LIGHTMED

Operator's Manual

LightLas 532

Green Laser Photocoagulator With LCD Control Panel

Operator's Manual

for the

LightLas 532

Green Laser Photocoagulator With LCD Control Panel

CE 0434

Directive 93/42/EEC
as amended by 2007/47/EC
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Operator's Manual for the LightLas 532 Green Laser Photocoagulator

Clinicians or Doctors should ensure that they are adequately knowledge of the operation procedures prior to using the LightLas 532 Laser system.

This Operators Manual should be studied and understood before proceeding to operate the equipment on patients.

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

CAUTIONS - Any modification to the Ophthalmic Laser will result in the necessity for it to be reclassified

CAUTIONS - U.S. law restricts this device to sell by or on the order of a physician

This Operators Manual contains confidential and proprietary information of the Manufacturer.

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Table of Contents

Section 1	*INTRODUCTION*	*9*
Section 2	*SAFETY*	*10*
	2.1 Product Classifications	*10*
	2.2 Warnings and Precautions	*11*
	2.3 Optical Hazards	*12*
	2.3.1 Nominal Ocular Hazard Distance (NOHD)	*12*
	2.3.2 Avoid Exposure to Laser beams	*13*
	2.4 Electrical Hazards	*13*
	2.5 Safety Controls and Features	*14*
	2.6 Product Labeling	*14*
	2.6.1 Console system	*14*
	2.6.2 Integrated Slitlamp LDU	*16*
	2.6.3 Laser Indirect Ophthalmoscope LDU	*18*
	2.6.4 Attachment LDU	*19*
	2.6.5 Safety Filter (Manually)	*20*
Section 3	*PRODUCT SPECIFICATIONS*	*21*
	3.1 LightLas 532 System Specification	*21*
	3.2 CSO SL980 and SL990 Slitlamp Specifications	*24*
Section 4	*PRINCIPLES OF OPERATION*	*25*
	4.1 General Description	*25*
	4.2 LightLas 532 Laser Controls and Displays	*33*
	4.2.1 Laser Console	*33*
	4.2.2 Slitlamp Delivery Unit	*40*
	4.2.3 Laser Indirect Ophthalmoscope (LIO)	*44*
	4.2.4 Two types of Integrated CSO SL980 and SL990 Slitlamp Controls Breakdown	*47*
Section 5	*INSTALLATION*	*51*
	5.1 Introduction and Requirements	*51*
	5.2 Unpacking and Receiving Inspection	*52*
	5.3 Tools and Equipment	*54*
	5.4 Setting Up the Laser System Parts	*55*
	5.4.1 Slitlamp Integrated LDU	*56*
	5.4.2 Laser Indirect Ophthalmoscope LDU (LIO)	*68*
	5.4.3 Endoprobes LDU	*69*
	5.5 Pre-check / Alignment Procedures	*72*
	5.5.1 Pre-check Laser console operation	*72*
	5.5.2 Pre-check / Alignment LDU	*74*

Section 6 *CLINICAL USE* *87*
6.1 Different types of LDUs Indication / Contraindication Use....88
6.1.1 Slitlamp Delivery Unit *88*
6.1.2 Laser Indirect Ophthalmoscope (LIO) *88*
6.1.3 Endoprobe devices *89*
6.2 General Warnings *90*
6.3 Possible side-effect or adverse reactions *92*
Section 7 *MAINTENANCE* *93*
7.1 Operator / User Maintenance *93*
7.2 Laser Beam Alignment Check *94*
7.3 System Output Power Checking Procedure *95*
Section 8 *TROUBLESHOOTING* *97*
8.1 Symptom / Warning *97*
8.2 Warning *99*
8.3 Error Codes *102*
Section 9 *European Community Issues* *106*
Section 10 *EMC Test Tables* *108*

LIST OF DRAWINGS / FIGURES

Figure	Description	Page
2.1	Laser Console Safety and Controls Labels	14
2.2	Laser Console Safety labels	15
2.3(a)	Integrated Slitlamp LDU with Labels (RH side)	16
2.3(b)	Integrated Slitlamp LDU with Labels (LH side)	17
2.4	LIO LDU with Labels	18
2.5	Attachment LDU with Labels	19
2.6	Microscope Doctor Safety Filter with Labels	19
2.7	Microscope Safety Filter with labels	20
4.1	System software start up screen shot	29
4.2	System software boot up ok and system is "Standby" mode	29
4.3	System software is ready to shutdown	32
4.4	Laser Console Controls and LCD Displays	33
4.5	LCD Panel Displays and Control	34
4.6	Integrated Slitlamp LDU Controls	40
4.7(a)	Attachment Slitlamp LDU Controls	41
4.7(b)	Truspot Attachment Slitlamp LDU Controls (New version)	41
4.8(a)	Front View of LIO LDU Controls	44
4.8(b)	Top View of LIO LDU Controls	44
4.9	SL980 Slitlamp Parts List and Controls	47/48
4.10	SL990 Slitlamp Parts List and Controls	49/50
5.1	Packing Carton for Integrated LDU and Slitlamp	52
5.2	Portable Carry Cases for Console and LDU's	53
5.3	Laser System Parts	55
5.4	Slitlamp table top ass'y	57
5.5(a)	Rear view box connection	57
5.5(b)	Removal fuse socket	58
5.5(c)	Removal fuses	58
5.5(d)	Removal voltage setting block and reinsert it back upon completion	59
5.6	Slitlamp Ass'y	59
5.7	Assembled Upper and Lower Housing Screw	60
5.8	Slitlamp mounted onto Table Top ready for Integrated LDU	60
5.9	Slitlamp arm ready for Delivery housing	61
5.10	Fit Delivery unit housing to the Slitlamp	62
5.11	Lock the housing securely to the Slitlamp when it is pushed against Chrome Stop screw	62

Figure	Description	Page
5.12	Align the keyways then fit the Zoom unit to the Delivery housing	63
5.13	Rotate the Zoom housing to the end stop	63
5.14(a)	Original Illumination Tower	64
5.14(b)	New modified Illumination Tower fitted	64
5.15(a)	Haag Streit Attaching Tonometer mount ready for Attachment LDU	65
5.15(b)	Zeiss 30SL Attaching the Tonometer mount and Attachment LDU Mounting Arm	65
5.15(c1)	Lightmed SYL9000 Attaching Tonometer mount ready for Attachment LDU	66
5.15(c2)	Lightmed SYL9000 Attaching the Tonometer mount and Attachment LDU Mounting Arm	66
5.16(a)	Haag Streit Mounting the whole attachment LDU to Tonometer mount & micromanipulator	67
5.16(b)	Zeiss Style 30SL Mounting the whole attachment LDU to Tonometer mount & micromanipulator	67
5.16(c)	Lightmed SYL9000 Mounting the whole attachment LDU to Tonometer mount & micromanipulator	67
5.17	Fiber tips cleaning	68
5.18	LIO connections in console	68
5.19	LIO LDU fiber connection	68
5.20	Endoprobe plug installation	69
5.21(a)	Standard System connection set-up	71
5.21(b)	Combo System Y-Joint connection set-up	71
5.21(c)	Sample of Delivery Fiber and Delivery Key Connection	71
5.22(a)	System boot up sequential display #1	72
5.22(b)	System boot up sequential display #2	72
5.22(c)	Initial Power on displays and outputs	72
5.22(d)	Sample of Delivery Fiber and Delivery Key Connection	72
5.23	Safety filter checks	73
5.24	Attach the Delivery fiber to the Zoom unit	73
5.25	Upper / Lower Slit Alignment Aiming Integrity and Focus Checkout	75
5.26	Realignment set screw location (X-Y axis)	76

Figure	Description	Page
5.27(a)	Checking Field of View set-up	76
5.27(b)	Checking manipulator operation on the target	76
5.28(a)	New Type Version Check Slitlamp focus on Target Rod and Laser focus of aiming beam	79
5.28(b)	Old type Version Adjust the Attachment LDU Spot Size Focus using the knob on the mounting arm	80
5.29	Old type version Adjusting Micromanipulator Arm to verify Laser Spot is in the Aperture Center	80
5.30	Old / New type version Adjusting sideways movement of Attachment LDU during alignment	81
5.31(a)	Fiber and Delivery Key fitted to Console Front Panel	82
5.31(b)	LIO Intensity Control Knob	83
8.1	Sample of Error code display	102

Record Sheet

	Installation Record Sheet	84/85/86
	Power Meter Calibration Record Sheet	96

Appendix I

	All the Accessories Listing Detailed	113/114

Section 1 INTRODUCTION

This manual is intended to provide the operator with an overview of the operation and safety requirements for the LightLas 532 Ophthalmic Laser. This manual is not intended to provide instructions on actual treatment procedures and it is expected that users will have undertaken training prior to using the equipment.

The Manufacturer and Distribution organization assume no liability through the use of this Laser system.

All care has been taken in the preparation and checking of this manual however there is no guarantee provided that all information is correct. The information provided in this manual is subject to change without notice.

Only approved or authorized accessories may be used in the LightLas 532. The Manufacturer and Distribution organization shall not be held liable or responsible for damages or injury caused as a result of using non-approved accessories. This includes all Optical Fiber systems, Laser Delivery Units, Safety Filters, Safety Glasses and Table units.

All maintenance and service work must be carried out by authorized and trained service agents and only those procedures outlined in the operator and service manual are allowed. Any service work carried out by unauthorized persons will void all warranties.

No circuit diagrams or component part lists are to be supplied for the LightLas 532. If you require technical documentation that is not provided in this manual then please contact the manufacturer or your local distributor in writing with your reasons for wanting them and then a copy of the service manual may be provided.

Before using the LightLas 532 Photocoagulator Laser system the operator should read this manual carefully and pay particular attention to the sections of Safety, Operation and Maintenance.

Section 2 SAFETY

This Laser system has been designed and tested to function in a safe and correct when used as indicated in this manual.

Do not use this laser before reading and understanding completely this Operators Manual.

It is important to remember that **this laser emits high levels of visible laser radiation which can cause permanent and irreparable eye and tissue damage.** Always observe precautions for laser safety including using warning signs, safety glasses and only operating the laser in a treatment room that provides protection to casual observers.

2.1 Product Classifications

The LightLas 532 Photocoagulator Laser is a Class IV laser product as specified in the standard IEC60825-1 (2007) and the USA 21 CFR's 1040.10, 1040.11.
The LightLas 532 Photocoagulator Laser is classified as Class I Type B Electromedical equipment as specified in the IEC60601-1 standard.
The LightLas 532 Photocoagulator Laser is classified as a Class II device according to the FDA CFR21 regulations.
The LightLas 532 Photocoagulator Laser is classified as a Class II Type B Medical Device according to the MDD 93/42/EEC (as amended by 2007/47/EC).

The LightLas 532 has been designed to comply with the following standards**:**

- **Laser standards**

  IEC 60825-1 (2007)
  USA 21 CFR 1040.10, 1040.11 (1997)
  IEC60601-2-22 (1995)
- **Electrical standards**

  IEC 60601-1:2005
  EN 60601-1:2006
  EN 60601-1-2:2007
  IEC60601-1-2 :2007
  USA UL 2601
  JIS T1001 (1992) and T1002 (1992)
- **Others**

  MDD 93/42/EEC (as amended by 2007/47/EC)
  EN 60601-1-6:2010
  IEC 60601-1-6 :2010

EN62366 :2008
IEC62366 :2007
EN 980:2008
ISO14971 (2012)

2.2 Warnings and Precautions

The following warnings and precautions apply to the LightLas 532 Laser System and should be observed by all users at all time:

- **DO NOT** look directly into the laser beam or at laser reflections since direct and reflected laser light from the laser aperture can cause permanent eye injury.
- **DO NOT** operate the laser unless observers are using the correct protective eyewear. The protective eyewear must have an optical density of OD4 or more at 532 nanometers wavelength. This information must be present on the eyewear.
- **DO NOT** use objects that can readily reflect light in the vicinity of the laser beam to avoid reflecting the beam in a hazardous manner.
- **DO NOT** fire the Laser directly onto flammable agents or gasses as the focused laser beam may cause ignition. **There is no AP/ APG protection.**
- **DO NOT** try to service or repair the laser other than what is included in this manual. Service should only be performed by an authorized and trained agent of the manufacturer.
- **DO NOT** fire the laser on a patient without first checking the operation of the laser and verifying the optical alignment of the treatment Laser beam.
- **ALWAYS** use the lowest power settings possible when treating a patient with the laser and start the treatment with minimum level of power.
- **ALWAYS** set the correct spot size and/or use the most appropriate one for the power setting and type of procedure that is to be performed.
- **DO NOT** put the laser into 'TREAT' mode until ready to operate on the patient.
- **DO NOT** inhale any laser plume generated by the Laser during surgery. Personnel should take an extreme measured precaution, such as wearing surgical masks or use plume evacuation systems when a treatment is undergoing. **Caution - Laser plume may contain viable tissue particulates.**
- **ALWAYS** take particular care of the optical fibers that connect the Laser Delivery Units to the Console to make sure they do not get damaged.

Additional clinical warnings may be found in Section 6.1.4 of this Manual.

- **ALWAYS** try to let the laser have its own or dedicated power outlet. Additional items may be plugged in a Multiple Portable Socket Outlet, which may be plugged into an additional outlet.

- **DO NOT** use the Laser Console if the ambient temperature is outside the range of 20 to 35°C. This temperature range is the rated operating temperature limits where the Laser system can be guaranteed to operate without any interruptions to normal use. Outside this range of temperature it is possible that the Laser will generate an error condition where the word "hold" is displayed and the system goes to Standby until the internal temperature returns to within normal limits then the Laser can be used again but the error condition may reoccur unless the rated temperature comes within limits.

2.3 Optical Hazards

Guidance for the safe use of Lasers and Laser systems is found in the standard IEC60825-1, the USA 21CFR 1040.10, 1040.11 and ANSI Z136.1 - 1986.

During normal operation of the LightLas 532 the operator is protected from Laser hazards by built in optical absorption Safety Filters. All other personnel in the area should wear protective eyewear to eliminate the risk of eye injury occurring.

The optical density (OD) of eye protection must be greater than or equal to 4 and the wavelength 532nm range is also specified on it. It is shown in the following format:

OD4+ @ 532nm

Otherwise, the safety glasses are NOT suitable for this purpose of eye protection. Safety Glasses are required to have the CE mark applied if used in the EU.

The LightLas 532 uses a Class II Laser Diode Aiming beam. Its wavelength range from 635 to 650 nanometers (nm) and the maximum power output is set at the factory to be less than 1mW delivered to the patients cornea. However it is always recommended to use the lowest aiming beam intensity during treatments.

The LightLas 532 Photocoagulator Laser has been classified as a Class 4 and its classification specified accordingly to the above quoted standards. This classification is also based on the Accessible Emission Limits (AEL) as calculated according to the standards.

2.3.1 Nominal Ocular Hazard Distance (NOHD)

The Nominal Ocular Hazard Distance (NOHD) is the distance between the equipment

and a person's eye for which the optical power, from the equipment, entering the dilated pupil of the person will be less than or equal to the Maximum Permissible Exposure (MPE) as specified in the standards (i.e. less than a Class 1 Laser Output).

The calculated NOHD for the LightLas 532 with different Laser Delivery Units is:

- 5 meters at maximum power settings for the Endoprobes
- 18 meters at maximum power settings and 1000µm spot size for Slitlamp Delivery Units
- 20 meters at maximum power settings for LIO

Therefore when the laser is in operation, all persons that are closer than these distances to the equipment should be wearing eye protection.

Patients, where possible, should have the untreated eye covered or protected from laser reflections.

2.3.2 Avoid Exposure to Laser beams

Reassembly or maintenance of the laser system should only be performed by authorized and trained personnel. The external housing of the laser system should never be removed otherwise you or standby observers could be exposed to dangerous levels of laser radiation and potentially lethal electrical voltages.

Eye safety filters are designed to protect physician's eyes from back scattered laser beams must always be used. They are integrated into the Slitlamp and LIO Delivery Units. When using the endoprobes a separate filter that attaches to the operating microscope must be used.

For other personnel that may be exposed to reflections or backscatter they must wear safety glasses or goggles. In any case NEVER look directly at the treatment laser beam as severe eye injury is likely. This means avoid looking into the aperture of any of the laser delivery units or the console.

2.4 Electrical Hazards

The Lightlas 532 Photocoagulator laser has been designed to apply the International Standards for Medical Equipment. The laser system is designed to operate with three terminal prongs AC voltage where the third prong pin is the earth-grounded prong.

Warning: It is not safe to operate the Lightlas 532 photocoagulator laser without an earth-grounded receptacle. There is possible risk of electric shock.

No cover or housing need to be removed by the operator or user. Only the authorized and trained service or agent can remove the cover or housing assembly

since there is possible of exposing laser radiation and high current or voltages.

2.5 Product Labeling

All the labels on the LightLas 532 comply with the requirements of the various regulatory standards referred to previously.

2.5.1 Console system

A full facsimile of all the safety and control labels is shown in the figures 2.1 and 2.2.

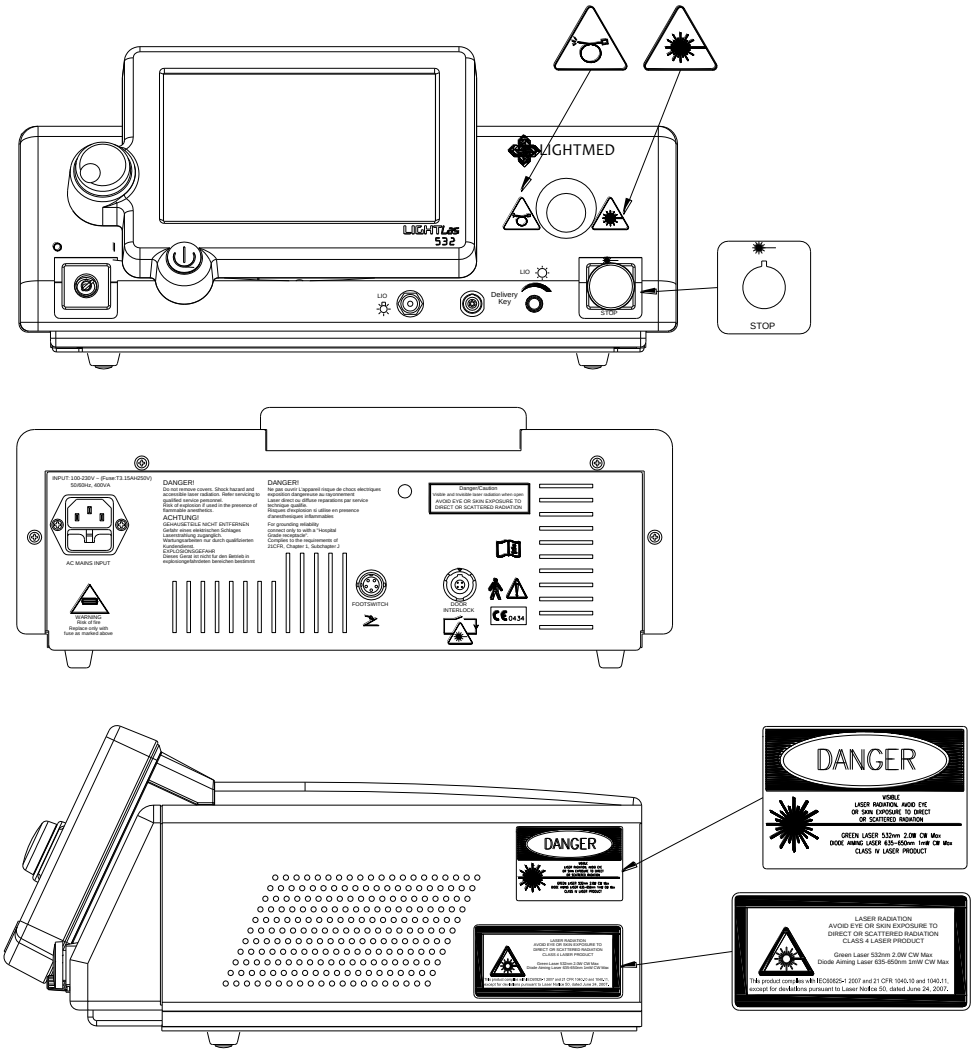


Figure 2.1
Laser Console Safety and Control Labels

2.5.1 Console system continues...

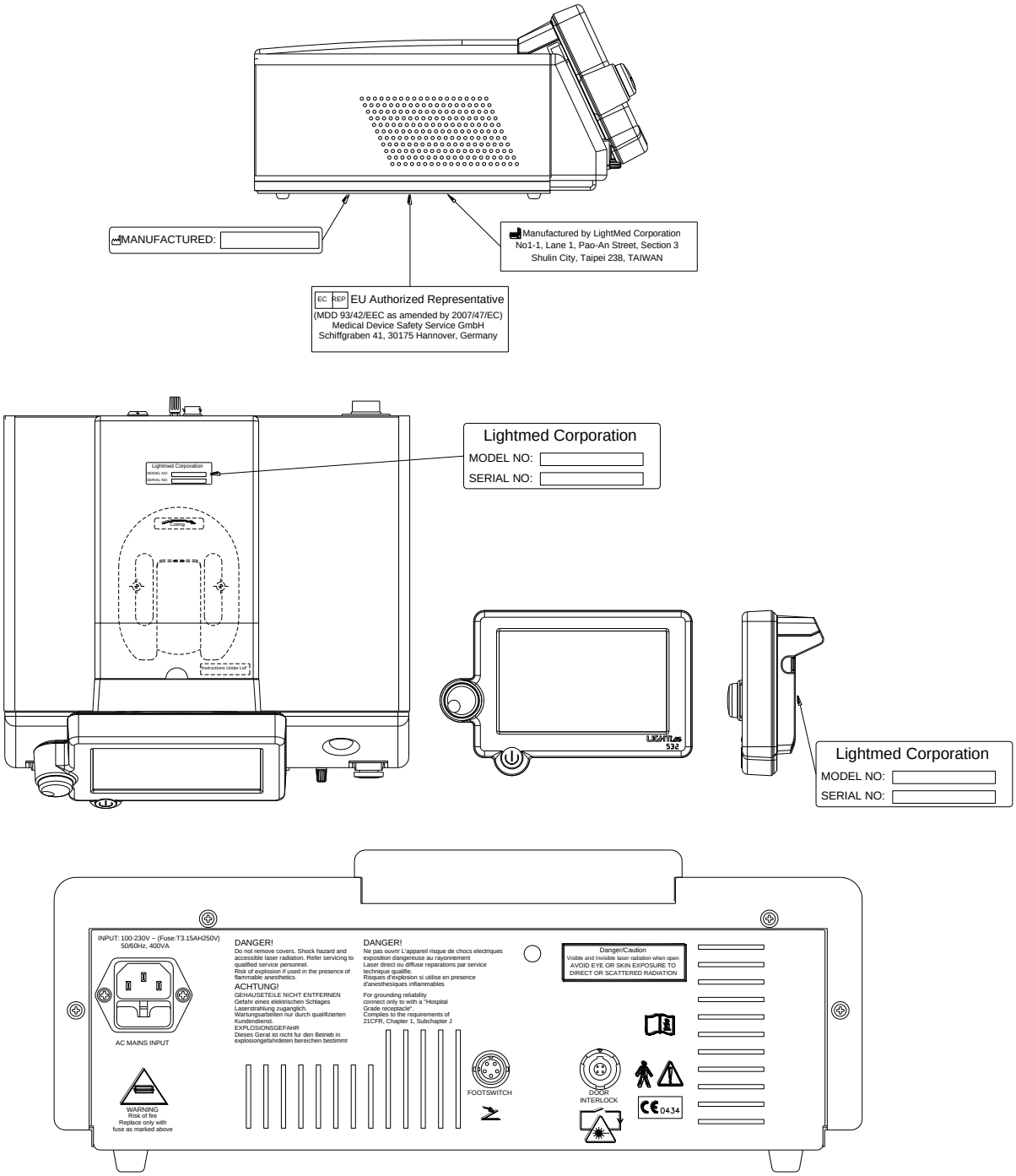


Figure 2.2
Laser Console Safety Labels

2.5.2 Integrated Slitlamp LDU

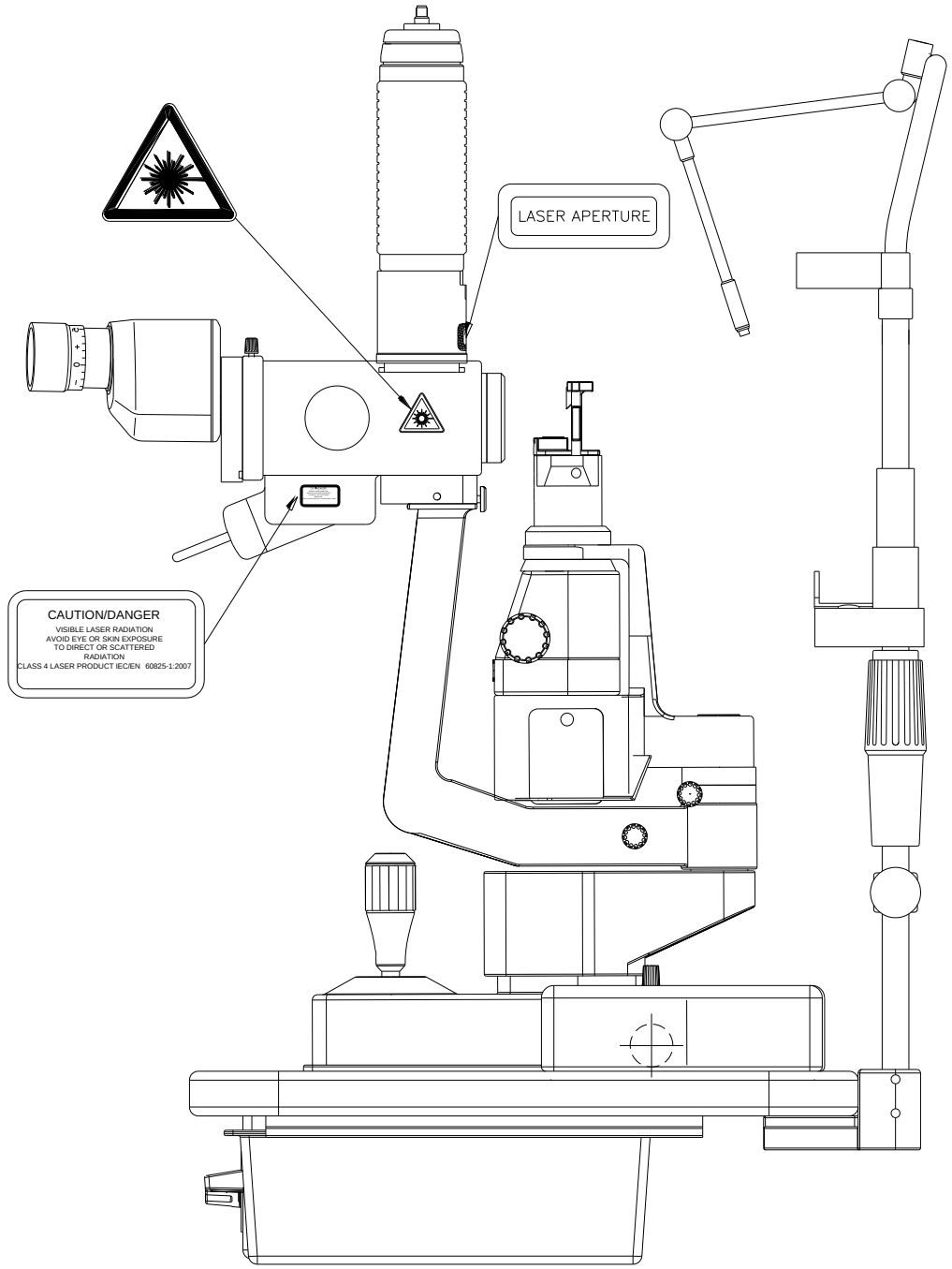


Figure 2.3(a)
Integrated Slitlamp LDU with labels (RH side)

2.5.2 Integrated Slitlamp LDU continues...

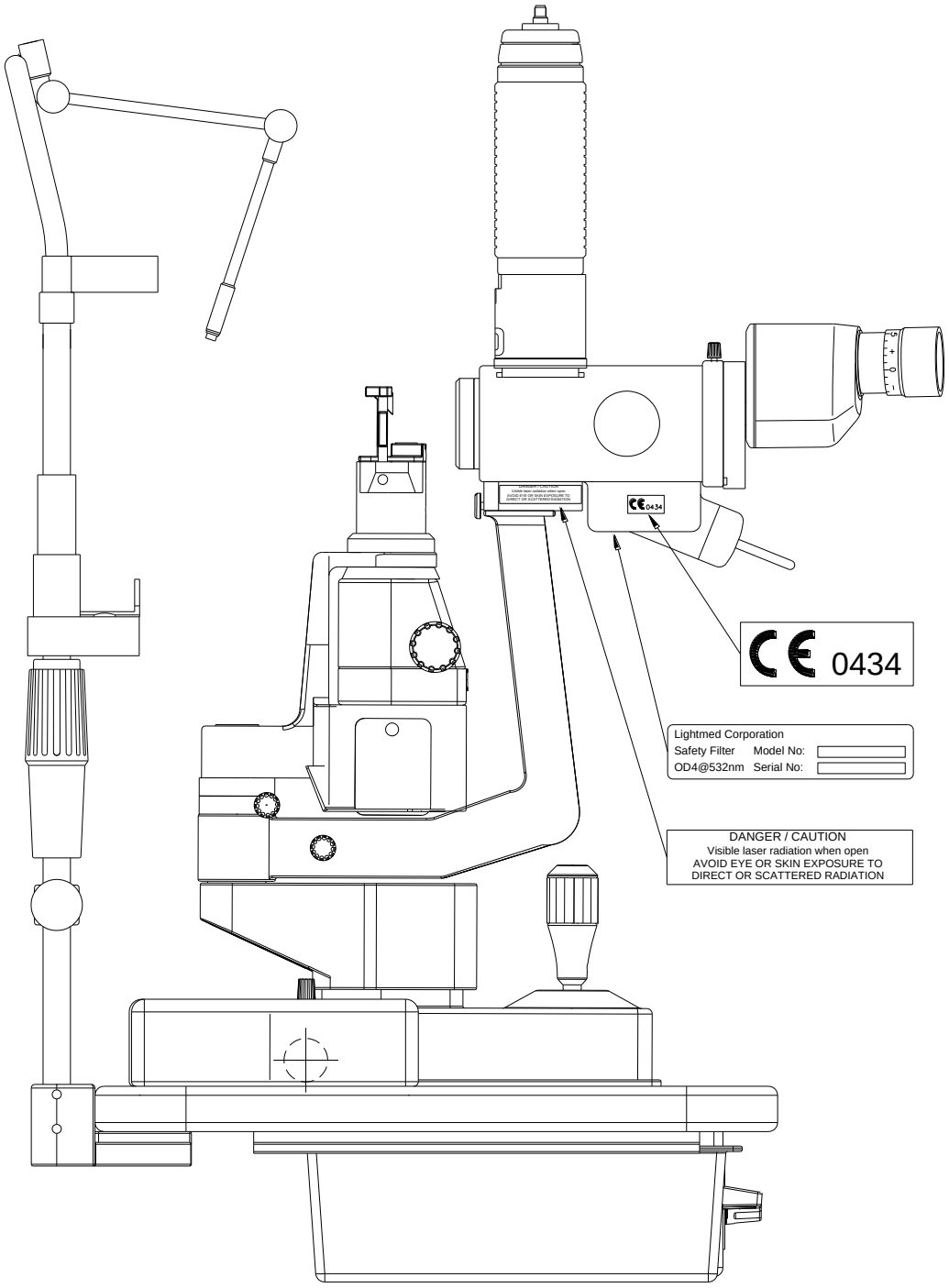


Figure 2.3(b)
Integrated Slitlamp LDU with labels (LH side)

2.5.3 Laser Indirect Ophthalmoscope LDU

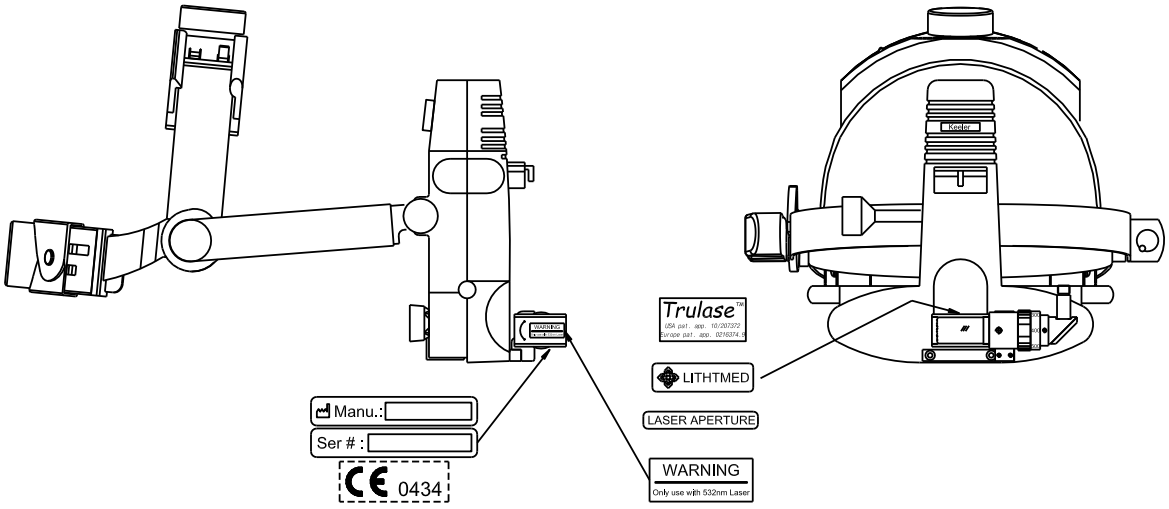


Figure 2.4 LIO LDU with labels

2.5.4 Attachment LDU

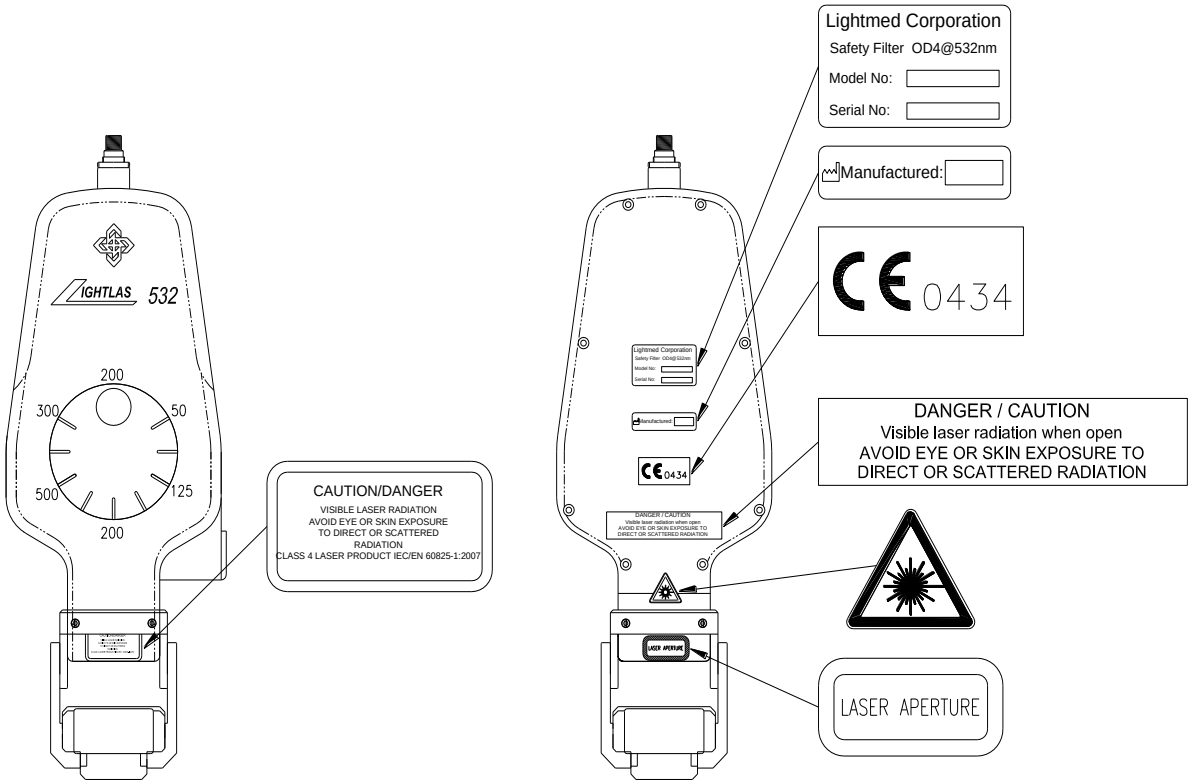


Figure 2.5

Attachment LDU with labels

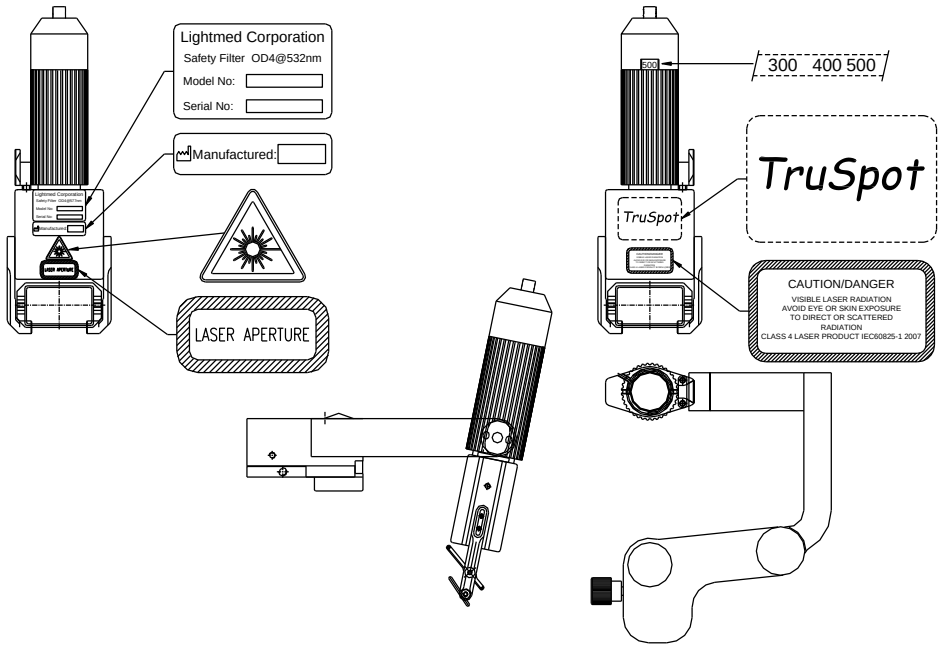


Figure 2.6

TruSpot Attachment LDU Labeling

2.5.5 Safety Filter (Manually)

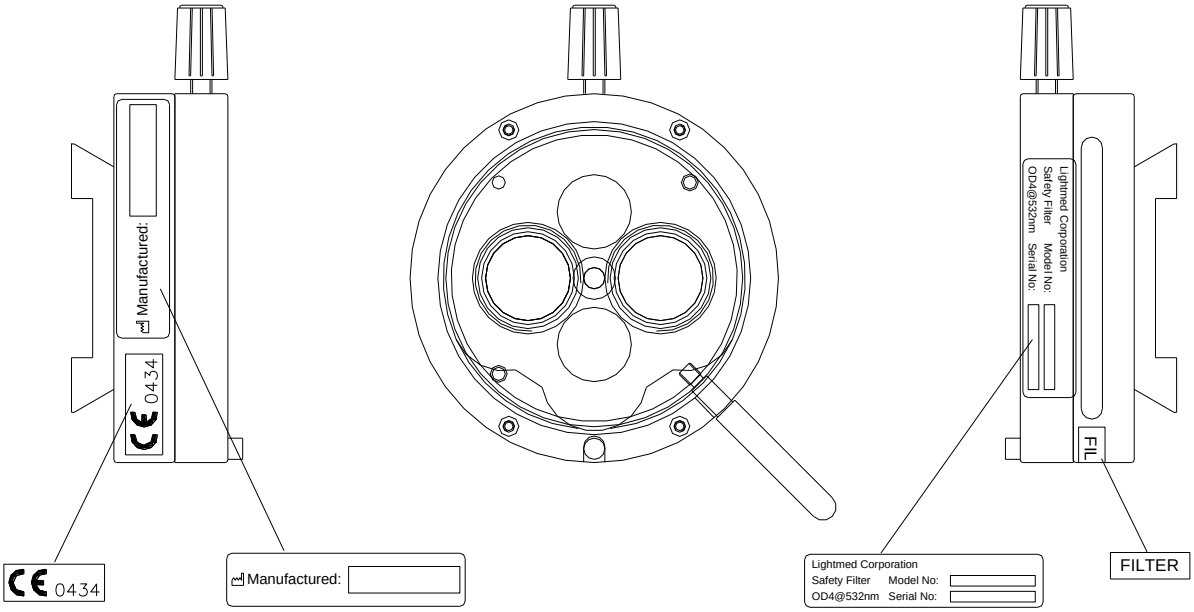


Figure 2.7
Microscope Safety Filter with labels

Section 3 PRODUCT SPECIFICATIONS

3.1 LightLas 532 System Specification

The following are the System Specifications for the LightLas 532 Ophthalmic Laser.

Console Laser System

General Specification

Electrical Input	:	100 to 230 Vac. 50/60 Hz Single phase
Power	:	400W
Fuse rating	:	T3.15AH250V @ 100-230Vac (Time Lag)
Temperature Range	:	Transport: -10 to 70°C Operating: 15 to 30°C Storage: -10 to 55°C
Relative Humidity Range	:	Operating: 30% - 85% non-condensing Storage and Transport: up to 95% non-condensing
Atmospheric pressure	:	Operating: 800-1060 mbar Storage and Transport: 500-1060 mbar
Cooling System	:	Fan cooled and TEC's for Laser Diode and Crystal
Dimensions (Total)	:	130mm(H) x 370mm(W) x 330mm(D)
Weight	:	13 Kg (System) 20 Kg (Packed)

Treatment Laser

Laser Type	:	Diode Pumped Frequency Doubled YAG
Wavelength	:	532 nm
Mode of Operation	:	CW
Power Output	:	2 W Maximum
Power Adjustment	:	Variable from 0.05 to 2.0 W
Exposure Duration	:	0.01, 0.02, 0.03, 0.04, 0.05, 0.06, 0.08, 0.1, 0.15 and 0.2 to 3.0s is 0.1s increment
Repeat Interval	:	Selectable from 0.01 to 3.0 secs and equal to or greater than exposure duration in same discrete steps as duration
SP Mode	:	Duty cycle selections - 7.5%, 150µs 'On' time - 10%, 200µs 'On' time - 12.5%, 250µs 'On' time - 15%, 300µs 'On' time - 17.5% ,350µs 'On' time - 20%, 400µs 'On' time

Doctor Safety Filter	:	OD4 at 532 nm
Safety Class	:	Class 4
Power Display accuracy:		Better than +/-20% of actual
Beam Divergence	:	< 0.2 NA

Aiming Laser

Laser Type	:	Red Laser Diode
Wavelength	:	635–650 nm (Red)
Mode of operation	:	Continuous Wave (CW)
Output power	:	Maximum of 1.0mW
Power adjustment	:	Continuously variable
Safety Class	:	Class 2

Laser Delivery Units (LDU)

Integrated Slitlamp LDU

Slitlamp model	:	CSO Model SL980 (Detailed refer to p.32)
Spot Sizes	:	50, 100, 200, 300, 400, 500, 1000 µm selectable on Zoom assembly of Delivery unit
Focus plane	:	All spot sizes Parfocal to Slitlamp focus plane
Fiber Length	:	2 m
Mounting	:	Direct to Slitlamp housing
Safety Filter	:	Fixed filter OD 4 @ 532nm
Beam Divergence	:	Cone angle of 20°

Attachment Slitlamp LDU

Slitlamp model	:	To attach on CSO Model SL990 (Detailed refer to p.32), Haag Streit models BM or BQ, most Haag Streit Clone Slitlamps and Zeiss SL30
Spot Sizes	:	50, 125, 200, 300, 500µm selectable on housing of Delivery unit
Focus plane	:	All spot sizes Parfocal to Slitlamp focus plane
Fiber Length	:	2 m
Mounting	:	On adapters fitted to Slitlamp Tonometer Mounts
Safety Filter	:	Fixed filter OD 4 @ 532nm
Beam Divergence	:	Cone angle of 20°

Laser Indirect Ophthalmoscope

Indirect model	:	Keeler All Pupil II
Retinal Spot size	:	300µm nominal at focus with 20D Laser Lens
Illumination power	:	From Laser Console or stand alone power source
Fiber Length	:	3 m

Weight	:	Less than 500g without laser attachment
Safety Filter	:	Fixed filter OD 4 @ 532nm
Beam Divergence	:	Cone angle 20°

Endo-ocular Probes

Probe Types	:	Straight, Curved and Aspirating
Fiber Length	:	3 m
Safety Filters	:	OD 4 @ 532nm in housing for installation to Operating Microscope before Laser can be fired
Sterile	:	Sterilized by Ethylene Oxide and a single use device only
Beam Divergence	:	0.2 NA

Accessories

Safety Filters

Types	:	To suit Zeiss, Moeller, Leica and Topcon Operating Microscopes
Safety Filter	:	OD4@532nm

3.2 CSO SL980 and SL990 Slitlamp Specifications

The following are the Slitlamp Specifications for the CSO SL980 and SL990 Slitlamps that are used in the LightLas 532 Photocoagulator Laser System. The SL980 is a Zeiss clone and the SL990 is a Haag Streit clone. Both Slitlamps have very similar specifications however the SL980 uses an illumination source below the viewing path and the SL990 uses illumination from above the viewing path.

Microscope	:	Galilean
Magnification Set	:	5 Step Drum Rotation
Eyepiece	:	12.5X
Magnification Ratio	:	6X, 10X, 16X, 25X, 40X
PD Range	:	48.5-80mm
Diopter Adjustment	:	+/-8
Slit Illumination	:	6V 20W Halogen Lamp
Slit Width	:	0-14mm (SL980) and 0-12mm (SL990)
Slit Length	:	1.8 – 12mm
Slit Apertures	:	0.3, 5.5, 9, 14mm(SL980) and 0.2, 1, 3, 5, 9, 12mm(SL990)
Slit Angles	:	0°- 180°
Filters	:	Red Free, Heat Absorbing, Cobalt Blue

Movement Ranges

Longitudinal (In/Out)	:	113mm
Lateral (Left/Right)	:	108mm
Vertical (Up/Down)	:	35mm
Fine movement range	:	10mm
Chin Rest Range	:	70mm

Section 4 PRINCIPLES OF OPERATION

4.1 General Description

The LightLas 532 Green Laser is an Ophthalmic Laser suitable for performing the following clinical procedures:

- Retinal Photocoagulation
- Pan Retinal Photocoagulation
- Endo photocoagulation
- Macular Treatments
- Laser Trabeculoplasty

The LightLas 532 Laser system has a wavelength of 532nm, which is in the visible spectrum and is a green light. A red aiming beam is used to position the treatment green light beam prior to delivery.

The word LASER is an acronym for "Light Amplification by Stimulated Emission of Radiation". The light from a laser has particular characteristics, which makes it a valuable tool for medical applications.

- The beam from a laser is collimated which means that the beam does not diverge and can maintain a constant diameter over a long distance. This means that the Laser beam can be focused to a very small spot with high energy and power densities.
- The beam is Monochromatic, which means that it is a single wavelength beam and therefore the effects of the beam on tissue are very predictable and reproducible.
- The light waves are coherent which means they are in phase with each other and do not interfere and generate losses in energy.

The LightLas 532 system consists of a laser console where the green laser is housed along with the electronic control system and power supplies and accompanies along with various Laser Delivery Units (LDU's). These LDU's include:

- Slitlamp Integrated into CSO model SL980
- Slitlamp Attachment for CSO model SL990 and other Haag Streit clones.
- Slitlamp Attachment for Zeiss model SL30 Slitlamp
- Laser Indirect Ophthalmoscope (LIO) using a Keeler II
- Endo photocoagulation hand pieces (Endoprobes)

When using these LDU's a microscope Doctor Safety Filter (DSF) is required to protect the doctor from unexpected reflections causing eye injury during the treatments. The DSF is mounted in the beam path of the microscope.

All the normal functions of a Slitlamp are available to the operator when using the LightLas 532 on a Slitlamp unit and when the doctor is using the LIO they will use a Contact Lens of either 20D or 28D.

On the laser console there is a remote control module that the doctor can remove from the top of the console and position it close to the treatment location so as to have easy access to the laser displays and controls. This remote control module is connected to the laser console by a flexible cable that is coiled up and sits in the recess area on the top of the laser console.

The doctor must first confirm the patient meets the treatment requirements of the indications and contraindications before proceeding with any treatment. Typically the doctors or their assistant will verify that the laser and delivery unit are operating correctly before positioning the patient in the Chinrest are for avoiding any patient inconvenience. This checking includes the laser output and alignment.

The doctor must set the laser power and pulse interval whenever the System is turned on. It is the responsibility of the doctor to set acceptable power levels and pulse intervals. It is recommended that always start with a lower power and shorter pulse interval to reduce any risk of unintended injury to the patient. By default setting the laser system, the power is set to 0mW, the pulse duration is set to 0.02 seconds and the pulse interval is set to "One" which means one shot per requested only. These settings can be altered and saved by the operators or doctors preference.

Conversely, the doctor can select a repeat pulse mode where the laser is pulsed repetitively according to the doctor's requirements. However, even in this mode, the laser is always under the control of the doctor's the footswitch, which means that whenever the footswitch is released, there will be no laser output.

The following paragraphs give a general description of the operation of the Laser System

The laser system console generates a controlled beam of the 532nm wavelength light that is focused to a small spot so that it can be delivered into an optical fiber that then connects to one of the Delivery units. The Slitlamp LDU's optical fiber has a diameter of 200µm and is 2 meters long and 3 meters long for the LIO. Special care must be taken with the fibers not to damage the jacket as this may create extra losses and may allow the laser beam to be transmitted at the damaged place along the fiber. Therefore the fiber should be kept off the floor and away from sharp edges.

The 532nm wavelength green laser light is primarily used as a source of energy to heat the tissue and thereby cause photocoagulation. The laser beam is directly applied to the treated tissue and absorbed by the melanin pigment within the retinal pigment epithelium and the choroid. This absorption converts the light energy into

heat energy which raises the temperature of the tissue being treated producing thermal coagulation of the protein. The green laser beam is readily transmitted through the cornea, lens, and vitreous regions of the eye. If the patient's eye does not allow for good transmission or introduces some dispersion of the beam then the patient is not suitable for this type of laser treatment. Increasing the laser power and pulse duration will generate more heat and therefore the coagulative effect will be greater.

If the power or duration of exposure is too high then the surrounding tissue may sustain some damage. Therefore, a careful selection of the power and pulse duration is essential to a successful treatment.

Different Types of LDU

For the Slitlamp Delivery Units and LIO, the laser beam is delivered into the patient's eye as a focused spot that can be positioned accurately by the doctor to the treatment site. When using the LIO the laser beam is delivered through a Contact Lens that is held by the doctor and assists in positioning the laser beam on the site and setting the desired spot size. For the Slitlamp delivery unit the spot size at the treatment site is adjustable and set by the doctor according to the type of treatment to be used. The spot size selector is located on the delivery unit attached to the Slitlamp and can be set from 50µm to 1000µm in a continuous adjustment for the Integrated SL980 design. As for Attachment LDU, it can be selected from 50µm to 500µm.

When using the Endoprobes, the doctor will use an Operating Microscope to view the patient's eye. These probes are inserted into the eye and used in very close proximity to the treatment site (almost in contact). The Endoprobes are sterile devices intended for direct patient contact and are a purchased item with a sterility guarantee.

For each LDU, a "Delivery Key" is used by the laser console as a means of determining which type of LDU is connected. The Delivery Key is required because each type of LDU has a different amount of loss through the optical elements and therefore the output power factor calibration will be different for each. The Endoprobes have the least loss of all the LDU's because the only losses are through the fiber itself and in the coupling of the laser beam into the fiber. The LIO has more loss than the Endoprobes as it has a collimating system, mirror, and focusing lens for the laser beam to be transmitted through and all of these have some contributing losses. The least efficient of the LDU's is the Slitlamp delivery unit. There are many optics in this unit due to the spot size adjustment zoom system so the losses are the greatest. Also when the small spot sizes are selected there may be some aperture of the beam that contributes to the losses.

When setting up the laser unit for the operation, the correct type of Laser Delivery Unit must be connected along with the Delivery Key that accompanies it. If no Delivery Key is inserted then the warning message "Delivery Key Not Found" on the LCD screen panel and system will wait for correction or reinserted before normal console operation resume.

The Delivery Key is also an additional safety feature that prevents unauthorized use of the laser unit. It is attached to the fiber for each of the LDU's to eliminate any risk of inserting the wrong Delivery Key. It is an essential requirement in order to ensure that the correct calibrated power level is delivered to the patient.

The following paragraphs describe the actual operation of the system

The system consists of two major parts: the console and the LCD touch control panel integrated with computer platform

Inside the Laser Console there are several operating components that put together to provide the output Laser beam such as:

- Laser Diode (808nm)
- Laser Cavity and optics system
- Thermal Electric Coolers and Driver units
- Electronic Microprocessor control system
- Power supply

First of all, main source power must be connected to the laser console system before the system is enabled to function accordingly. Secondly, a blue LED backlight power switch, located at the bottom of the screen (refer to fig. 4.3), on the LCD control panel display needed to be enabled and wait for system software to boot up before proceed to the next procedure (refer to fig. 4.1 - 4.2). Once the software is properly boot up, then the key-switch is inserted and turned to the ON position (with the Emergency switch in the out or OFF position). And then the console system microprocessor controller will perform some internal checks to verify that the machine is functioning as it should be. Few warning messages such as, "BBF Temperature Not Ready", "LBO Temperature Not Ready" ...etc. will display on the LCD when the console power is 'ON'. This process usually takes less than few seconds. If the temperature setting up process time is out of specification (> 5mins), there will be an error code shown on the LCD display (for more detailed refer to troubleshooting section of this manual).

Figure 4.1 System software start up screen shot

Figure 4.2 System software boot up ok and system is "Standby" mode

All operating conditions and switches are shown on the LCD control panel. The LCD control panel display consists of:

- Laser Power
- Laser Power Pulse Duration
- Pulse Interval
- Accumulated number of pulses
- The type of LDU connected
- Aiming intensity
- Mode of operation
- SP Mode Selection
- Customized treatment configuration
- Query or Help functionality

The mode of operation is an important function display because when the laser is turned ON STANDBY mode is automatically selected, which prevents any accidental firing of the LightLas 532 Laser System with LCD panel. In STANDBY mode, the footswitch is disabled and the shutter module blocker will obstruct the beam path is closed.

Only 'Standby' button switch is toggled, the system will be in treat mode. Then the footswitch and shutter are now enabled and the aiming beam is turned on. If the footswitch is pressed, the Green laser beam will be delivered into the fiber. The system will turn back to STANDBY mode in the following situations:

- No controls are operated for 10 minutes
- Any warning or error condition occurs

Prior to activate the 'Treat' mode, it is recommended that all operating conditions are to be set correctly such as patient positioning, power selection, pulses duration, interval duration, aiming beam intensity, spot size and illumination intensity. This will prevent the likelihood of accidental firing of the Green laser or unintentional delivery during the set up stages.

Output power distribution can fine tune through an up/down arrow switch button on the LCD touch control panel. The power setting will remain the same whenever the power is on which means the default setting screen will be primary unless it is replaced by another setting. The power can be adjusted from 50 to 2000 mWatts.

The pulse duration can be adjusted from 0.01 secs to 3.0 secs. by pressing the action key switch buttons on the LCD touch control panel. Similarly, the Repeat Interval

can be set from 0.01 to 3.0s by using the press action switches located directly below the Repeat Interval display. If the duration is adjusted beyond 3.0 seconds, the "Pulse Duration" display will show "CW" and the laser output will be continuous for as long as the foot switch is pressed down. If the interval is adjusted beyond 3.0 seconds, the "Repeat Interval" display will show "One" and the foot switch will need to be pressed every time the doctor wishes to fire the laser.

By default setting or when the laser is powered on for the first time, the pulse duration is 0.02 seconds and the repeat interval is set to "One". The laser output power is set to 0mW. These initial values can be changed by selecting the desired settings and by using the saving function button on the screen and key in the customized name. You may retrieve this setting by reopen the file folder.

Inside the Laser System there is a shutter module that completely blocks the beam path at all times except when the system is in the 'Treat' mode and footswitch is activated. The microprocessor constantly monitors the electronic sensors position and their integrity of the shutter at all times. Whenever the system boots up, it will check for the shutter position to validate if the shutter is engaged and functioned.

The shutter remains closed until doctor initialized the 'Treat' mode. This ensures that the patient is protected in the case of a misfire. When the footswitch is pressed the microprocessor will carry out various checks on the status of the laser system including the correct position of the shutter. After the microprocessor finishes the system checking, then the shutter will await to be opened or activated. If this is OK then the Laser Diode will be turned on for the selected pulse duration. There is a closed loop control system to ensure a stable output pulse. The footswitch must be released in order for next requested to be operated again. The position of the shutter will continuously be checked during all operating modes.

A sum of the total delivered Laser pulses is shown on the LCD Control panel located near the bottom right. A reset button switch is located next to the display button. You may clear the setting by pressing this button will reset the value.

In the case of an emergency, the Red Emergency Switch can be pushed in and locked down to cut off all power. Normally power can be turned off by using the key switch. In order to prevent unauthorized persons from operating the system, the key should not be left in the keyhole when the Laser System is not in use.

The software shutdown is processed through a push button on the LCD panel located near the left bottom of screen (refer to figure 4.3). The system will remain operation unless user's requested.

The user/doctor is expected to be trained and have knowledge in the intended use and application of the Green laser for performing any surgery. In addition, it would be expected to use the laser system in a clean and controlled environment. When

performing Endo photocoagulation procedures, a sterile surgical site should be used to reduce the risk of infection. European National Requirements may apply in some EU countries and are to be observed by those users (Refer to Section 9 of this manual).

The patient cannot have any influence over the operation and control of the New LightLas 532 Laser System. Depending on the type of surgery being performed, the delivery unit being used, and the condition of the patient, the doctor must decide on the modality of the Laser use and whether or not an assistant is required during the surgery.

As the laser system is designed to deliver the laser beam to heat the tissue, care must be taken to avoid dangerous situations that could cause a fire or an explosion. The Laser should never be fired in the direction of flammable gases or liquids which may be present in the operating room.

LCD Power
On / Off

Figure 4.3 System software is ready to shutdown

4.2 LightLas 532 Laser Controls and LCD Displays

4.2.1 Laser Console

All the LightLas 532 Photocoagulator's controls and displays are located either on the console front panel or the rear panel (refer to fig. 4.1.and 4.2). A detailed description of each control and display is explained on the next page.

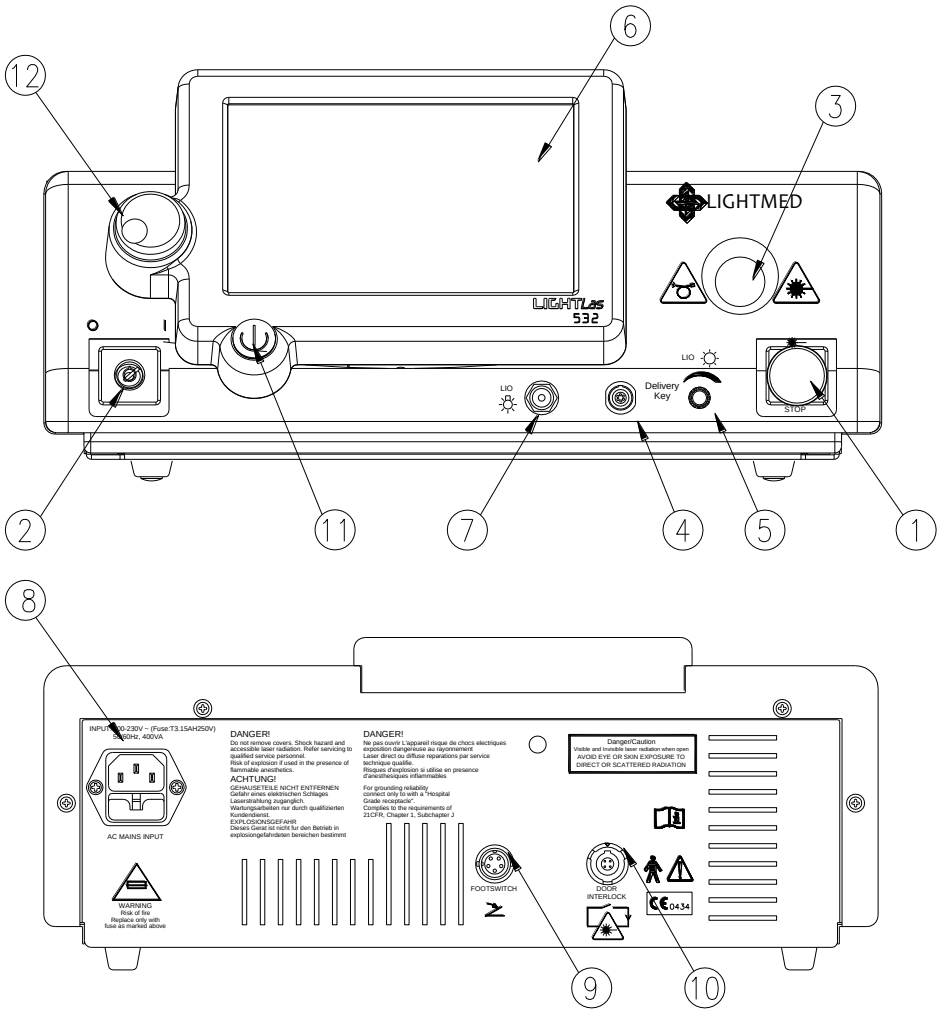


Figure 4.4
Laser Console Controls and LCD Displays

Legend

1. Emergency Stop Switch	2. Key Switch
3. Laser Aperture	4. Delivery Key Connector
5. LIO Illumination Control	6. LCD Control Panel
7. LIO Power	8. Main Power Inlet
9. Footswitch Connector	10. Remote Interlock Connector
11. LCD Control Panel Power Switch	12. Power Control Adjuster or Dial

4.2.2 LCD Display Panel

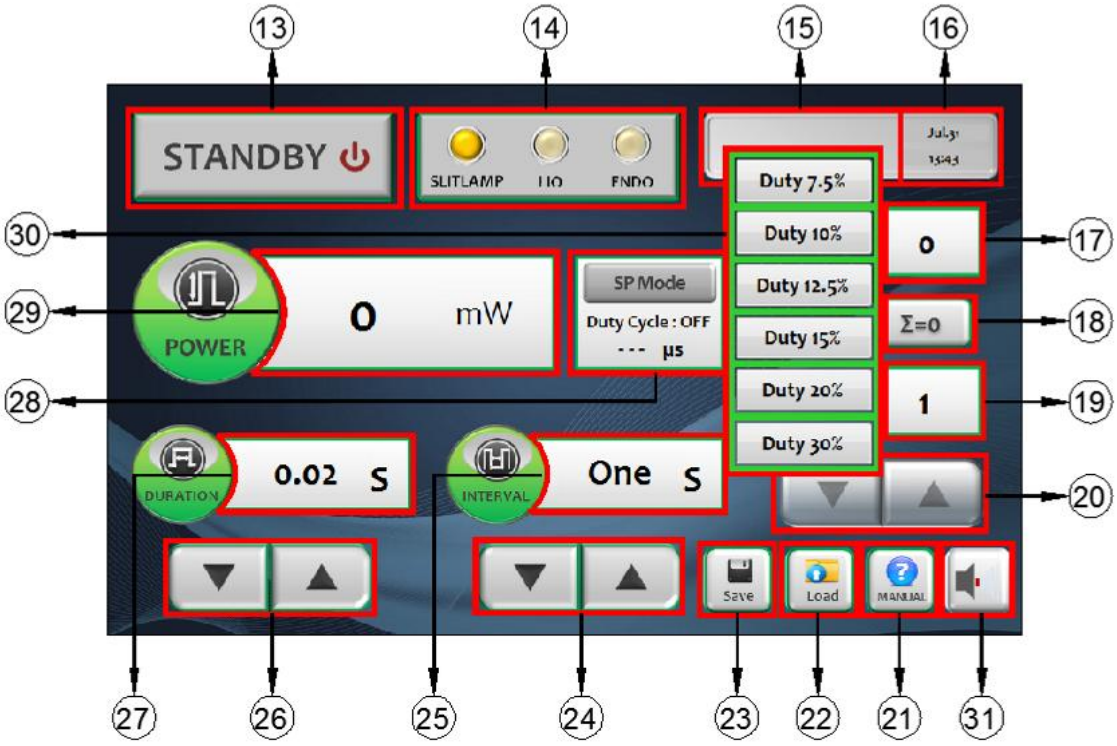


Figure 4.5
LCD Panel Display and Control

Legend

13. Mode Indication (TREAT / STANDBY)	14. Type of Delivering System Indicator
15. User Configuration Indication	16. Date and Time Indicator
17. Total Laser Shot Counter Display	18. Counter Reset Switch
19. Aiming Beam Intensity Indicator Display	20. Aiming Beam Intensity Setting Switches
21. Manual Inquiry	22. Loading Profile Inquiry
23. Saving Inquiry	24. Repeat Interval Setting Switches
25. Repeat Interval Display	26. Exposure Duration Setting Switches
27. Exposure Duration Display	28. SP Mode & Selection Display Icon
29. Preset Power Display	30. SP Mode Selection Icon
31. Buzzer Control Icon	

1. **Emergency Stop Switch**

   This switch is provided a fast response shutdown of the laser system in the event of some serious problem occurring. It is a RED color push switch that locks down when pushed and in, all internal power will be removed. In order for system to restore the power, the button switch must be twisted and released it.

2. **Key Switch**

   This key switch is the main power ON/OFF switch. The power can only be turned on by inserting the key and rotating clockwise to the ON position. In the ON position the key cannot be removed. The key should be stored in a safe and controlled place.

3. **Laser Aperture**

   The Laser Delivery Unit's fiber is connected here. The fiber connector must be fully screwed in since there is an interlock switch which must engaged in order for the Laser to function. No laser beam can be delivered through unless the fiber is securely attached.

4. **Delivery Key Connector**

   Each Delivery Unit has its own type of "Delivery Key" connector that must be fitted to this socket so the microprocessor can recognize it. **Always make sure the correct Delivery Key is inserted for the LDU that is being used.**

5. **LIO Illumination Control**

   When the LIO is connected to the LightLas 532 Laser Console, this control knob can be used to adjust the intensity of the Illumination lamp.

6. **LCD Control Panel**

   This LCD Control Panel locates in front of the Laser Console and can easily be removed by the operator and placed close to the site of the laser treatment in order to maintain good control over the laser settings and displays. A cable connects the LCD Control panel to the Laser Console and it is coiled up under the hinged top cover of the Laser Console. This is a touch panel control and software system embedded it. All controls are shown on the LCD panel including Duration, Interval, Aiming intensity, Output power, SP Mode selection, and Shot counter.

7. **LIO Power**

   This connector is used to provide the power source the LIO Illumination.

8. **Mains Power inlet**

This socket is used to connect the Laser Console to the mains power. The input voltage can be the range of 100 to 230 VAC as the internal PSU is an auto-ranging module.

9. **Footswitch Connector**

This connector is fitted for the footswitch module which is the laser trigger firing mechanism On/Off switch. This footswitch can be in wire or wireless module.

10. **Remote Interlock Connector**

It is a regulatory requirement that the LightLas 532 have this safety feature connector available. Two wires can be wired out from the interlock switch to the treatment door's switch and once the door opens the circuitry will be opened causing the system to be disabled. At this time, the warning message "inL rE-F" will show on the remote control panel display. Once the door shuts the system will go default back to STANDBY mode. By default setting a dummy "Interlock" connector is supplied with each console and it must insert in order for the system to operate correctly.

11. **LCD Control Panel Power Switch**

This is a power switch for the LCD control panel. By turning on this switch, the system software will be activated only not the console system itself therefore do remember to power on the console in order to establish the communication.

12. **Power Control Adjuster or Dial**

This control is used to adjust the laser output power. By default setting the laser power is at set at zero unless the reconfiguration is made. The setting can be adjustable from 50 mW to 2000 mW and by rotating the control clockwise will increase the power value and counter-clockwise will reduce it. The setting will be reset it when power is down.

13. **Mode Indication (TREAT / STANDBY)**

This indication can be toggled the two modes selections of "Treat" or "Standby".

14. **Type of Delivering System Indicator**

This display panel will indicate selected type of delivering system when the appropriate delivery key is inserted or applied. Always ensure the delivery key is inserted in order for system to function otherwise a warning message "Delivery Key Not Found" will show in the main LCD panel. There are three types of delivering systems: Slit Lamp, LIO, and ENDO.

15. **User Configuration Indication**

This box will display the user name configuration where appropriate user preference can be loaded from the folder.

16. **Date and Time Indication**

This display will show the current time and date. Reconfiguration is required for system to show the corrected time and date.

17. **Total Laser Shot Counter Display**

This display will indicate the sum of the total laser shots being fired during the treatment.

18. **Counter Reset Icon**

This icon switch will reset the total laser shot counter to zero.

19. **Aiming Beam Intensity Level Display**

This display will indicate aiming beam intensity level. The level scale starts from 1 to 10 and the higher number indicates the higher intensity. The maximum power can be applied to patient's eye is round 1.omW.

20. **Aiming Beam Intensity Control Switches**

These controls switches can adjust the aiming beam brightness of through two switches (up / down).

21. **Manual Inquiry Icon**

This icon will provide the detailed operator manual at any requested time.

22. **Loading Customized Configuration Profile Inquiry**

This inquiry icon will able to retrieve any customized configuration file.

23. **Saving Icon**

The system will store any customized configuration profile at requested time. This icon is used to store the profile at user.

24. **Repeat Interval Control Switches**

These switches are used to set the repeat interval duration, which is the time between each pulse of the treatment laser. Similar to the Duration switches, the left hand control will decrease the interval and the right hand control will increase the interval. In this mode the repeat pulse rate cannot be set higher than a 50% duty cycle. This means that the laser fire duration cannot be higher than the repeat interval duration. It means also that the repeat interval duration is greater than or equal to the exposure duration when pressing the down setting switch. The minimum interval is 0.01 second, and the maximum interval is

3.0 seconds. If the interval is adjusted beyond 3.0 seconds, then the Repeat Interval display will show "One".

25. Repeat Interval Display

This display will show the selected interval value and it ranges from 0.01 to One second.

26. Exposure Duration Setting Switches

These two switches control the duration of the exposure time that the treatment laser is given to the patient each time the footswitch is pressed in the Treat Mode. The left hand control will decrease the duration and the right hand control will increase the duration. The minimum duration is 0.01 seconds and the maximum duration is 3.0 seconds. If the duration is adjusted beyond 3.0 seconds, then the system will enter the continuous pulse mode. In this mode, the laser will output continuously until the doctor/user releases the footswitch. When this mode is activated, the Duration display will show "Con".

27. Exposure Duration Display

The system will store any customized configuration profile at requested time. This icon is used to store the profile at user.

28. SP Mode & Selection Display Icon

This icon is used to enable and disable SP Mode function and selected sub-threshold levels will also display. The upper information is the selected duty cycle and the bottom is the 'ON' or exposure time. The denominator is 2000µs and numerator is appropriate 'ON' time. The ratio of the two will be duty cycle.

29. Preset Power Display

This display will show the set power level and the display will change as the power is adjusted. By default setting the laser power is at set at zero unless the reconfiguration is made. The setting can be adjustable from 50 mW to 2000 mW and by rotating the control clockwise will increase the power value and counter-clockwise will reduce it. The setting will be reset it when power is down.

30. SP Mode Selection Icon

This drop down menu icon will enable the appropriate user preference sub-threshold duty cycle. There are five preset configurations and they are as follows: 7.5%, 10%, 12.5%, 15%, and 20%. The 'ON' time configurations are as follows: 150µs, 200µs, 250µs, 300µs, 350µs, and 400µs.

31. Buzzer Control Icon

This icon control knob can be used to adjust the volume of the laser fire audible warning. However the audible warning cannot be turned off.

Note: There are cooling fans inside of the Laser Console. This forced air is used to cool down the electronics component and specially the laser diode and cavity in the system. Therefore it is very important that the intakes cooling fans are not blocked otherwise the laser will overheat and an error condition will generate.

4.2.3 Slitlamp Delivery Unit

There are two types of Slitlamp delivery systems: Integrated System and Attachment LDU. More detailed breakdown description of these delivery systems can be found below and next few pages.

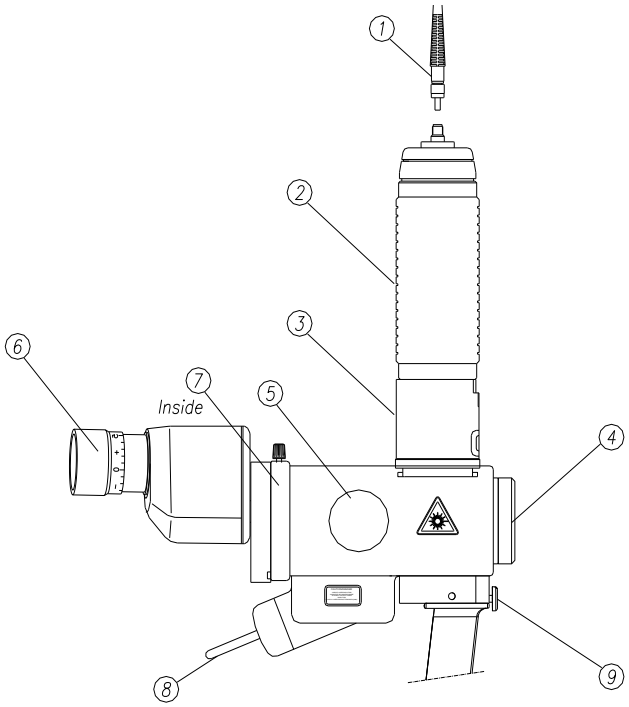


Figure 4.6
Integrated Slitlamp LDU Controls

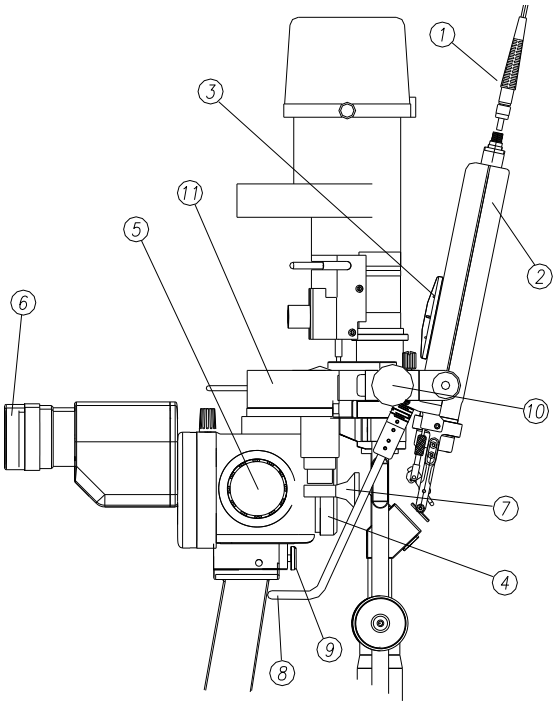


Figure 4.7a
Attachment Slitlamp LDU Controls

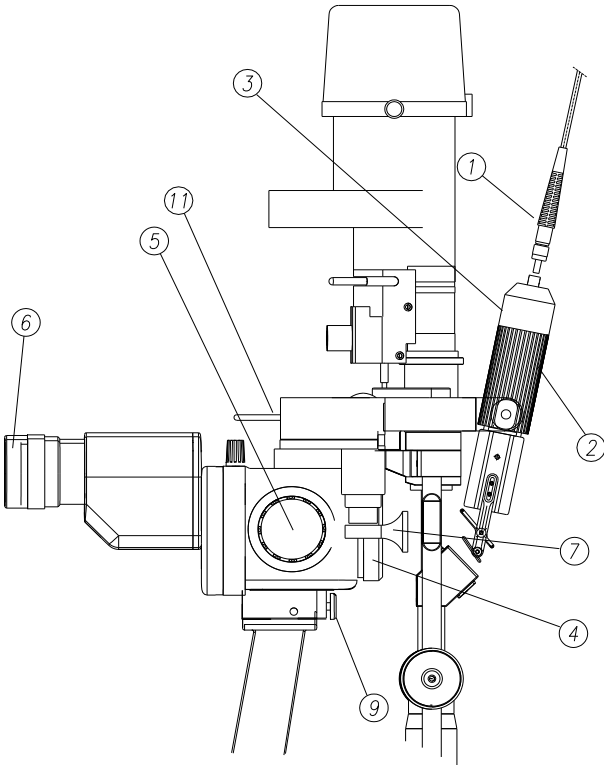


Fig. 4.7b
Truspot Attachment Slitlamp LDU Controls (New version)

1. **Optical Fiber**

   This optical fiber connects between the Slitlamp LDU and the Laser Console. The treatment laser and aiming beams are focused into the fiber.

2. **Zoom System**

   This optical system allows the laser beams spot size to be adjusted at the treatment site from 50 to 1000 μm by rotating the control.

3. **Spot size indicator**

   As the zoom system is adjusted the actual spot size at the treatment site is shown in this indicator window.

4. **Objective focus lens**

   This is part of the Slitlamp unit and the Laser beams are also focused by this lens to the treatment site. The focus length is 117mm.

5. **Magnifier Control**

   The magnification as seen by the doctor is adjusted using this control. The selected magnification is shown on the knobs. A larger magnification will give a larger image of the treatment site.

6. **Binocular and eyepieces**

   The doctor looks through the eyepieces to view the patient. The Interpupillary Distance can be adjusted as well as the individual's Diopter settings for each eyepiece.

7. **Doctor Safety Filter**

   This safety filter is a standard set-up in every Slitlamp LDU and is located at microscope housing. This filter will prevent back reflections during laser treatment which may cause injury to the doctor's eyes. Usually the filter is a fixed optic lens however it is also an option to install a moving filter. The orange filter provides protection >OD4 @ 532nm

8. **Micromanipulator Joystick (old version type only)**

   This joystick is used for doctor or operator to accurately position the laser beams spot within the central portion of the illumination field of the view.

9. **Focus Set Screw**

   This screw is used to set the viewing focus of the microscope to be in sharp focus on the Target Rod. Tightening this screw into the housing, the focus point is moved away from the Target rod and it is towards the user. Loosening this screw and then pushing the microscope housing up firmly against the screw sets, the focus more towards the patient.

10. LDU Spot Focus Adjuster (old version type only)

In order to set the correct focus point for the treatment and aiming laser, adjust this screw to get the smallest spot size possible at the focal plane.

11. LDU Spot Centering Adjuster

This is applied when the laser delivery unit is installed in order to accurately set the laser beam in the center of the field of view in the horizontal plane. It is located on the LDU mounting arm above the Tonometer mount. By moving the mounting arm right or left and swing this adjuster right or left until reaching position you need. If necessary repeat the adjustment until the alignment is correct.

Slitlamp LDU system can be integrated with two types of the slitlamp that carry by Lightmed are as:

- CSO SL980 (Integrated with Slilamp)
- CSO SL990 (Can be integrated with attachment slitlamp LDU system)
  More detailed breakdown is shown in section 4.2.4 (page 52 to 55)

4.2.4 Laser Indirect Ophthalmoscope (LIO)

The controls on the LIO (refer to Fig. 4.8 a-b) are used to adjust the position of the treatment laser beam to the Illumination spot. All other controls either adjust the Illumination spot or the fitment of the unit for the doctor. More detailed breakdown description can be found in the following pages.

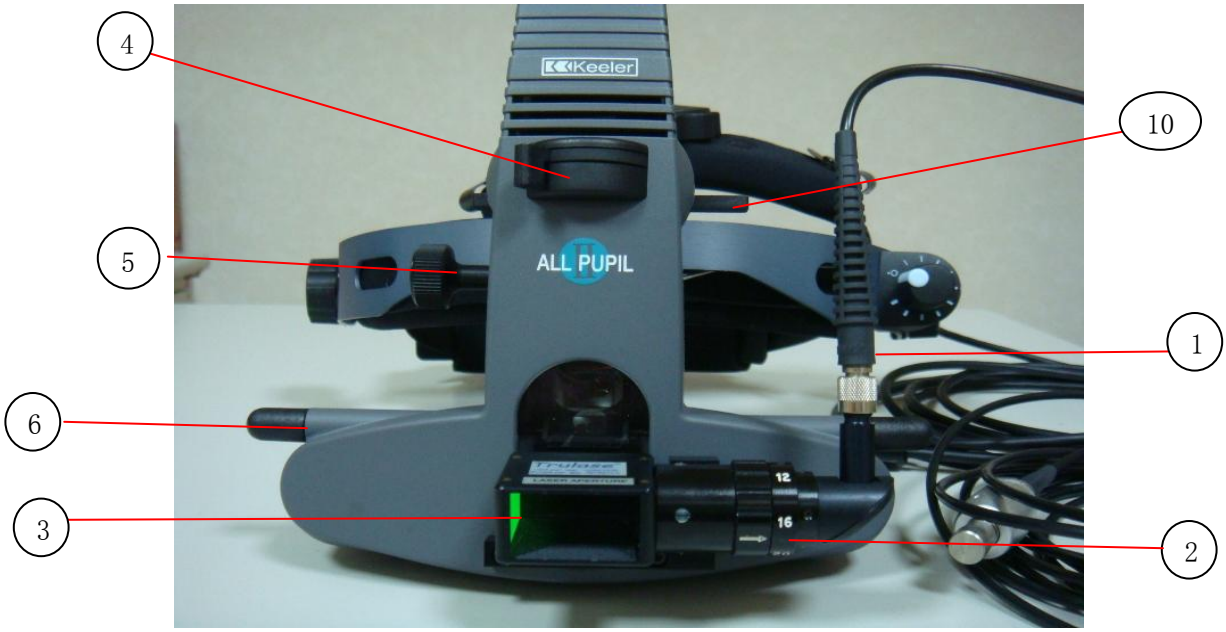


Figure 4.8(a) Front View of LIO LDU Controls

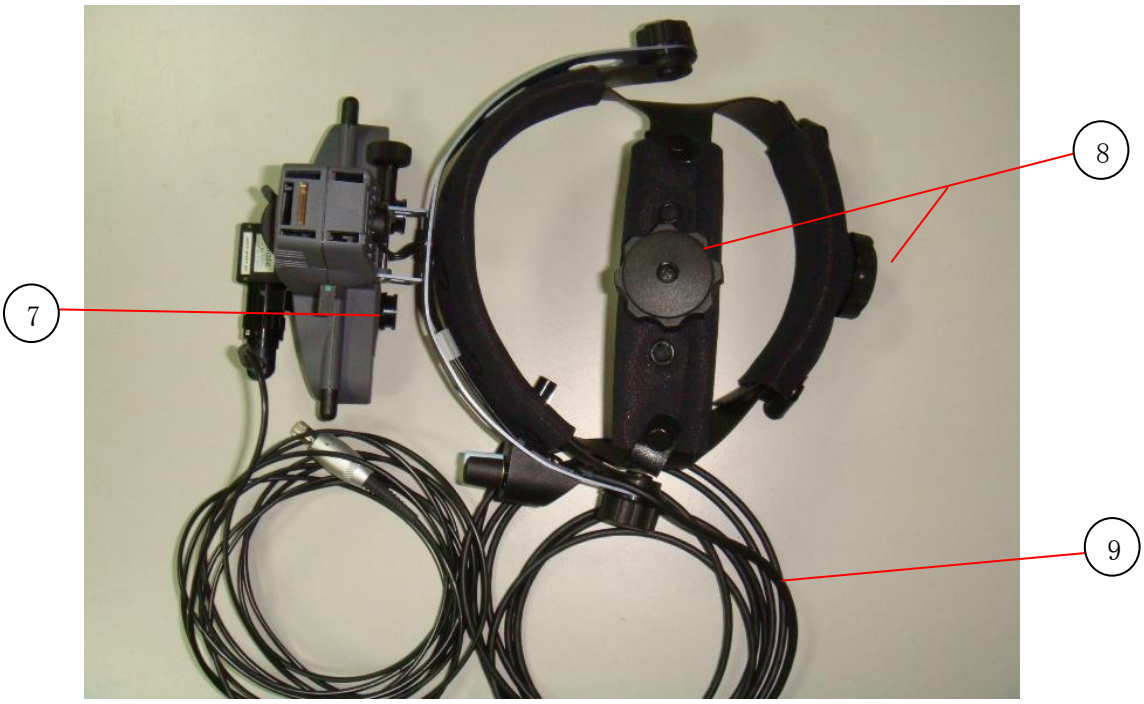


Figure 4.8(b) Top View of LIO LDU Controls

1. **Optical Fiber**

   The optical fiber connects between the LIO and the Laser Console. The treatment and aiming beams are focused into the fiber.

2. **Zoom System**

   This optical system focuses the laser beams to the correct spot size suitable for the intended application. The spot size can only be adjusted by the use of hand held Laser lenses.

3. **Vertical Treatment beam adjuster**

   This control, which can be adjusted from either side of the zoom housing, is used to adjust the vertical position of the Laser beams with respect to the illumination spot.

4. **Illumination spot size control**

   This controls the adjustment from either side of the illumination housing and is used to select the 3 different spot sizes and the defocus setting.

5. **Eye Housing Adjustment and Locking Control**

   This control is used to adjust from the entire eye piece housing up / down position and tighten up by locking it the screw.

6. **Illumination spot height adjuster**

   These two controls on either side of the LIO are used to change the position of the illuminated spot with reference to the field of view of the doctor.

7. **Eyepieces**

   The eyepieces are fixed to the LIO so it can be adjusted to the suitable interpupillary distance for the doctor. The special optical safety filters are built in to protect the doctor's eyes from possible back reflections of the laser beam treatment.

8. **Headpiece**

   The headpiece forms part of the LIO and is adjustable to suit any size of heads. The adjustment knobs can be found on the top and the back of the LIO. In addition on the side is control that allows the Illumination and Laser housings to the lifted up and out of the doctor's field of view.

9. **Illumination Cable**

   This cable connects to the Laser Console front panel and provides the power for the Illumination Lamp.

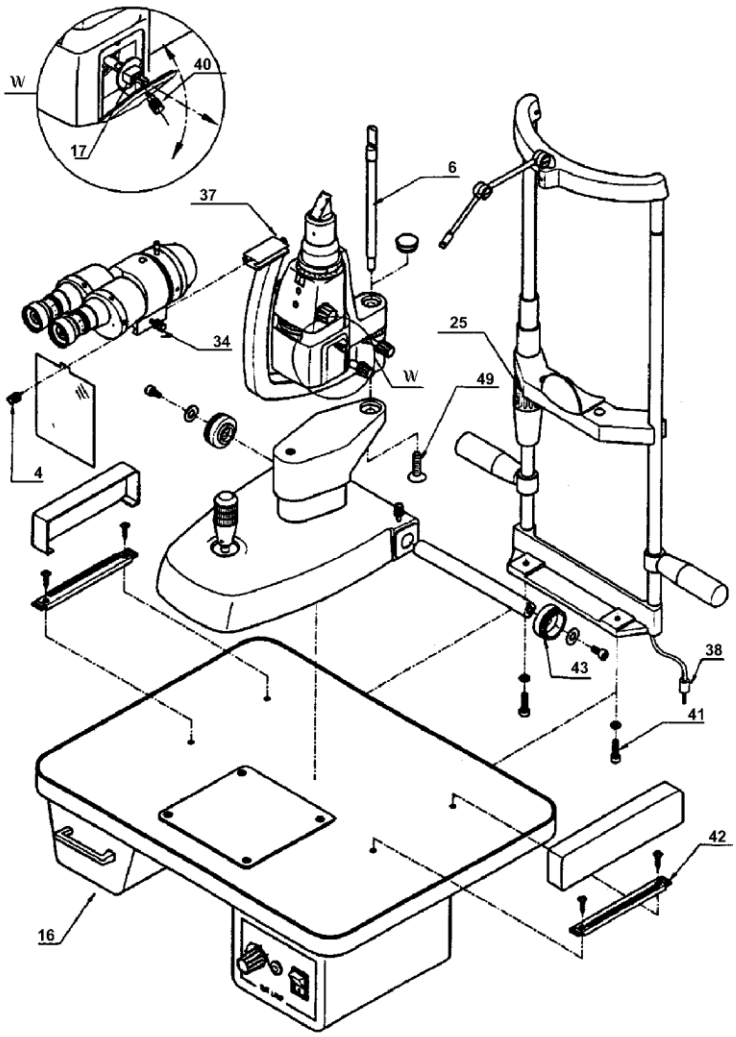
10. Illumination aperture filtering control

This control is used to filter out application required by physician or user. There are three types of filters such as, Red Free, Heat Absorbing, and Cobalt Blue.

4.2.5 Two types of Integrated CSO SL980 and SL990 Slitlamp Controls Breakdown

The CSO Slitlamps can be used as a standard diagnostic tool and all the standard Slitlamp functions are available.
The following figures 4.6 and 4.7 show all of the controls that can be found on the Slitlamps and the description of the components.

CSO SL980 Slitlamp Controls



LEGEND
1) Fixation point
2) Control lever for changing enlargement
3) Removable eye-pieces
4) Knob for clamping the breath screen
5) Breath screen cod. 10.02.06.117
6) Control handle cod. 10.02.02.090
7) Knurled ring for slit hight regulation and filters insertion
8) Slit projector head for Galileian 980
9) Joystick for lateral, longitudinal and vertical movements (x y z)
10) Base with orthogonal movements
11) Tabletop cod. 10.07.02-10
12) Transformer warning light
13) Main switch
14) Voltage selector to adjust luminosity
15) Transformer box cod. 10.02.10.900
16) Accessories box cod. 10.02.02.820
17) Lamp 12V 30W cod. 3008011230A
18) Crankcases cod. 10.01.01.135
19) Teflon sliding plate cod. 10.01.01.136
20) Knob to lock the projector
21) Scale for the projector position
22) Knob to lock the arm of the microscope
23) Slit projector head for 2X microscope
24) Knob for slit bulb replacement
25) Knob for the vertical setting of the chin-rest
26) Locking pins for chin-rest papers
27) Chin-rest
28) Knobs to change the slit width
29) Pointer for the eye positioning
30) Head rest
31) Galileian Microscope 980
32) 2 enlargements microscope
33) Knob to lock the base-slide of the instrument
34) Knob to lock the microscope
35) Connecting plug
36) Voltage-changer and fuse slots
37) Microscope position stop
38) Fixation point connector
39) Knob for hand rest
40) Knurled knob to open bulb soket lid
41) Screw for lock the chin-rest
42) Cog-slide 980 cod. 10.02.10.415
43) Cog-wheel 980 cod. 10.02.10.414
44) Knob to separate the microscope
45) Separator to insert the microcamera on the microscope gal. 980 cod. 10.02.10.300
46) Protection cover cod. 4013090
47) Chin-rest papers 100pcs. cod. 4014010
48) Maintenance wrenches
49) Fastening screw for lamp unit

CSO SL980 Slitlamp Controls continues...

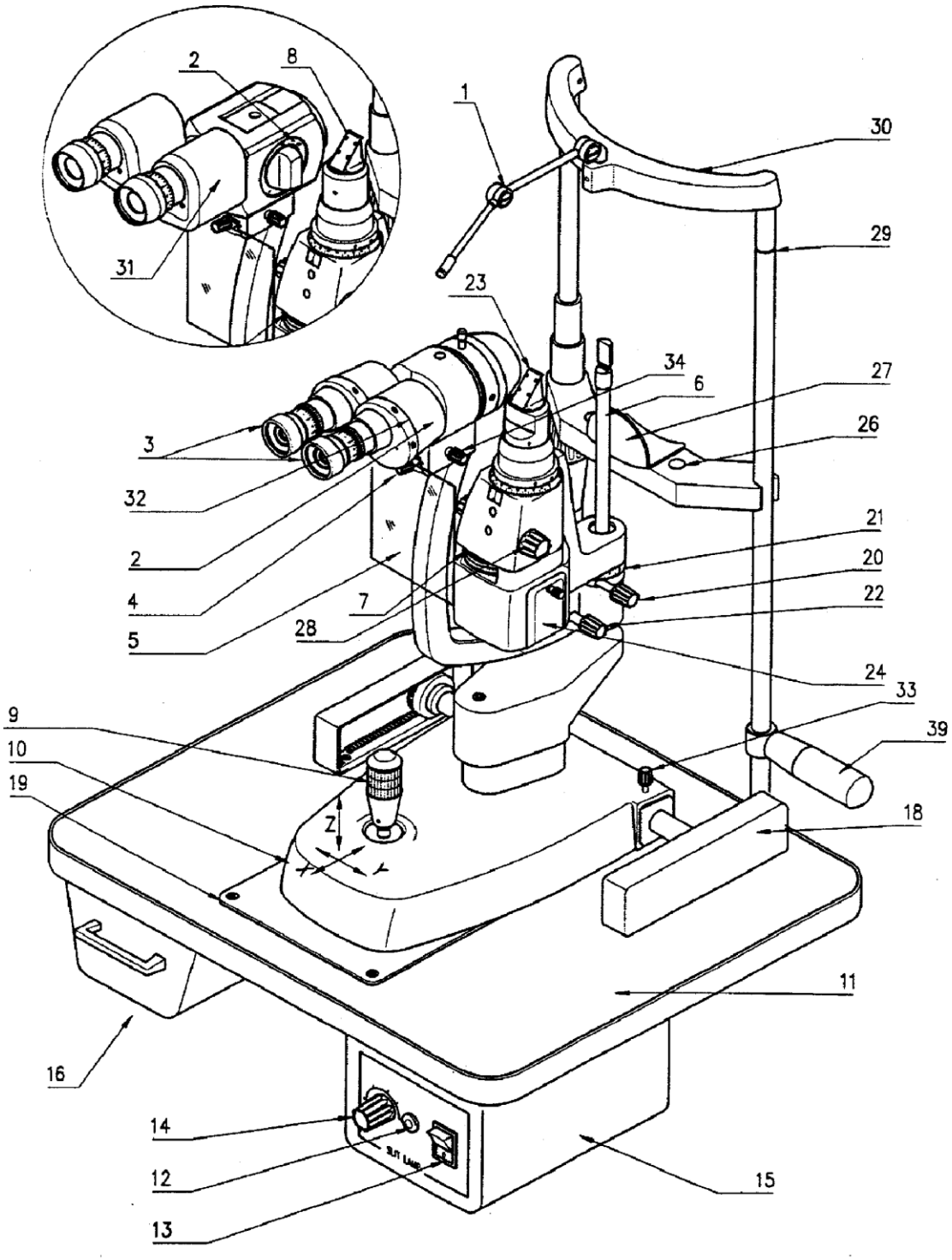
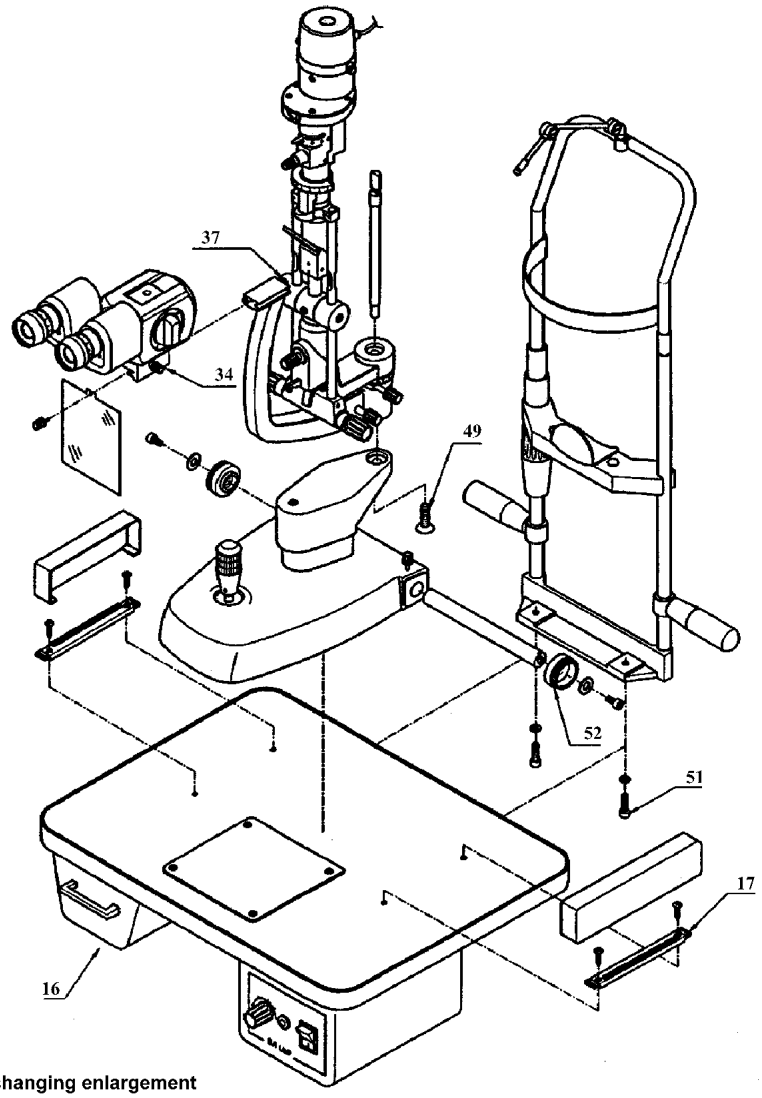


Figure 4.9 SL980 Slitlamp Parts List and Controls

CSO SL990 Slitlamp Control



LEGEND

1) Fixation point
2) Control lever for changing enlargement
3) Removable eye-pieces
4) Knob for clamping the breath screen
5) Breath screen cod. 10.02.06.117
6) Control handle for the slit rotation 90-0-90
7) Connecting plug of the projector lamp
8) Knurled ring for filters insertion
9) Joystick for lateral, longitudinal and vertical movements (x y z)
10) Base with orthogonal movements
11) Shaped tabletop code 10.07.02.-10
12) Warning light indicating the ignition of the transformer is on
13) Main switch
14) Voltage selector to adjust luminosity
15) Transformer box cod. 10.02.06.900
16) Accessories box with guides 10.02.02.820
17) Toothed guides code 10.02.10.415
18) Wheel protection crankcases code 10.01.01.135
19) Teflon sliding plate code 10.01.01.136
20) Knob to lock the projector
21) Scale for the projector position
22) Knob to lock the arm of the microscope
23) Holder of the tonometer plate
24) Knurled knob to lift the bulb holder
25) Ring for the vertical
26) Locking pins for chin-rest papers
27) Chin-rest
28) Knobs to change the slit width
29) Pointer for the eye positioning
30) Head rest
31) Microscope
32) Bulb feeding contacts
33) Knob to lock the base of the instrument
34) Knob to lock the microscope
35) Control handle for horizontal tilting
36) Control lever for vertical tilting
37) Microscope position stop
38) Graduated ring 90-0-90 determining the inclination of the slit during rotation
39) Lamp cover
40) Voltage-changer and fuse slots
41) Connecting plug
42) Fixation point connector
43) Setting rod code 10.02.02.090
44) Microscope separation knob
45) Separator
46) Protection cover code 4013100
47) Chin-rest papers: 100pcs. Code 4014010
48) Valve seat wrench
49) Bulb holder unit fastening screw
50) Transformer specifications plaque
51) Chin rest fastening screw
52) Cogwheel code 10.02.10.414
53) Halogen bulb PG22 6V 20W code 3008010620C
54) Bulb fastening knob

CSO SL990 Slitlamp Controls continues...

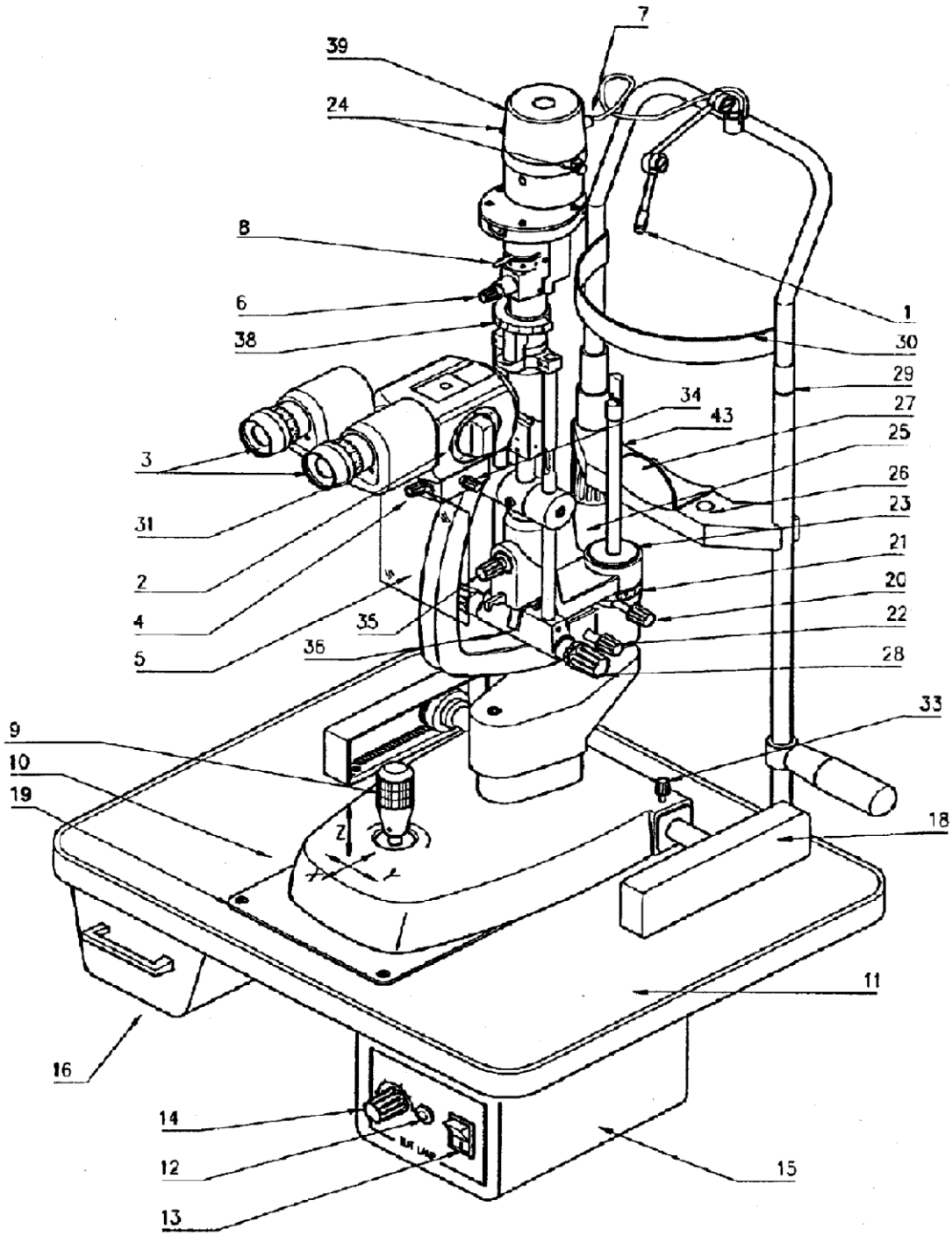


Figure 4.10
SL990 Slitlamp Parts List and Controls

Section 5 INSTALLATION

5.1 Introduction and Requirements

It is strongly recommended that the manufacturer or its authorized agent install the LightLas 532 Laser System at the operator site to ensure that the system is operating correctly, aligned and calibrated according to specification. After this initial installation it is the operator's responsibility to ensure the laser system is operating correctly whenever the laser is moved or relocated.

The following procedures should be followed in order to successfully install the laser system. The checklist and report form should be completed and a copy sent to the manufacturer. **In the event that the report is not sent to the manufacturer then the manufacturer reserves the right to decline any warranty claims that may be forthcoming.**

The installer should also retain a copy and the customer may keep a copy too.

All precautions care must be taken when installing the LightLas 532 to ensure that you or others are not exposed to any hazardous laser radiation. Always wear laser safety glasses suitable for the 532nm wavelength to protect your eyes.

The installation requirements are:

1. 100-230 Volts, 50 or 60Hz AC mains power supply with an earth connection. This is a single-phase outlet capable of delivering up to 400 Watts.
2. A motorized stand that the Table provided with the Slitlamp can be fitted to is required if one was not purchased with the Laser system. Ensure the Table is fitted securely to the Stand using the supplied screws.
3. A mains power cable is supplied but the connector may not suit the outlet available so it is advisable to have a spare locally compatible cable available. The Cable assembly must be CE approved for EU Countries.
4. A suitable room to place the Laser System in that provides for a safe working environment is required. As with other ophthalmic equipment a dimly lit room is preferred.
5. The Laser System has the facility to connect a remote door interlock to the Laser treatment room. If this option is required then the customer must organize this with an electrician and the manufacturer or authorized agent can provide instructions on how to connect to the Laser System. The Laser System is provided with a Bypass plug in the event that this option is not installed. This plug is referred to as the "Interlock Key" and must be inserted into the back of the console, in order for the system to operate. Do not remove this Bypass connector unless you intend to install the remote door interlock switches at the site. Removing the connector will prevent the Laser from operating.

6. If the user needs to move the Laser system to a new location it is recommended to lock all the movement screws on the Slitlamp and carefully transport to the new location. If the new location is at a different facility then the User should consider repackaging the Slitlamp Delivery system in its original foam packing prior to moving to the new site. This will help to prevent any damage occurring to the System. When the relocation is completed then the correct operation and functioning of the Laser system should be performed according to the following steps in this section and sections 7.2 and 7.3 of this Operator Manual.
7. The LightLas 532 Laser Console can be relocated easily as it is a portable device. When required to be used with the LIO or Endo-ocular Probes the Console can be carefully transported to the new surgery location. Treat the Laser Console with the same care as should be offered to any precision surgical device. When the Laser is set up at the new site check the operation as per Section 5.0 of this manual.
8. When installing the LightLas 532 as a System with Slitlamp onto a Table then care must be taken to ensure that the set-up is optimized for the User with all parts of the System correctly installed and mounted so that both the Patient and Doctor are comfortable and safe during the treatment. There are no specific safety issues when installing the System however it is recommended that the Motorized Table mains Power cable not be plugged into the same Multiple Portable Socket Outlet as the Laser Console and Slitlamp power supply cables. Use a separate wall mounted Power outlet.

5.2 Unpacking and Receiving Inspection

When receiving the laser system, there will usually be two cardboard boxes. One will contain the laser console. Depending on what was ordered, the other may contain the integrated system, AD delivery attachment kit, or the laser indirect ophthalmoscope. Refer to figures 5.1 and 5.2 for examples.

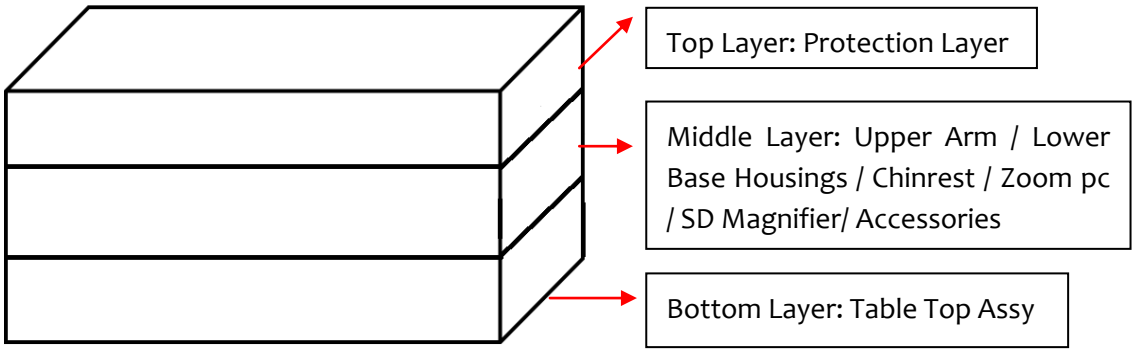
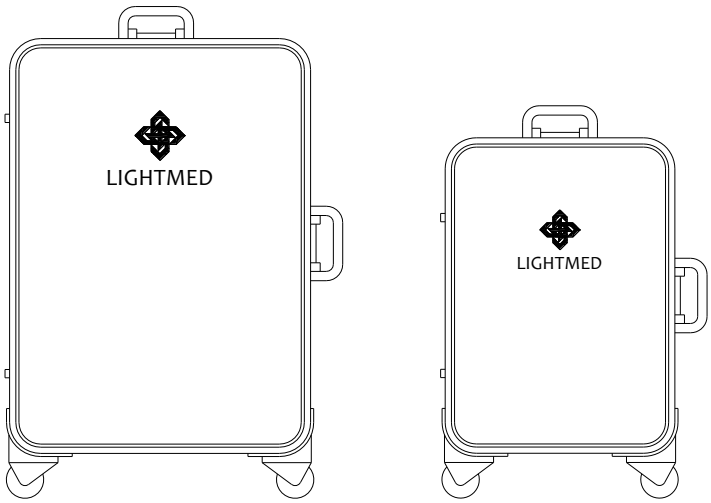


Figure 5.1
Packing Carton for Integrated LDU and Slitlamp (Optional)



Console Carrying Case LDU Carrying Case (Optional)

Figure 5.2 Portable Carry Cases for Console and LDU's

Upon receiving the system inspect the packing carton for any signs of mishandling, which must be reported to the freight handler before the instrument is unpacked. If there is damage, then the manufacturer reserves the right to decline any warranty claims that may be forthcoming so it is essential that the freight company will take full responsibility for any damages.

If the outer cardboard packaging looks OK then you can proceed to remove the internal packed assemblies (refer to Fig. 5.1). The contents of each layer are:

1. The top layer is just a protection layer.
2. The middle layer contains the Chinrest and Integrated LDU including the Zoom assembly, binoculars, eyepieces, target rod, target plate, cross-slide shaft and gears, gear covers, spare lamp, manual, mains power cable.
3. The bottom layer part contains the table top.

The packing checklist is used to confirm the individual layer contents and notify the manufacturer if any discrepancy. The motorized table is an optional and may be purchased from the manufacturer.

5.3 Tools and Equipment

In order to be able to effectively carry out a full initial installation of the Green Laser System the following tools and equipment are required and available from the manufacturer:

1. Laser Power Meter (to measure from 0 to 2 watts CW)
2. Optical Alignment tool kit, which includes:
   - Model Eye
   - Laser target tool
3. Photographic thermal paper (Zap-it or equivalent)
4. Set of metric Allen keys
5. Screwdrivers (Philips / Roberson)

It is both essential and mandatory to have the all above listed tools and equipment in order to assemble or disassemble Lightlas in a correct and safe way

5.4 Setting Up the Laser System Parts

Preparation

All the possible items used during installation of the Green Laser are shown below in Figure 5.3. From the top left-hand side in a clockwise direction the parts are:

1. Laser Console
2. Integrated Laser Delivery Unit Microscope assembly with Zoom unit
3. LIO Assembly
4. Fiber Delivery cable
5. Endoprobe Plug
6. Endoprobe
7. 4 Different Delivery Key Connectors
8. Attachment Laser Delivery Unit (New One without Micromanipulator-Truspot)
9. Microscope Laser Safety Filter units
10. Footswitch (including a Signal Receiver and a Footswitch Cable)

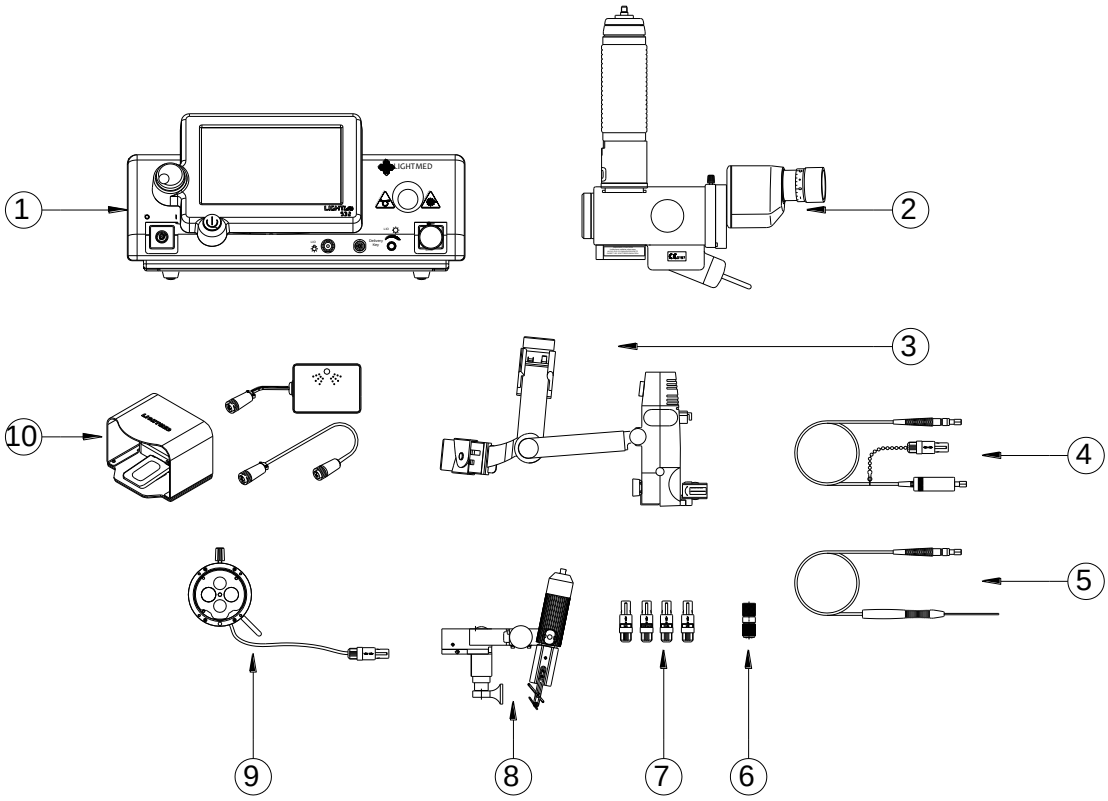


Figure 5.3
Laser System parts

All the items above and the rest of the system should be unpacked from their cartons and carry cases and inspected for transportation damage and general condition. Extreme care do not to touch the optic lens or parts and make sure all the items are available.

The System consist of two major parts as follows:

- LDU system (Slitlamp: Integrated or Attachment / LIO / Endoprobe)
- Console

LDU Systems

5.4.1 Slitlamp Integrated LDU

Prior to install the Slitlamp Integrated system, ensure all the corrected setup and equipment are in placed to proceed the installation steps.

System Part(s):

- Upper Arm Housing
- Lower Base Housing
- Table top
- Accessories (binocular, cover, chinrest, and target rod)

Procedures:

1. Unpack all the packaging items from the cartoon box
2. Lay the ready to go table on the final destination location (well level) and ensure all the accessories are installed including rail and joystick slide pad (refer to fig. 5.4)
3. Ensure the voltage and fuses rate setting are set up correctly, as default setting is 230VAC (refer to fig. 5.5a-d)
4. Take the Slitlamp upper arm housing and lower base housing with cross-slide shaft assembled (refer to fig. 5.6)
5. Assembled the upper and lower housing together by securing the screw at rear end of lower housing (refer to fig. 5.7)
6. Position the Slitlamp ass'y back to the gear rail and gently wheel it back and forth to get it smooth out
7. Ensure the Slitlamp ass'y is horizontally parallel in x-axis
8. Place the gear cover
9. Install the Chinrest ass'y and connect the fixation lamp to the source box and plug in the source power connection (refer to fig. 5.5a)

10. Clamp the fiber support arm into its holder

Figure 5.4 Slitlamp table top ass'y

Note: The table top can be accommodated in two types of stand that the Lightmed manufacturer such as, 'T' and 'C' types of table stand. All appropriate installation guides are inserted in the packaging .

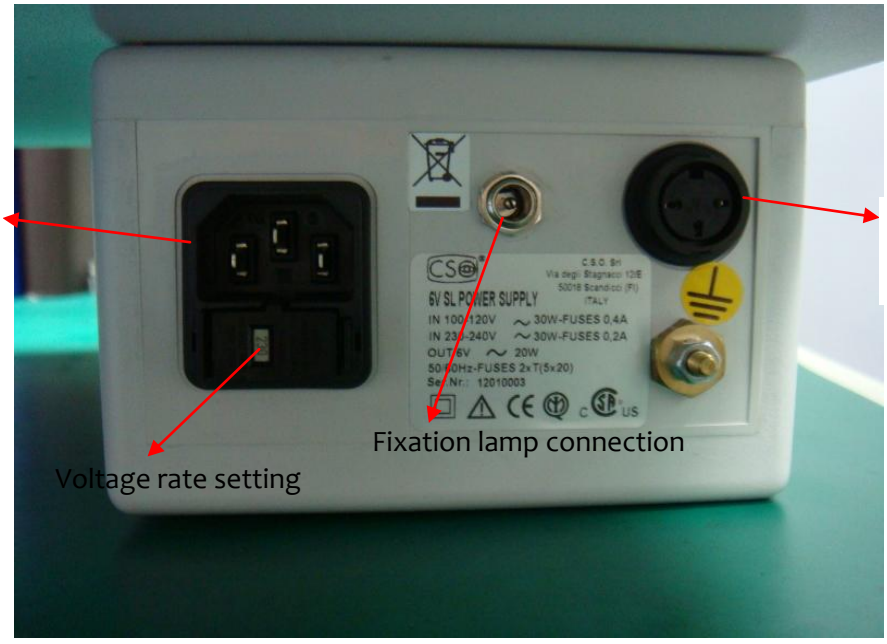


Figure 5.5 (a) Rear view box connection

Figure 5.5 (b) Removal of fuse holder

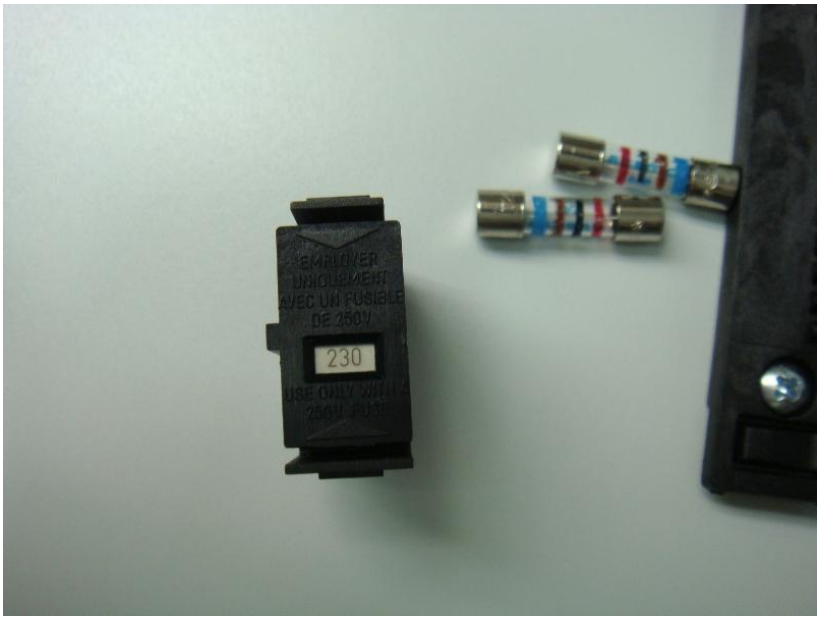


Figure 5.5 (c) Removal of fuses and check the fuses rate

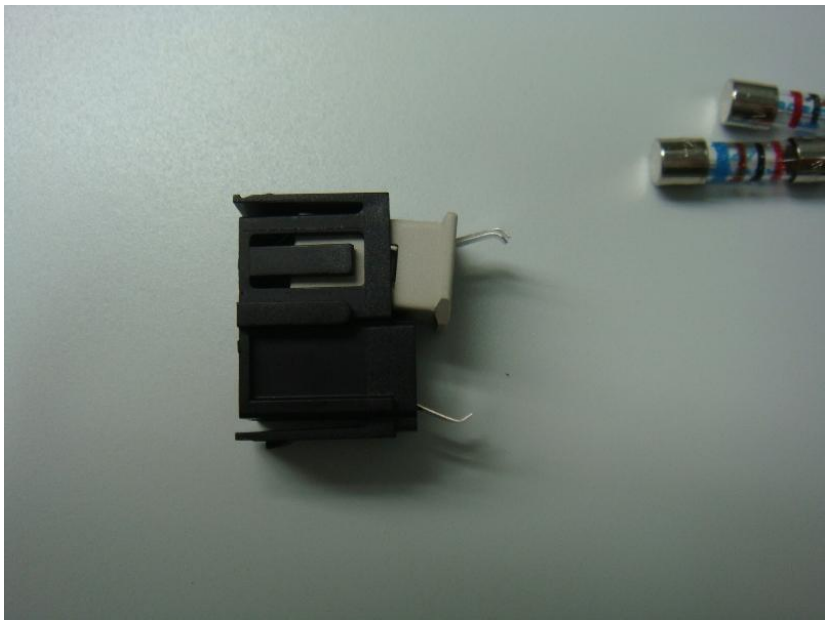


Figure 5.5 (d) Removal of voltage setting block and reinsert it back upon completion

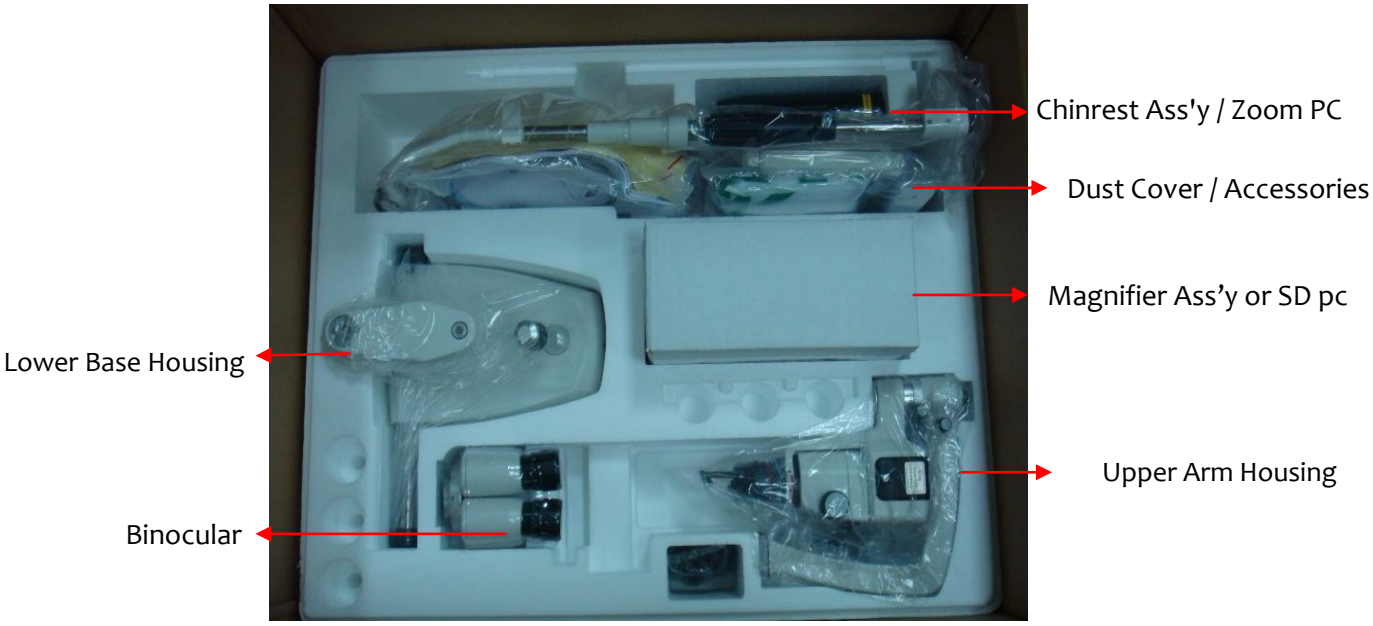


Figure 5.6 Slitlamp Ass'y

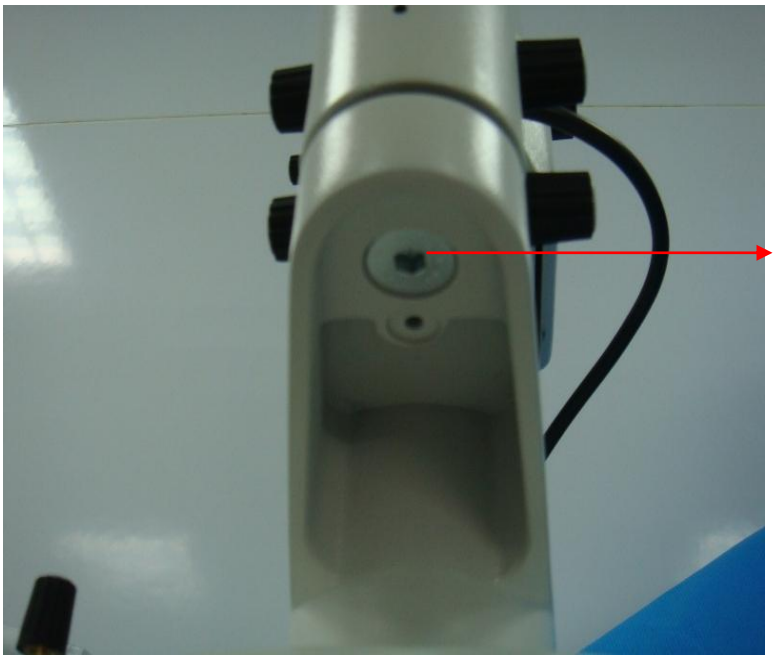


Figure 5.7 Assembled Upper and Lower Housing Screw

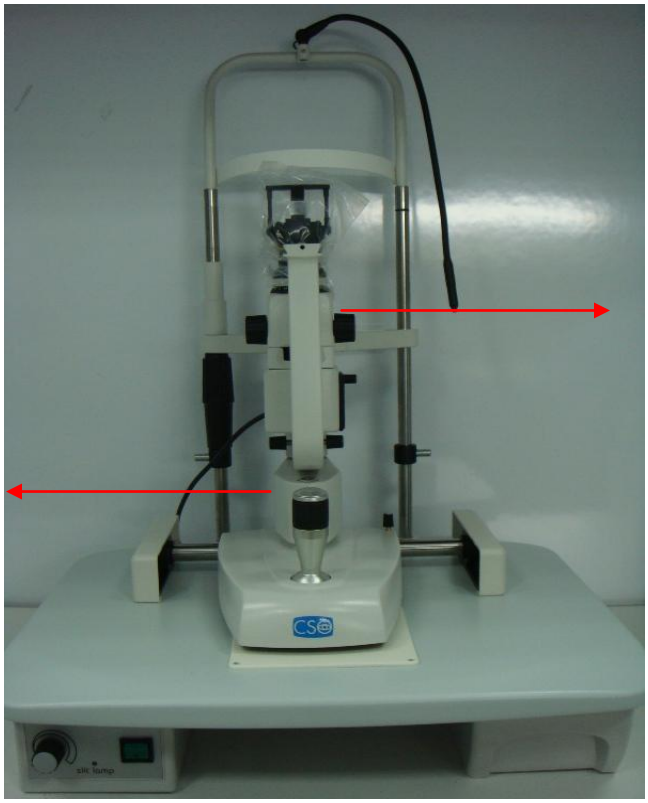


Figure 5.8
Slitlamp mounted onto Table Top ready for Integrated LDU

5.4.1A Integrated Slitlamp Delivery Unit (System Parts) continue…

Prior to continue the Integrated Slitlamp delivery unit parts system installation, ensure the slitlamp integrated main body housing and table top are corrected setup and equipment are in place.

System Part(s):

- SD Housing
- Zoom Piece

Procedures:

10. Ensure the locking screw is loosen prior to slide in the Slitlamp delivery unit (refer to fig. 5.9)
11. Slide the SD magnifier pc into the mounting plate arm and ensure it fully reach to the end of the stopper (refer to fig. 5.10)
12. Secure the locking screw and lock the housing by tightening the screw (refer to fig. 5.11)
13. Remove the zoom pc from the box and align the keyway against the delivery housing (refer to fig. 5.12-5.13) and rotate it in
14. Ensure zoom pc is all the way in and the spot size numbering indicator is facing towards operator's end
15. Proceed to pre-check / alignment section on page 77-80 upon completion of pre-installation procedures

Figure 5.9 Slitlamp arm ready for Delivery housing

Figure 5.10 Fit Delivery unit housing to the Slitlamp

Figure 5.11 Lock the housing securely to the Slitlamp when it is pushed against Chrome Stop screw

Figure 5.12 Align the keyways then fit the Zoom unit to the Delivery housing

Figure 5.13 Rotate the Zoom housing to the end stop

5.4.1B Attachment Slitlamp Delivery Unit

Prior to install the Attachment Slitlamp delivery unit, ensure all the corrected setup and equipment are in placed to proceed the installation steps.

System Part(s):

- Tonometer Mounting block (Haag Streit style / Zeiss 30SL / SYL9000)
- Attachment arm (Haag Streit style / Zeiss 30SL / SYL9000)
- Mounting screws (Haag Streit style / Zeiss 30SL / SYL9000)
- Safety Filters (only for combination system)
- Micromanipulator joystick
- New Modified Illumination Tower (Zeiss 30 SL type only)

Procedures:

1. Place the appropriate mounting post into the magnifier ass'y and secure with the correct mounting screw (refer to fig. 5.15a-c)
2. Swing the slitlamp tower aside prior to fit the appropriate whole attachment body into the mounting block (refer to fig. 5.16a-c)

   If this is the Zeiss 30SL attachment LDU type (refer to fig. 5.14a-b), a minor modification required prior move on to the next step:

   2a. Place a target rod

   2b. Turn on the slitlamp and set aperture setting to the smallest

   2c. Mark on the aperture spot size with pencil

   2d. Remove the old illumination tower and replace with newly modified one

   2e. Verify the new tower against the mark on target rod aperture spot and align and lock if it is confirmed

   2f. Align the spot position by adjusting the mirror if required

Figure 5.14 (a)
Original Illumination Tower

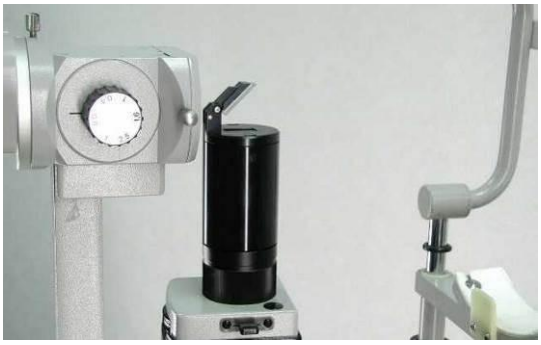


Figure 5.14 (b)
New modified Illumination Tower fitted

3. Attach the micromanipulator joystick to the LDU main body for the old version type only (refer to fig. 5.16a-c)
4. Proceed to pre-check / final alignment section on page 81-84

Figure 5.15 (a) Haag Streit
Attaching Tonometer mount ready for Attachment LDU

Figure 5.15 (b) Zeiss 30SL
Attaching the Tonometer mount and Attachment LDU Mounting Arm

Figure 5.15 (c 1) Lightmed SYL9000
Attaching Tonometer mount ready for HS Attachment LDU

Figure 5.15 (c 2) Lightmed SYL9000
Attaching Tonometer mount ready for AD Attachment LDU

Figure 5.16 (a) Haag Streit
Mounting the whole attachment LDU to Tonometer mount & micromanipulator

Figure 5.16 (b) Zeiss Style 30SL
Mounting the whole attachment LDU to Tonometer mount & micromanipulator

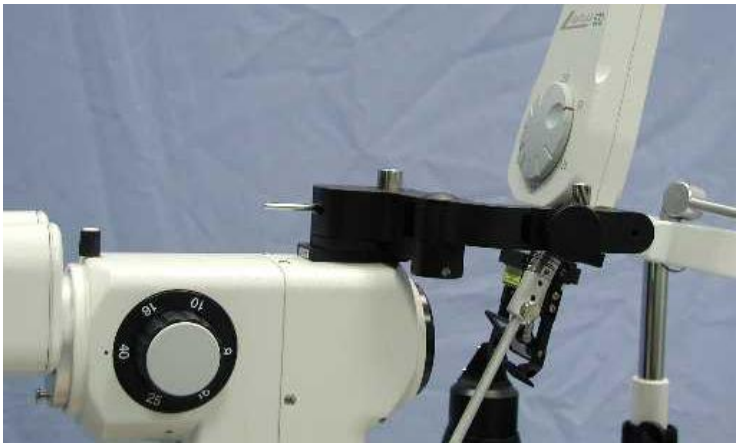


Figure 5.16 (c) Lightmed SYL9000 Mounting the whole attachment LDU to Tonometer mount & micromanipulator

5.4.2 Laser Indirect Ophthalmoscope LDU (LIO)

Prior to install the LIO delivery unit, ensure all the corrected setup and equipment are in placed to proceed the installation steps.

Accessories:

- LIO fiber
- LIO Delivery System set

Procedures:

1. Take a LIO delivery fiber and remove the fiber's protector one end at a time and clean it with alcohol prior to install to the console aperture and LDU (refer to fig. 5.17)
2. Plug in its delivery key and light source power connector (refer to fig. 5.18)
3. Make sure the fiber and the cable are fitted to the strain relief fittings on the LIO headpiece (refer to fig. 5.19)
4. Proceed to pre-check / final alignment section on page 85-86

Figure 5.17 Fiber tips cleaning

Figure 5.18 LIO connections in console

Figure 5.19 LIO LDU fiber connection

5.4.3 Endoprobes LDU

The endoprobe is sterilized single use device therefore there will be no installation procedures involved however, do want to ensure that the endoprobe packaging is not being opened prior to the treatment.

Two types of Endoprobes carry by Lightmed are:

- Straight (P/N 620009)
- Curved (P/N 620010)

Ensure Endoprobe plug is fitted prior to load to console laser aperture (refer to fig. 5.20)

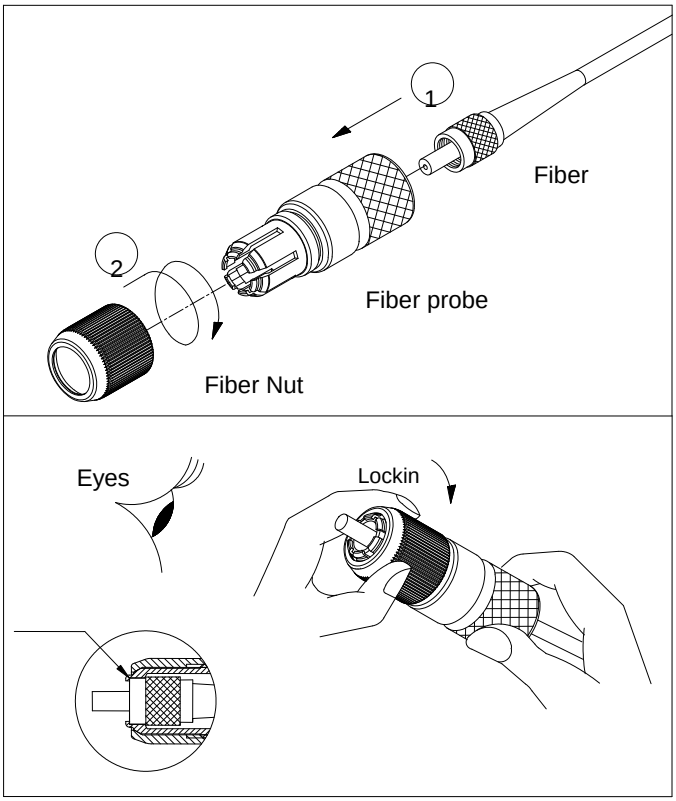


Figure 5.20 Endoprobe plug installation

Follow the pre-check procedures on the page 86 for further process.

Laser Console

Prior to install the laser console device unit, ensure all the corrected setup and equipment are in placed to proceed the installation steps.

Accessories:

- Power cord (110 or 220 VAC type)
- Delivery key (Slitlamp / LIO / Endoprobes)
- Footswitch (wire or wireless)
- Optical fiber (link from console aperture to the LDU could be Endoprobe or standard delivery one)
- Interconnector (Y-modified combination connector / treatment door switch / default dummy connector)
- On/Off Switch Key

Procedures:

1. Position the laser console onto the mounting plate and to the right side of the Slitlamp on the table top
2. Connect or fit all appropriate connectors (power cord, delivery key, interlock, footswitch, key switch, and Endoprobe or standard delivery fiber)
   2a. If this interlock is Y-modified connector, ensure the safety filter and YAG interlock connections are well fitted (refer to fig. 5.21b)
3. Ensure all the connections are fitted no leftover since the improper connection or no connection will result the system not functioning properly (refer to fig. 5.21a-c)

Note: Be extreme careful about the delivery fiber connection. The delivery fiber with the large fiber holder end with delivery key attached is connected to the console aperture and the another end is connected to appropriate delivery system (refer to fig. 5.21c)

Take special care when preparing the fiber to not stress the cable. Hold the connector when removing the protector caps from each end. Never pull on the cable or the cable sleeve as the fiber may be damaged

Figure 5.21 (a) Standard System connection set-up

Figure 5.21 (b) Combo System Y-Joint connection set-up

Figure 5.21 (c) Sample of Delivery Fiber and Delivery Key Connection

5.5 Pre-check / Alignment Procedes

5.5.1 Pre-check Laser console operation

Prior to pre-check the laser console device, ensure all the corrected installation or setup are in placed to proceed the following steps.

Procedures:

1. Reset the emergency pushbutton by unscrewing outward position
2. Power on the console by turning the key switch
3. Verify if the system passes the self-checking mode if not, proceed to troubleshooting section otherwise proceed to next step
4. Confirm if the remote control will reset to the standard operation mode (refer to fig. 5.22a-d)
5. Ensure the safety filter is installed prior trigger and fire the laser (refer to fig. 5.23)
6. Ensure the appropriate optical fiber (Endoprobe / standard delivery fiber) is attached from the console to the LDU system (refer to 5.24)
7. Check the output power of the system and ensure it is met the specification requirements according to the section 7.3 of this manual

Figure 5.22(a) System boot up sequential display #1

Figure 5.22(b) System boot up sequential display #2

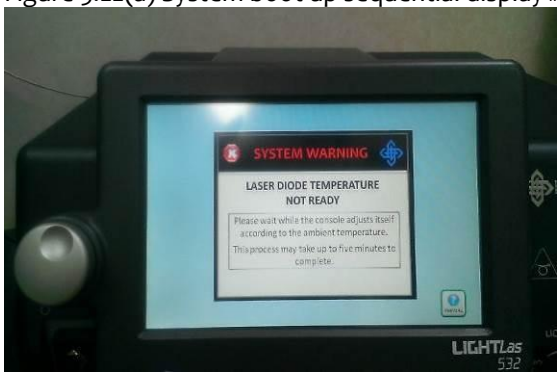


Figure 5.22(c) Power on console & system is initializing temperature process

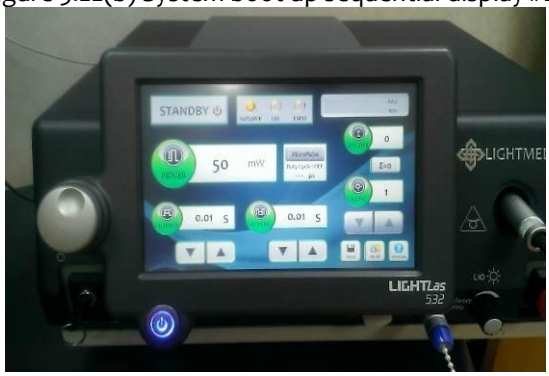


Figure 5.22(d) System is ready to go

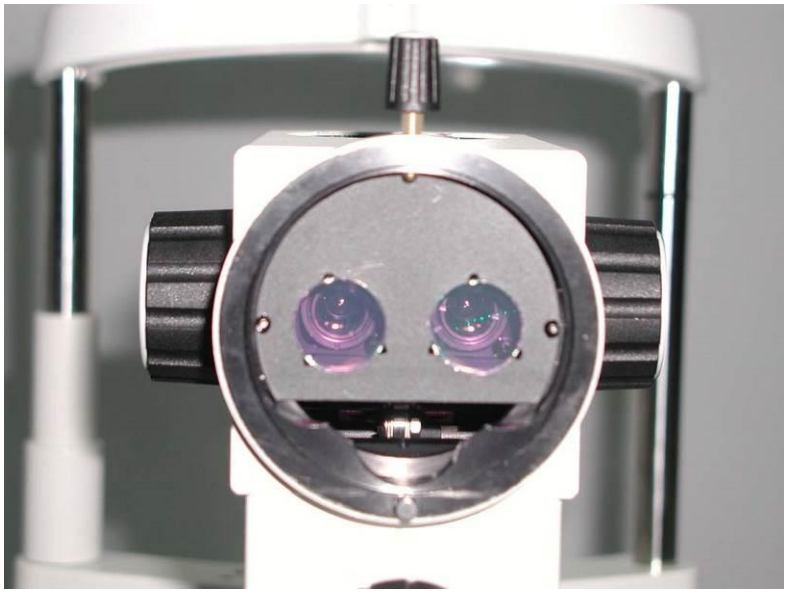


Figure 5.23
Safety filter checks

Figure 5.24
Attach the Delivery fiber to the Zoom unit

5.5.2 Pre-check / Alignment LDU

When the Laser Delivery unit has been fitted to the Slitlamp the alignment of the Laser beam with reference to the Slitlamp needs to be checked and adjusted accordingly. The following procedures will guide you through the entire pre-check and alignment process. Three different types of LDU systems are detailed as follows:

- Slitlamp (Integrated / Attachment)
- LIO
- Endoprobe

5.5.2.1A Integrated Slitlamp LDU

Prior to pre-check and realign the integrated Slitlamp LDU, ensure all the corrected installation or setup are in placed (including eye piece dioptre setting, fiber connection, and console setup and on) prior to proceed the following steps.

Slit Integrity Checkout

1. Insert the Slitlamp target rod into the Slitlamp or set up a target to view the Illumination spot
2. Set a narrow slit width with low intensity illumination and verify that the slit is focused and that the two slit lines are aligned together for the Integrated Delivery Unit Slitlamp. If not align, proceed to following steps:

2a. Unscrew the upper slit alignment screw slightly or lower slit alignment depending on your preference (refer to fig. 5.25)

2b. Choose one end as your starting reference and realign the another

Note: Do not over loosen the alignment screws completely specially the upper slit due to the slit prism module may fall off and break prism mirror

2c. Confirm it by illuminating the aperture to see if you have aligned them ok

2d. Process to the next step if it is aligned

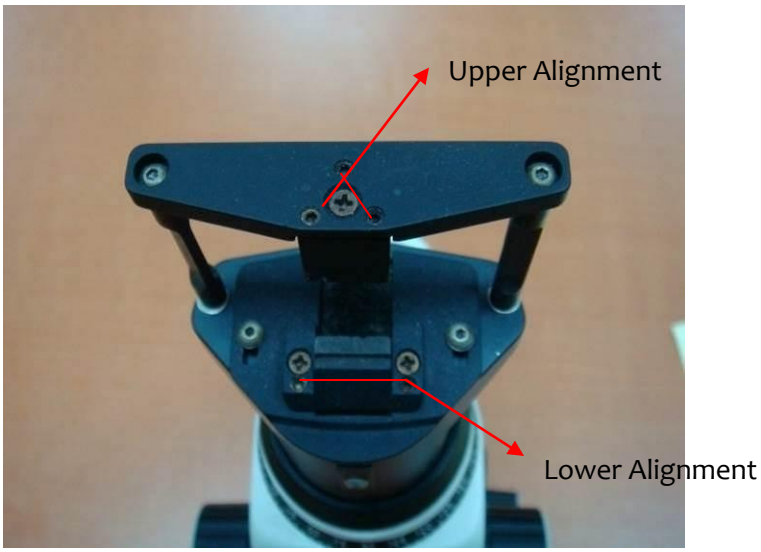


Figure 5.25 Upper / Lower Slit Alignment

Aiming Integrity and Focus Checkout

3. Set spot size to the smallest by adjusting the zoom pc

4. Power on the console and toggle the mode to "Treat" mode

5. Verify if aiming round spot is reflected on the target rod

6. Adjust the spot size from 50 to 1000µ by rotating the zoom pc and verify if the spot size is consistently enlarged from smallest to largest at same spot or location approximately

7. Loosen up the delivery housing screw and adjust it back and forth until the focus is correct and then secure the screw tightly (refer to fig. 5.11)

8. Remove the target rod and place a piece of black tape or thermal paper on the chinrest

9. Verify the slit and aiming beam focus are in focus together

Micromanipulator Joystick Movement Checkout

10. Place back the target rod and verify the micromanipulator joystick is moving within the full range of the field view when illumination spot is set at largest (refer to fig. 5.27a-b) If not, refer to below steps for fine tune-up SD housing:

    10a. Loosen the one of set screw (1.5mm allen key) at delivery housing (refer to fig. 5.26) depending the axis that is not reaching to the most far end perimeter of view of field

    10b. Realign while viewing through the binocular and repeat until aiming spot is with the full range of the field view (refer to fig. 5.27a-b)

    10c. Proceed to next stage once completion of realignment

Note: Usually this step is unlikely to be realigned unless due to the outer force impact during the transportation

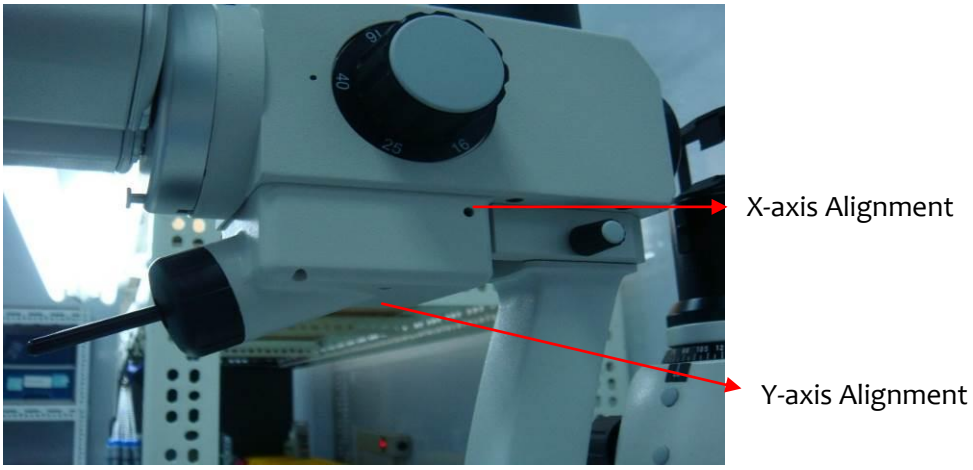


Figure 5.26 Realignment set screw location (X-Y axis)

Figure 5.27 (a) Checking Field of View set-up

Figure 5.27 (b) Checking manipulator operation on the target

Final Testing and Verification

11. Power on the console and ensure its delivery fiber is connected through the fiber holder (refer to fig. 5.24)
12. Configure the output power to 50mW, duration 0.2s, interval 0.2s, and spot size 50µ
13. Remove the target rod and place a thermal paper or black tape on the chinrest
14. Ensure the appropriate safety filter are attached accordingly (refer to fig. 5.23) prior to trigger fire the laser shot
15. Fire the shot and verify if the burn pattern is visible if not, increase the power
16. Increase the spot size to 75µ and 100µ to see if the burn pattern is also getting darker as the spot size increased
17. Verify if everything is consistently and accordingly to the installation, pre-check and alignment procedures, then the system is now ready to use accordingly.

Note: At the higher power settings it may be possible to see a faint luminescence glow at the target site when power setting is set at higher range furthermore this transmission is under the Class I laser limitation.

5.5.2.1B Attachment Slitlamp LDU

Prior to pre-check and realign the attachment Slitlamp LDU, ensure all the corrected installation or setup are in placed to proceed the following steps.

Slit Integrity Checkout

1. Set a narrow slit width with low intensity illumination and verify that the slit is focused. If the Slitlamp focus is OK then set it to a smaller spot size aperture and observe the red aiming beam.

Aiming Integrity and Focus Checkout

2. Set spot size to the smallest by adjusting the zoom pc
3. Power on the console and toggle the mode to "Treat" mode
4. Verify if aiming round spot is reflected on the target rod
5. Adjust the spot size from 50 to 500µ by rotating the zoom pc and verify if the spot size is consistently enlarged from smallest to largest
6. Adjust Mounting arm's black knob (old type version) or the Delivery Main Body locking screw (new type version) to align the focus correctly and then secure the screw tightly (refer to fig. 5. 28a-b)
7. Remove the target rod and place a piece of black tape or thermal paper on the chinrest
8. Verify the slit and aiming beam focus are in focus together

Micromanipulator Joystick Movement Checkout (applicable only to old version type)

9. Place back the target rod and verify the micromanipulator joystick is moving within the full range of the field view and in the center portion when illumination spot is set at largest **(Applicable only to old version type refer to fig. 5.29)**
10. Ensure the illumination spot is reasonable in the center portion of field of view. If not refer to below steps for fine tune-up:

    10a. Loosen the mirror nut that clamp to Main body (refer to fig. 5.30) and low or raise will center the beam correctly and retighten when achieved or

    10b. Loosen the set screw on the side of Tonometer using 1.5 mm allen key and adjust the rod on the Tonometer mount post (refer to fig. 5.30) in aside way to achieve the centering beam and retighten when achieved the position

    10c. Ensure the set screw is tighten and the rod is removed (keep it in a safe location) upon completion

Final Testing and Verification

11. Power on the console and ensure its delivery fiber is connected through the filber holder (refer to fig. 5.24)
12. Configure the output power to 50mW, duration 0.2s, interval 0.2s, and spot size 50µ
13. Remove the target rod and place a thermal paper or black tape on the chinrest
14. Ensure the appropriate safety filter are attached accordingly (refer to fig. 5.23) prior to trigger fire the laser shot
15. Fire the shot and verify if the burn pattern is visible if not also increase the power
16. Increase the spot size to 120µ and 200µ to see if the burn pattern is also getting darker as the spot size increased

Note: At the higher power settings it may be possible to see a faint luminescence glow at the target site when power setting is set at higher range furthermore this transmission is under the Class I laser limitation.

As for other types of Attachment Slitlamp LDU such as, the Haag Streit style or Zeiss 30SL system, the alignment techniques are quite similar and the technique is to align the Slitlamp focus and confirm it is at the same focal plane as the viewing optics. Then align the Laser beams so that at the smallest spot size setting you can clearly see that the Laser spot is at its smallest size at this focus plane. If this is OK then all other spot sizes will match what is shown on the Spot size display.

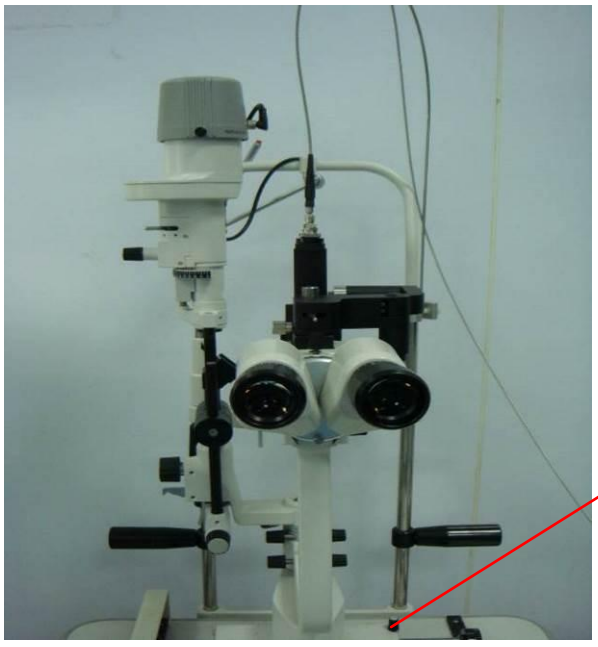


Figure 5.28(a) New Type Version
Check Slitlamp focus on Target Rod and Laser focus of aiming beam

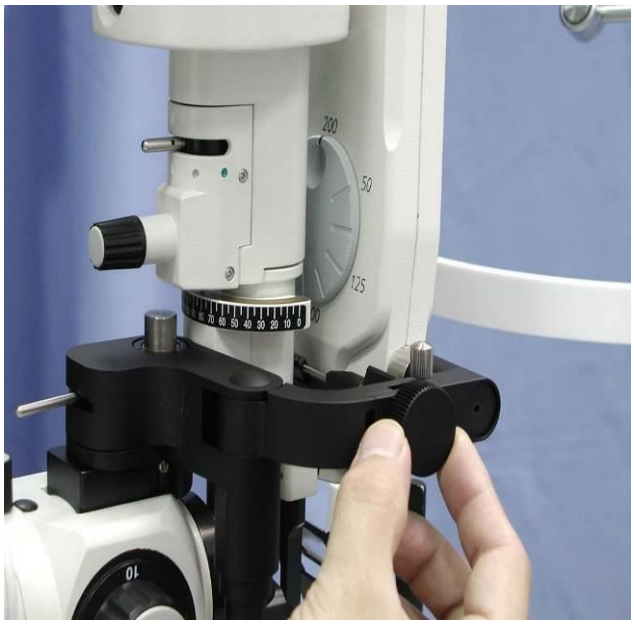


Figure 5.28(b) Old type Version
Adjust the Attachment LDU Spot Size Focus using the knob on the mounting arm

Figure 5.29 Old type version
Adjusting Micromanipulator Arm to verify Laser Spot is in the Aperture Center

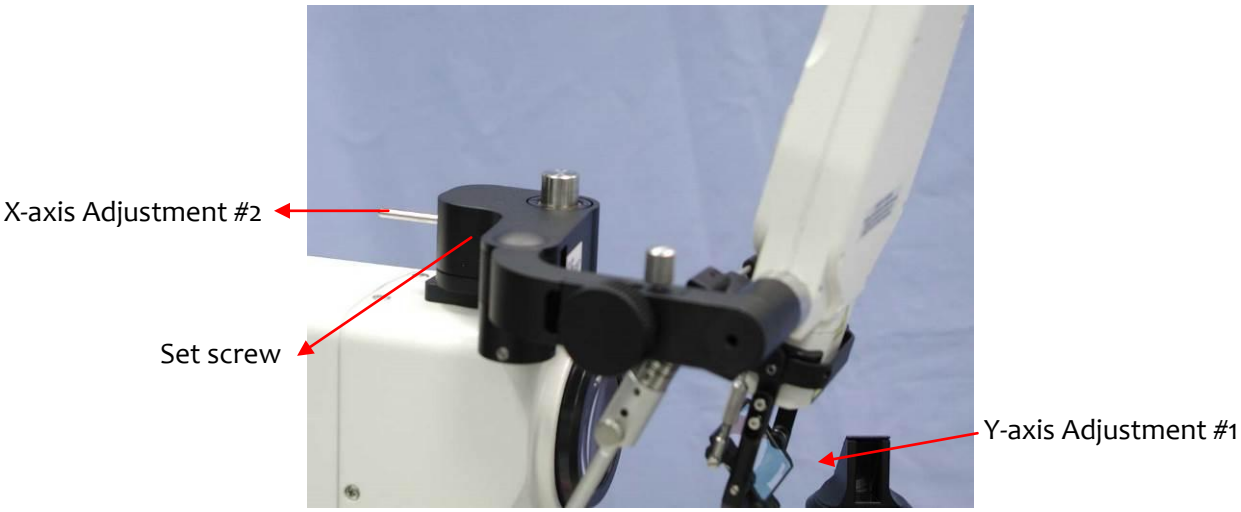


Figure 5.30 Old / New type version
Adjusting sideways movement of Attachment LDU during alignment

5.5.2.2 Laser Indirect Ophthalmoscope

Prior to pre-check and realign the LIO LDU, ensure all the corrected installation or setup are in place to proceed the following steps.

Procedures:

1. Power on the console and ensure all the connection and connectors are in place
2. Verify the aiming beam is being delivered correctly from LIO by shooting against the wall and set a focal distance of 30cm approximately
3. Fit the headpiece onto your head and adjust the two knobs to align the Interpupillary distance
4. Verify illumination intensity integrity by adjusting the console LIO illumination knob (refer to fig. 5.31a) or as for a standalone LIO system you may adjust the illumination intensity knob on the LIO unit (refer to fig.5.31b)

Figure 5.31 (a)
Fiber and Delivery Key fitted to Console Front Panel

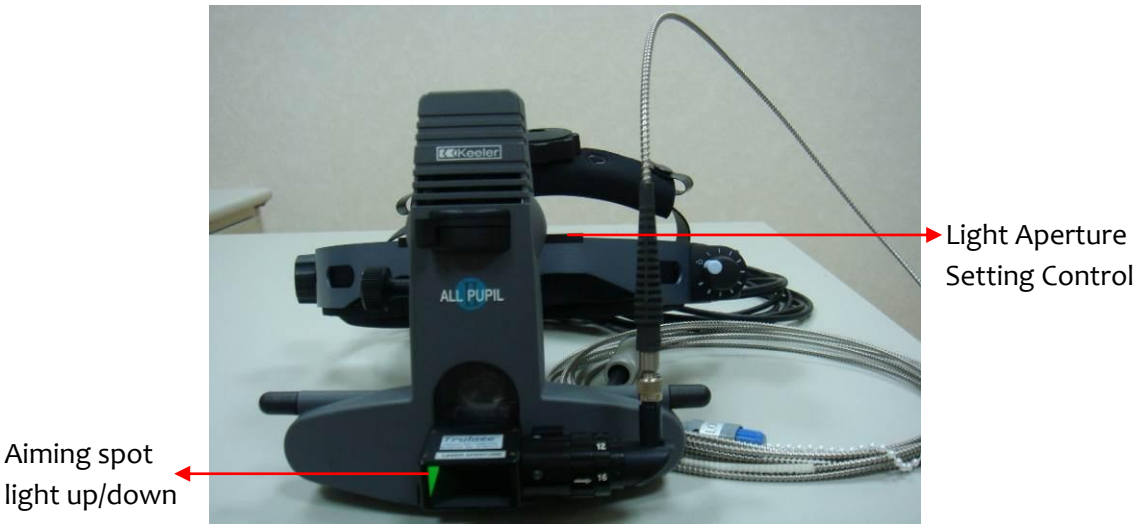


Figure 5.31 (b) LIO Intensity Control Knob

5. Verify the spot size or zoom system is accordingly (from smallest to largest size)
6. Ensure the different light aperture setting is also functioned accordingly (refer to fig. 5.31b)
7. Ensure aiming spot light is able to tilt in up/down position (refer to fig. 5.31b)

5.5.2.1 Endoprobes

The Endoprobes are sterilized single use devices so it is not possible to do any testing of them at installation time. It is recommended that if the doctor is to use Endoprobes that one unit be used as a reference for checking the Console operation and for Calibration testing.

Installation Record Sheet

Model: LightLas 532 **Console Serial Number: _____**

LIO Serial Number: _____ **Slitlamp LDU Serial Number: _____**

Safety Filter Serial Number: _____

1. System Setup (Tick for OK)

1.1 All parts received and checked OK. ☐

1.2 No damage to instrument packaging. ☐

1.3 Assemble Slitlamp Delivery Unit to Laser Console. ☐

1.4 Adjust cables then attach cable clamps etc. ☐

1.5 Plug in cables to Laser Console. ☐

1.6 Attach mains power cable. ☐

1.7 Attach Chinrest to Slitlamp if not yet fitted. ☐

1.8 Finish System assembly. ☐

2. Slitlamp Checks

2.1 Illumination Lamp Controls OK. ☐

2.2 4 filter wheel settings check OK. ☐

2.3 With Slit fully open 5 Aperture settings OK. ☐

2.4 With Large Aperture Set, Slit fully open get full circular spot. ☐

2.5 Slit is fully adjustable to closed position. ☐

2.6 When slit is closed there is no Illumination showing. ☐

2.7 Set narrow slit and check slit rotation $\pm$ 90^{o}around vertical. ☐

2.8 Load the target rod and set up the correct individual's ocular. ☐

2.9 Check that eyepieces fit firmly into binoculars and can be fully adjusted. ☐

2.10 Binoculars can be adjusted for interpupillary distance (PD). ☐

2.11 Check Slitlamp movements with joystick:

Vertical adjustment range OK. ☐

Sideways adjustment range OK. ☐

Forward adjustment range OK. ☐

Movements should be smooth. ☐

2.12 Illumination Tower and Binocular arm can be swung from side to side OK. ☐

2.13 The replacement Illumination Tower is fitted to the Zeiss SL130 (If applicable). ☐

3. Chinrest checks

3.1 Chinrest is not loose in anyway. ☐

3.2 Chinrest height is adjustable up / down and movement is smooth. ☐

3.3 Fixation lamp is operating OK. ☐

3.4 Fixation lamp can be rotated from side to side OK. ☐

3.5 Handles are fixed firmly to posts. ☐

4. Laser System Checks

4.1 Laser Power ON is indicated by Display LEDs being ON. ☐

4.2 Laser System does self-checks at Start up. ☐

4.3 Confirm that no Error messages are displayed. ☐

4.4 Confirm that the correct Delivery System indicator is shown on the Remote Control for each of the Delivery keys. ☐

4.5 Check and inspect that the Laser Safety Filters are assembled into the Doctor viewing path for all LDU's. ☐

4.6 The Laser System power shows ZERO until the power adjust knob is turned and when Power is adjusted this display should change to indicateindicate the new power setting. ☐

4.7 All Display Panel controls, switches and displays are functioning. ☐

4.8 The Aiming beam is visible and intensity is adjustable. ☐

5. Laser Delivery System Checks

5.1 Check the Aiming beam quality output from the Delivery fiber. ☐

5.2 For the Slitlamp Delivery verify the Doctor Safety filter is installed in the Doctors viewing path. ☐

5.3 If a Moving Safety filter is installed verify that it locates into the viewing path whenever the footswitch is pressed. ☐

5.4 Laser beam aligned OK to Slitlamp focus plane and illumination. ☐

5.5 Micromanipulator operates smoothly and adjusts Laser beam evenly within the Slitlamp Illumination spot (If applicable). ☐

5.6 Perform the Power meter check and calibration procedure. ☐

5.7 Aiming beam output is clear from LIO and is in center of illumination ☐

5.8 All Binocular Indirect controls function OK including:

5.8.1 Apertures are all selectable for the LIO. ☐

5.8.2 LIO Different Filters can be selected. ☐

5.8.3 LIO Illumination spot adjuster moves spot up and down. ☐

5.8.4 LIO Brightness control on Console varies brightness OK. ☐

5.8.5 Output from Endoprobe is circular and a clear spot. ☐

Installers Name : _____ Date: _____

Distributor Name: _____ Date: _____

Customer Name : _____ Date: _____

(Send this Installation Report to the Manufacturer immediately.)

Section 6 CLINICAL USE

The LightLas 532 is an Ophthalmic Laser intended to coagulate or burn structures within the patient's eye as a surgical treatment for the condition that the patient suffers from. During the surgical treatment, the Laser energy is delivered directly on to the patients eye tissue and thereby modifies the eye structure as required by the doctor.

The LightLas 532 Green Laser is used for performing the following clinical procedures:

- Retinal Photocoagulation
- Pan Retinal Photocoagulation
- Endo-photocoagulation
- Macular Treatments
- Laser Trabeculoplasty

Retinal, Pan Retinal photocoagulation and Endo-photocoagulation are treatments that involve the destruction of neovascular complexes for destroying areas of microinfarction or capillary closure.

The Retinal photocoagulation treatment, it can use the Slitlamp Delivery unit. As for the Pan retinal photocoagulation treatment it can use either the LIO or the Slitlamp Delivery units. Endo-photocoagulation is performed using the Endoprobes and should be practiced in a sterile environment.

Macular treatments involve the destruction of leaking vessels in the macular and paramacular regions in order to produce a chorioretinal adhesion that can resist ongoing vitreoretinal traction. This treatment is performed using the Slitlamp Delivery unit.

Laser Trabeculoplasy is the photocoagulation of the trabecular meshwork to create apertures and thereby increase the flow of the aqueous humor in order to treat open-angle glaucoma. This treatment is performed using the Slitlamp Delivery unit
The following warnings are typical of all Ophthalmic Green Laser products when used to perform the surgical procedures as listed above. The warnings are presented according to the type of Laser Delivery unit used as the warnings in some case are related to the means of delivery.

6.1 Different types of LDUs Indication / Contraindication Use

There are three different types of delivery system such as, Slitlamp Delivery unit, LIO and Endoprobes. They are explained in great detailed for their specific indication and countraindication uses as follows.

6.1.1 Slitlamp Delivery Unit

The Slitlamp Delivery unit allows the treatment of many Retinal conditions and Glaucoma while still being able to use all the standard diagnostic functions of the Slitlamp to which it is fitted.

Indications for use:

- Proliferative and non-proliferative diabetic retinopathy
- Retinal tears and detachments
- Lattice degeneration
- Laser trabeculoplasty in glaucoma treatment

Contraindications for use:

- Opaque cornea or lens, corneal edema, or blood in the vitreous humor that interferes with the treatment by scattering the beam
- Albino patients or eyes that have no pigmentation.

Additional Contraindications for use in trabeculoplasty:

- Aphakic eye with vitreous in the anterior chamber
- Neovascular glaucoma
- Glaucoma caused by congenital abnormalities of the angle
- Glaucoma secondary to active uveitis
- Less than 90° of open angle or extensive low-lying peripheral anterior synechiae present around the circumference of the angle

6.1.2 Laser Indirect Ophthalmoscope (LIO)

The Laser Indirect Ophthalmoscope allows for the treatment of panretinal disorders and adds the capability of transpupillary retinal photocoagulation to the diagnostic indirect ophthalmoscope. Use of the LIO enables delivery of the laser to pathologies in the far periphery of the retina and for treatment of supine patients.

Indications for use:

- Proliferative and nonproliferative diabetic retinopathy with pathology outside the arcades
- Retinal tears
- Lattice degeneration

- Localized retinal detachments
- Any eye requiring laser treatment out to the ora serrata
- Delivering laser treatment through small pupils or to eyes with semi-opaque focal lenses

Contraindications for use:

- Treatment sites close to the macula, within the arcades or where precise positioning of **t**he Laser is not possible, should not be attempted
- Opaque cornea or lens, or blood in the vitreous humor that interferes with the Laser delivery to the tissue requiring treatment by scattering the beam
- Do not treat albino patients that have no pigmentation

6.1.3 Endoprobe devices

The Endoprobes are typically used during Vitrectomy to perform endophotocoagulation procedures such as sealing retinal holes during a retinal detachment procedure or to perform panretinal photocoagulation (PRP) in the treatment of diabetic retinopathy

The Endoprobe is a blunt intraocular needle fitted to a handle and connected to the Laser unit by an optical fiber. The Red aiming beam is transmitted through the fiber and allows clear identification of the position and size of the Laser spot.

The Endoprobes are used in a sterile environment and the doctor will observe the eye through an Operating Microscope. A doctor safety filter must be fitted to the operating microscope between the Binoculars and the Microscope. The correct wavelength safety filter must be used to ensure for the safety of doctors' eyes.

The Endoprobes are sterilized and single use devices. Their performance can degrade which possible cause the delivered power decreased due to the transmission losses. A spare Endoprobe should be kept available for any situations where the Endoprobe is not performing satisfactorily.

Indications for use:

- During vitreous surgery to produce a chorioretinal scar around retinal breaks or retinal sites
- To perform PRP in proliferative diabetic retinopathy
- To perform intraoperative PRP on a scleral buckle
- To perform intraoperative PRP around focal neovascularization

Contraindications for use:

- Do not treat albino patients, or eyes that have no pigmentation

6.2 General Warnings

- Doctors should ensure they have extended training before attempting to carry out any of the indicated procedures. Doctors will take full responsibility for the setting of the Laser unit operating characteristics, techniques and methods used during treatment. They must use their own clinical judgment in determining all aspects of the treatment carried out.
- For all type of Delivery units always ensure that the power levels are not set too high at initially.
- Always set the power levels according to the tissue effects. Remember that highly vascularized and pigmented tissue will require less power than lightly pigmented.
- The Aiming beam and Green laser beams are coaxial and if there is any distortion to one of them then the other may also be distorted and this can lead to inconsistent tissue effects and clinically unsatisfactory results.
- By reducing the spot size by half will increase the power density by a factor of four so be very careful not to deliver too much power to the site.
- If the delivery of the Laser does not produce satisfactory tissue effect then increase the pulse duration first then the power level. The aim is to produce a grey-white burn.
- Any assistant personnel in the treatment room should always wear appropriate laser safety glasses suitable for the 532nm wavelength laser while the Laser unit is in use.
- Outside the treatment room should be placed Laser warning signs or any appropriate warning signs for the country the Laser is being used in. Generally the warning signs should state minimum as: ***"Danger/ Caution Laser Radiation, avoid eye or skin exposure to direct or scattered laser radiation."***
- The laser can coagulate blood vessels up to 1.5mm in diameter. For larger diameter vessels coagulation may be difficult so other means such as electrocautery may be needed.
- When treating a patient's eye, ensure that untreated eye should cover with protective shield from the unwanted laser reflection that can lead to irreversible eye damage.
- Avoid directly firing the Laser onto the flammable liquids or gases
- Avoid any wet condition near console or footswitch although footswitch is rated IPX8 but still not recommend use in the wet condition to avoid the electrical hazards.

- Any precaution measured should be taken during any surgical process. All personnel should always wear the protective gears such as, gown, cap, mask, latex gloves, and safety goggles.

  Caution - Laser plume may contain viable tissue particulates

- When positioning the Laser for treatment always keep the Aiming beam in a good focus so that the resultant tissue effect is clinically satisfactory.
- The beam divergence of the Laser beam from the Endoprobes is higher in air than in a fluid medium so when using the Endoprobes in air a higher power setting will be required to get an equivalent burn as seen on the retina at a given distance.
- When using the LIO always ensure that the headpiece is adjusted to be firmly fit to the doctor's head so that good control is always maintained over the beam positioning. The Illumination Lamp housing can get warm but this is normal.
- When using any Laser Contact Lens in treatments, it is essential that they are effective and suitable for the procedure with the LightLas 532 Laser. Due to the individual len coating can affect the treatment performance quality which may result in poor treatment.
- The optical fibers that connect from the any/all Laser Delivery units to the Laser Console must always be treated with care. Never try to bend the fibers into loops smaller than 200mm in diameter instead just leave them loose or draped over a suitable surface. Never allow a fiber to run along the floor or to be in walkways where they could be stepped on or crushed with a trolley wheel. Also ensure that the fiber ends are kept covered whenever they are not inserted in the Laser unit so they remain clean which will extend their lifetime. Avoid touching the fiber ends as this may leave deposits on them, which can cause damage when the laser is fired into the fiber.

6.3 Possible side-effect or adverse reactions

During or following surgical treatment with the LightLas 532 Green Laser there are some potential effects or reactions that should be considered. They are similar to any other surgical procedure and include:

- **Pain:** this i**s** generally minimal but dependent on the treatment performed.
- **Sepsis:** care should always be taken to ensure that possible infection risks are minimized.
- **Bleeding:** post-operative bleeding must be considered and the patient should be observed and evaluation made for each on an individual basis.
- **Perforation:** this is more likely to occur when using the Endoprobes so particular care is required. In particular it is important not to bring the end of the probe closer to the tissue whilst firing the Laser.
- **Intraocular pressure:** the IOL pressure can increase as a result of the Laser treatment so the patient should be monitored and treated accordingly where this is a potential issue.
- **Venous Pressure:** patients should be cautioned against performing any activity that could increase their venous pressure in their head or eyes. Avoid rubbing their eyes, blowing their nose and prolonged sneezing or coughing. The head should be slightly elevated during sleep, while recovering from the treatment

For the LightLas 532 Green Laser several key safety issues to consider are:

- All laser treatment indications and contraindications are well documented and readily available for the doctors to reference.
- There is a long history already for the various treatments when using a Green Laser, so all possible side effects and adverse reactions are well understood.
- The doctor should always ensure they are adequately trained to perform the Laser procedures in LightLas 532 Green Laser system.

Section 7 MAINTENANCE

The LightLas 532 Photocoagulator Laser has been designed to require minimal maintenance. There are several simple routine procedures that are to be carried out by the operator (see 7.2) but aside of these there are no operator maintenance requirements.

The manufacturer however does recommend that the LightLas 532 be serviced by an authorized service agent every 12 months. During this Preventative Maintenance (PM) service visit the Laser System will be Calibrated and Aligned and the general operating function confirmed.

It is a requirement that on an annual basis (every 12 months) the LightLas 532 has the Power meter calibrated to a known calibrated meter and have its earth leakage current and earth resistance measured according to EN60601-1. These procedures can only be performed by an authorized service agent of the manufacturer.

If at any time you have concerns about any aspect of the Operation / Calibration or Alignment of the Laser System you are urged to contact the authorized representative or the manufacturer in order to decide on a suitable course of action.

Refer to Section 9 of this Manual for particular National requirements of EU Countries.

7.1 Operator / User Maintenance

The following procedures are those that the manufacturer recommends that the operator of the Laser System perform routinely. The operator or service person must always take care not to expose yourself to hazardous laser radiation when performing any of the maintenance procedures. Always wear safety glasses if operating the laser.

1. Cleaning the external surfaces of the Laser

To clean the outside of the LightLas 532 console, wipe over using a damp (but not dripping) cloth or use a mild cleaning agent. Do not use any solvents or do not spray or pour any cleaning agents directly on the equipment. Use a dry cloth afterwards or allow to air dry.

This procedure should be carried out as often as required but at least every 3 months.

Avoid touching the optical parts, as there is a specific procedure to clean them.

When the Laser System is not in use keep it covered using the Dust Cover.

2. Cleaning the Optics

The optical surfaces of the Laser System are; the objective lens, the illumination tower prism, the eyepieces and any other Slitlamp accessory that may have been purchased.

The process for cleaning all these optical surfaces is the same.

Moisten one end of a cotton tip (Q-tip) or a folded lens tissue (Kodak or similar) with 100% Methanol or Ethanol and then gently wipe across the optic. Use one Q-tip or tissue per wipe then discard and repeat with a new one until the optic surface is totally clean.

Never wipe an optic with a dry Q-tip or tissue, as this will scratch the glass.

7.2 Laser Beam Alignment Check

The Laser performance can deteriorate if the optics are not clean. It will depend on the environment that the Laser System is used in how often the optics should be cleaned however the optical surfaces should be cleaned at least every three months. To check the alignment of the LightLas 532 Treatment Laser beam to the Aiming beam procedure is detailed in the Installation procedure that can be found in Section 5 of this manual. The beams should always be centered together because they are delivered together by an optical fiber.

At the Target site (focal plane) it is also necessary to make sure the beams are centered and focused in the center of the Illuminated spot. There are adjustment screws for the Slitlamp LDU and for the LIO the Optics housing can be rotated to adjust the horizontal plane and a mirror adjustment for the vertical plane.

There are no adjustments for the Endoprobes.

For all LDU's it is important that the delivered Laser beams are round in shape as this then means the alignment of the fiber to the internal Laser cavity is correct. If this alignment is bad then the fiber may become damaged particularly at high power settings.

If the output beam from the fiber is checked and whether with the Aiming beam or the Treatment beam it is anything other than a round spot then there is a strong possibility that the alignment of the Laser beams into the fiber has changed or the fiber is damaged in some way. In either case it is important to get the alignment checked by a Service person to verify if the system is OK to be used. If the output beam looks OK with another fiber then it is most likely that the fiber is damaged and the Laser alignment in the Console is OK.

7.3 System Output Power Checking Procedure

This system output power checking procedures are intended to ensure the LightLas 532 system performance validation and it must be carried out by an authorized and trained service agent. Therefore if you believe the Laser System is out of specification or requires extended Calibration procedures you should have the system checkout and verified by authorized and trained service prior to use the equipment.

More detailed of these procedures are explained in the Service Repair Manual refer to calibration section.

The procedure for checking the System Output Power is the same for the Endoprobes, Slitlamp and LIO delivery units and the detailed procedures are listed below:

Equipment Required:

- Power meter (Coherent Labmaster, Fieldmaster or Newport) CW 2W +/- 0.1W
- Safety glasses OD4+ / 532nm

Procedures:

1. Ensure to plug the correct delivery key to the Laser Console as the front panel indicator will show the correct unit is attached.
2. Set the remote controls panel setting to 50% duty cycle which the pulse interval and pulse duration both set to 0.05 sec.
3. Set the system to Treat Mode and aim the output Aiming beam at the center of the Power Meter detector with the spot size at around 5mm diameter or 50% of the active detector area.
4. Set the Laser Power to levels of 100, 500, 1000 and 1500 mw and for each setting fire the laser using the footswitch and note the External Power Meter reading. For the Integrated Slitlamp Delivery the output power should be checked at both the 200µ and 1000µ spot size settings and for the Attachment Delivery Unit use the 100µ and 500µ spot sizes.

Note: For the Slitlamp Delivery units ensure that the Slitlamp Illumination tower is pushed to one side so that it cannot block any of the Laser beams.

5. Ensure the reading multiply it by 2 (X2) to get the true power level as it is being fired at 50% duty cycle. Record the X2 reading for each power setting on the System Output Power Record Sheet.
6. Validate the measured power readings (X2) must be within +/-20% of the set power for the system to be passed.

7. Ensure the readings fall within the +/-20% tolerance if not, then recheck the system and make sure the External Meter is set up properly and the fiber has no sharp bends or damage to it. Replace another fiber to validate it because the damaged fiber can introduce significant power losses.
8. If the checking data definitely out of tolerance then the manufacturer or authorized distributor must be contacted and the Laser System calibration adjusted according to the procedure in the Service manual.
9. Be sure to complete the record sheet and keep the copy in the system records.
10. This system throughput check should be performed at least once a year to ensure the o/p power performance is within the specified accuracy.

System Output Power Record Sheet				
Power Meter Model:_____ Serial Number:_____				
Checked by:_____ Date:_____				
Delivery Unit type:_____				
Displayed Power	**Meter Reading**	**Reading X2**	**Min. / Max.**	**Pass / Fail**
100 mw			80 / 120 mw	
500 mw			400 / 600 mw	
1000 mw			800/1200 mw	
1500 mw			1200/1800mw	

Section 8 TROUBLESHOOTING

The Lightlas system 532 is designed to have a service free part as possible. It is divided into three major sections such as, Symptom, Warning, and Error code.

8.1 Symptom

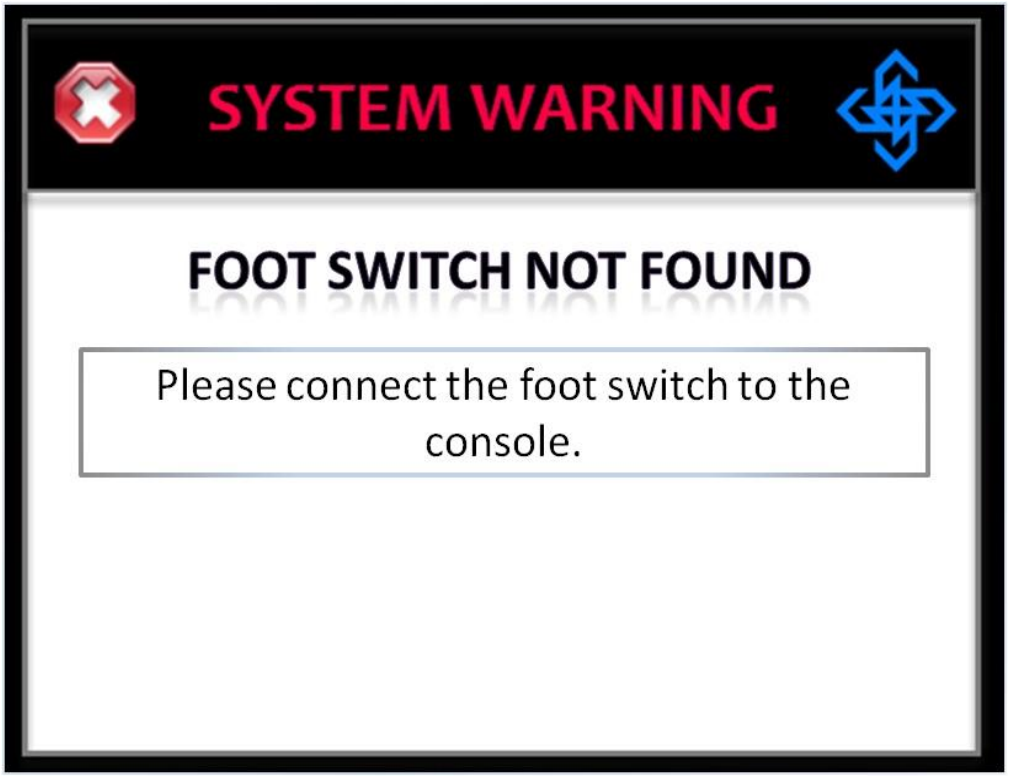
A completed listing of Lightlas system 532 symptoms or warnings and along with the suggested corrective action is explained as following:

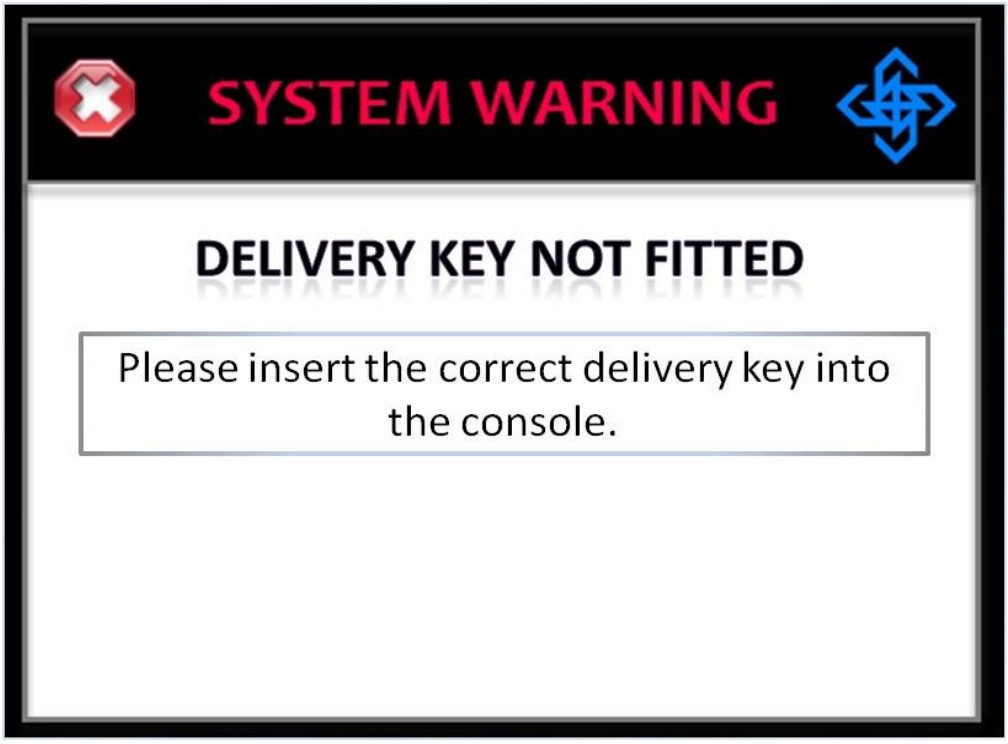
Symptom(s)	Cause(s)	Remedy action(s)
No power / no display	-Power failure -Remote control panel connector not connected	-Check the power source or connector -Check the power fuses -Check the emergency button is outward ON position -If the problem persists, call the authorized service or manufacturer for further assistance
No lamp illumination (SD only)	-No power to the lamp -Lamp is burned out	-Check the lamp voltage distribution (+12) -Check the lamp integrity -Check that there is no dust and/or fingerprint on the bulb -Call the authorized service or agent for assistance
No aiming beam (SD only)	-Aiming beam intensity needs to be calibrated -Aiming beam electric circuit failure	-Reboot the system -If the problem persists, call the authorized service or manufacturer for further assistance

No or low output of the Green laser beam	-Fiber is damage -Treat mode is not activated -Output power not selected -Laser cavity decayed -Electronics malfunction	-Check the fiber integrity by replacing a new one -Activate the Treat mode -Selected the specified power -If the problem persists, call the authorized service or manufacturer for further assistance

8.2 Warning

A completed listing of Lightlas system 532 warnings and the suggested corrective action are detailed as following:


SYSTEM WARNING
FOOT SWITCH NOT FOUND
Please connect the foot switch to the console.


SYSTEM WARNING
DELIVERY KEY NOT FITTED
Please insert the correct delivery key into the console.


SYSTEM WARNING
COMMUNICATION FAILURE
Please check the console state or contact your local service representative.

8.3 Error Codes

If during normal operation of the Laser System or during the Startup or Special Modes, if a fault, error, or warning condition is found by the microprocessor then the Laser System will go to the Standby mode and an error or warning message will be shown on the Display Panel. The Laser System cannot be operated when an error message is displayed.

Call authorized service if an error message is regularly shown on the system display.

Note: Under no circumstances should unauthorized or untrained personnel attempt repairs. Refer to the warranty conditions for further details.

The error codes of the Lightlas system are usually shown in 3-digits or 4 digits codes (refer to fig. 8.1).

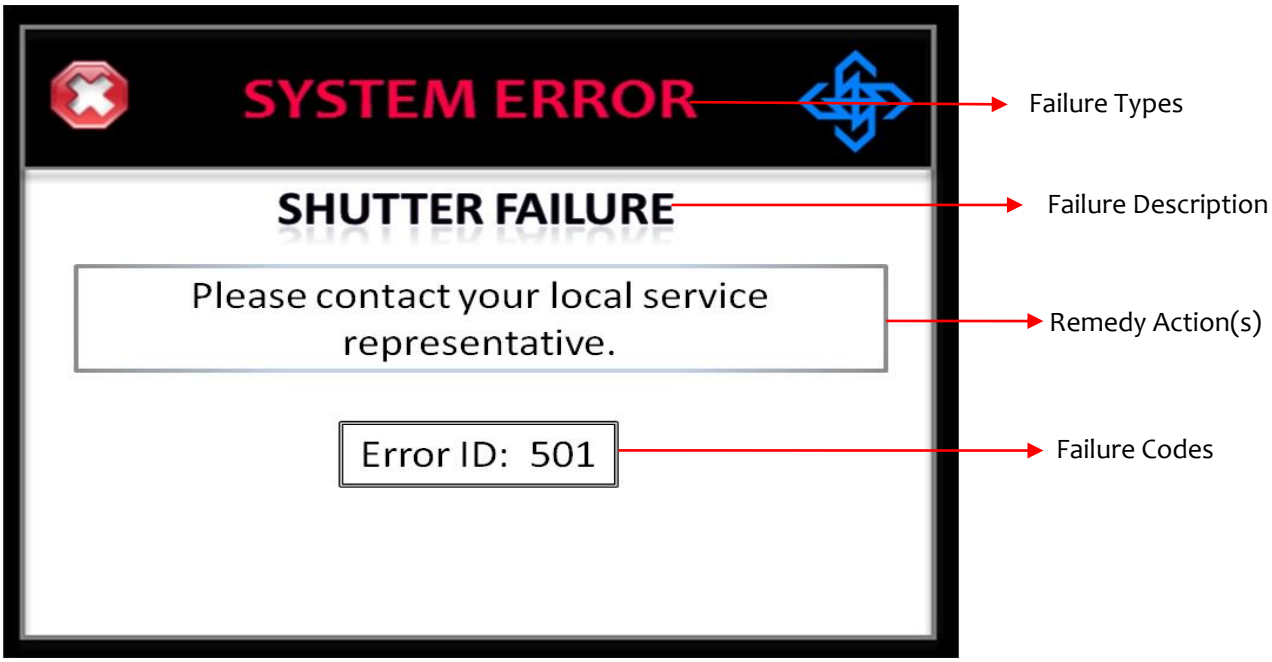


Figure 8.1 Sample of error code display

A complete listing of the Lightlas 532 error codes along with the suggested corrective actions are shown below:

Error code	Cause(s) / Description	Remedy Action(s)
Err 500 - ROM	-System failed to pass the software integrity test	-Reboot the system -If the problem persisted, call the authorized service or manufacturer for further assistance
Err 501 - Shutter Failure	-Shutter failed to open or close	-Reboot the system -If the problem persisted, call the authorized service or manufacturer for further assistance
Err 502 - Laser Diode Current Too High	-Laser diode current is out of range or over the limits	-Call the authorized service or manufacturer for further assistance
Err 503 - Aiming Laser Failure	-Aiming laser beam failure or the laser intensity is > 1mW	-Call the authorized service or manufacturer for further assistance
Err 5041 - Laser Diode Temperature Out of Tolerance +/- 2.5C	-Ambient temp. is too high or low which causes the laser laser temp. TEC unable to reach the stable or preset value within 5 mins.	-Reboot the system -If the problem persisted, call the authorized service or manufacturer for further assistance
Err 5042 - Laser Sensor Failure	-Laser sensor failure (opened or shorted sensor)	-Power off ; call the authorized service or manufacturer for further assistance
Err 5043 - Cavity Temperature Out of Tolerance +/- 2.5C	-Cavity Temperature sensor can not reach to the preset +/- 2.5C	-Reboot the system -If the problem persisted, call the authorized service or manufacturer for further assistance
Err 5044 - Cavity Temperature Sensor Failure	-Cavity temp. sensor failure or the sensor is open or shorted circuit	-Call the authorized service or manufacturer for further assistance
Err 5051 - Remote Communication Error	-No communication between remote and the laser console within the time of frame of 300ms	-Reboot the system -If the problem persisted, call the authorized service or manufacturer for further assistance

Err 5052 - Remote Time Up Error	-Timer in remote stopped running for 1ms	-Reboot the system -If the problem persisted, call the authorized service or manufacturer for further assistance
Err 5053 - Remote ROM Error	-mismatched code in the remote software when booting up	-Reboot the system -If the problem persisted, call the authorized service or manufacturer for further assistance
Err 5054 - Remote Configuration Error	-Can not configure laser console operation	-Reboot the system -If the problem persisted, call the authorized service or manufacturer for further assistance
Err 506 - Delivery System Shutter Failure	-Slitlamp safety filter could not close within 1s	-Check the safety filter moving operation -Reboot the system or call the authorized service or manufacturer for further assistance
Err 5071 - System Time Up Error	-The system stop running for 1ms	-Reboot the system -Call the authorized service or manufacturer for further assistance
Err5072-Communication Error	-No communication between the panel control and console CPU	-Reboot the system -Call the authorized service or manufacturer for further assistance
Err 508 - Calibration Error	-The system is uncalibrated	-Call the authorized service or manufacturer for further assistance
Err 510 - Watchdog Error	-System watchdog flag	-Reboot the system -Call the authorized service or manufacturer for further assistance
Err 5121 - Power Too High	-The measured o/p laser power is exceeded by 20% of the preset power value	-Call the authorized service or manufacturer for further assistance
Err 5122 - Power Too Low	-The measured o/p laser power is under by 30% of the preset power value	-Call the authorized service or manufacturer for further assistance

Err 5123 - No Power or Zero Power	-The measured o/p laser power is less than 10mW while the duty cycle is set off	-Call the authorized service or manufacturer for further assistance
Err 5124 - Power Photodiode Sensor Error	-Power photodiode sensor failure	-Call the authorized service or manufacturer for further assistance
Err 513 - System Error	-The system stop running for 1ms	-Call the authorized service or manufacturer for further assistance

Section 9 European Community Issues

1. **Declaration of Conformity**

   LightMed Corporation declares that the LightLas 532 Ophthalmic Frequency Doubled YAG Laser System complies to the requirements of the MDD Regulation and meets, (where applicable), the Essential Requirements of Council Directive 93/42/EEC as amer pertaining to Medical Devices.
   National Requirements of EU Countries may not have been considered but will be implemented if and when required by the local Distributors. This includes local language translations of relative Instructions for use and labeling.

   We hereby notify appointment of Medical Device Safety Service GmbH Schiffgraben 41, 30175 Hannover, Germany to act as the European Authorized Representative as defined in Article 1, § 2(g) of the Directive 98/79/EEC

   The following standards have been applied and tested.

   IEC60601-1
   IEC60601-1-1
   IEC60601-1-2
   IEC60601-1-4
   IEC60601-2-22
   IEC60825-1
   ISO14971

2. **Warranty**

   The LightLas 532 Frequency Doubled YAG Laser conforms to the requirements of the MDD (93/42/EEC as amended by 2007/47/EC) and thereby in the EU Countries the Warranty as specified in the applicable regulations will apply. Your local Distributor will be able to confirm the details.

3. **Specific German Requirements/ Nationale Anforderungen in Deutschland**

   Since 01.01.1993 the User has had responsibility for accident prevention for laser equipment. According to section 5 of this rule the laser equipment manufacturer has to be registered by a responsible Notified authority and reviewed by an expert laser agent, in according to Section 6.

   The laser Equipment has to be verified by Technical Safety Inspection annually for the following items. The test results are to be recorded and kept in a devices appendix.

1. Function Test including:
   - Measuring of laser output
   - Laser-Power-Off-Testing
   - Long-distance remote interlocking
   - Fiber optic cable
2. Measuring of electrical leakage currents
   - According to DIN VDE 0751, Part 1, 9 (with 230 VAC/50 Hz max. 500uA)
3. Measurement of PE resistance (Rated value: < 0.1 Ohm in appliance inlet plug < 0.2 Ohm in power plug)

Der Anwender wird hiermit auf seine Pflichten aus der Unfallverhütungvordchrift LASERSTRAHLUNG (VBG93) in der Fassumg vom 01.01.1993 hingewiesen. Hierzu: Durchführungsanweisung vom Oktober 1995. Nach #5 dieser Vorschrift muss der Betrieb eiens Lasers bei den zuständigen Behörden angemeldet, und nach #6 ein sachkundiger Laserchutzbeauftragter schriftlich bestellt werden.
Das Lasergerät muss einmal jährlich einer sicherheitstechnischen Kontrolle unterzogen werden (MPBetreibV,#6)

1. Funktionsprüfung
   a. Messung der Laserleistung
   b. Laser-Not-Aus-Taster
   c. Fernverriegelung
   d. Lichtleiter
2. Messung des Erdableitstroms
   a. NachDIN VDE 0751,Teil 1, Schaltbild 9 (bei 230 VAC/50Hz max. 500µA)
3. Messung des Schutzleiterwiderstands
   a. (Sollwert: <0.1 Ohm am Gerätestecker <0.2 Ohm am Netzstecker)

Über das Ergebnis der Prüfung ist eine Bescheinigung auszustellen, die bei den Geräteunterlagen (Medizinproduktebuch) aufbewahrt werden muss.

Section 10 EMC Test Tables

Guidance and manufacturer's declaration – electromagnetic emissions		
LightLas 532 is intended for use in the electromagnetic environment specified below. The customer or the user of the LightLas 532 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	LightLas 532 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	LightLas 532 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and LightLas 532			
LightLas 532 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of LightLas 532 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and LightLas 532 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

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

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

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

Guidance and manufacturer's declaration – electromagnetic immunity

LightLas 532 is intended for use in the electromagnetic environment specified below. The customer or the user of LightLas 532 should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % *UT* (>95 % dip in *UT*) for 0,5 cycle 40 % *UT* (60 % dip in *UT*) for 5 cycles 70 % *UT* (30 % dip in *UT*) for 25 cycles <5 % *UT* (>95 % dip in *UT*) for 5 sec	<5 % *UT* (>95 % dip in *UT*) for 0,5 cycle 40 % *UT* (60 % dip in *UT*) for 5 cycles 70 % *UT* (30 % dip in *UT*) for 25 cycles <5 % *UT* (>95 % dip in *UT*) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of LightLas 532 requires continued operation during power mains interruptions, it is recommended that LightLas 532 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE *UT* is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

LightLas 532 is intended for use in the electromagnetic environment specified below. The customer or the user of LightLas 532 should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of LightLas 532 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$ 800 MHz to 2,5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy.

To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which LightLas 532 is used exceeds the applicable RF compliance level above, LightLas 532 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating LightLas 532.

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

APPENDIX I

Optional Accessories

The following accessories can be purchased from the Distributor to use with the LightLas 532 Photocoagulator Laser Product. **The accessories are only available for customers outside the EU Countries due to the requirements for CE Marking** and the manufacturer not having control over the use of the attachments that are available and their indications for use.

- Safety glasses OD7+ @ 532nm (CE Marked) Part Number 620003
- Fiber for Keeler LIO Part Number 620028
- 20D Indirect Laser Lens Part Number 600237
- 28D Indirect Laser Lens Part Number 600238
- Slitlamp SL990-2X Part Number 600250
- CSO Beam Splitter Part Number 600018
- Observation tube Part Number 600023
- Endo Probes Straight(20Gages) Part Number PD720.10
- Endo Probes Curved (20 Gages) Part Number PD720.20
- Endo Probes Curved (23 Gages) Part Number PD723.10
- Endo Probes Curved (23 Gages) Part Number PD723.20
- Endo Probes Curved (25 Gages) Part Number PD725.10
- Endo Probes Curved (25 Gages) Part Number PD725.20
- Straight Endo Probes Illuminate Part Number PD723.30A
- Curved Endo Probes Illuminate Part Number PD723.35A
- Endo Probes Aspirating Part Number PD720.60

The following accessories are designed and manufactured by Lightmed

- Adjustable Headband Part Number YL0621,YL6022
- Motorized Table Part Number TB0016
- Integrated Laser Slitlamp Delivery Part Number SD0008
- LIO Delivery on Keeler Pupil Ⅱ Part Number LK0001
- Operating Microscope Safety Filter (Manual filter) Part Number MS0000,MS0001
- Attachment Laser Delivery Unit (Haag Streit style) Part Number HS006,HS0007
- Attachment Laser Delivery Unit (Zeiss 30SL style) Part Number ZS0000,ZS0002
- Attachment Laser Delivery Unit (LightMed SYL9000) Part Number YG0013,YG0014
- Delivery attachment (adapter) for LightLas YAG Truspot Part Number AD0021
- Delivery attachment (adapter) for Haag Streit Compatible Truspot Part Number AD0000

- Delivery attachment (adapter) for Zeiss Compatible Truspot — Part Number AD0002
- Delivery attachment (adapter) for Haag Streit BM900 Truspot — Part Number AD0003

The following are **spare part** accessories:

- Slitlamp Bulb, 6 Volt 20 Watt, Pre-focused with base — Part Number 240012
- Chinrest Papers — Part Number 600026
- Footswitch — Part Number LCA903
- Delivery Key – Slitlamp — Part Number SD5100
- Delivery Key – LIO — Part Number LI9100
- Delivery Key – Endo — Part Number LCA190
- Delivery Fiber (2 meters long) — Part Number SD5000
- Delivery Fiber without key — Part Number SD5001
- Delivery Fiber Assembly For LIO (3 meters long) — Part Number LK6000
- Remote Interlock Connector — Part Number LCA180

Attention: The accessories are passive (do not emit laser radiation) and depend on the main device (Lightmed LightLas 532).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