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Operator Manual

AURA™ PT

Ophthalmic YAG Laser System

CE 0197

Directive: 93/42/EEC
Doc. No.: UM-0035610
Rev. No.: A

Operator Manual for the AURA™ PT Ophthalmic YAG Laser

Clinicians and Doctors should ensure that they are adequately trained in the procedures that the AURA PT YAG Laser will be used for prior to operating the equipment.

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

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

CAUTION **Any unauthorized modification to the AURA PT Ophthalmic YAG Laser will result in the necessity for it to be reclassified**

CAUTION **U.S. law restricts this device to sale by or on the order of a physician.**

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

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Lumenis Inc. 3959 W. 1820 S., Salt Lake City, UT, 84104

WEB Address:
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Contents of Manual

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Section 1. INTRODUCTION

This manual is intended to provide the operator with an overview of the operation and safety requirements for the AURA PT Ophthalmic YAG 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 accessories that are approved for the AURA PT may be used. 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.

All maintenance and service must be carried out by authorized service agents and only those procedures outline in the Operator and Service manuals are allowed. Any service work carried out by non authorized persons will void all warranties.

No Circuit Diagrams or component part lists are supplied with the AURA PT. 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 AURA PT YAG Laser system the operator should read this manual carefully and pay particular attention to the sections on Safety, Operation and Maintenance.

Section 2. SAFETY

Contents

This Laser has been designed and tested to function safely and correctly when used as indicated in this manual.
Do not use this laser before reading and understanding completely the Operator Manual.

It is important to remember that this laser emits high levels of invisible 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 safe environment that provides protection to casual observers.

When servicing the AURA PT YAG Laser always observe Safety precautions and warnings as indicated in this manual. When not viewing through the binoculars and in particular when the cover is removed from the Laser Arm wear safety glasses of OD5 or greater @ 1064nm to protect your eyes.

2.1 Product Classifications

- The AURA PT YAG Laser is a Class IIIB laser product as specified in the IEC standard 60825.1 (2001) and the USA 21 CFR's 1040.10, 1040.11.
- The AURA PT YAG Laser is classified as Class I Type B Electromedical equipment as specified in the IEC Standard 60601.1.
- The AURA PT YAG Laser is classified as a Class II device according to the FDA CFR21 regulations.
- The AURA PT YAG Laser is classified as a Class IIB Medical Device according to the MDD (93/42/EEC).
- The AURA PT YAG Laser has been EMC tested and approved according to the requirements of the international standard IEC60601.1.2.

2.2 Conformance to Standards

The AURA PT device has been designed and built to comply with the requirements of the following standards:

- **Laser standards**

  EN 60825-1:1998+A1:2002+A2:2001

  USA 21 CFR 1040.10, 1040.11 (1997)

  EN 60601-1-2-22:1996

- **Electrical standards**

  IEC 60601-1:1988+A1:1991+A2:1995

  EN 60601-1:1990+A1:1993+A2:1995+A13:1996

  EN 60601-1-2 (2001)

  USA UL2601

  JIS T1001 (1992) and T1002 (1992)
- **Others**

  MDD 93/42/EEC

  IEC60601-1-4 (1996) + Amendment A1(1999)

  EN ISO 14971 (2000) + A1 (2003)

2.3 Warnings and Precautions

The following warnings apply to the AURA PT Laser and should be observed by all users

- **DO NOT** look directly into or at the Laser beam or at specula laser reflections. Direct and reflected laser light can cause permanent eye injury.
- **DO NOT** operate the laser unless observers are using the correct protective eyewear. Protection is afforded by using protective eyewear having an optical density of OD5 at 1064 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** use the Laser in the presence of flammable agents as the focused laser beam may cause ignition. **There is no AP / APG protection.**
- **DO NOT** operate the Laser unit without all the cables connected as there is a risk of electric shock from the back panel connectors.
- Invisible and visible laser radiation is emitted from the Laser aperture during operation of the equipment.
- **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 agent of the manufacturer.
- **DO NOT** use the Laser on a patient without first checking the operation of the Laser and verifying the optical alignment of the treatment YAG Laser to the Aiming beams.
- **ALWAYS** use the lowest energy settings possible when treating a patient with the laser and start the treatment at minimum energy.
- **ALWAYS** note the “Preset Energy” display when adjusting the Energy and confirm the actual test fire energy is close to the Preset value.
- **DO NOT** put the Laser into TREAT mode until ready to operate on the patient.

2.4 Optical Hazards

Guidance for the Safe use of Lasers and Systems is found in the IEC standard 825.1, the USA 21CFR 1040.10, 1040.11 and ANSI Z136.1 - 1986.

During normal operation of the AURA PT YAG Laser the operator is protected from Laser hazards by built in optical absorption filters in the viewing optical path. All other personnel in the area should wear protective eyewear to eliminate the risk of eye injury occurring. When servicing the Laser, it is recommended to wear safety glasses of OD5 or greater @ 1064nm to protect your eyes.

Viewing through any optical attachments to the Slitlamp is safe for the operator's eye because of the built in safety filters. An optical density of at least 5 (five) and 1064nm in wavelength range must be used by any other personnel that are not directly looking through an accessory. The Optical density (OD) and wavelength are marked on safety glasses for example in the following form:

OD5 at 1064nm

Otherwise the safety glasses are NOT suitable for eye protection.

The AURA PT YAG Laser uses a Class I Laser Diode Aiming beam. The wavelength is 635 nanometers, and the maximum power output is set at the factory to be less than 200 microWatts (μW). The maximum safe power that can be visualized by the retina is 390 micro Watts so the delivered beam to the patient is less than this however it is recommended to always use the lowest practical aiming beam intensity during treatments.

The AURA PT YAG Laser has been classified a Class 3B Laser product according to the standards quoted above. This classification is based on the Accessible Emission Limits (AEL) as calculated according to the standards assuming the laser beam energy is delivered through a dilated pupil of diameter 7mm to the posterior capsule surface in the eye.

In single pulse operation the maximum energy allowed is 30mJ for a Class 3B Laser. In double pulse operation the maximum cumulative energy allowed is 40mJ. In triple pulse operation the maximum cumulative energy allowed is 45mJ. These limits are calculated according to the CFR 21 regulations as their AEL's are lower than the IEC 825.1. The product then complies to both requirements.

The Nominal Ocular Hazard Distance (NOHD) is the distance between the equipment and a persons eye for which the optical energy, 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.

The calculated NOHD for the AURA PT YAG Laser at single pulse (nominal) and at triple pulse (maximum) is:

Single Pulse Energy = 11 meters
Triple Pulse Energy = 20 meters

Therefore when the Laser is in single pulse mode all persons that are closer than 11 meters to the equipment should be wearing eye protection and in triple pulse mode all persons that are closer than 20 meters should wear eye protection. These NOHD are calculated assuming that the person would not be using any eye protection. If some eye protection is being used then the distances would require to be recalculated.

2.5 Electrical Hazards

The AURA PT YAG Laser has been designed to comply with International Standards for Medial Electrical equipment. The Laser System is designed to operate with a 3 terminal mains AC voltage supply with the third pin being the Earth or Ground connection.

WARNING	**It is not safe to operate the AURA PT YAG Laser without an Earth or Ground connection. Risk of electrical shock is possible.**	

The earth connection provides protection against electrical shock as it provides a path away from the operator or Service person for any fault condition.

2.6 Safety Controls and Features

The AURA PT YAG Laser has been designed to meet the safety features as required by the various standards identified in section 2.2. But in addition, the AURA PT also includes a number of additional safety features to enhance the safety of the Laser System.

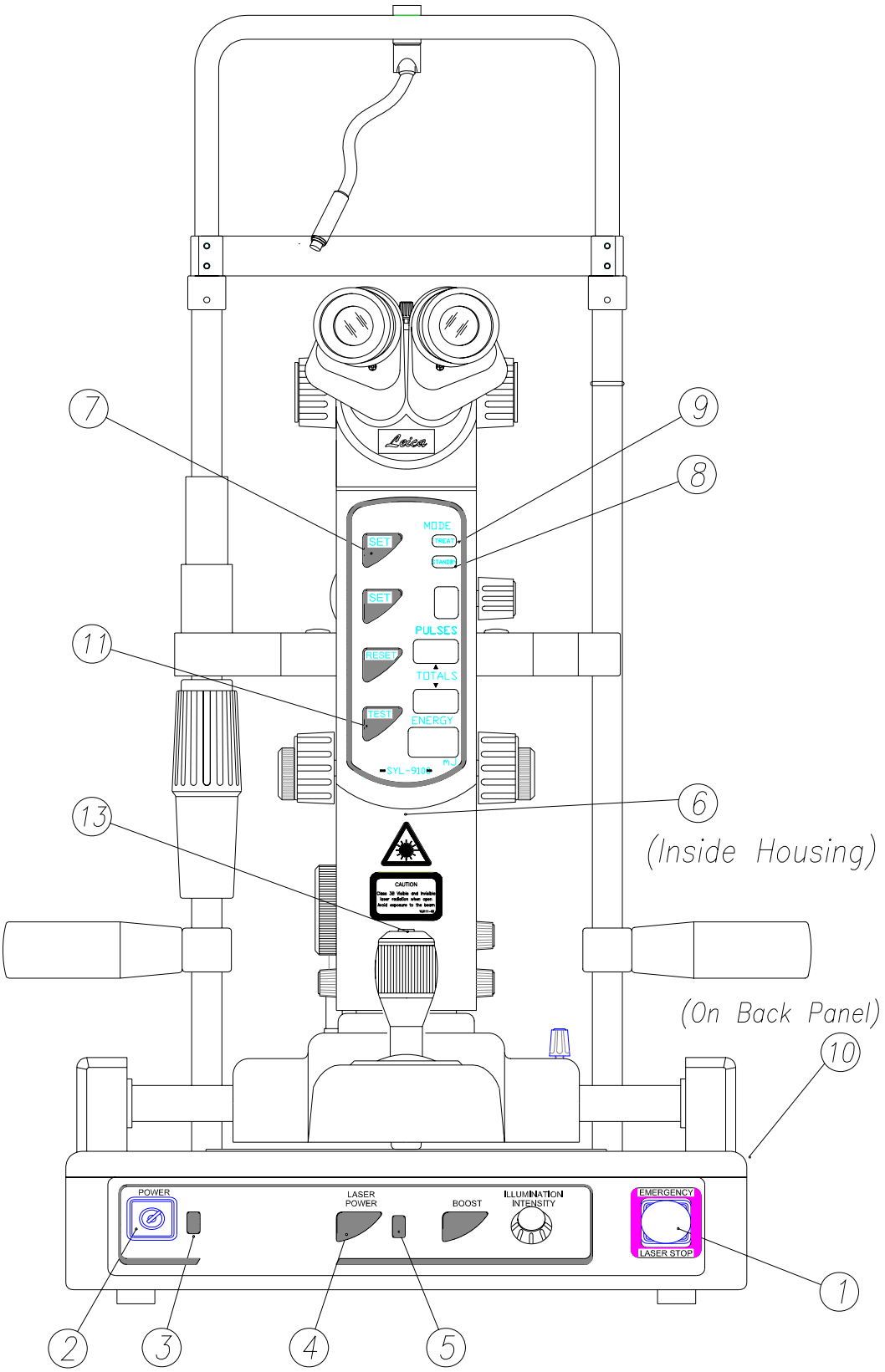


Figure 2.1 Safety Controls

The following identifies the various safety features included in the AURA PT:

1. Emergency Stop Switch
Should an emergency condition arise, pressing the Emergency Stop button will switch both laser and slit lamp power supplies off. Only when safe, to release the button rotate it in either direction and the button will automatically pop up.

2. Key Switch
The Key switch is the main power ON/OFF switch. Rotate the key in a clockwise direction to turn the device ON. When the key is on the ON position the key cannot be removed. The key should be stored in a safe, controlled place when the device is not in use.

3. Power ON Indicator
The green lamp located next to the key switch indicates when illuminated, that the power is being applied to the system.

4. Laser Power ON/OFF Switch.
With the key switch in the ON position, pressing this button for at least 0.5seconds, the Laser Power ON indicate will illuminate and after approximately 7seconds delay, laser emissions will be possible. Power is immediately removed when the switch is pushed to turn OFF. By default, whenever power is applied to the system, this switch will be in the OFF state.

5. Laser Power ON Indicator
The yellow lamp located next to the Laser ON/OFF switch, when illuminated, indicates that the power is being applied to the Laser electronics.

6. Shutter Attenuator
The Laser System is fitted with a mechanical shutter that kept in the closed position by a spring under tension. The shutter blocks the treatment laser beam path unless the system is on TREAT mode and the fire switch is pressed. At this point, the shutter momentarily opens (less than 100ms) to allow the treatment laser pulse through and then shutter closes. At all times, the shutter position is detected by two sensors which are continuously by the microprocessor.

7. Mode Set Switch
This press switch toggles the Laser System between the STANDBY and TREAT modes. In the Standby mode the Laser cannot be fired by the Joystick fire-switch and the Shutter is always closed. The Treat mode is only the only mode that will allow external laser emissions.

8. Standby Indicator
When this indicator is illuminated, the Laser System is set to STANDBY mode. In the mode, no external emission will be delivered.

9. Treat Indicator
When this indicator is illuminated, the Laser System is in the TREAT mode and the Laser energy CAN be delivered to the patient. If none of the Laser System are operated for period of 5mins, the laser System will automatically toggle back to STANDBY mode.

10. Remote Door Interlock
On the rear of the Control Box there is a connector from which 2 wires can be connected to a switch on the door(s) of the treatment room and wired so that the switch(s) go open circuit if the door is opened. When the connection is broken, by opening the door, a warning tone is sounded and the Laser System will toggle to standby Mode to prevent laser from firing. This is a user installable feature and the manufacturer supplies a connector with the two pins shorted together so that the Laser will function normally if this feature is not utilized.

11. Test Fire Switch
Pressing this switch in either STANDBY or TREAT modes, will fire the laser but keeping the shutter closed. The purpose is that it provides the operator a safe way to check the laser's output energy. The updated energy is displayed on the Display panel.

12. Test Fire Operation
Whenever the Energy control is adjusted or the number of pulses is changed the Laser system does an automatic test fire to verify the new Energy level. The Energy is displayed on the Display panel.

13. Joystick Fire switch checks
The microprocessor monitors the signal from the fire switch in order to be certain that the switch contact is good. If the fire switch is held down when in TREAT mode for too long the System will go to the Standby mode. Also it is not possible to go to the TREAT mode if the Fire switch is ON.

14. Self Checks
On power up, the Laser system of the AURA PT performs a series of internal checks, displays the software version number as well as firing a several test fires. If the test passes then the Energy of the last shot is displayed and the unit enters Standby mode. If the microcontroller detects that Laser System requires a Voltages Calibrated then it will automatically start this test. If this situation occurs, the Display Panel will show "CAL". This test takes approximately 10 minutes to perform and should only occur once or twice a year. If during the test, problems are detected, the Laser System will display the appropriate Error message.

15. Other
In addition to these particular safety controls there are a number other features that have been designed into the AURA PT YAG Laser System:

- All the controls are located so as to prevent the operator inadvertently firing the laser.
- The Laser System has protective housings on the Laser and optical system to prevent exposure to laser emissions. The protective housings on the entire system are designed to prevent exposure to high voltage shock. Special tools are required to remove the housings and only authorized agents are permitted to remove the housings.
- There are optical safety filters built into the Laser System to protect the operator's eyes from being exposed to the Laser beam when using the equipment.
- The Laser system has been designed to comply to the Electrical Safety standards for Earth connections and Earth leakages.

- If the Laser System is not used or no controls are operated for 5 minutes the System will go back to the STANDBY Mode if it was set into the TREAT Mode.
- If the Operator or User of the Laser holds the Joystick Fire Switch down for longer than 1 second then if the unit was in the TREAT Mode it will jump back into the STANDBY Mode.
- When the Laser Power Supply is being charged, following a Laser Fire, the TREAT Indicator will momentarily go OFF and the STANDBY Indicator will momentarily go ON to show that the charging function is occurring. The Laser cannot be fired while the Laser Power Supply is being charged.

With all these controls and features the AURA PT YAG Laser is a very safe instrument when used correctly and as indicated in the Operators Manual.

2.7 Product Labeling

All the labels on the AURA PT YAG Laser comply with the requirements of the various regulatory standards referred to previously. An illustration of all the safety and control labels is shown in the figures 2.2 and 2.3.

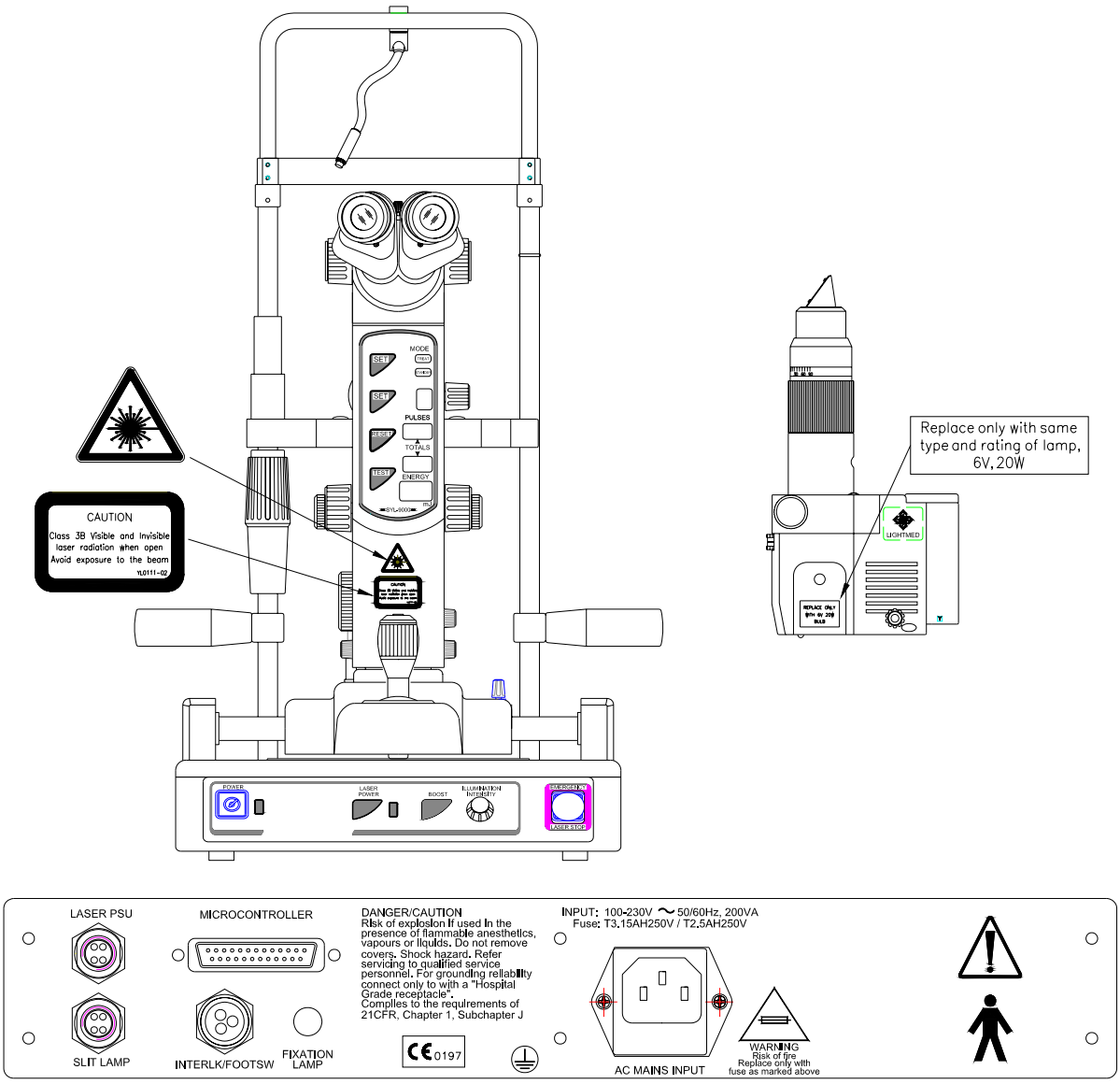
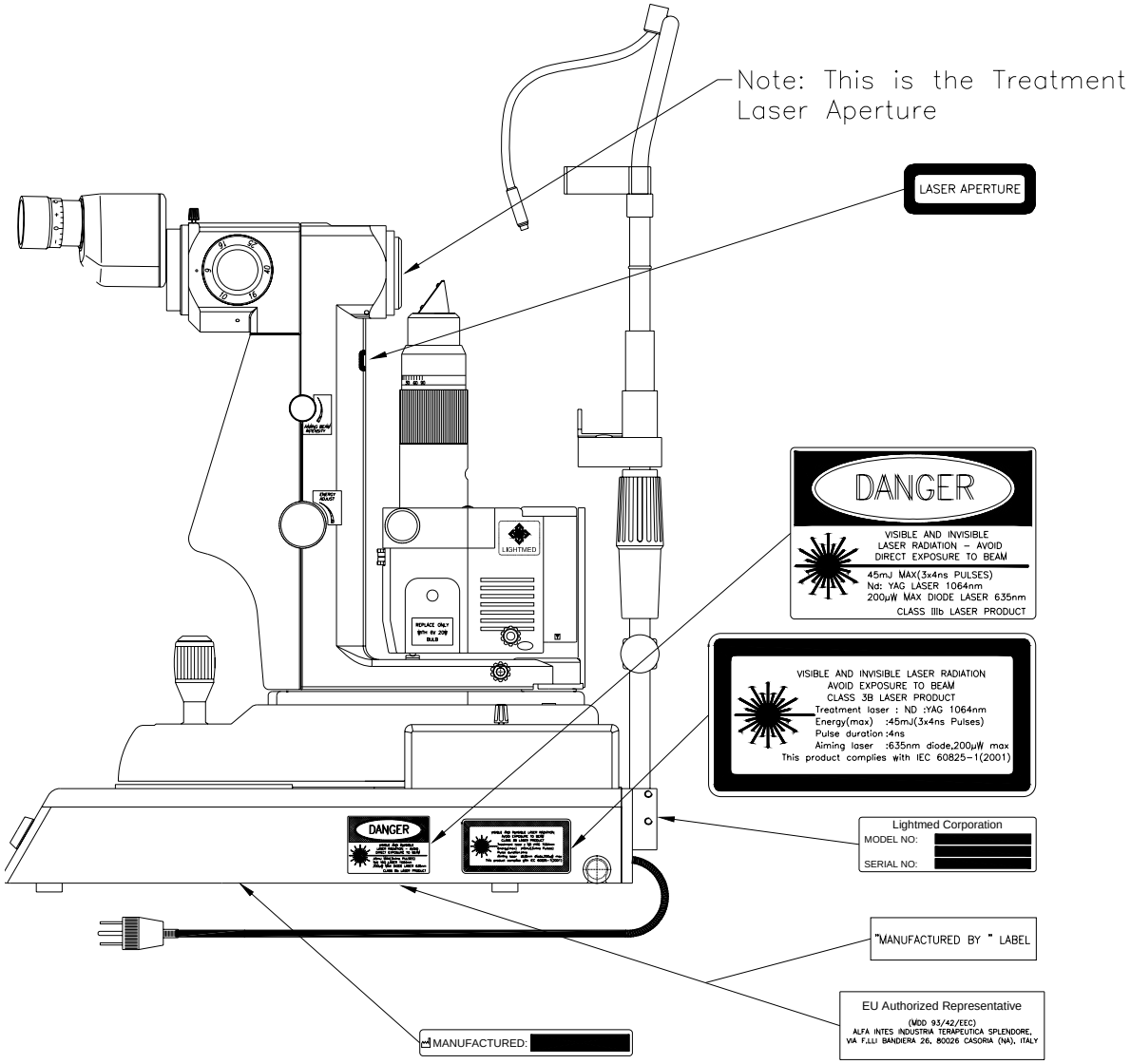


Figure 2.2 Safety and Control Labels



Safety Labels
Figure 2.3

Section 3. PRODUCT SPECIFICATIONS

Contents

3.1 AURA PT System Specification

The following are the System Specifications for the AURA PT Ophthalmic YAG Laser.

Treatment Laser

Laser Type:	Neodymium Yttrium Aluminum Garnet (Nd:YAG)
Wavelength:	1064 nm
Mode Structure:	Fundamental
Mode of Operation:	Q-switched (CQ-Crystal)
Energy Output:	Maximum of 45 mJ in Triple pulse mode Nominally 10 mJ maximum in Single pulse mode
Energy Adjustment:	Continuously variable across full energy range
Burst Mode:	1, 2 or 3 pulses each burst with the separation between pulses of 20 µs (nominal).
YAG Offset Focus:	Continuously variable from Anterior (-)500µm to Posterior (+)500µm. Detent steps @ 0, +/-150, 250, 500µm
Pulse Width:	4 ns +/- 2ns
Repetition Rate:	2.5Hz for single pulse
Air Breakdown:	Better than 4 mJ
Spot Size:	8µm (FWHM)
Cone Angle:	16°
Focal Length:	107 mm
Ocular Safety Filter:	OD5 at 1064 nm
Safety Class:	Class 3B
Energy Display accuracy:	Better than +/-20% of actual

Aiming Laser

Laser Type:	Laser diode twin beam
Wavelength:	635 nm (Red)
Mode of operation:	Continuous Wave (CW)
Output power:	Maximum of 200µW
Power adjustment:	Continuously variable
Safety Class:	Class 1

General

Electrical Input:	100-230V AC 50/60Hz Single phase
Power:	200VA
Fuse rating:	T3.15 AH250V @ 100-120V AC (Time-Lag)
	T2.5 AH250V @ 200-230V AC (Time-Lag)
Temperature Range:	Transport: -10 to 70°C
	Operating: 20 to 40°C
	Storage: -10 to 55°C
Relative Humidity	Operating: 30% -85% non-condensing
Range:	Storage and Transport: up to 95% non-condensing
Atmospheric	Operating: 800-1060 mbar
pressure:	Storage and Transport: 500-1060 mbar
Cooling System	Air convection
Dimensions (Total)	520mm(H) x 320mm(W) x 450mm(D)
Weight	21 Kg (System)
	28 Kg (Packed)

Slitlamp

Type : Specially altered CSO 950 to include Laser system in the binocular arm.

3.2 CSO 950 Slitlamp Specifications

The following are the Slitlamp Specifications for the CSO 950 Slitlamp that is used in the AURA PT YAG Laser System.

Microscope:	Galilean
Magnification Set:	5 Step Drum Rotation
Eyepiece:	12.5X
Magnification Ratio:	6X, 10X, 16X, 25X, 40X
PD Range:	55 - 75mm
Diopter Adjustment:	+/-8D
Real Fields of View:	5.2 - 40mm
Slit Illumination:	6V 20W Halogen Lamp
Slit Width:	0 - 13mm
Slit Length:	2 – 12.5mm
Slit Apertures:	0.3, 6, 10, 13mm and continuous
Slit Angles:	0° - 180°
Filters:	Red Free (Green)
	Heat Absorbing
	Cobalt Blue
Illumination Intensity:	0 - 600,000 Lux

Movement Ranges

Longitudinal (In/Out):	90mm
Lateral (Left/Right):	105mm
Vertical (Up/Down):	30mm
Chin Rest Range	80mm

3.3 Optional Accessories

Non-European Customers

The following accessories can be purchased from the Distributor to use with the AURA PT YAG 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.

Item	Part Number
Abraham Capsultomy Lens	600036
Abraham Iridectomy Lens	600035
Bearing Plate for Tonometer mounting (Type T900)	600027
Beam Splitter for YAG Laser	600022
Observation Microscope for Assistant (use with Beam Splitter)	600023
870Z Tonometer mount	600163
Adapter for video camera (Requires P/N 600022)	600025
Adapter for camera (Requires P/N 600022)	600024
Motorized Table with central drive column (Includes Top)	600015
Motorized Table with side drive column (for wheelchair access)	600016
Safety glasses OD5 @ 1064nm	620001

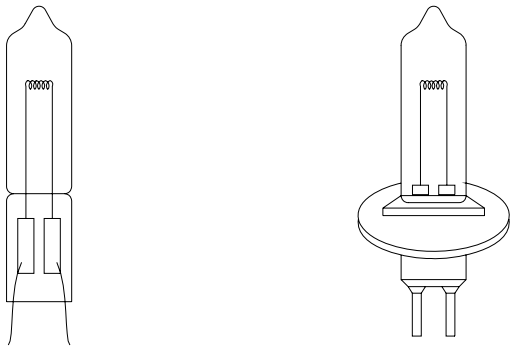
The following are **spare part** accessories:

Item	Part Number
Slitlamp Bulb, 6 Volt 20 Watt, type HLX64250	240013
Slitlamp Bulb, 6 Volt 20 Watt, type HLX64251	240012
Fixation Lamp Bulb for Chinrest	240014
Chinrest Papers	600026
Model Eye Kit	YL0508
Model Eye Membranes (bag of 25)	540010

European Customers

The following accessories are **available for use within the EU Countries** however the physician must ensure that the indications for use of the attachments that fit to these adapters are satisfactory. The manufacturer assumes no responsibility for use of the AURA PT when used with any attachments. The user should ensure that any attachments used have the **CE Mark** applied and are approved for use within the EU Countries.

Item	Part Number
Bearing Plate for Tonometer mounting (Type T900)	600027
Beam Splitter for YAG Laser	600022
Observation Microscope for Assistant (use with Beam Splitter)	600023
870Z Tonometer mount	600163
Adapter for video camera (Requires P/N 600022)	600025
Adapter for camera (Requires P/N 600022)	600024



P/N: 240013
Type HLX64250

P/N: 240012
Type HLX64251

Use these drawings to help identify the correct lamp for your Slitlamp
Figure 3.1

Section 4. PRINCIPLES OF OPERATION

Contents

4.1 General Description

The AURA PT is an Ophthalmic YAG Laser that has been designed for performing Posterior Capsulotomy, Pupillary Membranectomy and Iridotomy procedures.

The YAG Laser has a wavelength of 1064 nanometers (nm) which is in the near infrared spectrum and is invisible to the human eye.

The word LASER is an acronym for "Light Amplification by Stimulated Emission of Radiation". The light from a Laser has particular characteristics which make 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.

Because the YAG Laser beam is invisible the AURA PT YAG Laser uses a twin beam Red aiming laser system to provide a means of focusing the YAG beam on the tissue.

The Laser systems are housed in a specially designed Slitlamp which has been adapted for use as a Laser delivery system. All the normal functions of a Slitlamp are available to the operator.

When the system is being used as an Ophthalmic YAG Laser to perform a capsulotomy or membranectomy procedure the physician will normally use a contact lens in order to direct the Laser energy to the part of the eye being treated. The contact lens also helps to hold the eye still and open during the procedure.

The physician will normally turn the Laser System ON and check its operation before positioning the patient in the Chinrest and adjusting to the correct height. After selecting a low energy setting the physician can view the patients eye and after confirming that the indications

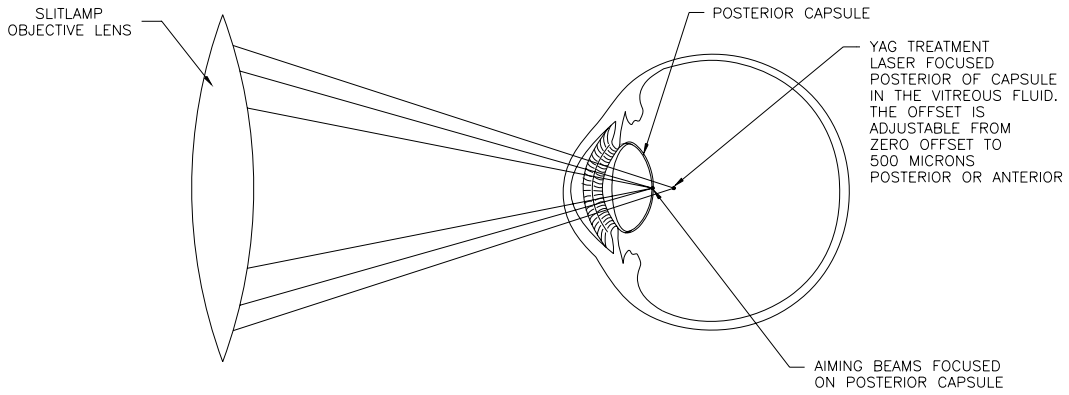
and contraindications permit the procedure then the Laser can be put in the TREAT mode and by viewing the Aiming beams on the posterior surface of the capsule the laser can be focused correctly and then using the joystick fire switch the laser can be fired in order to put a hole in the capsule. Several laser shots will normally be required in order to produce a large enough hole in the posterior capsule to give clear vision to the patient.

All of the controls and displays on the Laser System are used by the physician in order to prepare the laser for the procedure and ensure that normal operating conditions are occurring. For full details on **Clinical Use** see Section 6 of this manual.

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

The Laser System generates a focused light beam of the wavelength 1064 nanometers (nm) at the same focal plane as the Slitlamp. This Laser beam has a spot size of approximately 8 microns and its energy is adjustable and selected by the Operator.

The focused Laser energy will create a small plasma effect (or spark) in the eye media which in turn causes an acoustic wave that can disrupt or create a hole in the adjacent tissue. This is commonly called the Opto-acoustic effect.



YAG Laser Focusing for Treatment

Figure 4.1

The size of the plasma effect is directly proportional to the amount of energy in the focused Laser beam. Therefore as the energy is increased the plasma will also increase and this then generates a stronger, more powerful acoustic wave which can make larger holes in the tissue. This stronger acoustic wave can also damage the Intra-ocular lens (IOL) if the plasma effect is focused too close to the IOL. Therefore to prevent this happening it is important to focus the Laser beam more posterior or further away from the tissue that is to be disrupted when increasing the Laser energy. This avoids damaging the IOL and also gives the best and most effective disruption effect on the tissue.

When the Laser energy is reduced then the effect is the reverse of the above so the focus needs to be brought closer to the tissue.

In the AURA PT the Treatment Laser beam is normally defocused posterior to the Aiming beams (Slitlamp focal plane) by a fixed distance. This distance has been set to provide the optimum tissue effect at energies of 1.0 to 1.5 milli-joules (mJ) which is the typical settings for posterior capsulotomy procedures.

In the AURA PT the Treatment Laser beam focus is adjustable by a Control that is located on the left hand side of the Laser Arm. The focus can be set by the Doctor to the most appropriate offset according to the Energy set and the procedure that is being carried out. The (+) or Posterior offset sets the YAG Laser treatment beam posterior or behind the Aiming beams (Slitlamp focal plane) by the setting as indicated on the control. The Control is calibrated in micrometers µm (microns). The (-) or Anterior offset sets the YAG Laser treatment beam anterior or in front of the Aiming beams (Slitlamp focal plane) by the setting as indicated on the control. As a guide, for Posterior Capsulotomy procedures this offset should be set to around 150µm for Energies of 1.0 to 1.5 milli-joules (mJ). As the Energy is increased the offset is increased accordingly. The Doctor should always start with a lower energy setting and larger offset to ensure that no damage is caused to the IOL. Remember that a larger offset will mean that there is less effect on the capsule surface so it is important not to have too much offset such that a higher energy is used than necessary.

The Treatment Laser beam is invisible to our eyes so a visible red Aiming beam system is used to allow precise positioning of the Treatment Laser beam. The Aiming system originates from a Red laser diode which is split into two collimated beams that are then focused such that they are parfocal to the Slitlamp and coaxial with the Treatment Laser beam. This means that the Aiming beams focus together exactly at the focal plane for the Slitlamp and the centre point for the Aiming beams and Treatment Laser beams are the same at the focal plane of the Slitlamp. The intensity of the Aiming beams is set by the small knob on the right hand side of the Slitlamp Arm near the display.

Note: It is recommended that the lowest effective treatment Laser energy be used to perform Opto-acoustic procedures as a means of minimizing unwanted side effects such as IOL damage or retinal damage. Always start the procedure at the minimum energy. Also, where a larger YAG Laser offset focus may reduce the likelihood of IOL damage, this needs to be considered carefully such that an unnecessarily high energy is not used to overcome the larger offset. (Refer to Indications for use Section 6.3 of this manual for further warnings.)

The AURA PT YAG Laser System consists of two main parts;

1. The base is called the **Control Box** and in here are the power supplies and mains power switches. Also the Slitlamp Illumination controls are on the front panel of the Control Box. The Chinrest is fixed to the rear of the Control Box.
2. The **Slitlamp** is mounted on top of the Control Box and in the Arm of the Slitlamp are all of the optical modules including the Laser beams, Energy adjuster and the control and Display circuits. On the front panel of the Arm are 4 switches which are used to set the operating modes of the Laser System.

Mains power must be connected to the Laser System then when the key-switch is turned ON (with the Emergency switch in the out or ON position) the Slitlamp Illumination is turned on. The power on indicator should be illuminated and in this mode of operation the Slitlamp can be used as a standard diagnostic instrument. The CSO 950 has all the functions of a standard Slitlamp and a full range of accessories are available for use with it if required. All the electronics and laser functions will not operate in this mode.

To turn ON the electronics in order to set and use the Laser functions the Laser ON/OFF switch must be pressed. When this switch is turned on there is an indicator lamp which comes on and then the displays on the front panel of the Slitlamp Arm will turn on. The System controller performs some internal checks and some Laser test shots are fired to verify the correct operation of the Laser.

All the operating conditions are shown on the display and the switches can be used to change operating modes or perform functions. The display shows the Energy selected, number of Pulses set, accumulated number of pulses and energy and the MODE of operation. The MODE of operation is an important display. When the Laser ON/OFF switch is turned ON then the mode, “STANDBY” is automatically selected. This prevents any accidental firing of the Treatment Laser by disabling the fire switch and keeping the internal mechanical shutter, that is in the beam path, closed.

By pressing the Mode Switch the system is set into the “TREAT” mode of operation. The fire switch and shutter are now enabled and if the fire switch is pressed then the shutter opens momentarily to allow the Treatment beam to be delivered from the front of the Slitlamp Arm through the objective (or focusing) lens. The “STANDBY” mode can be selected by pressing the Mode Switch again.

It is recommended that prior to going into the Treat Mode, all operating conditions, such as patient positioning, energy selection, number of pulses and Slitlamp Illumination be set correctly. This prevents the likelihood of accidental firing of the treatment laser during the set up steps.

On either side of the Slitlamp Arm are large knobs which are used to control the energy level of the delivered Treatment Laser beam. Whenever these knobs are rotated, the Energy display changes to indicate the Preset new energy setting. When the adjustment has been made then a test fire is initiated and this energy is then displayed. When a test fire is made the energy is not delivered through the system because the mechanical shutter is closed preventing any energy

from being delivered. On the shutter there are sensors which the controller uses to ensure the shutter is in its correct position at all times otherwise an error condition will occur.

Whenever the Treatment Laser is fired the energy of the shot is measured and displayed. An audible beep is sounded to indicate to the Operator that a Laser shot has been fired. If the delivered Laser Energy has changed by more than 20% from the previous treatment shot then a short burst of 3 beeps will sound to warn the Operator to check the Laser Energy.

If the System is in the TREAT mode then the accumulated pulses and energy displays are incremented and the laser can be fired again in around 1 second. In the case of an emergency the Red Emergency Switch can be pushed to turn off all power. Normally power can be turned off using the key-switch. The key should not be left in the key-switch when the Laser System is unattended.

4.2 Ophthalmic YAG Laser Controls and Displays

All the Controls and Displays for the AURA PT YAG Laser are located either on the Control Box front panel or the Laser head arm / display panel. The following figure 4.2 shows all of these controls and displays and then there is a description following.

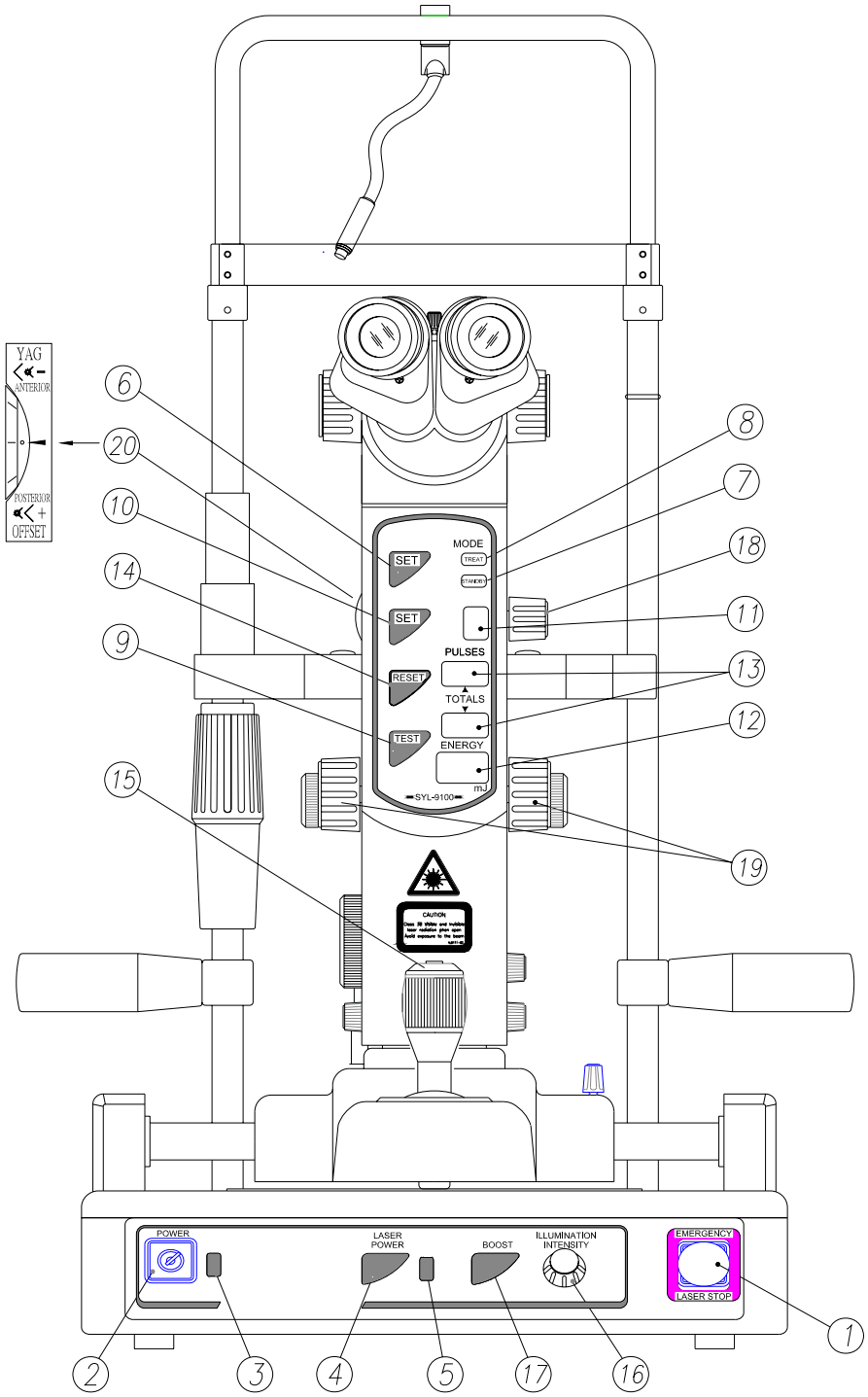


Figure 4.2 YAG Laser Controls and Displays

Item	Feature	Description
1	Emergency Stop Switch	This switch is provided to enable a fast response shutdown of the Laser System in the event of some serious problem occurring. It is a RED push switch that locks down when pushed and in this position all power to the internal parts is removed. The switch must be rotated to reset to the ON position.

Item	Feature	Description
2	Key Switch	The 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, controlled place.
3	Power ON	Indicator A green lamp indicates that the power is turned on to the system.
4	Laser Power ON/OFF Switch	This press switch applies power to the internal electronics so that the Laser system including the Aiming Laser turns on. There is a built in delay to operate this switch ON. This means that the user has to push the switch for at least 0.5 seconds to make the electronics turn on. Power is removed immediately when the switch is pushed to turn OFF. Whenever the power is turned ON to the system this switch is in the OFF condition.
5	Laser power ON Indicator	A yellow lamp located next to the Laser ON/OFF switch indicates that the power is turned on to the Laser electronics
6	Mode Set Switch	This press switch toggles the Laser System between the STANDBY and TREAT modes. In the Standby mode the Laser cannot be fired by the Joystick fire switch and the Shutter is always closed. The Treat mode is only used when the operator wants to deliver a pulse of laser energy to the patient and in this mode the Joystick switch is enabled and the shutter will open.
7	Standby Indicator	When this indicator is illuminated the Laser System is in the Standby mode and the Laser energy CANNOT be delivered to the patient.
8	Treat Indicator	When this indicator is illuminated the Laser System is in the Treat mode and the Laser energy CAN be delivered to the patient.
9	Test Fire Switch	This press switch can be used in either the Standby or Treat modes to fire the laser. The Shutter is always closed during the test fire and this features allows checking of operation and Energy levels. The Energy is displayed on the Display panel
10	Pulses Set Switch	This switch when pressed advances the number of pulses that the Laser will deliver in burst mode. When the Laser is first turned ON only 1 (single) Pulse mode is selected. Pressing the switch once will advance to 2 (double) Pulse mode and pressing again will advance to 3 (triple) Pulse mode. Pressing again will return back to 1 (single) Pulse mode. Whenever the Pulse mode is changed the laser does a test fire to measure and display the new Energy level. The number of Pulses selected is displayed on the Pulses display.
11	Pulses Display	This LED indicates the number of pulses that will be delivered whenever the YAG Laser is fired. This display will change whenever the Pulses Set Switch is pressed

Item	Feature	Description
12	Energy Display	This 7-segment display shows the measured Energy level of the YAG Laser. This display is also used to indicate the approximation of the selected energy whenever the Energy adjustment control is changed.
13	Totals Displays	Whenever the Laser System is in TREAT mode and the Laser is fired with the Joystick switch these Displays increment to record / display the Total number of pulses delivered and the Total energy delivered. The displays are always reset to zero when the Laser System is switched ON.
14	Totals Reset Switch	This switch can be used to reset both the Totals displays to zero. This reset would be done between patients and also would be done after doing performance and operating checks before using the Laser on patients.
15	Joystick fire switch	When this switch is pressed and the Laser System is in the TREAT mode a pulse or burst of pulses will be delivered from the Laser unit. The fire switch must not be held down in the ON position otherwise the microprocessor will detect this and put the Laser System back into the Standby Mode. Also if the Fire Switch is pressed in Standby Mode it is impossible to go into the TREAT Mode.
16	Slitlamp Illumination intensity adjuster	This provides control over the brightness of the Illumination lamp in the Slitlamp.
17	Slitlamp Illumination Boost Switch	This switch can be used by the physician to momentarily provide maximum illumination to the patient's eye. This control is not intended to be used for long periods of time.
18	Aiming Beam Intensity Control	Located on the Right hand side of the Laser head arm this control provides continuous adjustment over the intensity of the Aiming beam spots. At minimum intensity there is still some illumination of the Aiming beams.
19	Energy Adjustment Control	Located on either side of the Laser head arm are the two knobs which provide the means to adjust the energy level of the YAG Laser. Because the YAG Laser always fires at its maximum energy level this control actually attenuates down the delivered energy, optically. When this control is adjusted the microprocessor displays an approximation of the selected energy on the ENERGY display located on the Front Panel display. When the adjustment has been made then the Laser performs a test shot to measure the actual energy and then this is also displayed.

Item	Feature	Description
20	YAG Laser Focus Offset Control	Located on the left hand side of the Laser Arm is a control that allows the YAG treatment laser beam focus point to be adjusted posterior (+) or anterior (-) to the Aiming beams focus. This control needs to be set by the doctor to the most appropriate offset for the procedure being carried out. In general Posterior Capsulotomy and Membranectomy procedures will use the Posterior offset and Iridotomy procedures will use Anterior offset. Zero offset means that the YAG Laser beam is set to the same focus plane as the Aiming beams and Slitlamp illumination.

4.3 CSO 950 Slitlamp Controls

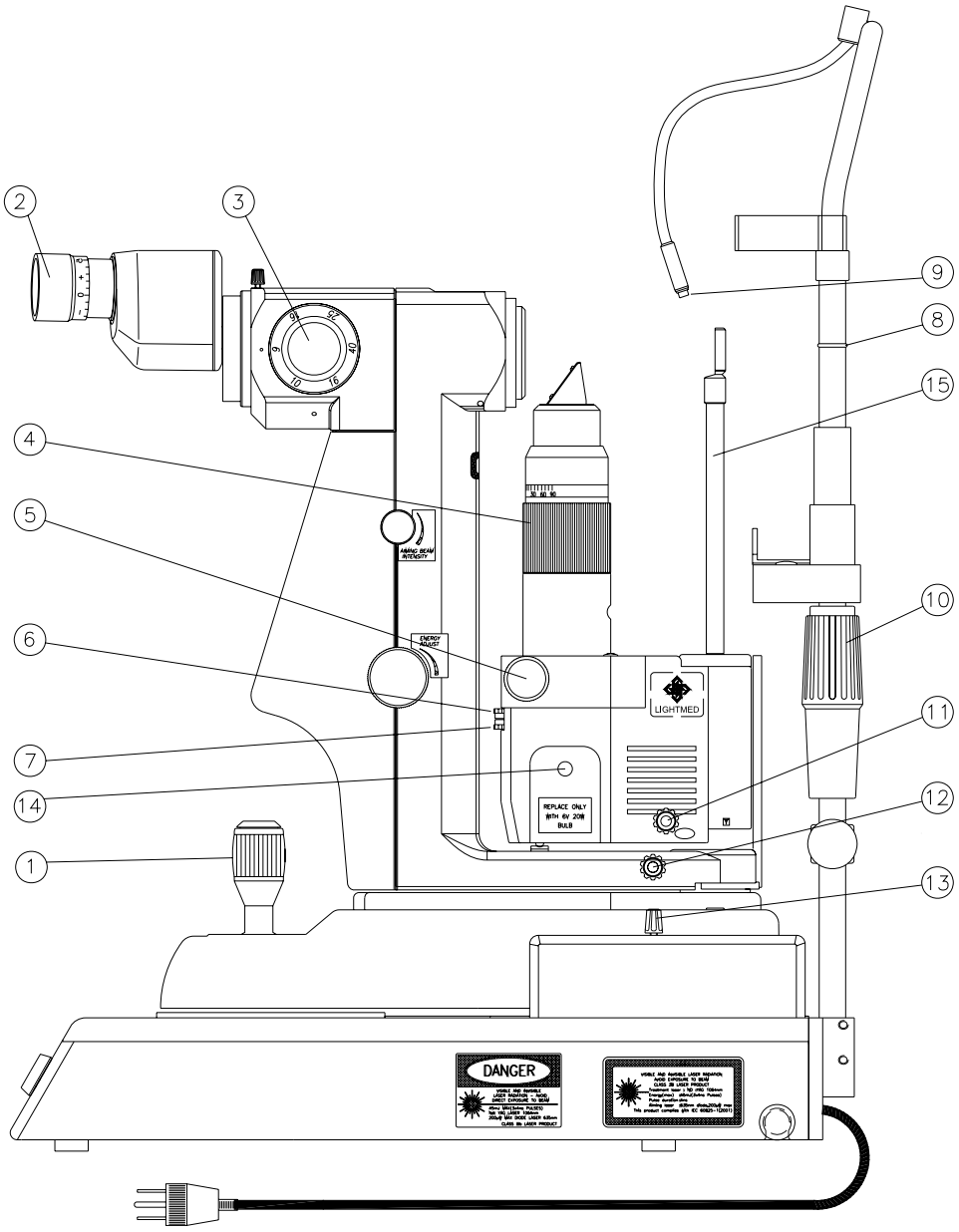


Figure 4.3 CSO 950 Slitlamp Controls

Item	Feature	Description
1	Joystick arm	The joystick provides control over the horizontal and vertical movements of the Slitlamp. Rotating it adjusts the vertical height.
2	Eyepiece focus ring	Both eyepieces have this adjustment which gives a +/-8 Dioptre adjustment to the viewing focus. Always adjust for focus going in a negative direction
3	Magnification Adjuster	The viewing field can have different magnifications set by rotating this control. Magnifications of 6X, 10X, 16X, 25X, 40X

Item	Feature	Description
4	Slit rotation Collar	When this collar is rotated the Illumination Slit is rotated through a maximum of 180 Degrees. At the center detent position the Slit is vertical.
5	Slit width control	On either side of the Illumination tower is a control knob which can be used to change the width of the Slit.
6	Illumination Aperture Wheel	This wheel has different size apertures machined in it and this then provides control over the size of the Illumination spot and the slit height
7	Illumination Filter wheel	This wheel has 4 settings and provides 4 different colors settings for the Illumination. The settings give Blue, Red free, Heat absorbing and natural colors
8	Canthus Mark	This mark indicates the ideal height for positioning the patients eye in order to be able to use the full vertical adjustment range of the Slitlamp
9	Fixation Lamp	The physician will use this lamp as a reference source for the patient to look at while being looked at by the physician
10	Chinrest Height adjuster	This control can be used to raise or lower the patients head in order to align their eye to the canthus mark on the Chinrest post.
11	Locking screw for Illumination Tower	This screw locks the rotation movement of the tower
12	Locking screw for Laser head arm	This screw locks the rotation movement of the Laser head arm
13	Locking screw for Base	This screw locks the horizontal movement of the base. This should always be locked when the laser unit is not in use
14	Lamp housing ring	This ring holds the Illumination Lamp in place. If the Lamp has to be replaced then this ring is undone to gain access to the lamp.
15	Target Rod	This target rod is inserted into the Slitlamp in order to set the eyepiece oculars and to inspect or check the Slit Illumination. The Rod cannot be used to check the Laser operation and must be removed from the Slitlamp before proceeding to use the Laser System in any way.

4.4 Start up and operation of the Laser System

In Section 6 of this manual, **Clinical Use**, there is detailed information on how to turn the Laser unit ON, make adjustments to both the Slitlamp and the Laser System and then operate the laser.

The following is a Start up procedure for the Laser system.

Note: The AURA PT YAG Laser is a Class 3B Laser unit and can be hazardous to the user and other persons in the vicinity of the Laser. Before turning the laser ON read and understand the warnings that apply to this instrument that are contained in Section 2 of this manual.

Start up procedure:

1. Make sure all cables are correctly connected to the Laser unit.
2. Plug the mains cable into an Earthed (3 Pin) mains socket outlet.
3. Get the key for the unit from the responsible person who is in charge of it.
4. Insert the key and then turn ON the keyswitch. Note that the Emergency Switch must be in the ON (out) position. The Slitlamp Illumination will turn ON.
5. Adjust the Slitlamp Illumination controls to the required settings (Intensity, Color, Slit, Aperture).
6. Press the Laser ON/OFF switch to turn on the Laser System.
7. At this time test shots are fired and the version of software, displays and error conditions are displayed. Pressing the Laser ON/Off switch again will turn OFF the Laser System but leave the Slitlamp ON.
8. If everything is OK then the Laser System will go to the Standby mode, in single pulse mode and will display the Laser energy that is currently set.

NOTE: Should the system at any time detect an error condition, the system will shut down to a safe state and display an error message (code) on the display. If an error message is display, initially try turning the system off then on again to see if the error condition is resolved. Occasionally the message "CAL" maybe displayed after this action. If this occurs, the system is performing a self check which will take approximately 10minutes to perform. If the error message condition does not clear, the please contact your service representative as your system requires a service.

9. At this time the Aiming beam intensity and the YAG Laser energy can be adjusted and, as well as the YAG Laser offset focus can be adjusted to the required levels by rotating the controls that are located on the sides of the Laser head arm. Always start at the minimum settings with the YAG offset focus set to the most appropriate for the intended procedure.

NOTE: When using the Laser System on a patient always set the Aiming beam intensity and the YAG laser energy to the lowest setting possible before positioning the patient or starting to carry out the procedure.

10. When the laser is in the Standby Mode the Joystick fire switch and the shutter will not operate so the YAG Laser energy cannot be delivered from the objective lens. The laser can only be fired by pressing the TEST switch on the Display panel. By pressing this switch the Laser energy can be checked for each shot fired on the Energy Display.

11. As well as adjusting the YAG Energy Control knob the YAG Laser can also be set in either single, double or triple pulse mode by pressing the PULSE SET switch. Setting these modes means that for one fire switch operation there will be either one pulse or a train of two or three pulses together. The energy of the train of pulses will be summed together on the Energy Display.

12. Whenever the Pulse mode is changed or the YAG Energy level is adjusted the YAG Laser will do a Test fire and then show the new Energy level on the Energy Display.

13. To check the correct operation and alignment of the lasers it is necessary to carry out some simple procedures. These procedures are detailed in Section 7 of this manual. The procedures that should be carried out are:

    A. Air breakdown check The YAG energy is set to maximum in single pulse and the Laser System is set to TREAT Mode. Make sure the Illumination Tower is not in line with the objective lens and that all people present are wearing safety glasses then press the joystick fire switch and you should observe as small "spark" in midair at the focus point of the system.

    When the Laser is new this Air breakdown will occur at less than 4 millijoules (mJ).

    B. YAG Laser Alignment check The YAG Laser beam must be aligned to the Aiming beams and they should both be in the central region of the Illuminated field of view. The clip on Target Plate should be fitted to the Chinrest and have some Thermal Paper stuck to it. Focus the Illumination spot, set to the 10mm Aperture, on the target plate and then finely adjust the Aiming beams until they are on top of each other on the target. Set to minimum YAG Energy and in TREAT mode fire one shot on to the target plate and then check that the YAG beam and Aiming beams are centered to each other and that they both are close to the center of the Illumination Spot. If the beams are NOT aligned then the Laser must not be used until a full optical alignment procedure is carried out by a service person.

    It is also necessary to check the Offset alignment. Set to minimum YAG Energy, zero YAG offset focus and in TREAT mode fire one shot on to the target plate and then check that the YAG beam and Aiming beams are centered to each other and that they both are close to the center of the Illumination Spot. Adjust the YAG Laser focus to +500µm offset and finely adjust the Aiming beams to a new place on the Target and again at minimum energy fire the Laser. The YAG beam burn mark should still be in the center of the Aiming beams but should now be a large diameter. Repeat at the –500µm offset and the burn should again be a larger diameter burn. If the Beams are NOT aligned or if the burn marks are not larger when the offset is at the + or – settings then the Laser must not be used until a full optical alignment procedure is carried out by a service person.

14. Because the YAG Laser beam is invisible the position of it can only be set by using the Aiming beams. To do this, inside the laser system, two beams of equal intensity are generated and then delivered through the objective lens to the focus plane. By moving the Slitlamp joystick backwards and forwards and observing the target plate the Aiming beams will go from two spots through to a single spot when they are at the focal plane. When they are set to a single spot the Laser is set to the correct focus point.

15. After operation of the unit is finished then the Laser System can be turned OFF using the key-switch. Remove the key and return it to the responsible person.
16. Cover the unit with the Dust Cover provided and turn OFF the mains power or disconnect the mains cable from the outlet socket.

Section 5. INSTALLATION

Contents

5.1 Introduction and Requirements

It is strongly recommended that the manufacturer or its authorized agent install the AURA PT Laser System at the Operators 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 when ever 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 request a copy also.

The installation requirements are:

1. 100-230 Volts, 50 or 60Hz AC mains power supply with an earth connection.
2. A motorized stand with table or a fixed table top to place the Laser System on top of. If a fixed height table is to be used then it is advisable to use chairs that are easily height adjustable so as to be able to comfortably position the patient in the Chinrest.
3. A mains power cable for the system is supplied but the plug may not suit the available outlet available. If it does not, it is recommended that a suitably qualified and authorized person fit the appropriate plug for your outlet.
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. 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. Where the User requires moving the Laser system to a new location it is recommended to lock all the movement screws and carefully transport to the new location. If the new location is at a different facility then the User should consider repackaging the Laser

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 6.1 and 6.2 of this Operator Manual.

5.2 Unpacking and Receiving Inspection

The Laser System is supplied packed in a strong cardboard carton. Inside this carton are 3 separate boxes and each one contains one of the Laser Systems assemblies. Refer to figures 5.1 and 5.2.

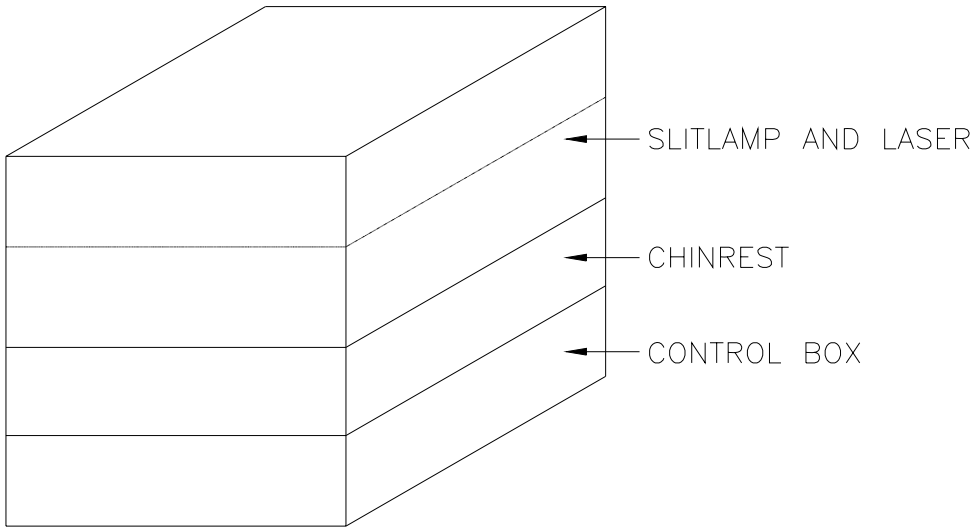
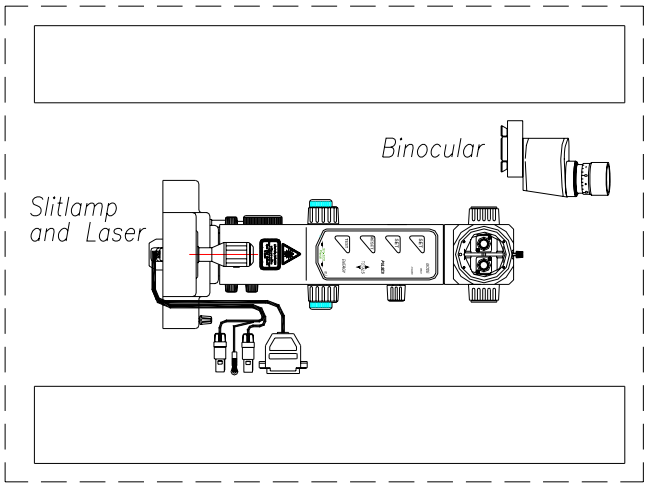
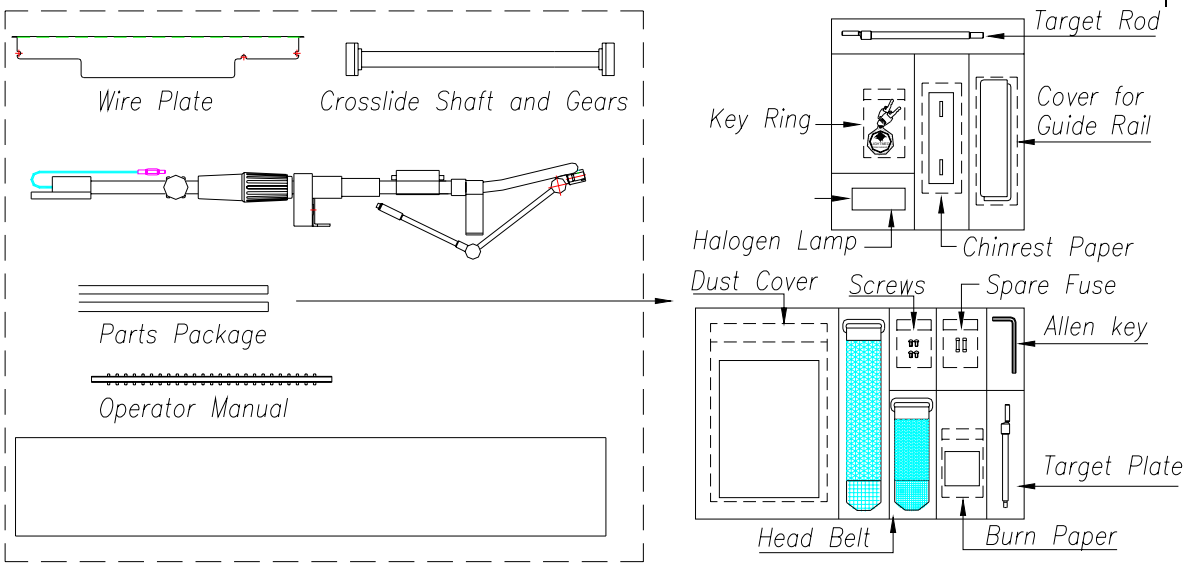


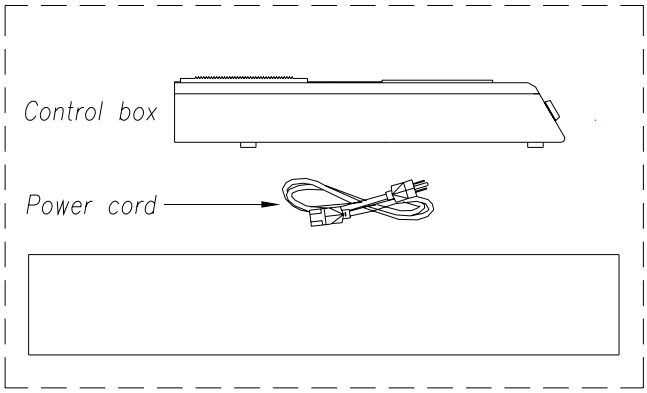
Figure 5.1 Packaging Carton



STEP 1: Remove the Slitlamp and Laser System along with its foam packing by the straps.



STEP 2: Remove the Chinrest and its foam packing from the carton.



STEP 3: Remove the Control Box and power cable from the foam.
The keys are taped to the top of the Control Box.

Figure 5.2 Steps to follow when removing the Laser System from its Packing Carton.

Upon receiving the system inspect the Packing Cardboard 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 accepts responsibility for any damages.

If the external carton packaging is OK then you can proceed to remove the 3 individually packed assemblies. The contents of each assembly are:

1. The top part contains the Slitlamp and Laser Arm unit complete, binoculars, eyepieces, target rod, target plate, cross-slide shaft and gears, gear covers, spare lamp, spare fuses, and some tools for assembly.
2. The middle part contains the Chinrest assembly, Operator Manual, Dust cover and Laser system documents.
3. The bottom part contains the Control Box, Mains power cable, and the keys for the key-switch.

Open each part and confirm the contents. Refer to the packing check list for reference.

5.3 Tools and Equipment

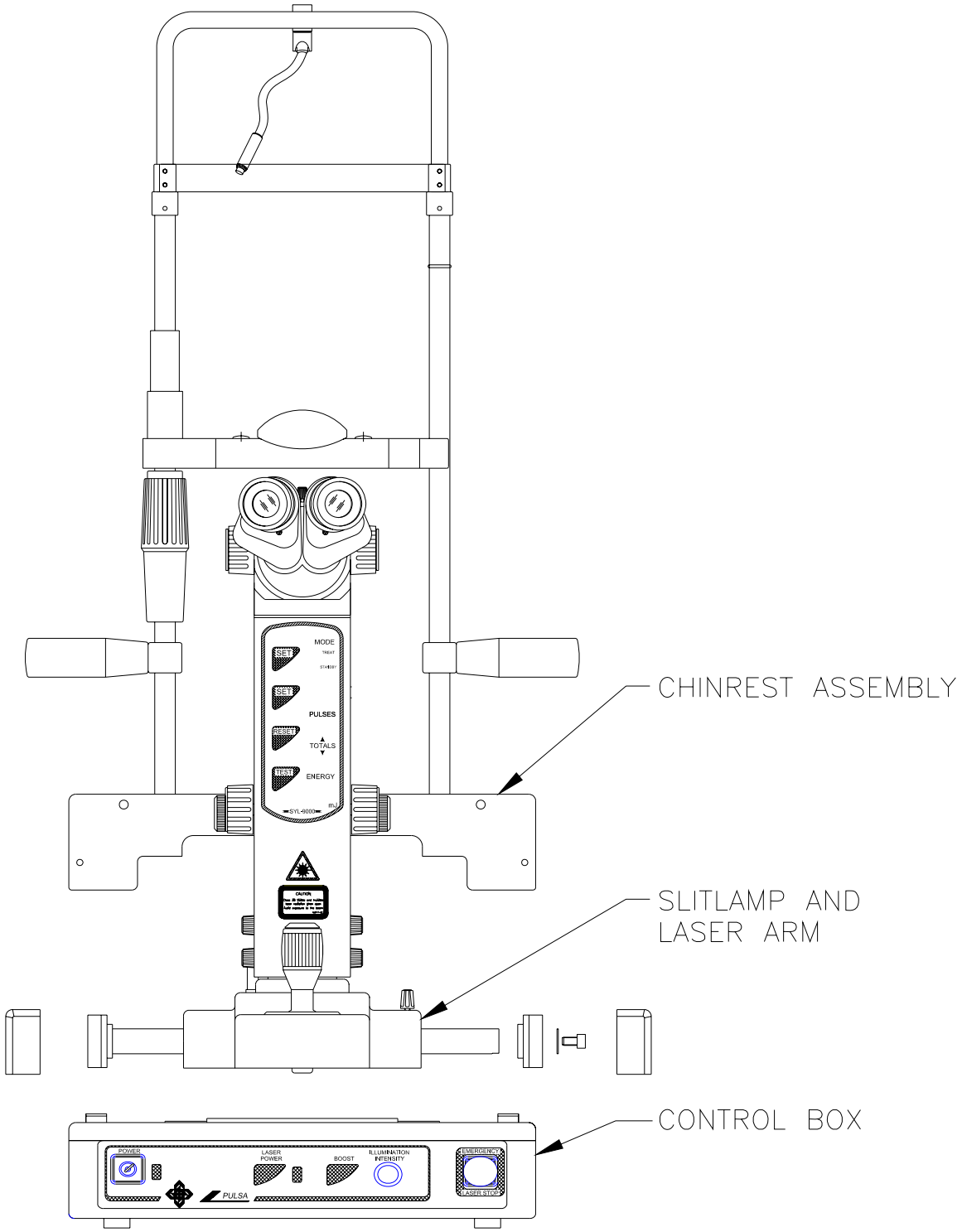
In order to be able to effectively carry out a full initial installation of the Laser System the following tools and equipment are required and available from the manufacturer;

1. Laser Energy Meter (to measure 0 - 40 milli-Joules Q-switched)
2. Optical Alignment tool kit which includes:
   - Magnifier offset tool
   - Model Eye
   - Laser target tool
3. Photographic thermal paper (Zap-it or equivalent)
4. Set of metric Allen keys
5. Standard tools such as screwdrivers

If the AURA PT Laser System is to be used as a Portable System and it needs to be relocated at various times then the tools necessary in order to assemble and disassemble are supplied with the YAG Laser.

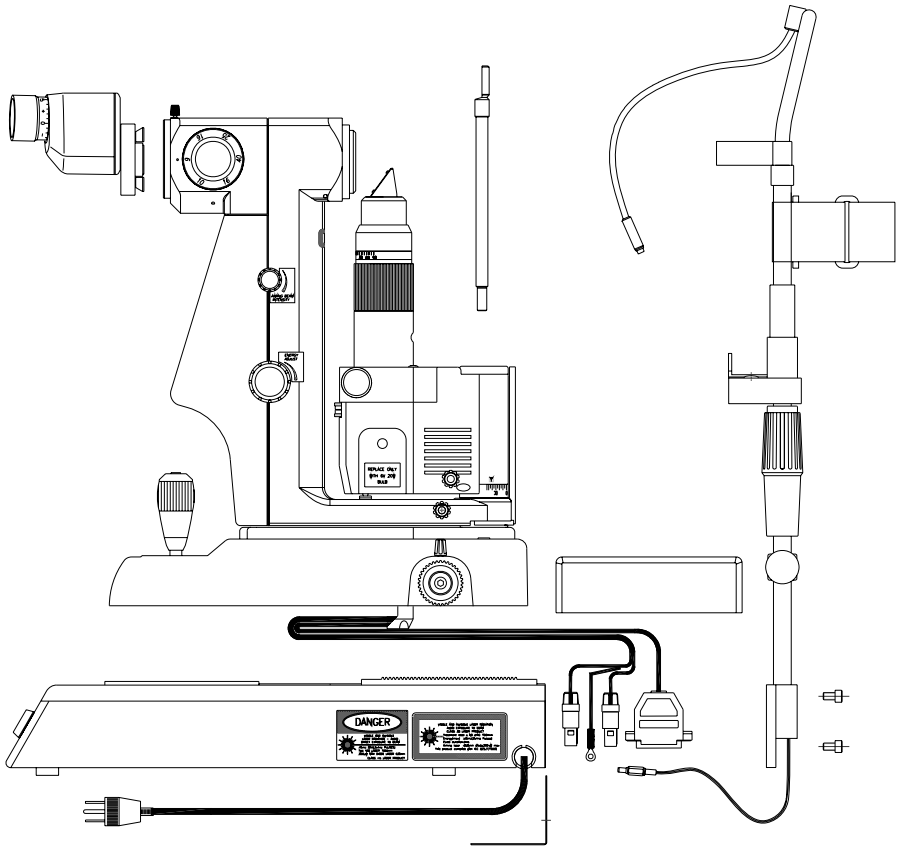
5.4 Unpacking and Setting Up the System

1. Place the Control Box on the table top then remove the 3 cable plates from the top of the Box.
2. Remove the Slitlamp from its box and install the crosslide shaft by removing one of the gears then sliding the shaft through and then refitting the gear.
3. Carefully place the Slitlamp on top of the Control Box with a cable going to each side. Make sure the Slitlamp is square to the top and when OK fit the two gear covers. Make sure the cables are positioned so that they do not rub unnecessarily on the cable plates when the Slitlamp is being moved. See Figure 5.4 (c).
4. Refit the 3 cable plates to the Control Box top then move the Slitlamp to its fully forward position in the center of the Control Box. Make sure the two cables are looped without any tension on the side plates then move the Slitlamp sideways to make sure the movement is smooth.
5. Set the positions of the cables and when they are OK attach the connectors on to the back panel of the Control Box. There are three connectors to be fitted. (The Interlock Bypass connector should already be in place) and then attach the Earth Wire from the Slitlamp Laser Arm to the terminal on the back panel and make sure the screw is tight.
6. Check the voltage changer switch and ensure it is set to the correct operating voltage for the installation site.
7. Now the Chinrest can be attached to the back of the Control Box. When this is fitted it also clamps the cables from the Slitlamp Laser Arm in the Slots on the top plate. Therefore it is essential to get the cables to lay correctly before fixing the Chinrest. See Figures 5.4 (b) and 5.4 (c).
8. Plug the cable from the Chinrest fixation lamp in to the connector on the back panel of the Control Box.
9. Fit the binoculars and eyepieces to the Slitlamp Laser head.
10. Attach the Mains power cable to the socket on the back of the Control Box.
11. If a motorized stand is to be used and it is set to operate from the same mains voltage as the Control Box then it may be connected to the “Stand Power” Connector on the back panel of the Control Box. The motorized stand must not exceed an operating power rating of 100 watts otherwise it should be connected to a separate power outlet.
12. If a remote door interlock is to be used then the connector can be plugged into the Control Box instead of the Bypass plug.
13. The Laser System can now be plugged into the mains power outlet and the system can be turned ON.
14. For full details of how to operate the Slitlamp and Laser System refer to Sections 6.1 and 6.2 of this manual. In these sections are full descriptions and some functional checks to be performed and these are required to be done during the installation.

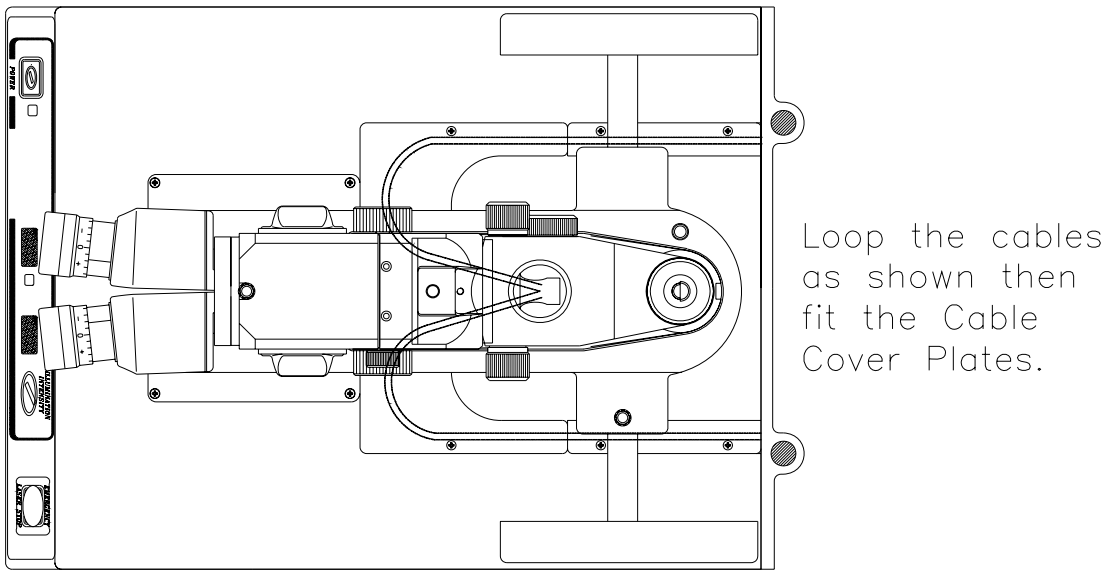


Assembly of YAG Laser System

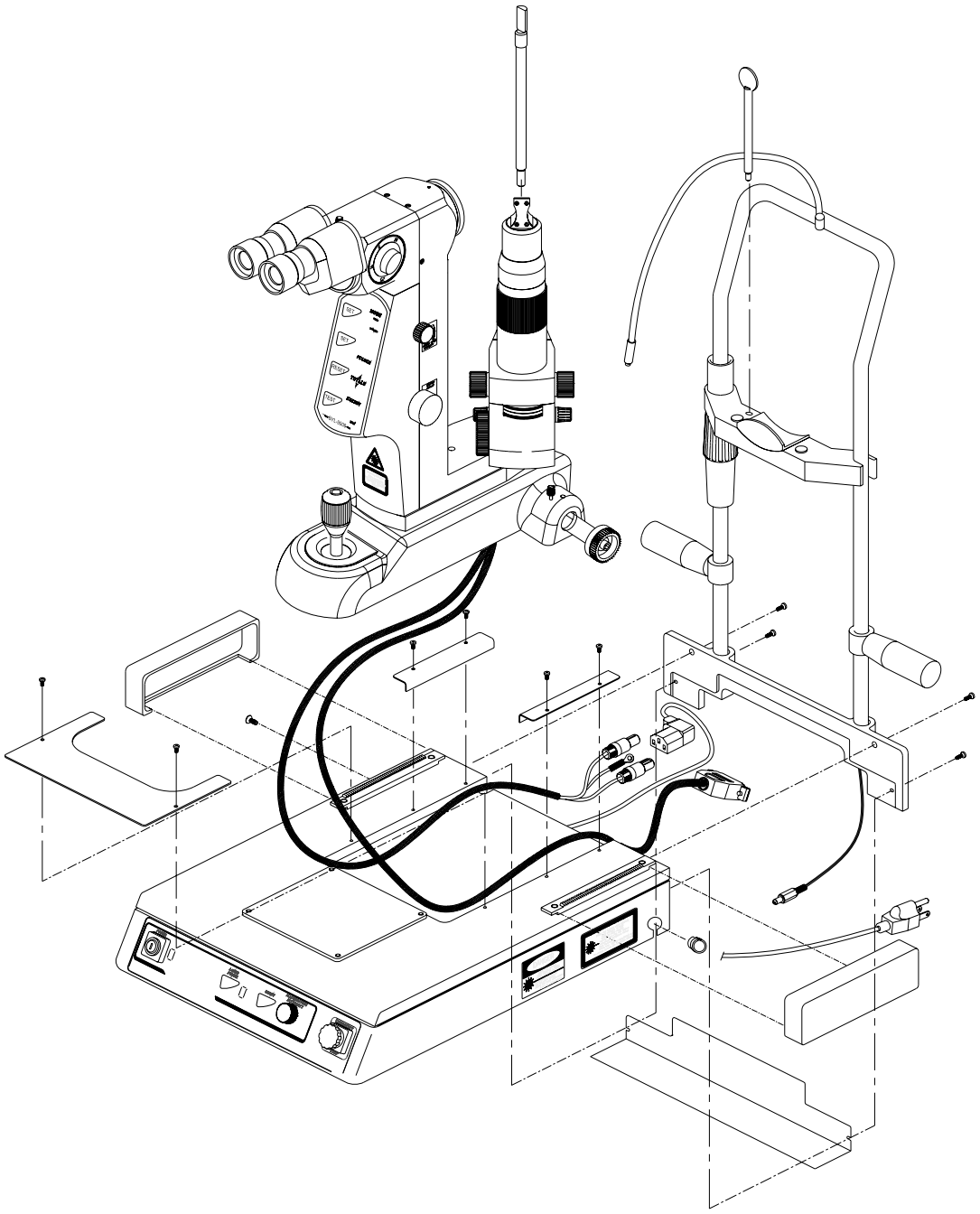
Figure 5.4 (a)



Assembly of YAG Laser System
Figure 5.4 (b)



Positioning the Slitlamp Cables
Figure 5.4 (c)



Exploded View of AURA PT for Installation
Figure 5.4 (d)

5.5 Installation Checklist and Report

AURA PT PACKING LIST		**Page 1 of 2**
Model: AURA PT	**Serial Number: _____**	Check if OK
1.0	System Setup	
1.1	All parts received and checked OK.	
1.2	No damage to instrument packaging.	
1.3	Assemble Slitlamp Arm to Control Box.	
1.4	Adjust cables then attach cable plates / covers.	
1.5	Plug in cables to Control Box.	
1.6	Mains operating voltage is set to correct voltage _____ VAC.	
1.7	Attach Chinrest to Control Box.	
1.8	Finish System assembly.	
2.0	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 (13, 10, 6, 0.3, and adjustable).	
2.4	With 13mm 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 + 90oround vertical.	
2.8	With Target Rod inserted confirm eyepieces can be adjusted fully and set to correct oculars.	
2.9	Check that eyepieces fit firmly into binoculars.	
2.10	Binoculars can be adjusted for intrapulpillary distance (PD).	
2.11	Check Slitlamp movements with joystick:	
	(a) Vertical adjustment range OK.	
	(b) Sideways adjustment range OK.	

AURA PT PACKING LIST

	(c) Forwards adjustment range OK.	
	(d) Movements should be smooth.	
2.12	Illumination Tower and Laser Arm can be swung from side to side OK.	
3.0	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.	
4.0	Laser System Checks	
4.1	Laser Power ON indicator is on when switch is pressed.	
4.2	Laser System does test shots at Start up.	
4.3	System Software version is displayed during test shots. Software version is _____	
4.4	Confirm that no Error messages are displayed.	
4.5	There should be a Display of the system energy and when the Energy is adjusted this display should change to indicate the new energy setting.	
4.6	All Display Panel controls, switches and displays are functioning.	
4.7	The two Aiming beams are visible and their intensity is adjustable.	
4.8	Perform the Air breakdown check (Section 7.2 part 3). Record Minimum Air breakdown energy level _____mJ	
4.9	Perform the Laser beams alignment check (Section 7.2 part 4).	
4.10	The YAG Laser offset control is functioning (Section 7.2 part 4).	
4.11	Perform the Energy meter check and calibration procedure.	

Installers Name: _____ Date: (MM/DD/YY) _____

Distributor Name: _____ Date: (MM/DD/YY) _____

Customer Name: _____ Date: (MM/DD/YY) _____

(Send this Installation Report to the Manufacturer immediately.)

Section 6. CLINICAL USE

Contents

6.1 Use of the AURA PT System as a Slitlamp Microscope

The System can be used as a Slitlamp Microscope very safely due to the inclusion of the Laser ON/OFF switch. When this switch is turned OFF and the Key-switch and Emergency switches are both ON, the Slitlamp Illumination Lamp is turned ON and in this mode the Slitlamp can be used safely because the Electronics and Laser units are turned OFF.

Therefore to operate the system as a Slitlamp Microscope, follow these instructions.

1. Connect the AURA PT to the mains power and turn the power ON.
2. Turn the key-switch to the ON position (The Emergency Switch must be ON, which is the pulled out position). The Power ON indicator should be ON.
3. The Illumination Lamp will now be ON and its intensity can be adjusted using the controls on the front panel of the Control Box. The Boost switch is only intended for intermittent use and continuous use will shorten lamp life.
4. (1) Insert the Target rod in the pivot post of the instrument and adjust the eyepieces to the examiners Pupillary Distance (PD). Then adjust the focus of the eyepieces to the examiner's refractive error by turning the eyepiece focusing ring in a negative direction. The corrective powers are engraved in diopters on the eyepieces. Remove the focusing rod when the settings are made.

   (2) Insert the Target rod in the pivot post of the instrument, set the 16X magnification and then adjust the eyepieces to the examiners Pupillary Distance (PD). Then adjust the focus of the eyepieces to the examiner's refractive error by turning the eyepiece focusing ring in a negative direction. The corrective powers are engraved in diopters on the eyepieces. Remove the focusing rod when the settings are made.
5. Adjust the height of the chin rest by turning the chin rest height control knob until the patient's canthus is in line with the canthus mark on the headrest post.
6. The microscope's height is adjusted by rotating the joystick handle and observing the slit image through the microscope until the slit is centered on the patient's cornea.
7. Move the slit lamp with the joystick held firmly and slightly inclined toward the operator, until the slit appears sharply on the cornea. The ball foot will slide on its base. The accuracy of this rough adjustment is checked by the naked eye. The fine adjustment is now done while observing the slit through the microscope.
8. Tilt the joystick, which is now held lightly at its upper end, until the slit appears sharply at

the depth of the eye which is to be observed. The horizontal motion of the base can be locked by tightening the base locking screw. Lock the base whenever the Slitlamp is not in use.

9. The slit width can be adjusted by rotating the slit width control on either side of the Illumination Tower.
10. The angle between the illumination system and the microscope can be varied between 0^{o} and 90^{o} to either the left or to the right. The angle is indicated on the scale of the Laser head arm.
11. Slit rotation is achieved by twisting the collar on the tower to the left or right. The degree of rotation is indicated by the scale above the rotation collar.
12. Magnification is altered by rotating the Control on the Magnifier head. The magnifications are indicated on the dial and the positions are also click stopped.
13. When the Illumination locking screw is loosened, the slit can be scanned away from the center of the field of vision for retro-illumination, scleral scatter, etc. The slit lamp is centered again by aligning the pointer to the centering line and retightening the screw.

ADJUSTING SLIT WIDTH

The slit width is varied by rotating the slit width control on either side of the instrument.

ADJUSTING SLIT LENGTH

The slit length is adjusted by rotating the Aperture wheel. The wheel has five stops for adjustments of 13, 10, 6 and 0.3mm diameter and a continuous length adjustment.

FILTERS

The Filter wheel has four positions which are color coded as follows:

Blue Mark	=	Cobalt blue filter
Orange Mark	=	Heat absorbing filter
White Mark	=	No filter
Green Mark	=	Red free filter

6.2 Use as an Ophthalmic YAG Laser

To use the AURA PT System as an Ophthalmic YAG Laser the operation of the Slitlamp must

first be followed and then the Laser ON/OFF switch can be pressed to turn on the Power supply to the Electronics and the Laser units.

To start up the YAG laser and check its operation and function before using on a patient follow these instructions.

NOTE: Before using the AURA PT YAG Laser on a patient follow these instructions and make sure as an operator of the equipment that you are familiar with the indications and contra-indications for use of the Laser. Read section 6.3 Clinical Guidelines and also fully understand the safety aspects of the Laser system as described in Section 2 of this manual.

1. Refer to Section 6.1 to turn on the Slitlamp unit.
2. When the Key-switch is turned ON and the Slitlamp has been set up correctly the Laser ON/OFF switch can be pressed and held down until the ON indicator is turned ON.
3. When the Laser power is turned ON the Display turns ON and shows all Eights (8) and at this time the displays can be checked to make sure they are all working OK.
4. The displays will now change to show the version of software that is installed in the Laser system and at this time the YAG laser will fire several test shots to confirm that the Electronics and Laser unit is operating correctly.
5. If everything is OK then the Laser System will go to the Standby mode, in single pulse mode and will display the Laser energy that is currently set.

NOTE: If there are any problems then the Display should show an Error message to indicate the type of problem that exists. If an Error message is displayed then try turning off the power and then turning it back on again. This may fix the problem.

6. (1) At this time the Aiming beam intensity can be adjusted and the YAG Laser energy can be adjusted to the required levels by rotating the controls that are located on the sides of the Laser Head arm.

   (2) Also the YAG Laser offset focus can be adjusted to the required setting by rotating the control located on the side of the Laser Head arm.

NOTE: When using the Laser System on a patient always set the Aiming beam intensity and the YAG laser energy to the lowest setting possible and, as well the YAG Laser offset focus to the most appropriate setting, prior to positioning the patient or starting to carry out the laser procedure.

7. When the Laser is in the Standby Mode the Joystick fireswitch and the shutter will not operate so the YAG Laser energy cannot be delivered from the objective lens. The laser can only be fired by pressing the TEST switch on the Display panel. By pressing this switch the Laser energy can be checked for each shot fired on the Energy Display.
8. As well as adjusting the YAG Energy Control knob the YAG Laser can also be set in either single, double or triple pulse mode by pressing the PULSE SET switch. Setting these modes means that for one fire switch operation there will be either one pulse or a train of two or three pulses together. The energy of the train of pulses will be summed together on the Energy Display.

Note: For the same Energy delivered in single, double and triple pulse mode the single pulse condition will have more effect because all the energy is contained in a single short pulse and the energy density is thereby larger.

9. Whenever the Pulse mode is changed or the YAG Energy level is adjusted the YAG Laser will do a Test fire and then show the new Energy level on the Energy Display.

10. To check the correct operation and alignment of the lasers it is necessary to carry out some simple procedures. These procedures are detailed in Section 7 of this manual. The procedures that should be carried out are:

    A. Air breakdown check The YAG energy is set to maximum in single pulse mode and the Laser System is set to TREAT Mode. Make sure the Illumination Tower is not in line with the objective lens and that all people present are wearing safety glasses then press the joystick fire switch and you should observe a small "spark" in midair at the focus point of the system.

    When the Laser is new this Air breakdown will occur at less than 4 milli-joules (mJ).

    B. YAG Laser Alignment check The YAG Laser beam must be aligned to the Aiming beams and they should both be in the central region of the Illuminated field of view. The clip on Target Plate should be fitted to the Chinrest and have some Thermal Paper stuck to it. Focus the Illumination spot, set to the 10mm Aperture, on the target plate and then finely adjust the Aiming beams until they are on top of each other on the target.

    Set to maximum YAG Energy, zero YAG offset focus and in TREAT mode fire one shot on to the target plate and then check that the YAG beam and Aiming beams are centered to each other and that they both are close to the center of the Illumination Spot. Adjust the YAG Laser focus to +500µm offset and finely adjust the Aiming beams to a new place on the Target and again at minimum energy fire the Laser. The YAG beam burn mark should still be in the center of the Aiming beams but should now be a large diameter. Repeat at the –500µm offset and the burn should again be a larger diameter burn. If the Beams are NOT aligned or if the burn marks are not larger when the offset is at the + or – settings then the Laser must not be used until a full optical alignment procedure is carried out by a service person.

11. Because the YAG Laser beam is invisible the position of it is only able to be set by using the Aiming beams. To do this, inside the laser system, two beams of equal intensity are generated and then delivered through the objective lens to the focus plane. By moving the Slitlamp joystick backwards and forwards and observing the target plate the Aiming beams will go from two spots through to a single spot when they are at the focal plane. When they are set to a single spot the Laser is set to the correct focus point. If the Aiming beams cannot be focused on top of one another then the optical alignment procedure must be carried out by a service person.

12. When the YAG Laser treatment is to be performed, after setting all the operating conditions, then select TREAT mode and operate on the patient as required. When the

treatment is finished then select STANDBY mode immediately and record the accumulated TOTALS if required. If there are no more required patients to be treated then the system should be turned off.

6.3 Indications for Use

The AURA PT YAG Laser delivers pulses of 1064nm wavelength laser light to patients under the control of physicians. The effect of the Laser, on tissue, will depend on the energy level set, pulse duration, spot size, type of tissue and the tissue pigmentation.

The AURA PT has its effect on the tissue by what is called an Opto-acoustic effect rather than bulk tissue heating. When the laser is fired in the ocular media plasma bubble is formed and this explosion creates an acoustic wave around the central focus spot that directs the energy back towards the tissue. The plasma also provides a shielding effect that scatters the incident light so that the structures beyond are protected from damage. Also because of the incident cone angle of the Laser beam, after the focus point, the beam is diverging and therefore the energy density will be lower on the retina.

NOTE: The manufacturer and distributor organization assumes no responsibility for actions of physicians when using this equipment. Physicians must ensure they use the correct methods, techniques and settings in performing the treatments to the patient. This includes the setting of the Energy levels, Pulse settings and number of shots fired and all other parameters.

It is strongly recommended that all physicians undertake some training and gain some experience on the procedures before actually treating a patient. A Model Eye can be purchased as an accessory to assist in the training and to gain some experience.

The laser beam can cause serious and permanent injury if not used correctly. All safety precautions must be observed at all times when using the laser system.

The AURA PT YAG Laser is **Indicated For Use** in the following procedures:

1. **Posterior Capsulotomy and Pupillary Membranectomy.**
2. **Iridotomy (hole in the Iris)**

These Indications for use are discussed separately in the following sections.

6.3.1 Posterior Capsulotomy and Pupillary Membranectomy

There are a number of techniques for performing Posterior Capsulotomy and Pupillary Membranectomy procedures but common to all is that care is required with conditions within the eye that may cause difficulty in viewing the capsule membrane. This is very important. The following are the Indications and Contraindications for use of the YAG Laser on aphakic and pseudophakic patients for these procedures.

Indications for use:

- The patients may be of any age or sex.
- The eye must have its natural lens removed.
- The eye should be medically stable.
- Visual acuity should be worse than 20/30.
- Visual acuity should be measurably hampered by the membrane.
- Pupillary Membranectomy is limited to treatment of membrane in the pupillary space.

Contraindications for use:

- Eyes that have no potential visual function
- Corneal cloudiness, lesions, scars or edema that prevent accurate viewing of the target.
- Cloudy intra-ocular media that will affect the laser beam absorption.
- Ocular inflammation
- Uncontrolled glaucoma
- Inability to fixate normally can cause possible damage to adjacent intra-ocular structure.
- Glass intraocular lens. There is the risk of fracture of the glass.
- Posterior chamber IOLs are more prone to damage due to:
  - the gap between the IOL and the capsule is too small
  - many shots are used and the total energy is larger
- If there is a high risk of retinal detachment. This requires absolute minimum number of shots to be used.

Warnings:

As with any other surgical procedure there are potential risks in performing YAG Posterior capsulotomy or pupillary membranectomy procedures including;

- Transient or continued elevation of Intra-ocular pressure (IOP) can occur as a result of these procedures. Patients should be monitored carefully during the post operative period and if the IOP is more than 5mm Hg above baseline then treatment should be given. The potential use of high energy levels and large number of pulses when treating pupillary membranes can cause an acute increase in the IOP.

  If the patient cannot be checked until the next day and has a baseline pressure of more than 20 mm Hg or has glaucoma, the prophylactic treatment should be given.

  Allergies and medical history should be reviewed. If there are no contraindications such as asthma or congestive heart disease, a drop of Timolol 0.5 percent at the end of the treatment should suffice. Alternative medications are pilocarpine or a carbonic anhydrase inhibitor. The possibility of a delayed pressure rise after use of these medications must be considered and an examination on the next day is indicated.

  Glaucoma patients require an increase in dosage of medication. Glaucoma patients on intensive therapy should be observed closely for 4-6 hours following treatment.

  For management of sight threatening pressure elevation, the following should be considered.
  - progressive intravenous administration of mannitol

- anterior chamber paracentese
- anterior chamber washout
- emergency washout

High-risk patients should be treated with multiple sessions, with a few shots administered at low energies per session.

- Rupture of the Anterior Hyaloid face can occur as a result of performing a posterior capsulotomy. Where this occurs the patient is at risk of having forward movement of the vitreous resulting in corneal edema. If the opening in the posterior capsule is small then a posterior chamber IOL offers some protection against this forward movement.
- Intraocular lenses (IOLs) are all susceptible to damage such as pitting or cracks from the YAG Laser. Posterior chamber IOLs are more prone to damage and the risk of damage is increased if the posterior capsule lies close to the IOL and if higher energy levels are used or total energy delivered increases.

There are a number of actions that can reduce the likely hood of damaging IOLs.

1. Use a recommended contact lens when performing the procedure.
2. Maintain precise focusing and alignment of the Aiming beams.
3. Set the correct posterior YAG Laser offset focus for the energy used.
4. Always use the lowest possible energy to open or cut the membrane.
5. Do not rapidly fire the laser, use burst mode or make successive shots through the same position on the IOL.
6. Optimize the view of the capsule or membrane surface by correct set up of the Slitlamp controls.
7. Avoid YAG treatment on patients with Glass IOLs unless absolutely necessary and in this case use extreme care and low energies.
8. Keep the patient still to avoid firing the laser in the wrong place.

Where pitting of the IOL occurs the physician should consider the risk to patient against the potential benefits of continuing the procedure. The position and size of the pitting should be taken into account when making the decision.

- Retinal damage such as detachments, tears, holes and cystoid macular edema are potential risks following YAG posterior capsulotomies. The plasma that is formed as a result of the Laser pulse provides a shielding effect that scatters the incident light and also the cone angle of the YAG Laser Beam means that the beam is diverging, reducing the energy density on the retina. Accurate positioning and focusing of the Aiming beams is very important.
- Mild bleeding can occur if the membrane is vascularized but will generally stop immediately. If the bleeding continues then treatment should occur. Bleeding may interfere with continued treatment of the YAG procedure.
- There is a risk of patients developing a pupillary block following a YAG posterior

capsulotomy if they have undergone an extracapsular cataract extraction without also having an iridectomy. Patients should be advised to contact the treating physician immediately if pain develops after surgery.

In addition to the above there are a number of recommendations in the operation and carrying out of the Laser procedure. These are listed below.

1. Correct and accurate focusing is of utmost importance for proper use of any Ophthalmic YAG Laser system. The following procedures should be followed to ensure optimal surgical application of the AURA PT.
   a) The invisible beam of the Nd: YAG is parfocal in air with the visible dual aiming beams. The intersection of twin aiming beams, where the two red spots become one, locates centrally the focal point of the YAG laser energy. The YAG beam has a small posterior focus to the Aiming beams. Ensure the correct focus is set and do not use the Anterior (-) focus settings at any time when performing Posterior Capsulotomy or Membranectomy procedures.
   b) Multiple reflections of light from the aiming beams and slit-lamp illumination present difficulties in focusing. Use of a contact lens, slight off-axial direction of the slit-lamp, and selective positioning of the patient may decrease this problem.
   c) In the aphakic patient, the focal point of the YAG beam is generally placed directly on the posterior capsule.
   d) In the pseudophakic patient, particularly with a posterior chamber intra-ocular lens, the focal point of the YAG is generally placed slightly more posterior to the posterior capsule, thus giving two adjacent red spots on the capsule. (Care must be taken to ensure that the focal point is POSTERIOR to the capsule, because an anterior focus will also produce two red aiming spots). The predominant effect of the YAG energy shock wave is anterior to the focal point, therefore targeting directly on the pacified capsule increases the risk of damage to an IOL immediately anterior to the capsule. If the membrane does not open, the focal point should be brought forward slightly. Successive shots, however, should be positioned to avoid repeated firings through the same spot on the IOL. Each exposure reduces the PMMA damage threshold for subsequent exposures.
   e) Better depth perception for use in treatments may result when the slit-lamp illumination is positioned slightly off-axis to the Aiming beams.
   f) Concentrate, above all, on careful and precise aiming technique. Do not deliver YAG pulses in rapid succession, rather attempt to place each shot with deliberation.

2. Plan each membrane discission before starting. In particular, note the relative position of the center of the pupil prior to dilation in order to obtain a central opening. Also look for stretch lines in the membrane that can aid discission by tearing.

3. Plan the size opening you will need based on the prediction for postoperative fundus examination. Always make the smallest opening allowable. (Sufficient acuity can often be achieved with only a 2mm opening).
4. Start all therapies at the minimum energy dosage level possible and verify effect before increasing energy levels.
5. If disruption effects are insufficient, attempt to aim more precisely before increasing energy.
6. Use the least number of pulses required to achieve the desired end result.
7. Be prepared to schedule multiple treatment sessions if cloudiness or turbidity interfere with Aiming or disruption treatment.
8. Do not fire the Laser into optical obstructions such as accumulated bubbles, visible marks on an implant or implant lettering.
9. In the case of membranes very close to the posterior surface of a posterior chamber implant, start with a pulse slightly more posterior to the membrane and move gradually anterior until just sufficient disruption is achieved.
10. Exercise special caution when membranes are heavily laden with cortex. Avoid admixture of cortex.
11. Perform your initial membranectomies with aphakic patients or on patients where the implant is clearly separated from the membrane.
12. Use a proper YAG contact lens, especially when membranes are close to or touching an implant. Be sure to hold the lens perpendicular to the laser beam axis.
13. Avoid cutting too close to the iris in order to minimize the likelihood of hemorrhage.

    The physician will decide on the exact dosage levels and therapeutic strategies. Dosage levels will vary from situation to situation, depending on many factors, for each case. Your own judgment, based on teaching sessions and personal experience, will serve as the best guideline for application.
14. Three methods have been accepted in the opening of pupillary membranes: The central or cruciate approach, defocus and the semicircular approach.

a) Central or Cruciate Approach

The usual strategy is to create a cruciate opening beginning near the 12 o'clock position then moving downward to the 6 o'clock position. Shots are then placed laterally towards the 3 and 9 o'clock locations. Care should be taken not to place the shots too close to the iris or bleeding will result. Bleeding will generally stop spontaneously but may be aggravated by further treatment.

If the IOL is in close proximity to the rear surface of the capsule, the focus point of the treatment laser should be placed slightly posterior to the capsule. This will minimize pitting and damage to the IOL. The focus position is achieved by focusing on the capsule by merging the two red aiming dots, then advancing the joystick forward until the two spots separate by approximately one spot diameter. Start firing

with energy set to below 1.0 mJ depending on capsule density. If results are not obtained at energies around 2.0 mJ, the approach should be re-evaluated before proceeding. Potential cause for the need of high energy for disruption may be a media problem, incorrect focus, highly opaque membrane or instrument difficulties.

If the IOL is in close proximity to the rear surface of the capsule, the focus point of the treatment laser should be placed slightly posterior to the capsule. This will minimize pitting and damage to the IOL. The focus position is achieved by focusing on the capsule by merging the two red aiming dots. The offset focus can be achieved by one of two means.

Firstly the YAG Laser offset focus control can be set to Zero Offset and then after merging the two red aiming dots advance the joystick forward until the two spots separate by approximately one spot diameter and increasing the spot separation as the energy is increased.

The second method is to use the YAG Laser offset focus control to set the appropriate offset before starting the procedure. A posterior offset of around 150µm should be set for the starting energy so that when the aiming beams are merged the YAG treatment laser is very unlikely to damage the IOL.

Start firing with the energy set to below 1.0 mJ depending on capsule density. If results are not obtained at energies around 2.0 mJ, the approach should be re-evaluated before proceeding. Potential cause for the need of high energy for disruption may be a media problem, incorrect focus, highly opaque membrane or instrument difficulties.

The IOL may be marked or pitted during a capsulotomy procedure. The incidence of damage can be reduced by the two following methods.

b) Posterior Defocus Approach

This technique is useful when the posterior membrane is located very close to the IOL and direct aiming on the membrane may damage the IOL. The membrane can be ruptured by an acoustic wave that can be produced by firing of 1 to 2 mJ in the vitreous. The approach is as follows. Set energy at 1.0 to 2.0 mJ and aim the two dots for coincidence in the center of the pupil. Deliberately defocus the instrument posteriorally by advancing the joystick until the aiming dot separation is two diameters or more and then fire the laser. A slightly higher energy can be set if required.

Deliberately defocus the YAG Laser treatment beam by the same methods as described in (a) above by either method that is preferred, and then fire the laser. A slightly higher energy can be set if required however use care to increase the offset of the YAG laser beams as the energy level is increased otherwise damage may occur to the IOL.

c) Modified Cruciate Approach

This approach is useful if the IOL is prone to pitting. If, after the strategy of beginning the capsulotomy in the 12 o'clock position, there is an indication of IOL marking, then the usual cruciate pattern should be modified. Instead of the 12 to 6 o'clock progression across the visual axis, an opening in the shape of a Christmas tree should be performed. Shots placed at the 12 o'clock position, 4:30 and 7:30 locations without any shots placed in the central optical axis will produce such a desired opening. The same low energy settings and focus approaches apply as with the cruiciate strategy.

15 Posterior Membranectomy

The approach is similar to capsulotomy, except that the membrane has no elastic property. The laser is aimed directly at the posterior capsule with only a small posterior YAG offset focus unless the energy is set high in which case it may be appropriate to increase the offset. The technique of looking for tension lines does not apply.

When a membrane is very opaque and has no elastic properties, treatment with higher pulse energy may be required. Typically, lots of shots at very high power are required. A contact lens should be used. In some cases several hundred shots are required. Care must be exercised as prolonged firing may cause prolonged inflammation and elevated Intra-ocular pressure.

Postoperative care described in the previous warning section on capsulotomy is indicated.

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6.3.2 Posterior Capsulotomy and Pupillary Membranectomy

The AURA PT YAG Laser offers the alternative of opening or putting a hole in the Iris by cutting as a result of photo disruption rather than burning when using photocoagulation.

The following are the Indications and Contraindications for use of the YAG Laser on phakic, pseudophakic or aphakic patients for this procedure.

Indications for use:

- The patients may be of any age or sex.
- The eye must be at risk of some form of pupillary block glaucoma.
- The pupillary block should be potentially responsible for glaucomatous damage to the optic nerve as a result of the IOP levels that are known to cause such damage.
- For treatment of patients where photocoagulation iridotomy has been unsuccessful.

Contraindications for use:

- Eyes that have no potential visual function.
- Cloudy intra-ocular media or opacities of the media such that visualization of the iris is inadequate.
- Eyes that do not have glaucoma with pupillary block.
- Eyes that have a glass intraocular lens as there is a risk of fracture of the glass.
- If there is a high risk of retinal detachment. This requires absolute minimum number of shots to be used.
- If there is a risk of uncontrolled bleeding, inability to create a hole in the iris or hole closure as a result of chronic uveitis, hemophilia, Nystagmus, neovasular glaucoma, engorged iris blood vessels or uncooperative patients.

Warnings:

As with any surgical procedure there are potential risks and complications that can arise as a result of performing a YAG Iridotomy. The physician should always assess the potential benefits of performing a YAG Laser Iridotomy considering these risks.

The potential risks of YAG Laser Iridotomy procedures are:

- An acute increase in pressure following treatment is common. Ideally the patient should be checked regularly up to four hours following the procedure. Treatment should be given if the pressure rise is more than 5 mm Hg above the baseline.

Allergies and medical history should be reviewed. If there are no contraindications such as asthma or congestive heart disease, a drop of Timolol 0.5 percent at the end of the treatment should suffice. Alternative medications are pilocarpine or a carbonic anhydrase inhibitor. The possibility of a delayed pressure rise after use of these medications must be considered and an examination on the next day is indicated.

Glaucoma patients require an increase in dosage of medication. Glaucoma patients on intensive therapy should be observed closely for 4-6 hours following treatment.

The decision to use additional medical treatment in the event of IOP increase should be based on each individual patient's situation. Any pre-existing conditions must be considered.

The use of a few drops of apraclonidine pre-and post-laser can reduce the rate of acute intra-ocular pressure rises.

- Lens damage is possible from performing YAG Laser iridotomies and opacification of the underlying anterior lens capsule has been observed (the opacities cleared without formation of a cataract). The risk of damage is increased where high energy levels (greater than 10 millijoules (mJ) and more than triple burst mode) are used, inaccurate Laser focusing takes place and Laser energy is applied directly to the lens through the pupil. Also if a hole already exists in the iris or there is apposition of the peripheral iris to the lens then applying further Laser energy can cause lens damage. There are a number of actions that can reduce the likely hood of damaging the lens.

  1. Use a recommended contact lens when performing the procedure.
  2. Maintain precise focusing and alignment of the Aiming beams on the iris treatment site.
  3. Set the correct anterior YAG Laser offset focus for the energy used. This ensures that the spot size will be larger on the treatment site than if set to the zero offset. The more anterior offset then the larger the spot size at the treatment site. With the anterior offset at the 500µ setting the spot size will be around 150µ.
  4. Always use the lowest possible energy and minimum number of pulses per burst for each treatment shot.
  5. Select an iris treatment site that is on the periphery and the site should be located under the upper eyelid whenever possible.
  6. Optimize the view of the iris by correct setup of the Slitlamp controls.
  7. Avoid treatment at a site that already has a totally or partially patent hole.
  8. Keep the patient still to avoid firing the laser in the wrong place.

- Retinal damage is theoretically possible although the risks are considerably lower than when using the YAG Laser to perform posterior capsulotomy or pupillary membranectomies. The same precautions that reduce the risk of lens damage should be observed for this risk.

  Transient self-limited tricking hemorrhage can occur in around 25% of eyes undergoing YAG Laser iridotomy. The YAG Laser does not cauterize blood vessels so eyes with

engorged iris blood vessels, hemophilia patients or those receiving anticoagulant treatments offer an increased risk of bleeding and hyphemia. In otherwise normal patients bleeding will stop immediately and can be controlled with light pressure against the contact lens.

If bleeding does occur then further YAG treatment may aggravate it. The use of a few drops of apraclonidine pre-and post-laser can minimize bleeding and reduce the rate of acute intra-ocular pressure rises. Photocoagulation may be required if other measures do not stop the bleeding.

- Localized corneal edema or scaring is possible above the iridotomy site. Opacities generally clear within a few days and the changes described do not interfere with visual function. Accurate positioning and focus of the Laser beam and lower energy settings are important.
- For patients with chronic uveitis there is the possibility of closure of the iridotomy weeks or months after the treatment. The closure rate of iridotomies is much lower when using the YAG Laser than when treating with a photocoagulator laser.
- Long term control of glaucoma is not always seen after a successful iridotomy. This is the case for both YAG and photocoagulator iridotomies. Patients should be further monitored for persistent glaucoma following iridotomy treatment.

In addition to the above warnings there are a number of recommendations in the operation and carrying out of the YAG Laser iridotomy procedure and they are listed below.

1. Correct and accurate focusing is of utmost importance for proper use of any Ophthalmic YAG Laser system. The following procedures should be followed to ensure optimal surgical application of the AURA PT.
    a) The invisible beam of the Nd:YAG Laser is parfocal in air with the visible dual aiming beams. The intersection of the twin aiming beams, where the two red spots become one, locates centrally the focal point of the YAG laser energy at the same focal plane as the Slitlamp. Also the YAG beam has a control to adjust the offset focus to the Aiming beams. The focus can be set posterior (+) or anterior (-) Ensure the correct focus is set and it is typical to set an anterior offset when performing the Iridotomy procedure so as to avoid damaging the lens or lens capsule when the hole is produced in the Iris. Where possible set an Anterior offset focus to the YAG Laser beam.
    b) Multiple reflections of light from the aiming beams and slit-lamp illumination present difficulties in focusing. Use of a contact lens, slight off-axial direction of the slit-lamp, and selective positioning of the patient may decrease this problem.
    c) Better depth perception for use in treatments may result when the slit-lamp illumination is positioned slightly off-axis to the Aiming beams.
    d) Concentrate, above all, on careful and precise aiming technique. Do not deliver YAG pulses in rapid succession, rather attempt to place each shot with deliberation.
    e) The Laser should not be focused on or near iris blood vessels as the shock wave may produce bleeding.

f) To avoid induced beam astigmatism the Laser shot should enter the eye at no more than 30 degrees from the visual axis.

g) Good patient fixation should be maintained.

2. An anterior segment treatment contact lens is recommended as this lens increases the convergence angle and energy density to the treatment site. In addition it provides better control over the eye position, keeps the eyelid open and increases the magnification. Contact the manufacturer or authorized agent for more information on contact lens supply.
3. Use of Pilocarpine Hydrochloride (1% - 4%) should be applied several hours prior to the treatment to produce meiosis and stretch on the iris that aids the iridotomy treatment.
4. The treatment site selected should be superiorly between the 9 and 3 o'clock position, nasally to avoid inadvertent macular damage but not at the 12 o'clock position.
5. The treatment site should also be at the mid to far iris periphery, central to the arcus senilis and in an area of an iris crypt if one exists and is usable as this area is thinner.
6. The treatment site should be away from an intra-ocular lens if possible.
7. Start all therapies at the minimum energy dose level possible to achieve the opening but it should be noted that the likelihood of completing an iridotomy with one pulse is higher with the use of around 10 millijoules (mJ) however there is an increased risk of bleeding and crystalline lens damage. The benefits of easier and quicker iridotomy must be weighed against increased risks of bleeding when using higher energy settings.
8. Typical YAG Laser energy settings of 4 to 8 millijoules (mJ) are required. A full thickness opening in one shot is desirable although up to 4 shots may be required. If required the energy may be increased in 1 to 2 millijoules (mJ) steps or the burst mode increased to 2 to 3 pulses per shot. It is not recommended to set energy levels higher than 10 millijoules (mJ). Start at low energy settings first and increase the energy based on the observed effects not just previous operations.
9. Typically the YAG Laser offset should be set to an Anterior setting to avoid possible damage to the structures behind the Iris. If the offset is set too high then the energy may need to be set to unacceptably high levels to get the desired effect. Where the effect is poor, reducing the offset closer to zero may help to achieve the desired effect.
10. In dark brown irides without crypts it may be an advantage to set a higher starting energy of close to 10 millijoules (mJ) single pulse.
11. Once an opening is produced or if it is unclear whether an opening is patent it is not advisable to continue treatment at that site as it exposes the lens capsule to the possibility of damage from the Laser pulse. An extended burst mode of more than 3 pulses also has the potential to expose the underlying lens capsule to damage if the iris opening is produced before the bursts are completed.
12. Inability to perforate the iris using the above treatment parameters may indicate incorrect focus, a media problem, an instrument malfunction or a very strong iris.

13. After each pulse of Laser energy is delivered the treatment site should be inspected and if the anterior lens capsule is clearly visible then no further Laser treatment should be applied to that site.
14. Following Laser treatment the patient's eye should be observed with the contact lens for 2 to 3 minutes to ensure that no iris bleeding has occurred. Pressure can be applied to the contact lens to control bleeding.
15. The anterior chamber can be treated with topical corticosteroids after removal of the contact lens to decrease reaction.
16. In the aphakic and pseudophakic patients at least 3 iridotomies may be required to ensure full relief of aqueous entrapment that may be localized into sectors.
17. Postoperative care should include monitoring of intra-ocular pressure, inflammation, bleeding, and lens clarity.

Ophthalmology References

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4) The Q Switched Laser: Principles and clinical results. F Fankhouser; In: Trokel SL (ed) YAG Laser Ophthalmic Microsurgery. Norwalk, CT: Appleton-Century-Crofts, 1983.
5) Histopathological Characteristics of neodymium YAG Laser iridotomy in the human eye. MF Goldberg, MO Tso and M Mirolovich. Br J Ophthalmol, 1987.
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8) A comparison of Nd:YAG and argon laser iridotomies AL Robin and IP Pollack; Ophthalmology, 1984.

Section 7. MAINTENANCE

Contents

7.1 Operator / User Maintenance

The AURA PT YAG 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 AURA PT be serviced by an authorized service agent every 6 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 AURA PT have the Energy meter calibrated to a known calibrated meter and have its earth leakage current and earth resistance measured according to IEC 60601-1. These procedures can only be performed by an authorized service agent of the manufacturer.

The Energy meter calibration procedure is detailed in 7.3. This is a requirement of the regulatory bodies.

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.

7.2 Routine Maintenance Procedures

The following procedures are those that the manufacturer recommends that the operator of the Laser System perform routinely.

1. **Cleaning the external surfaces of the Laser**

   To clean the outside of the AURA PT wipe over using a damp (but not dripping) cloth. Use a mild cleaning agent and do not use any solvents. 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.

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.

3. **Checking the Air breakdown**

This procedure can be used to check the performance of the treatment laser system. The performance can be affected by a number of conditions including;

- The YAG cavity alignment, age and performance
- The cleanliness of the optical elements
- The temperature and humidity levels
- The repetition rate of firing the laser.

Therefore this procedure can only be used to give an indication of performance. If the treatment laser is performing well in the ocular media of a patient then it is reasonable to suggest that the Laser performance is OK. This procedure can be carried out when ever it is considered necessary.

To check for Air breakdown follow this procedure.

Note: Follow all safety precautions as detailed in Section one of this manual in particular the use of safety glasses is essential as in this procedure you will be observing the Laser beam (indirectly) without the protection of viewing through the binoculars and therefore the safety filters.

1) Turn the Laser System ON and set maximum energy single pulse then put the Laser in to TREAT mode.

2) Ensure that the Illumination tower is moved to one side so that it does not interrupt the beam path.

3) Position the Slitlamp base so that the focus point for the System is in free air. Do not have the target plate or target rod attached to unit.

4) Viewing from the operator's side of the Laser System, observe the focus plane area then fire the laser using the joystick fire switch.

5) When the Laser is fired you should observe a "spark" at the focus plane (approx. 107mm in front of the objective-focusing lens).

6) Reduce the Laser energy until you find the lowest energy where approximately 50% of the Laser shots are producing a “spark” in the air. This energy level is called the Air breakdown energy. Don’t fire the Laser too rapidly. Around 1 shot per 3 seconds is recommended.

7) When a Laser System is new the Air breakdown energy is less than 4 mJoules however over time this energy level can be expected increase. If there is no Air breakdown at the maximum energy level then you should call the authorized service agent to discuss any course of action to be taken.

4. **Checking the Laser beams alignment**

For safety it is very important that the Treatment and Aiming laser beams are aligned correctly to each other and that the YAG Laser Offset focus control functions correctly. Because the Treatment Laser is invisible the position of the beam can only be found by using the Aiming beams.

This procedure should be carried out regularly by the operator and must be performed whenever the Laser System is transported or moved to a new site. The most likely cause of misalignment will come from mishandling during transport of the unit. Check the alignment at least once a month.

To perform this procedure you will require a small piece of photographic or thermally sensitive paper (a sample piece is supplied with each Laser System) and the Target Plate. The piece of photographic paper should be attached to the target plate. Refer to figure 7.2.

1) Fit the Target Plate to the Chinrest

2) Turn on the Slitlamp Illumination and select the 6 or 10 mm diameter full aperture (no slit). Make sure the oculars on the eyepieces are set correctly to your eyes.

3) Move the Slitlamp so that the Illumination spot is focused on to the paper on the Target Plate.

4) Turn on the Laser System in the Standby mode and finely adjust the Slitlamp position so that the two Aiming beam spots merge to a single spot.

   Note: If the Aiming beams do not merge to a single spot at any time then the Optical Alignment is wrong and you must call on authorized service agent to repair the system. Do not use the Laser on a patient in this situation, as you cannot be sure of the correct positioning of the Treatment Laser.

5) The Aiming beams should fall in the central region of the Illumination spot.

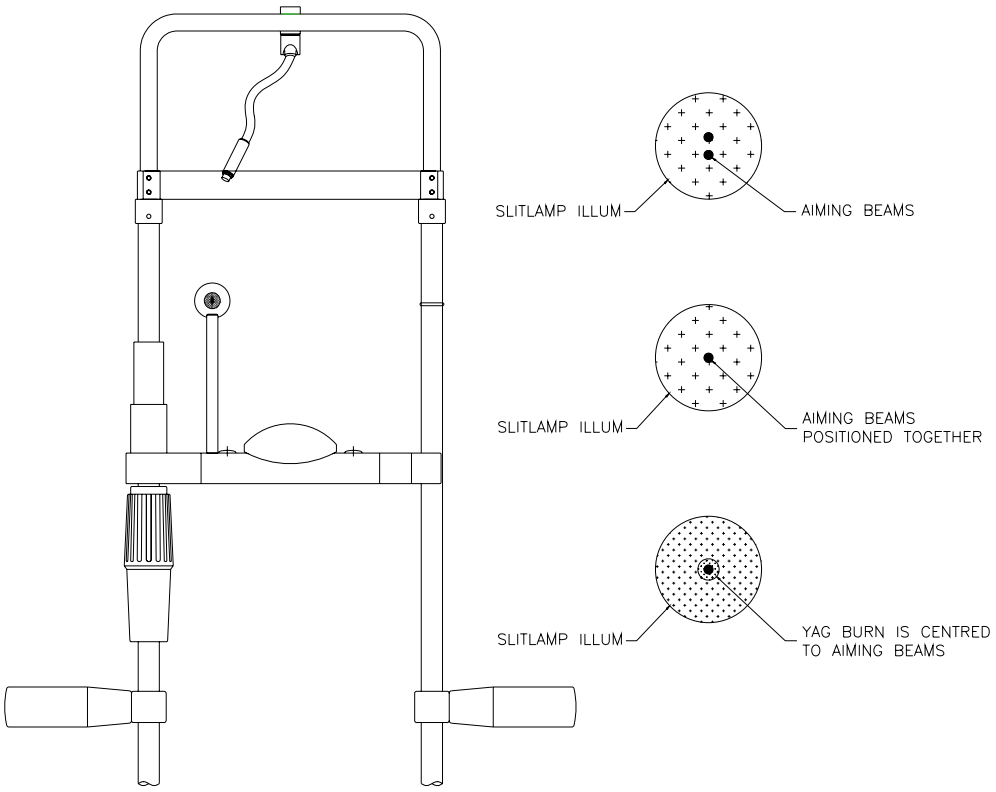

Figure 7.1 Laser Beams Alignment Checks

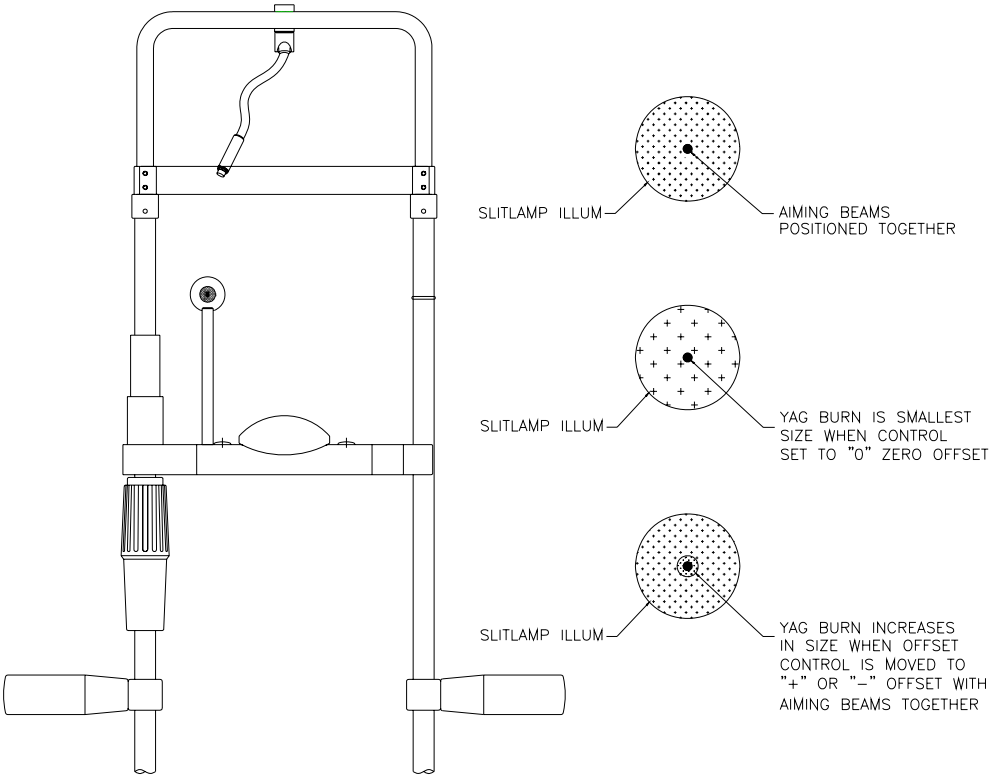

Figure 7.2 YAG Laser Beam Offset Focus Checks

6) Set the YAG Laser energy to the minimum setting or at least less than 1 milli-Joule. Adjust the YAG Laser offset focus to the Zero setting and put the Laser into Treat mode. Check again to be sure the Aiming beams are together as one spot then fire one YAG Laser shot onto the Photographic paper. Note that for additional accuracy read the "Energy Totals" display and press the "Reset" Switch between each shot. This Display gives an extra decimal place for the readings than the Energy Display.

7) Look through the binoculars and check the burn mark that is on the paper and confirm that the burn mark and the Aiming beams are centered to each other and still within the central region of the Illumination spot. Repeat the test on a new area of the target to confirm this is OK if required. At the Zero offset setting the burn mark should be a small spot.

8) Set the YAG Laser offset focus to (-)500µm then reposition the aiming beams to a new area on the target and when the spots are merged fire the laser and observe the spot size of the burn mark compared to the spot when the offset was set to Zero offset. The spot size should be larger and the burn mark will not be so clearly defined. Repeat these steps with the offset control set to the (+)500µm. If the burn mark is not clear enough then increase the energy by 1mJ and try again. The burn marks should also still be centered to the aiming beams.

9) Note that the YAG laser burn marks created when the laser is fired are centered correctly to the aiming beams, and the burn marks are larger when the offset is introduced by the control, compared to the zero offset setting, then the alignment is acceptable.

Note: If the Treatment and Aiming beams are not centered to each other or the offset focus is incorrect then the Optical Alignment is wrong and you must call an authorized service agent to repair the System. Do not use the Laser on a patient in this situation as there is a risk that you may fire the laser into the IOL or some other structure in the eye inadvertently.

7.3 Calibration Procedures

The Calibration and Alignment procedures for the AURA PT must only be carried out by an authorized service agent. Therefore if you believe the Laser System requires Calibration or Alignment you should request service assistance and not use the equipment until the adjustments have been made.

The procedures for Calibration and Alignment are detailed in the Service Repair Manual for the AURA PT however it is a regulatory requirement to include the Energy Meter Calibration procedure in this manual.

Energy Meter Calibration Procedure

Note: This procedure can only be carried out by an authorized agent of the manufacturer. Always observe safety precautions as detailed in Section One of this manual at all times.

This procedure should be carried out whenever a service or repair is performed on the AURA PT YAG Laser.

This procedure must be carried out at least once a year (every 12 months) to ensure accuracy of the Energy meter.

A. Calibration Check

Notes: 1. Use an appropriate Energy Meter that can measure in milli-joules (mJ) and has been calibrated according to the manufacturer's instructions and is traceable to N.I.S.T. Energy meters can be bought from Coherent, Ophir or Molectron. The Energy meter must be specified to measure Pulsed energy in the range of 0.1 milli-joules (mJ) to 50 milli-joules (mJ) for Qswitched Nd:YAG Lasers (wavelength of 1064nm). The manufacturer can provide further details if required.

2. The Laser beam from the AURA PT must not be focused to a small spot on the detector but instead the Laser beam should fill approximately 60% to 80% of the detector surface area. This can be determined by placing Zap-it or equivalent thermal paper in front of the detector and with the laser energy set to maximum adjust the position of the detector until the fired Laser shot produces a burn mark that is a large enough diameter to ensure no damage to the detector.

3. Use eye protection when performing this procedure (OD5 @ 1064nm).

1) Turn on the Laser System and set for maximum energy, single pulse and Treat mode.
2) Set up the Energy meter and fix the detector to the Chinrest or top of Laser head arm.
3) Put the thermal paper in front of the detector and position the detector between the focal plane and the objective lens such that the Aiming beams are defocused but both spots still fall within the detector area. This should occur at around 70mm from the front surface of the objective lens. Ensure the Illumination Tower is not in the central position where is can block the Laser beams.
4) Fire the Laser on to the thermal paper and observe the burn mark. Adjust the position of the detector or the Slitlamp until the YAG burn fills 60% to 80% of the detector area. Lock the Slitlamp base at this position.
5) Remove the thermal paper from in front of the detector and then turn on the energy meter and select a suitable range to measure energies between 1 and 10 millijoules.
6) Set energy levels of 1 and 8 millijoules and fire 5 shots at each setting recording the energy readings from the AURA PT display and the external meter. For the AURA PT display read the "Energy Totals" display and press the "Reset" switch between each shot. This Display gives an extra decimal place for the readings than the normal Energy Display.
7) Calculate the average energies for each set of 5 shots and compare the results. The AURA PT energy display readings and averages must be within +/- 20% of the external meter readings. If the readings are within this specification then no further adjustments are necessary. A full Energy Calibration Record should be completed to record the energy checks and to verify calibration accuracy across the full range of energies.

B. Calibration Adjustment

If the Calibration checks indicate that the Energy meter needs to be adjusted then follow this procedure. Continue to observe all safety precautions.

1) With the Laser System power turned OFF remove the Laser Arm cover so as to access the microprocessor circuit board that is fixed to it. The Energy adjustment potentiometers are located on this PCB.
2) Turn the Laser System ON and set to single pulse and TREAT mode. Ensure that the external energy meter detector is still correctly located so that the Laser beam fills 60% to 80% of the detector area.
3) Set the Laser energy to 8.0 to 9.0 mJ and adjust VR2 on the microprocessor PCB so that the AURA PT energy reading is within $\pm$ 10% of the external energy meter. View the AURA PT Energy again on the "Energy Totals" display and Reset between shots.
4) Now set the Laser energy to 1.0 mJ and adjust VR4 on the microprocessor PCB so that the AURA PT energy reading is within $\pm$ 10% of the external energy meter. View the AURA PT Energy again on the "Energy Totals" display and Reset between shots.
5) Set the Laser energy back to the 8.0 to 9.0 mJ and readjust VR2 if required.
6) Set maximum energy and compare the energy readings. Adjust VR2 if required.
7) Set minimum energy and compare energy readings Adjust VR4 if required.
8) Repeat steps 3 through to 7 until the AURA PT energy readings are within $\pm$ 10% from 1.0 mJ to maximum energy and within $\pm$ 20% below 1.0 mJ.
9) Verify the AURA PT energy readings on the "Energy Totals" display are within $\pm$ 20% of the external energy meter at:
    - minimum energy
    - 1.0 milli-joules (mJ)
    - 2.0 milli-joules (mJ)
    - 5.0 milli-joules (mJ)
    - 8.0 milli-joules (mJ)
    - maximum single pulse energy
    - maximum triple pulse energy
10) Record the energy readings on the Energy Calibration Record page after you are sure the Calibration is to specification. Confirm the accuracy of the recorded energy readings.
11) If for any reason the AURA PT Laser System cannot be calibrated contact the manufacturer for assistance.

Record Sheet 2 Energy Calibration Record Sheet

ENERGY CALIBRATION RECORD

Model: AURA PT DATE: _____

Serial No: _____

External Energy meter: _____ Next Calibration due date: _____

Energy Setting	Energy Readings						Average
Minimum energy	External						
	AURA PT						
1.0mJ	External						
	AURA PT						
2.0mJ	External						
	AURA PT						
5.0mJ	External						
	AURA PT						
8.0mJ	External						
	AURA PT						
Maximum single	External						
	AURA PT						
Maximum triple	External						
	AURA PT						

All energy readings and averages within ± 20% (Pass / Fail) _____

Testers name: _____ Signature: _____

Results verified by: _____ Signature: _____

7.4 Trouble Shooting Guide

Except for the following items in this section there are no operator serviceable components in the AURA PT YAG Laser. If you are experiencing problems with the Laser System please contact an authorized service agent or the manufacturer for assistance.

1) Mains Electrical Power

The AURA PT will automatically operate from 100-230V AC 50/60Hz Single Phase AC mains voltage. The power cable plugs into the back panel of the Control Box. Ensure that the power cable is securely plugged in to both the Control Box and the mains power supply. The Laser System should only be used with a 3 Pin mains power supply that is properly earthed.

2) Mains Power Fuses

The mains power fuses are located in the input power socket on the back panel of the Control Box. There are 2 fuses and for 100-120 Volt operation they are rated at TH3.15 Amps and for 200-230 Volt operation they are TH2.5 Amps. For both fuse ratings they are Time-Lag types rated at 250 volts. Spare fuses are provided with each Laser System. If the fuses blow then it will normally indicate a failure inside the system so if you replace a fuse and it fails again then you should call the authorized service agent for assistance.

3) Remote Door Interlock

If the Laser System cannot be operated, the control switches do not work and there is a constant warning tone then it is probable that the bypass connector on the back panel of the control box or the switch / cable assembly to the door interlock are not connected properly or there is an open circuit somewhere that is causing the problem. Make sure that the bypass connector is attached correctly and if you are using a door interlock then get it checked by the people that installed it for you. Installation of the door interlock is not an option provided with the Laser unit.

4) Replacement of Illumination Lamp

If the Illumination Lamp fails to come on then first check to make sure that mains power is connected to the Laser unit, the key-switch is ON and the Emergency Switch is pulled out (ON).

If you are sure the Lamp is broken then make sure the Laser System is turned OFF and the lamp is cooled down. Note that the lamp can be VERY HOT so do not touch it unless you are sure it is cool. Loosen the Lamp housing ring and carefully remove the Lamp from its socket. Replace with the new lamp using the plastic envelope to insert it fully into the socket. NEVER TOUCH THE LAMP WITH YOUR FINGERS. Install the lamp socket back into the housing and retighten the ring. Turn the power back on and make sure everything is operating correctly.

5) Fixation Lamp Replacement

If the fixation lamp fails to come on check the connections on the back panel of the Control Box and make sure the Slitlamp Illumination is working. If you are certain that the lamp is faulty then unscrew the lamp cover, remove the lamp and replace with a new lamp.

6) Error and Warning Messages

The Laser System microprocessor can detect many failures or problems with the internal components. If these conditions occur there are a series of messages that will be shown on the Display panel. See Section 7.5 for details of these messages.

7.5 Error and Warning Messages

If during normal operation of the Laser System or during the Start up or Special Modes 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 used when an Error message is displayed.

A list and description of these messages is below:

Message	Description
Err 01	The Shutter position is incorrect. It may be jammed open or shut. One of the shutter sensors may be faulty.
Err 02	The circuit that detects Laser pulses may be faulty.
Err 03	The Laser cavity has delivered more pulses than selected.
Err 04	The Aiming laser has failed. This may be a laser diode or circuit fault.
Err 05	The microprocessor has detected a memory or program problem.
Err 06	The Laser cavity single pulse voltage level is too high.
Err 07	The Laser cavity triple pulse voltage level is high.
Err 08	The Laser cavity voltages have changed too much since the last service test was done.
Err 09	There is no energy detected by the microprocessor when the YAG Laser is fired.
Err 10	There may be a fault in the fire switch circuitry. Ensure that the Joystick or Foot switch is no pressed when laser system is turned on. Otherwise, contact you service representative as soon as possible.
Usr 01	The Laser cavity has fired 10,000 shots and it is now recommended that the Laser System be checked by a Service person for calibration.
Usr 02	The Laser cavity conditions have changed significantly since the last service test was done and the Laser System should be serviced soon.
Usr 03	The average Laser cavity energy has deteriorated significantly since the last service test was done and the Laser System should be serviced soon.

These messages are displayed on the Display panel with the Energy Total and Energy LED's. If one of these messages is displayed then write down what the displayed message is then turn off the power to the Laser System, wait 10 seconds and then turn back on. If the message has gone then the Laser System can probably be used however it is recommended that you report the message display to the authorized agent so that it can be discussed with the agent and the manufacturer to determine any course of action.

If any of the Warning (Usr) messages are displayed then the manufacturer recommends that the Laser System be checked by a service person to ensure the unit is operating to specification and calibrated

correctly. Failure to organize a service of the system at this time is at the discretion of the physician. It should however be clearly understood that to not organize a service may cause a breakdown failure in the near future, or for the Laser System to not be operating to specification, which may indicate an unsafe condition. A simple procedure can be performed to verify whether the calibration is correct. Contact the nearest authorized service agent to have this check performed.

The **Usr01** message will continue to be displayed every time the Laser System is turned on as a reminder to the Doctor that the system checks are due for checking. The Laser unit can continue to be used even if this message is being displayed and is provided simply as a reminder that the checks are due.

Either the User or a Service person can **reset the Usr01 message**. The manufacturer recommends that when this message is displayed the Operator organize for a service visit in order to verify the correct operation and calibration of the Laser system. However where the Operator decides this is not required they can reset the message by holding the "**Test**" and "**Totals Reset**" switches ON when the power is turned ON to the Laser system. Doing this will reset the message so that after a further 10,000 Laser shots the message will show again.

If an error message appears every time the Laser unit is turned on then the system must be serviced. Call the authorized agent to organize the repair of the system.

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

Also remember that there are some conditions where for safety, the System will jump back to the STANDBY Mode from the TREAT Mode. These conditions are;

1. After 5 minutes of no use or no change to any of the controls.
2. If the Joystick Fire Switch is held down for longer than 1 second when the System is set in the TREAT Mode.
3. If the Remote Door Interlock is interrupted (only if installed by the customer).
4. Should the system at any time detect an error condition.

Note: If the system does detect an error condition, the system will shut down to a safe state and display an error message (code) on the display. If an error message is display, initially try turning the system off then on again to see if the error condition is resolved. Occasionally the message "CAL" maybe displayed after this action. If this occurs, the system is performing a self check which will take approximately 10minutes to perform. If the error message condition does not clear, the please contact your service representative as your system requires a service.

If any of the Error conditions occur the system will shut down to a safe condition.

To continue to use the System it must be reset back into the TREAT Mode by pressing the "Mode" Set Switch or in the case of an Error condition by turning off the power then turning back on again.

There are 6 conditions where the AURA PT will sound an audible warning to the Operator and they are:

1. For any operation of any of the Control press switches on the front panel of the Display.
2. If the Laser System is turned ON and the Remote Interlock connection is open circuit. (e.g. if the Interlock connector is removed).
3. A short audible tone is sounded whenever a Laser shot is fired using the Joystick Fire Switch in the Treat Mode.
4. If the Delivered Laser Energy changes more than 20% from the previous delivered Laser shots then a short burst of 3 beeps will sound to warn the Operator to check the Energy levels.
5. When the Laser is Test fired there is a short audible warning.
6. If the Joystick Fire Switch is held down too long then the System will jump to the Standby Mode and if this occurs an audible beep is sounded.

Whenever an audible warning is heard by the Operator the reason for the warning should be checked in order to confirm that the Laser operation is satisfactory to continue with the Treatment. Except for the normal warnings that are to be expected such as the pressing of the Controls and the Laser firing, if the Laser continually sounds warnings such as the 20% over Energy or the Interlock condition then they should contact the authorized Service distributor to check the Laser.

Section 8. CUSTOMER SUPPORT, SALES, AND SERVICE

In addition to the following Lumenis offices, which provide customer support, sales, and service, Lumenis has distributors worldwide. Contact your local office for the distributor in your vicinity.

Lumenis
24000 Condensa Street
Santa Clara, CA, 95051, USA
General Sales and Service:
Tel: 408.764.3000 / 877.LUMENIS
Fax: 408.764.3999 / 800.505.1133
Service Center:
Tel: 877.LUMENIS or 877.586.3647
Fax: 408.763.3327

Lumenis (Germany) GmbH*
Heinrich-Hertz-Strasse 3
63303 Dreieich-Dreieichenhain, Germany
Tel:+ 49.6103.8335.0
Fax:+ 49.6103.8335.300
(*Authorized Representative per Medical Device Directive 93/42/EEC)

Lumenis (Holland) BV
Amstelveen, The Netherlands
Tel:+ 31.20.347.5060
Fax:+ 31.20.347.5099

Lumenis (France) SARL
Orsay, France
Tel:+ 33.1.69.33.14.20
Fax:+ 33.1.60.19.57.23

Lumenis Ltd.
Yokneam, Israel
Tel:+ 972.4.959.9000
Fax:+ 972.4.959.9050

Lumenis Japan Co. Ltd.
Tokyo, Japan
Tel:+ 81.3.5789.8300
Fax:+ 81.3.5789.8310

Lumenis (HK) Ltd.

Kowloon, Hong Kong
Tel:+ 582.2174.2800
Fax:+ 852.2722.5151

Lumenis (Holland) BV
Beijing Office
Beijing, P.R. China
Tel:+ 86.10.6510.2620
Fax:+ 86.10.6510.2621

Lumenis (Sweden) AB (S)(A)
Kritianstad, Sweden
Tel:+ 46.44.21.21.26
Fax:+ 46.44.21.21.79

Internet: www.Lumenis.com
Email: information@lumenis.com