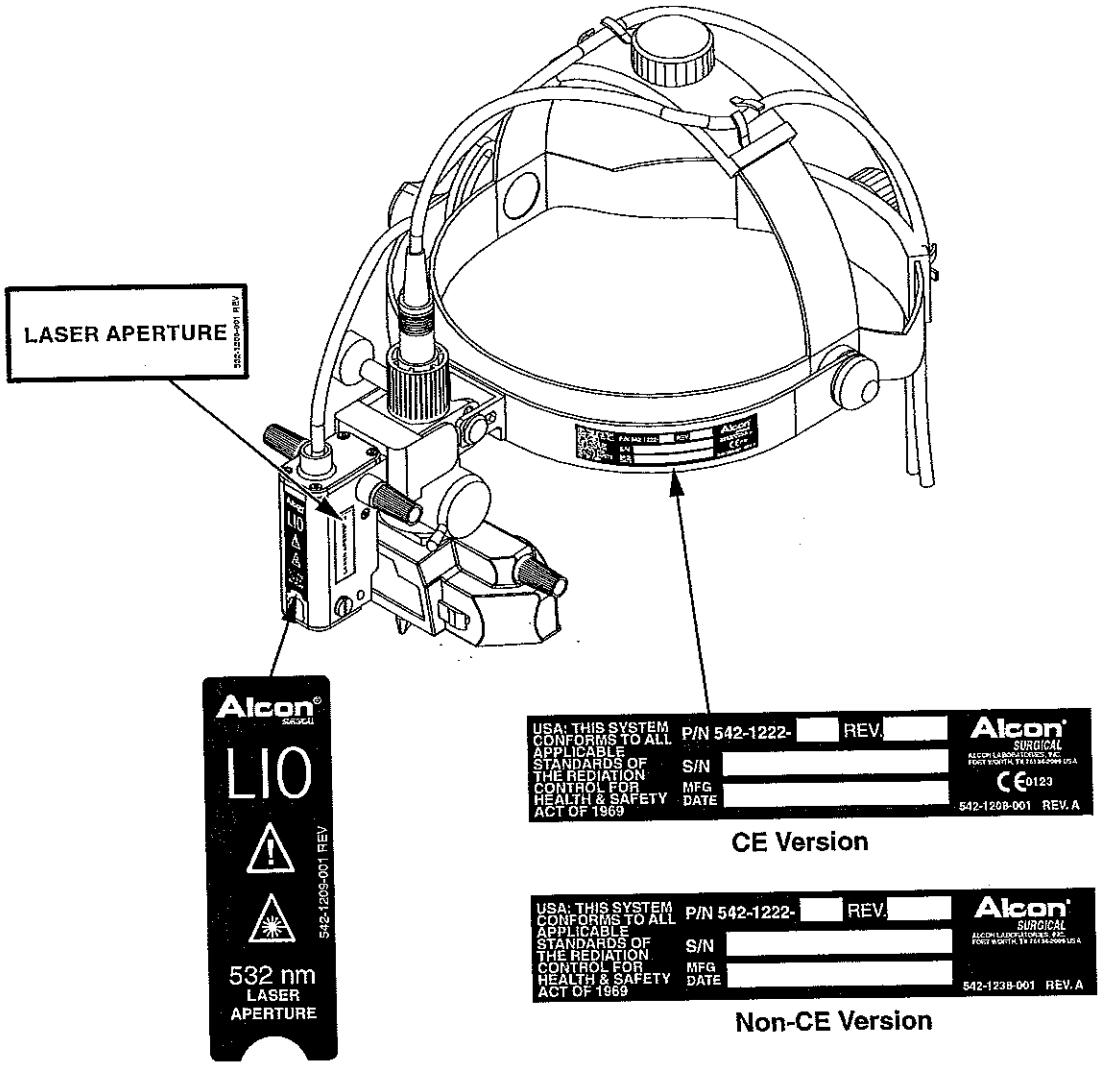


Figure 6-13
Alcon LIO Labeling

Table 6-2
Alcon LIO Technical Specifications

CATEGORY	SPECIFICATION
Dimensions	Width: 30.5 cm (12 inches) Length: 21.5 cm (8.5 inches) Height: 16.5 cm (6.5 inches)
Headset Weight	600 g (.77 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 Humity: 10% to 90% with no condensation
Miscellaneous	EyeLite® 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. Class I, IEC 601-1

ALCON LIO SAFETY FEATURES

- Labels on the instrument warn the operator about laser dangers. These labels are shown in Figure 6-13.
- 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 specially designed aperture.
- A permanent doctor's filter on the LIO 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 stop switch located on the EyeLite® console can be used to shut off power to the laser. After using the emergency stop button, 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 EyeLite® off when not in use.

- Turn the LIO illumination power supply off when not in use.
- Only authorized personnel thoroughly familiar with the recommendations contained in this manual may operate the LIO. 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

POWER SUPPLIES

For information on desktop (Heine EN 20-1) and portable (Heine Accubox II) power supplies refer to the documentation provided with the power supplies.

CONNECTING THE ALCON LIO TO THE EYELITE®

1 Connect the laser fiber from the LIO termination to the Laser Aperture connector on the EyeLite® front panel.

2 Attach the power cord from the LIO to your power supply (see Heine EN 20-1 or Heine Accubox II documentation) and switch on illumination. **Note: Use the extension power cord for the Heine EN20-1 desktop power supply.**

USING THE OPTICS OVERBAND

The swiveling overband allows the laser optics to be pushed up out of the operator's field of view (see Figure 6-14). It is locked in the end position and can only be released by pressing the Overband Adjustment Knob.

To adjust the overband, press the Overband Adjustment Knob with the right hand and adjust 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.

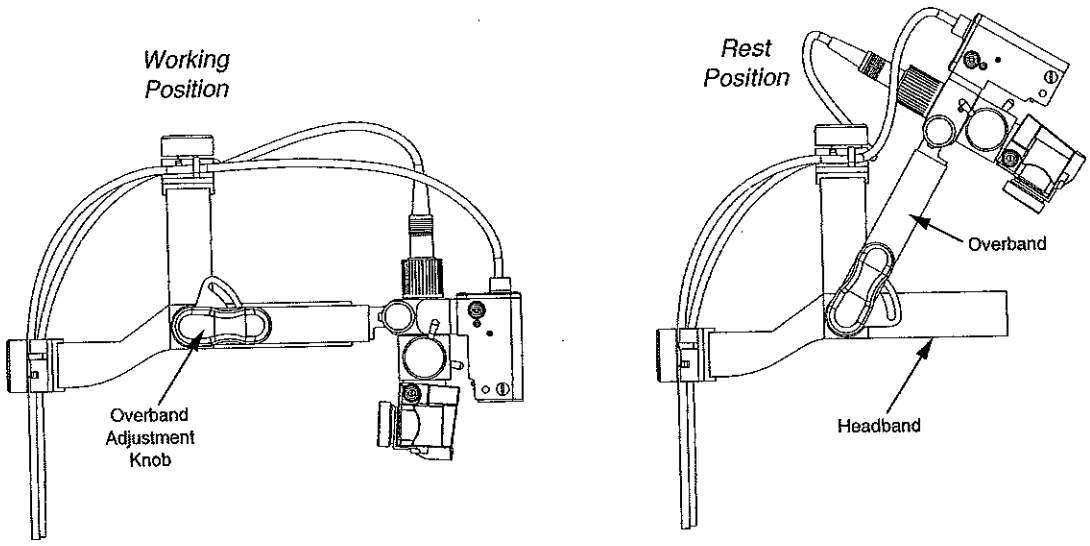


Figure 6-14
Adjusting The LIO Overband

OBSERVATION OPTICS ADJUSTMENT

1 Unscrew the Observation Optics Adjustment Knob so that the Observation Optics are free to move (refer to Figure 6-15). The Observation Optics Adjustment Knob can be unscrewed and reversed to the other side for left-handed operators.

2 Place the LIO 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 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.

4 Using the Illumination 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.

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

6 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.

7 Remove the LIO 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.

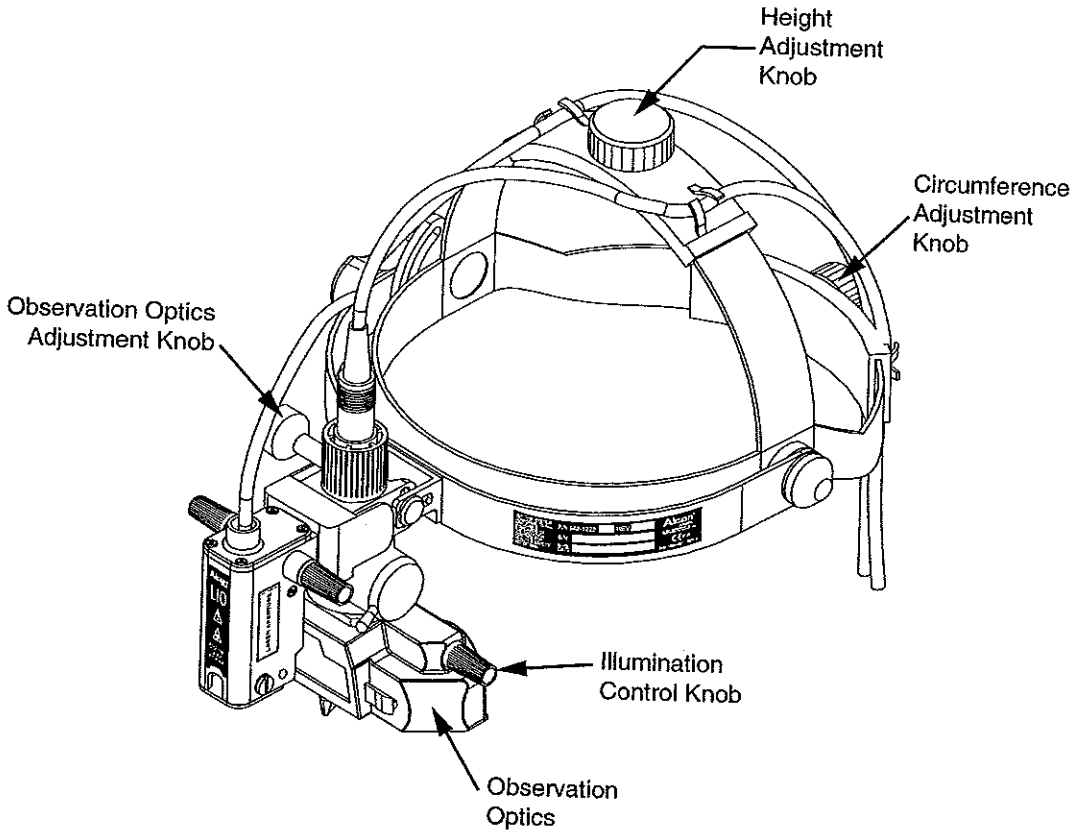


Figure 6-15
Observation Optics Adjustment Knobs (CE version shown)

Controls for observation and illumination (refer to Figure 6-16)

The Aperture Lever allows you to choose three different-sized apertures and one aperture with diffuser. The choice of aperture size depends mainly on the size of the patient's pupil (the medium illumination spot is the recommended setting). In the case of light-sensitive patients (photophobics) and for certain other examinations, e.g. in the periphery, the diffuse aperture setting is recommended.

Green, blue, and yellow filters can be selected with the Filter Lever independent of the selected aperture.

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 medium or small illumination spot size setting, otherwise clipping (shadow) of the illumination spot will occur.**

The Illumination Control Knob can be rotated to move the illumination beam in the vertical plane.

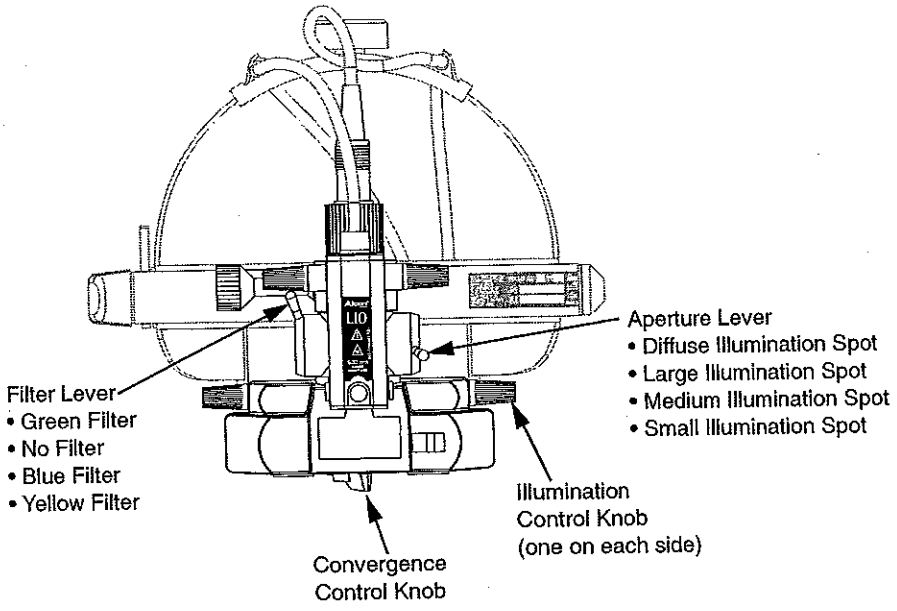


Figure 6-16
LIO Controls for Observation and Illumination

CAUTION

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

USING THE ALCON LIO FOR OBSERVATION

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

1 Turn the Illumination power supply on.

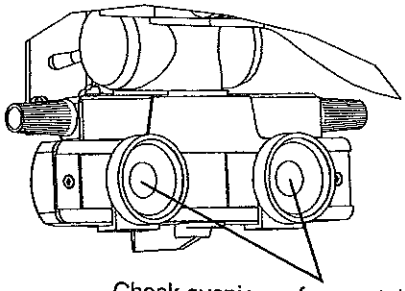
2 Adjust the light intensity with the power supply illumination control knob.

USING THE ALCON LIO FOR LASER TREATMENT

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

> ***WARNING!***
>
> **All the personnel in the room during the operation must wear protective safety goggles with a minimum optical density OD 4 to filter 532nm radiation.**
>
> **Before each use of the headset, the operator must check the permanent doctor's filter for scratches, breaks, or alterations. If there is any doubt, discontinue use of device and please call Alcon Technical Service.**

1 Check the doctor's filter for scratches, breaks, or alterations (see Figure 6-17).



Check eyepieces for scratches, breaks, or alterations in Doctor's filter.

Figure 6-17
Checking the Doctor's Filter on the Alcon LIO

2 Turn the EyeLite® console on and make the appropriate selections as specified in Section Three.

3 Turn on the LIO Illumination power supply.

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

5 Set the power to minimum by turning the Power Adjust knob on the EyeLite® console counterclockwise. If the power parameter is not set to the minimum, the message "Set power to minimum" will appear on the display.

6 Press the Reset key to reset the shot counter to 0.

NOTE: Shot counter remains set at the value recorded during the last laser operation. The counter is automatically reset to 1 after 9999 shots. The counter can be manually reset to 0 by pressing the Reset key.

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

7 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 goggles (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.

8 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.

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

WARNING!

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

10 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.

11 Use the Vertical Control Knob (see Figure 6-18) on the laser delivery adaptation to aim the the laser at the desired location.

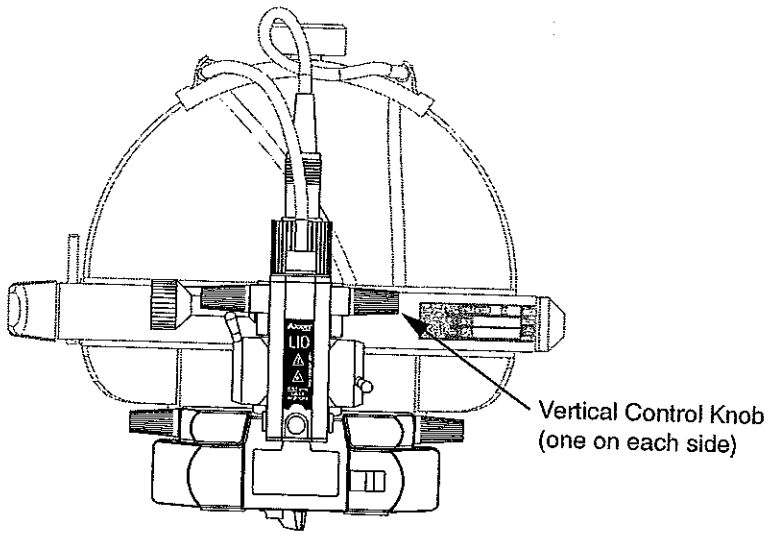


Figure 6-18
Location of Vertical Control Knob for Aiming Laser

12 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 120 seconds 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.

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

14 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 ask you to select a terminal starting with the Slit Lamp Terminal. All other parameters are set in the default selection.

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 stop button on the front panel must only be used in case of emergency. After using the emergency stop button, 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 MAINTENANCE

This section of the manual is designed to inform the operator of 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 the 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's filter for damages or scratches

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

Mirror and Lens Cleaning

The mirrors and lenses of the LIO headpiece 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 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.

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.

Changing The Illumination Bulb

1 Ensure that power switches on the EyeLite® and illuminator power supply are in the OFF (O) position.

2 Disconnect power cords from power source.

3 Pull the Cord Socket away from the Bulb Connector (see Figure 6-19).

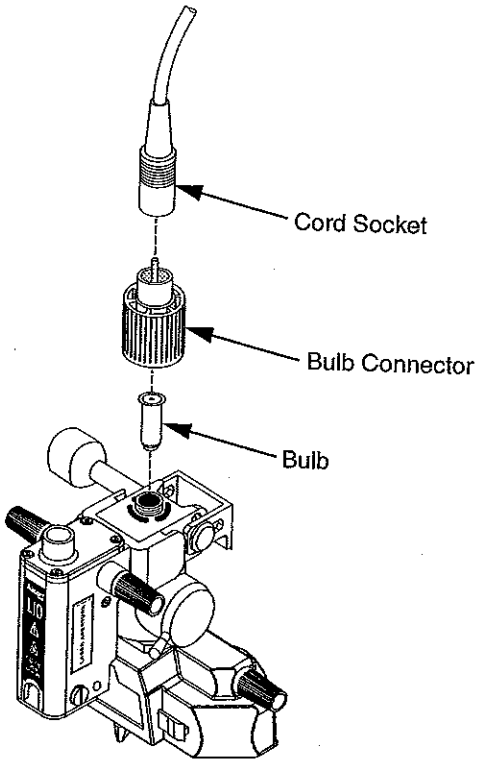


Figure 6-19
Alcon LIO Bulb Replacement

4 Unscrew and remove the Bulb Connector and pull the Bulb out of the socket.

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

CAUTION

Do not touch the glass part of the 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 that the Bulb locating pin engages in the slit in the housing.

7 Rest the Bulb Connector on the base of the Bulb and screw in firmly.

8 Re-connect the Cord Socket.

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 Spare Parts Numbers

Bulb 6V- (P/N: 542-1119-001)
6V NiCd battery for Accubox II (P/N 542-1207-001)
Clip (P/N: 9QF455011)
Power Extension Cable (P/N 542-1204-001)

Alcon LIO Accessories

20 D Lens (301-334)

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ADDENDUM

THIS ADDENDUM IS SHIPPED FOR YOUR CONVENIENCE WITH THE UPGRADE KITS FOR THE LIO-AT, WHICH IS USED EXCLUSIVELY WITH THE *OPHTHALAS®* 532 *EYELITE®* LASER SYSTEM.

PLEASE NOTE THAT THIS ADDENDUM IS DESIGNED TO SUPPLEMENT YOUR *EYELITE®* OPERATOR'S MANUAL, RATHER THAN TO BE USED AS AN INDEPENDENT MANUAL. THEREFORE, PLACE THIS ADDENDUM IN YOUR *EYELITE®* OPERATOR'S MANUAL BEHIND THE "ACCESSORIES AND PARTS" DIVIDER.

ALCON LASER INDIRECT OPHTHALMOSCOPE-ADVANCED TECHNOLOGY (LIO-AT)

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905-5420-104 D, TEXT ONLY

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ALCON LASER INDIRECT OPHTHALMOSCOPE - ADVANCED TECHNOLOGY (LIO-AT)

Introduction

The Alcon Laser Indirect Ophthalmoscope - Advanced Technology (LIO-AT) is an accessory for use exclusively with the *EyeLite®*. 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 *EyeLite®*. The operating laser beam output power can be adjusted between 0.10W and 1.7W (minimum).

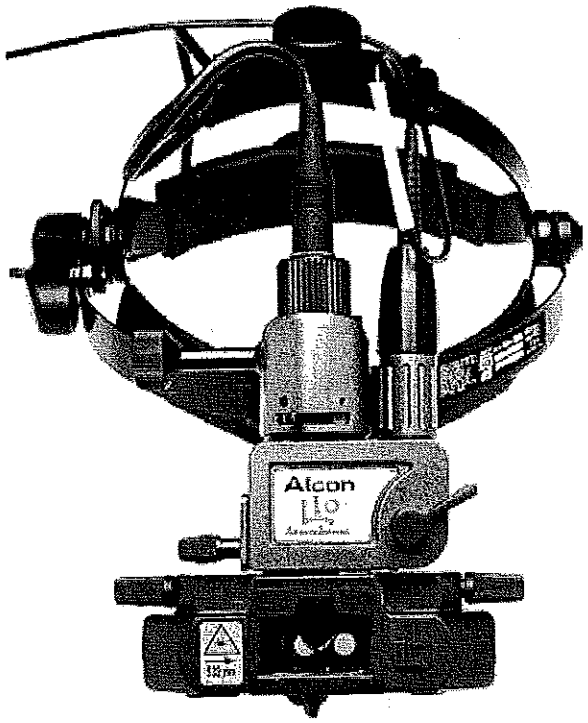


Figure A-1
The Alcon Laser Indirect Ophthalmoscope-Advanced Technology

The LIO-AT is connected to the *EyeLite®* 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 Dr. filter protects the surgeon against incidental laser beam reflections. The operator will have a colored view through the Dr. filter due to blocking of the 532 nm wavelength (green). Catalog numbers for the LIO-AT are listed below.

Catalog Number 8065741106 (120 V)
Catalog Number 8065741107 (230 V)

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 *EyeLite®* 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 Dr. 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 goggles (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 *EyeLite®* is connected to a service computer.

Before each use of the headset, the operator must check the permanent Dr. 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 securing 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

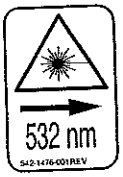
The labels and icons shown in Figure A-2 are found on the Alcon LIO-AT and are defined as indicated.

Refer to Operator's Manual

Duty Cycle

Laser Radiation

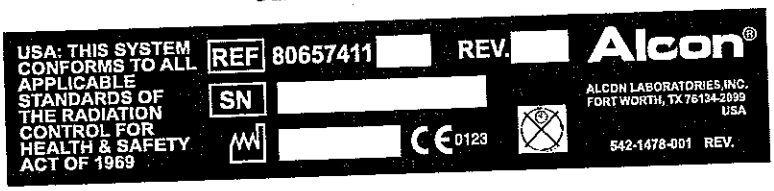
Manufacture Date



Laser Aperture

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

CE Identification Label



cUL-UL Identification Label

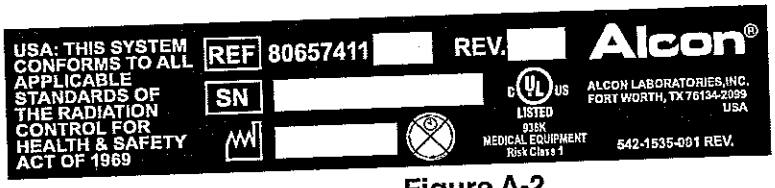


Figure A-2
Alcon LIO-AT Labeling

Table A-1
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®* 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 Dr. 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 stop switch located on the *EyeLite®* console can be used to shut off power to the laser. After using the emergency stop button, 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 *EyeLite®* 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 *EyeLite®*

1. Connect the fiber from the LIO-AT termination to the Laser Aperture connector on the *EyeLite®* 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 A-3). 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.

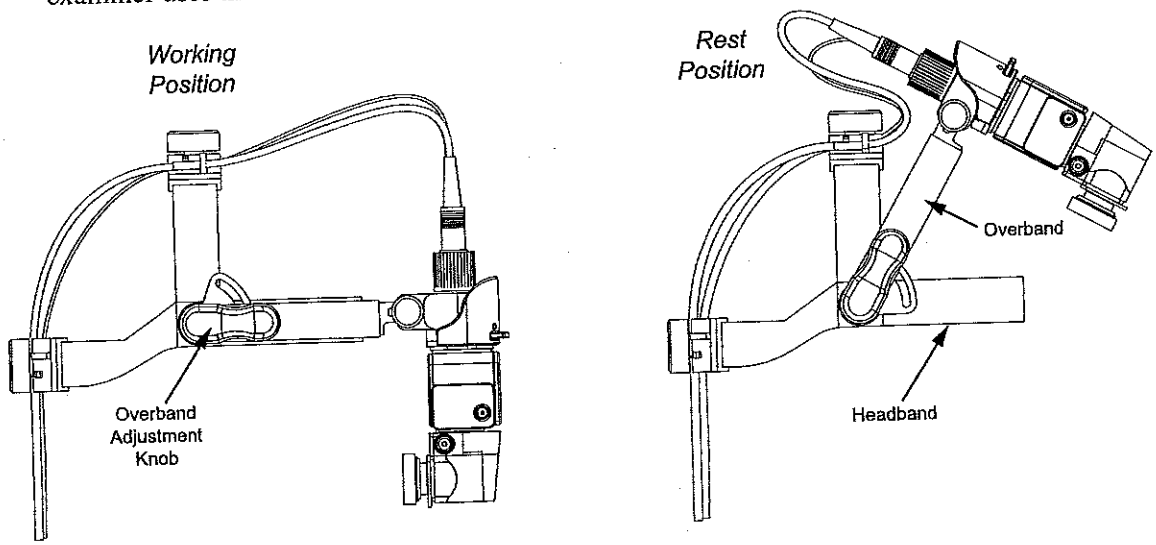


Figure A-3
Adjusting The LIO-AT Overband

Observation Optics Adjustment

1. Loosen the Observation Optics Adjustment Knob (see Figure A-4) 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 A-4) 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.

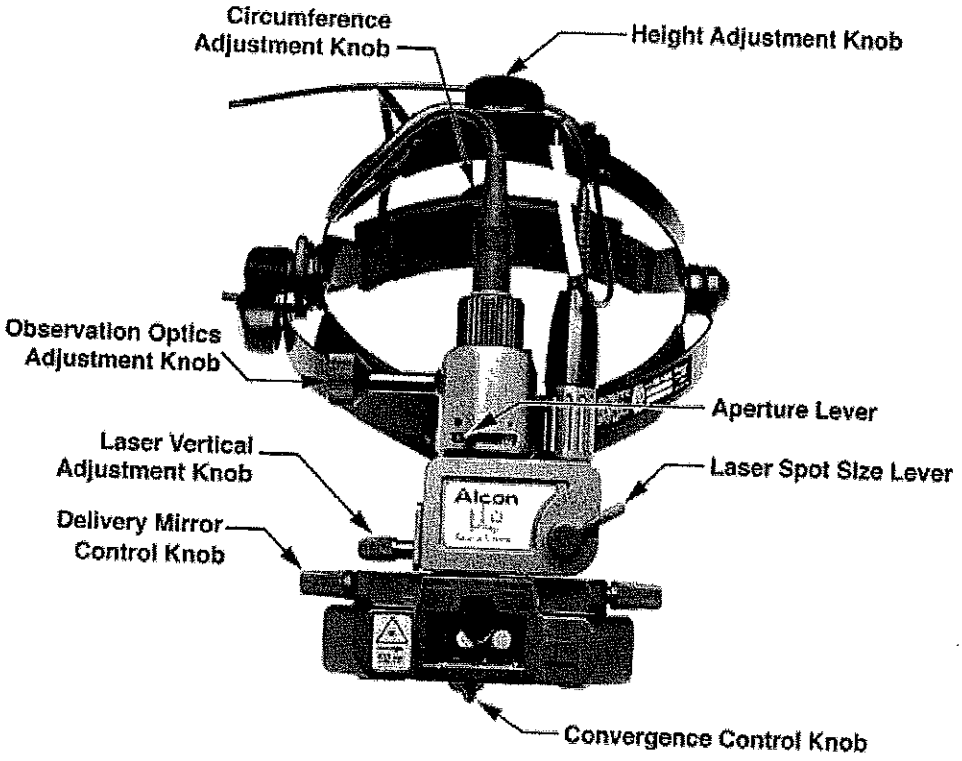


Figure A-4
LIO-AT Controls and Adjustments

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 *EyeLite®*. **Note: Put dust cover on fiber termination to protect fiber when not connected to *EyeLite®*.**

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 goggles with a minimum optical density OD 4 to filter 532nm radiation.**
>
> **Before each use of the headset, the operator must examine the permanent Dr. 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.

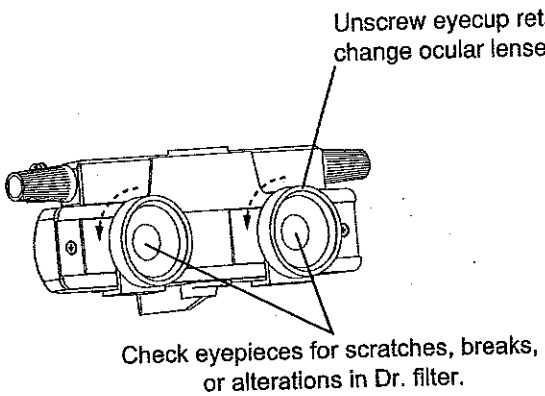


Figure A-5
Eyecup Retainers and Ocular Lens on the Alcon LIO-AT

2. Turn the *EyeLite®* 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 to minimum by turning the Power Adjust knob on the *EyeLite®* console counterclockwise. If the power parameter is not set to the minimum, the message "Set power to minimum" 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 goggles (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 A-4). 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 A-4) 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 ask you to select a terminal starting with the Slit Lamp Terminal. All other parameters are set in the default selection.

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 stop button on the front panel must only be used in case of emergency. After using the emergency stop button, 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 Dr. 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.

Changing The Illumination Bulb

1. Ensure that power switches on the *EyeLite®* 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 A-6).

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.

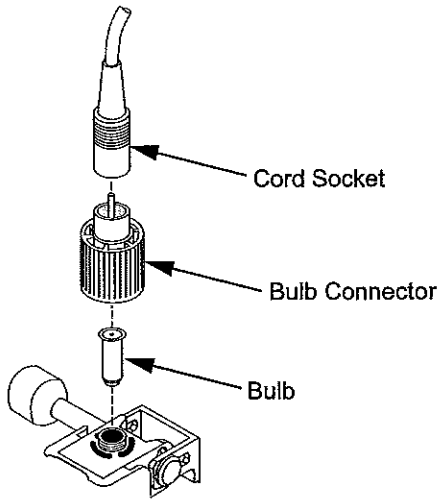


Figure A-6
Alcon LIO-AT Bulb Replacement

Calibration

Alcon 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 of the Operator's Manual 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

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