USER'S MANUAL

OptoYag M

OptoSLT M

OptoYag&SLT M

CE 1304

OptoYag M, OptoSLT M, OptoYag&SLT M User's Manual	
User's Manual revision:	**4.8**
Date of revision:	**June 2020**

This User's Manual applies to the following Optotek laser systems:

Name: ***Medical therapeutic laser device/ Medicinska terapevtska laserska naprava***

Type/Model:

OptoYag M *Q-switched Nd:YAG (1064 nm) laser system*
Code: 81 9 00 000 M

OptoSLT M *Frequency-Doubled Q-switched Nd:YAG(532 nm) laser system*
Code: 82 9 00 000 M

OptoYag&SLT M *Combined Q-switched Nd:YAG (1064 nm) and Frequency-Doubled Q-switched Nd:YAG (532 nm) laser system*
Code: 83 9 00 000 M

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Information including technical specifications contained in this Manual is subject to change without notice!

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1 Introduction

Read this manual thoroughly in order to avoid any problem that may occur during installation, use, and/or maintenance of the device, and could result in damage to the device, operator or patient!

This User's Manual describes the use of the Optotek OptoYag M, OptoSLT M and OptoYag&SLT M ophthalmic laser systems. It is intended to be used by the owners and operators of the instrument.

The User's Manual contains the following information:

- ❒ an introduction to the OptoYag M, OptoSLT M, OptoYag&SLT M and their principles of operation;
- ❒ safety information;
- ❒ instructions for using the instrument;
- ❒ treatment instructions;
- ❒ routine care and maintenance information;
- ❒ troubleshooting;
- ❒ specifications;
- ❒ installation, warranty and calibration information.

1.1 Conventions

The following conventions are used in this User's Manual:

Attention to the information marked with this sign is mandatory in order to avoid situations that could cause injury or equipment failure!

Attention to the information marked with this sign is mandatory in order to avoid situations that could cause injury or equipment failure!
Additional information/explanation related to the warning is provided!

The action described in the text is PROHIBITED!

The action provided in the text is MANDATORY!

1.2 Intended use

This User's Manual describes the use of the Optotek OptoYag M, OptoSLT M and OptoYag&SLT M laser systems that are intended to be used by licensed ophthalmologists only!

Indications for use OptoYag M 1064 nm: Posterior capsulotomy; Iridotomy;

Indications for use OptoSLT M 532 nm: selective laser trabeculoplasty (SLT) – IOP reduction in open-angle glaucoma

1.3 Contraindications

Contraindications OptoYag M 1064 nm treatment:

Posterior capsulotomy - Irregularities of the cornea; Active inflammation in the eye; Macula swelling; Glass IOLs; Uncontrolled IOP

Iridotomy – Edematous or opacified cornea; completely closed angle; angle closed due to inflammation (uveitis or neovascular glaucoma)

Contraindications OptoSLT M 532 nm treatment:
IOP over 25 mmHg; Reduction of IOP for more than 25%; Juvenile glaucoma; Primary or secondary narrow-angle glaucoma; Inflammatory or Uveitic glaucoma; Any disease process or malformation that blocks the angle; Post-traumatic glaucoma

1.4 Side effects

Side effects of OptoYag M 1064 nm:

Posterior capsulotomy – Damage to intraocular implant; Displacement of IOL into eye's vitreous (very rare); Macular edema; Macular holes; Corneal edema; Inflammation of the iris; Retinal detachment; Increased pressure in the eye, glaucoma (usually short-term effect that can be controlled with anti-glaucoma drops)

Iridotomy – Increase in intraocular pressure (usually, the IOP spike is transient – 24 hours after the treatment); Anterior uveitis or inflammation within the eye; Swelling of, abrasions to, or opacification of the cornea; Damage to cornea endothelium; Bleeding of the iris; Macular edema

Side effects OptoSLT M 532 nm:
Transient IOP elevation; Mild anterior chamber inflammation; Mild discomfort during the procedure and tender eyes; Bleeding and hyphema; Choroidal effusion; Macular edema; Corneal haze; Shifts in refractive error (both myopic and hyperopic)

1.5 YAG treatment beam

The YAG treatment beam provides the physician with a precise and safe tool for performing posterior capsulotomy and iridotomy.

The YAG treatment beam is derived from a solid-state laser module that produces short (approximately 5 ns), individual pulses of focused infrared light with a wavelength of 1064 nanometers (nm).

The output of the laser module is passed through several optical modules to allow the beam leaving the objective lens of the slit lamp microscope to be focused to a high energy spot with a diameter of about 10 microns.

The YAG treatment beam operates by photodisruption. The energy of the pulses produced by the laser is adjustable and the energy density at the focal point is sufficient to create a small ionization site (plasma) in the vitreous cavity. The plasma produces an acoustic wave that radiates from the focal point and ruptures or disrupts adjacent tissue. This is known as the "photodisruptive effect".

Once formed, the plasma absorbs and scatters further incident light. This shields the underlying structures from damage. The beam divergence after the focal point protects the retina from damage that could otherwise occur by the absorption of concentrated Nd:YAG treatment energy.

The laser pulses are accurately positioned by means of a 'twin dot' aiming laser and an integrated slit lamp microscope. The treatment and aiming laser systems exit the microscope along its YAG optical axis and focus at the slit lamp center of rotation.

Refer to the Chapter 7 "System Operation" for instructions on using the laser system.

1.6 SLT treatment beam

The SLT (selective laser trabeculoplasty) treatment beam is derived from the YAG laser module, but it is frequency doubled and beam shaped to provide the physician with a precise and safe tool for performing selective trabeculoplasty.

The SLT treatment beam produces short, individual pulses of focused green light with a wavelength of 532 nm and a low energy density spot 400 microns in diameter.

The SLT treatment beam operates by reducing intraocular pressure. The energy of the pulses produced by the laser is adjustable but much lower than the solid-state laser. It does not produce a photodisruptive effect.

The laser pulses are accurately positioned by means of a coaxial aiming beam to selectively target a pigmented trabecular meshwork of cells. The 532 nm wavelength is absorbed more readily by the pigmented cells, causing them to be destroyed but leaving the trabecular support structure intact.

Refer to Chapter 7 "System Operation" for instructions on using the laser system.

1.7 Medical device classification

According to medical device classification criteria defined in 93/42/EEC - Annex IX and Rule 9, the OptoYag M, OptoSLT M and OptoYag&SLT M are classified as Class IIb medical device.

93/42/EEC: ANNEX IX - RULE 9:
All active therapeutic devices intended to administer or exchange energy are in Class IIa unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the of the energy, in which cast they are in Class IIb.

According to Canadian Medical Device Regulation (CMDR) Classification Rules – Part 1 and Rule 9 the OptoYag M, OptoSLT M and OptoYag&SLT M are classified as Class III medical device.

CMDR PART 1 - RULE 9:
If the administration or withdrawal by a device described in the subrule (1) is potentially hazardous, taking into account the nature of the administration or withdrawal, the intensity of the energy and the part of the body concerned, the device is classified as Class III.

2 Safety

2.1 Safety classification and warnings

The OptoYag M, OptoSLT M and OptoYag&SLT M are classified as Class IIIb/3B laser product and Class I Type B electrical protection product. They comply with the following standards:

EN 60601-1:2006/A1:2013/A12:2014 *- Medical Electrical Equipment, part 1: General Requirements for Basic Safety and Essential Performance Equipment*

EN 60601-2-22:2013 *- Requirements for Safety of Diagnostic/ Therapeutic Equipment*

EN 60825-1:2014 *- Safety of Laser Products*

EN 60601-1-2:2015 *- Electromagnetic Compatibility*

EN ISO 10993-1:2009/AC:2010, Biological evaluation of medical devices – Part 1: Evaluation and testing within risk management process

The following laser safety warnings apply to the end users:

Eye Protection

Visible or invisible laser radiation is emitted from the delivery system when it is in laser READY mode and trigger button is pressed. Do not look into laser treatment beam!

The operator is protected against the hazard while in the normal operating position due to protective filters installed in the instrument.

Appropriate safety glasses (OD 5 / LB5 @ 1064; OD 5 / LB5 @ 532 nm) should be available outside the room for all people requiring the access. Any viewing ports or windows to the room must be covered.

Safety interlocks and warning lamps may be fitted to the room.

Avoid using reflective instruments during the laser procedure. It is recommended that all surfaces in the room have matt finish to prevent accidental reflection of the laser beam.

Slit Lamp Illumination Emission Warning

The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity will exceed the safety guideline after 2 minutes.

YAG (1064nm) Laser Emission Warning

Applies to the OptoYag M and OptoYag&SLT M laser systems.

Class 3B/IIIb Laser Product: avoid direct exposure to the laser beam!

Viewing through slit lamp including optional camera is safe for the viewing eye because the built-in filter provides protection.

Protection of at least OD5 / LB5 @ 1064 nm must be provided for the eye that is not directly viewing through the slit lamp.

All other persons attending the procedure (except the patient being treated) must wear safety goggles designed to prevent transmission of 1064 nm wavelength laser light (OD5 / LB5 @ 1064 nm).

SLT (532nm) Laser Emission Warning

Applies to the OptoSLT M and OptoYag&SLT M laser systems.

Class 3B/IIIb Laser Product: avoid direct exposure to the laser beam!

Viewing through slit lamp including optional camera is safe for the viewing eye because the built-in safety shutter provides protection. Protection of at least OD5 / LB5 @ 532 nm must be provided for the eye that is not directly viewing through the slit lamp.

All other persons attending the procedure (except the patient being treated) must wear safety goggles designed to prevent transmission of 532 nm wavelength laser light (OD5 / LB5 @ 532 nm).

Aiming (650 nm) Laser Emission Warning

Class 2/II Laser Product: do not stare into the laser beam!

Damage to the retina is highly improbable, but it is still advisable to avoid staring into the aiming beam except under controlled conditions.

Reflection Warning

Objects that reflect visible light will reflect laser light too. Avoid placing reflective materials in the laser beam path.

Safety Signs

Safety signs should display Class 3b/IIIB and Class 2/II warning during laser operation.

2.2 Safety notes - residual risks warnings

Read this Manual carefully before operating the device!

Laser devices are classified according to the potential risk involved.

OptoYag M, OptoSLT M and OptoYag&SLT M are classified as Class 3B lasers. It means that improper use of the equipment can lead to direct or scattered laser radiation exposure what may pose a risk to the eyes and skin.

Never look directly into the laser aperture! The laser beam should be directed towards the treatment area only

All personnel present in the laser area must wear laser safety eyewear. The safety eyewear must provide a protection level for 532/1064 nm of at least LB5 (according to EN207).

The laser beam can be reflected from several metal surfaces other than those normally considered as reflective surfaces. Always ensure that all metal objects like watches, jewelry, etc. are removed from the laser area. Many metal surfaces are able to reflect infrared radiation although they do not seem as such.

The area where the maximum permissible radiation level may be exceeded (so called "laser area") must be marked with laser warning label. The warning light at the entrance to the operating room must indicate the laser operation. Only authorized personnel should be allowed to access this area during laser operation.

Using the wrong laser mode.
Applies to the OptoYag&SLT M laser system only.

The OptoYag&SLT M can be operated in either YAG or SLT mode. Always check if the correct mode is selected before using the system. **Failing to use the correct laser mode may result in serious eye injury!**

Output laser energy differs from the set value for more than 20%.

Make sure to have the device checked and calibrated annually!

Unintentional laser self-shot.

In case of unintentional laser self-shot, press the emergency stop button, switch off the device, and call the authorized representative.

Operator's misunderstanding of laser emission parameters.

Read the Chapter 7 of this Manual!

Use of device by unauthorized personnel.

OptoYag M, OptoSLT M and OptoYag&SLT M should be used only by trained personnel! Remove the key from the keyswitch in order to prevent the unauthorized use of the device.

Unauthorized service personnel.

OptoYag M, OptoSLT M and OptoYag&SLT M should be installed, maintained, repaired and/or modified by authorized personnel only!

If the device does not perform as described in this Manual, notify your Optotek authorized representative! Annual maintenance of the system is mandatory. The results of the maintenance procedure should be documented as required in the Chapter 9 of this Manual.

If the system is installed, maintained, repaired and/or modified by an unauthorized person, the warranty is voided!

Touching the wires of broken or damaged mains cable.

Check the mains power supply cable for eventual damage periodically. If the cable is damaged or broken, contact the Optotek authorized representative immediately!

Maintenance of the system.

Refer to the Chapter 9 of this Manual!

Fire and explosion.

Do not install the system in the explosion risk areas! Do not use flammable anesthetics and disinfectants during the device operation.

Electric shock.

In order to avoid electric shock, the system must be connected to the mains supply with protective earth only!

2.3 Electromagnetic compatibility

OptoYag M, OptoSLT M and OptoYag&SLT M require special precautions regarding electromagnetic compatibility (EMC) and need to be installed and operated according to EMC requirements listed in the tables below.

⇒ Portable and mobile RF communication equipment may affect the system operation.

⇒ The mains supply and footswitch should be replaced by the authorized service personnel.

⇒ The system should not be used adjacent to or in combination with other equipment. If such use is necessary, the normal operation of the system in such configuration must be verified before the first use.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSION		
The OptoYag M, OptoSLT M and OptoYag&SLT M are intended for use in the electromagnetic environment specified below. The customer or the user of the devices should assure that they are used in such environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions **CISPR 11**	GROUP 1	The OptoYag M, OptoSLT M and OptoYag&SLT M use RF energy only for their internal function. Therefore, their RF emissions are very low and are unlikely to cause any interference in nearby electronic equipment.
RF emissions **CISPR 11**	Class A	
Harmonics emissions **IEC 61000-3-2**	Class A	
Voltage fluctuations/ flicker emissions **IEC 61000-3-3**	Complies	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The OptoYag M, OptoSLT M and OptoYag&SLT M are intended for use in the electromagnetic environment specified below. The customer or the user of the devices should assure that they are used in such environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) **IEC 61000-4-2**	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, 15 kV air	Floors should be wooden, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst **IEC 61000-4-4**	± 2 kV for power supply lines ±1 kV for input/output lines	± 2 kV for power supply lines N.A.	Mains power quality should be that of a typical commercial or hospital environment. If the power supply is polluted with higher bursts, the process of treatment can be interrupted, without side effects to patient. The device should be switched on again in case of interruption.
Surge **IEC 61000-4-5**	± 1 kV differential mode (line(s) to line(s)) ± 2 kV common mode (line(s) to earth)	± 1 kV differential mode (line(s) to line(s)) ± 2 kV common mode (line(s) to earth)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines **IEC 61000-4-11**	0 % U_T (>95 % dip in U_T) for 0,5 cycle (0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°) 0 % U_T (100 % dip in U_T) for 1 cycle 70 % U_T (30 % dip in U_T) for 25/30 cycles (0°) 0 % U_T (100 % dip in U_T) for 250/300 cycle	0 % U_T (>95 % dip in U_T) for 0,5 cycle (0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°) 0 % U_T (100 % dip in U_T) for 1 cycle 70 % U_T (30 % dip in U_T) for 25/30 cycles (0°) 0 % U_T (100 % dip in U_T) for 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the devices requires continued operation during power mains interruptions, it is recommended that the devices are powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field **IEC 61000-4-8**	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The OptoYag M, OptoSLT M and OptoYag&SLT M are intended for use in the electromagnetic environment specified below. The customer or the user of these devices should assure that they are used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF **IEC 61000-4-6**	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands between 150 kHz to 80 MHz 80% AM at 1 kHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands between 150 kHz to 80 MHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the devices including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d = 1.166 * √P d = 1.166 * √P 80 MHz to 800 MHz d = 2 * √P 800 MHz to 2,7 GHz where **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and **d** is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range.[b]
Radiated RF **IEC 61000-4-3**	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	Interference may occur in the vicinity of equipment marked with the following symbol: 

	Band [Mhz]	Modulation	Maximum power [W]	Distance [m]	Immunity test level [V/m]	Compliance level
Proximity fields from RF wireless communications equipment **IEC 61000-4-3**	380-390	Pulse modulation 18Hz	1,8	0,3	27	27 V/m
	430-470	FM ± 5kHz deviation 1kHz sine	2	0,3	28	28 V/m
	704-787	Pulse modulation 217Hz	0,2	0,3	9	9 V/m
	800-960	Pulse modulation 18Hz	2	0,3	28	28 V/m
	1700-1990	Pulse modulation 217Hz	2	0,3	28	28 V/m
	2400-2570	Pulse modulation 217Hz	2	0,3	28	28 V/m
	5100-5800	Pulse modulation 217Hz	0,2	0,3	9	9 V/m

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

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

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the (equipment or system) is used exceeds the applicable RF compliance level above, the (equipment or system) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the (equipment or system).

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

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30mm (12 inches) to any part of the OptoYag M, OptoSLT M or OptoYag&SLT M medical device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The emissions characteristics of this equipment make it suitable for use in professional healthcare environment (ambulance, hospitals, industrial areas) (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

2.4 Slit lamp illumination

The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity will exceed the safety guideline after 2 minutes.

Avoidance of overexposure to potentially hazardous optical radiation of the slit lamp illumination (ISO15004 standard) - information supplied by the manufacturer:

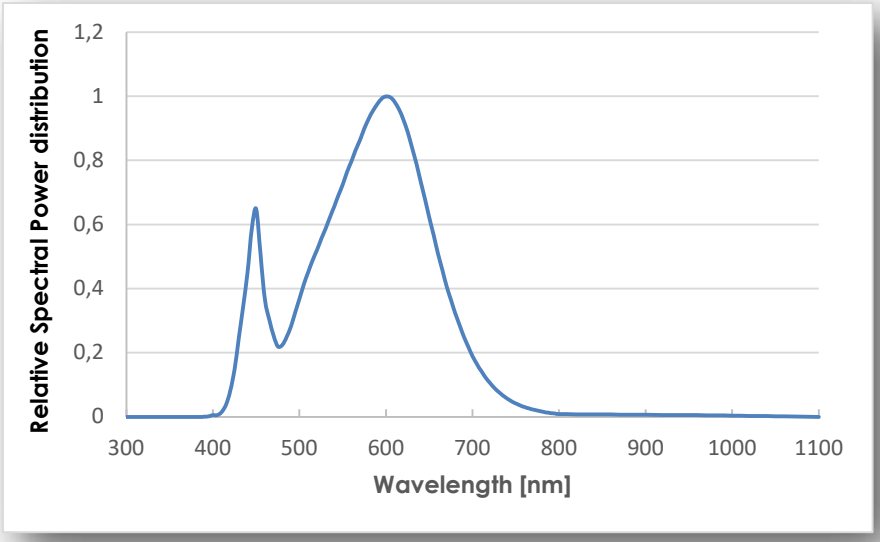


Figure 2.1: *The relative spectral power distribution of the instrument*

The spectrally-weighted photochemical source radiance, both phakic LB and aphakic LA:

LA = 541 mW/(cm² sr); 305 nm to 700 nm
LB = 523 mW/(cm² sr); 380 nm to 700 nm

Spectrally weighted photochemical radiances LB and LA give a measure of the potential that exists for a beam of light to cause photochemical hazard to the retina. LB gives the measure for eyes in which the crystalline lens is in place. LA gives this measure either for eyes in which the crystalline lens has been removed (aphakes) and has not been replaced by a UV-blocking lens or for the eyes of very young children.

The value stated for this ophthalmic instrument gives a measure of hazard potential when the instrument is operated at maximum intensity and maximum aperture. Values of LB and LA over 80 mW/(cm²*sr) are considered high for beams which wholly fill a dilated pupil.

The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. For instance, at a radiance level of 80 mW/(cm²*sr), 3 min irradiation of the dilated (8 mm diameter) pupil would cause the retinal exposure dose level to attain the recommended exposure limit. If the value of radiance were reduced to 40 mW/(cm²*sr), twice that time (i.e. 6 min) would be needed to reach the recommended limit. The recommended exposure dose is based on calculations arising from the American Conference of Governmental Industrial Hygienists (ACGIH) - Threshold Limit Values for Chemical Substances and Physical Agents (1995-1996 Edition).

While no acute optical radiation hazards have been identified for ophthalmic instruments, it is recommended that the intensity of light directed into the patient's eye be limited to the minimum level which is necessary for diagnosis. Infants, aphakes and persons with diseased eyes will be at greater risk. The risk may also be increased if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 h. This will apply particularly if the eye has been exposed to retinal photography.

2.5 Safety eyewear protection level

OptoYag M Calculation

Need for safety eyewear based on the Maximum Permissible Exposure (MPE), the Nominal Ocular Hazard Distance (NOHD) and the Optical Density (OD).

For additional information, refer to ANSI Z136.1-1993, ANSI Z136.3-1996, or European Standard EN 60825-1: 2014.

The following formula was used to calculate the worst case NOHD for OptoYag M:

$$\boldsymbol{NOHD = \frac{1}{\theta}\sqrt{\frac{4}{\pi}\frac{\Phi}{MPE}\,Pf - a^2}}$$

where

a	=	the beam waist diameter;
θ	=	full angle beam divergence;
Φ	=	maximum energy of one laser pulse or maximum CW laser power;
Pf	=	the profile correction factor (1 for uniform profile, 2 for Gaussian irradiance profile);
MPE	=	Maximum Permissible Exposure, in energy density units (energy per unit area);
NOHD	=	Nominal Ocular Hazard Distance (measured from laser aperture)
	=	the distance required to reduce the power density to the MPE.

MPE = 2 x 10^{-2} J/m²

NOHD = 7.0 m

All personnel who are within the NOHD are considered to be within the controlled area and shall wear eye protection with a minimum optical density (OD) of:

O.D.= -LOG (E_{MPE} / Power density) = 4.59

For maximum safety, the safety eyewear has to conform to the protection level LB5.

OptoSLT M Calculation

The following formula was used to calculate the worst case NOHD for OptoSLT M:

$$\boldsymbol{NOHD = \frac{1}{\theta}\sqrt{\frac{4}{\pi}\frac{\Phi}{MPE}\,Pf - a^2}}$$

where

a	=	the beam waist diameter;
θ	=	full angle beam divergence;
Φ	=	maximum energy of one laser pulse or maximum CW laser power;
Pf	=	the profile correction factor (1 for uniform profile, 2 for Gaussian irradiance profile);
MPE	=	Maximum Permissible Exposure, in energy density units (energy per unit area);
NOHD	=	Nominal Ocular Hazard Distance (measured from laser aperture)
	=	the distance required to reduce the power density to the MPE.

MPE = 2 x 10^{-3} J / m²

NOHD = 204 m

All personnel who are within the NOHD are considered to be within the controlled area and shall wear eye protection with a minimum optical density (OD) of:

O.D.= -LOG (E_{MPE} / Power density) = 4.53

For maximum safety, the safety eyewear has to conform to the protection level LB5.

NOHD calculation references:

1. **EN 60825-1:2014** – Safety of laser products -- Part 1: Equipment classification and requirements (IEC 60825-1:2014)
2. Measured and calculated at Optotek, July, 2009 and April, 2019.
3. Safety goggles supplier CE certificate

2.6 Safety features

The **OptoYag M, OptoSLT M** and **OptoYag&SLT M** have been designed and produced according to the following standards:

- **EN 60601-1:2006/A1:2013/A12:2014**, Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance
- **EN 60601-2-22: 2013**, Requirements for Safety of Diagnostic/Therapeutic Laser Equipment
- **EN 60825-1:2014**, Safety of Laser Products
- **EN 62304:2006/A1:2015**, Medical Device Software – Software Life Cycle Processes
- **EN 60601-1-2:2015**, Electromagnetic Compatibility
- **EN 62366-1:2015**, Application of usability engineering to medical devices
- **EN ISO 10993-1:2009/AC:2010**, Biological evaluation of medical devices – Part 1: Evaluation and testing within risk management process
- **EN ISO 15004-1:2009**, Ophthalmic Instruments – fundamental requirements and test methods; Part 1; General requirements applicable to all ophthalmic instruments
- **EN ISO 15004-2:2007**, Ophthalmic Instruments – Fundamental requirements and test methods; Part 2; Light hazard protection
- **EN ISO 10939:2017**, Ophthalmic Instruments – Slit lamp microscopes
- **EN ISO 14971:2019**, Medical devices – Application of risk management to medical devices
- **MDD 93/42/EEC**, Medical Device Directive
- **EN ISO 13485:2016**, Quality Management System

Most important safety features provided in accordance with the requirements of the appropriate standards are:

FEATURE	DESCRIPTION
Keyswitch lock	The laser can only be turned on with the correct key. The key can not be removed while in the ON position.
Emergency stop button	When pressed it switches off all power and eliminates risk of laser radiation. Releasing the Emergency button restarts the system into the STANDBY mode.
Laser READY/STANDBY indication	After completing power up diagnostics, yellow STANDBY indication glows. By pressing READY/ STANDBY button, system goes into READY mode. A delay of two seconds is implemented before laser emission can occur.

FEATURE	DESCRIPTION
Safety remote interlock	Unit is supplied with a bypass plug. User should connect the connector to a door interlock switch, preventing the laser from firing, when the door is opened.
Safety shutter	Each laser is equipped with a spring loaded safety shutter that keeps the laser path blocked unless the system is in READY mode.
Laser energy measurement	The energy of each laser pulse is measured. If the pulse energy is higher by more than 20% or lower by more than 50% of the preset energy, the system shuts down automatically and display an error message.
Laser energy deviation warning	The system warns the operator if delivered energy deviates more than – 20% from the set value.
Protective housing	Protective housing on the Laser head and Power Supply console protect user from the laser emission and high voltage shock. It can not be removed without tools and can only be opened by authorized service personnel.
Location of controls	All the operator controls are located so there in no risk of unwanted laser exposure.
Ocular filters	Oculars on the laser contain safety filters to limit the exposure level to the operator's eyes to the Class 1 limit.
IEC compliance labels	Locations and illustrations of the safety compliance labels are contained in the safety labels section.
Electrical leakage protection	A medical grade power supply is used to comply with the requirements of EN 60601-1 for earth leakage protection.

System also includes a number of additional safety features:

FEATURE	DESCRIPTION
Memory test	After power up, system check the microprocessor memory. If a fault is detected, an error code is displayed and laser can not be switched to READY mode.
Laser power up test	After the memory test, system performs self test of the laser cavity. If a fault is detected, an error code is displayed and laser can not be switched to READY mode.
Shutter monitor	A dual sensor shutter monitor checks the correct opening and closing the safety shutter. If a fault is detected, an error code is displayed and the system must be restarted.
Automatic test fire	When system switches between STANDBY and READY mode, five test shots are performed. If a fault is detected, an error code is displayed and laser does not enter the READY mode.
Fault conditions	If the system detects a fault during operation, an error code is displayed on the User interface display. Warnings can be cleared by the operator, while errors result in a system shut down.

2.7 Safety labels

In compliance with MDD 93/42/EEC and International Standard EN 60601-1, this section contains a facsimile of every safety label and voltage/power rating label attached to the OptoYag M, OptoSLT M and OptoYag&SLT M.

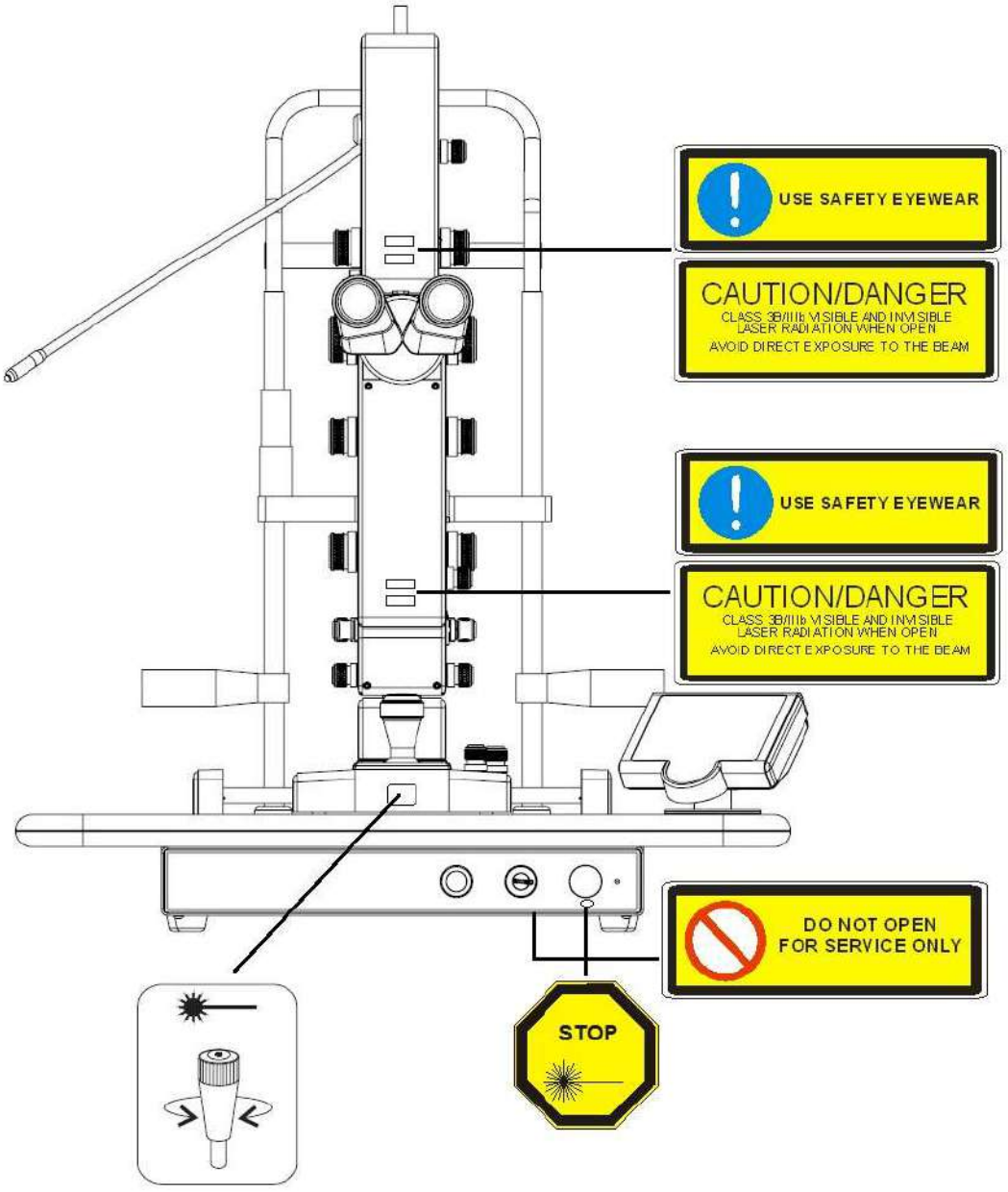


Figure 2.2: **Safety label locations – front view**

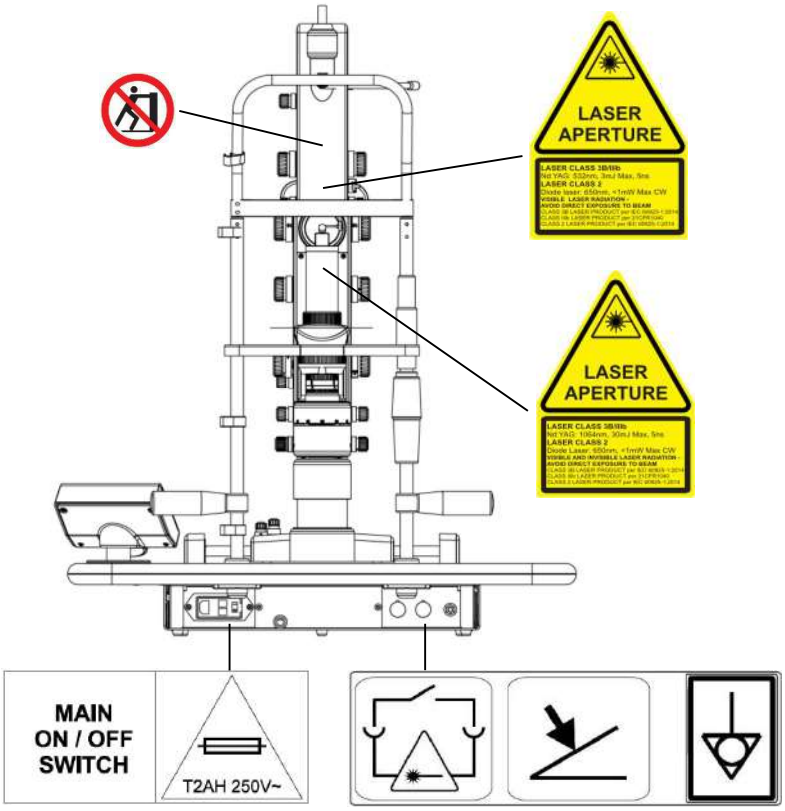


Figure 2.3: *Safety label locations – rear view*

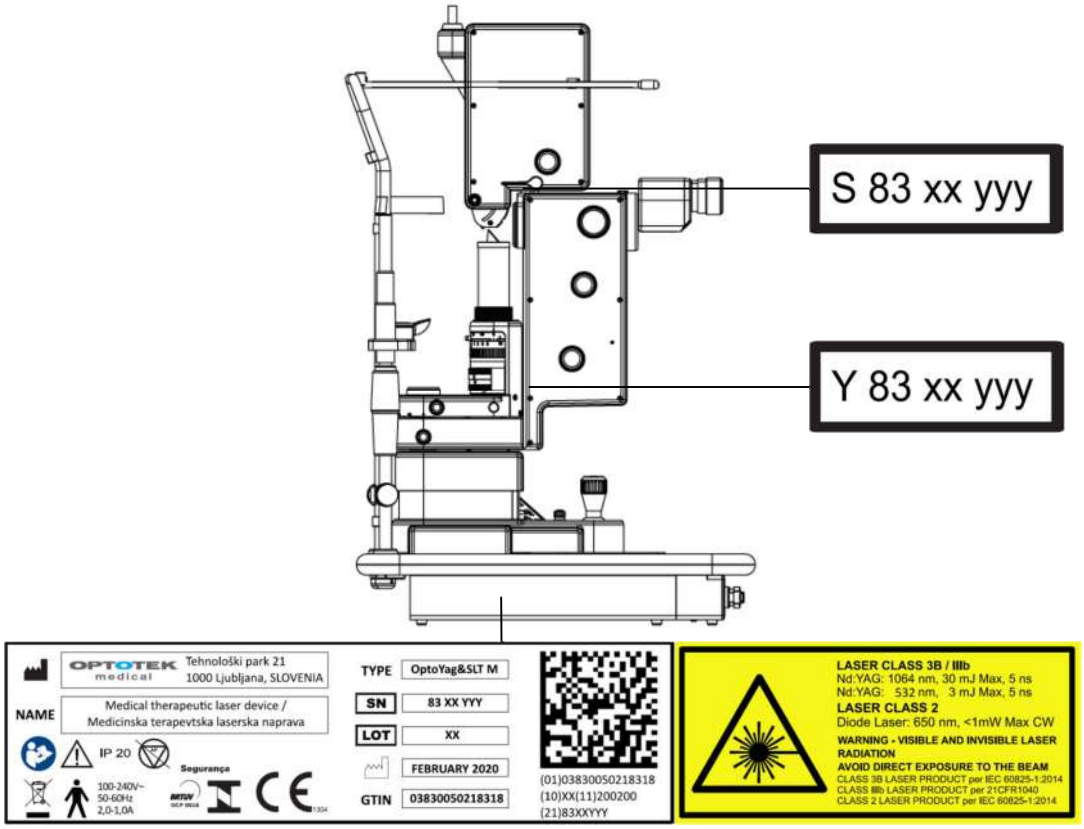


Figure 2.4: *Safety label locations – side view*

COMPLIANCE LABEL: indication of origin, model reference, serial number, type of protection, degree of protection and production date.

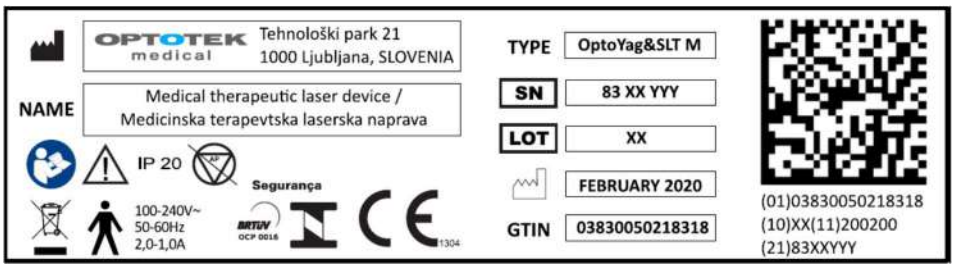


Figure 2.5: *Compliance label description*

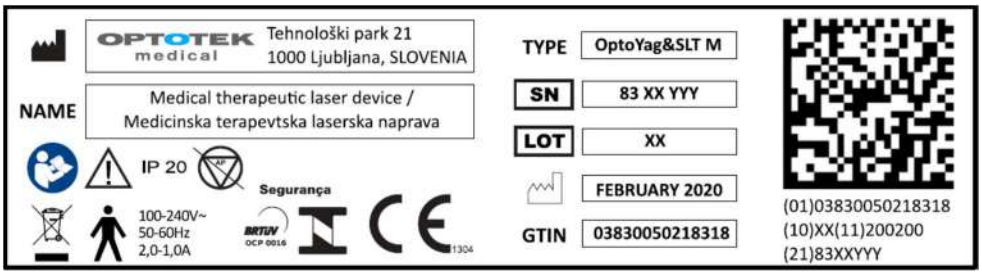
SYMBOLS:

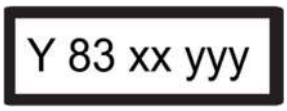
	Manufacturer details		**CE marking** *The product is compliant with the MDD Directive 93/42/EEC and subsequent amendments.*
NAME	**Name of the device**	**SN**	**Serial number in text format**
	Operating Instructions *Read the User's Manual before use, because of safety reasons!*	**LOT**	**Batch/Lot code**
	Caution *To signify caution. Consult User manual for important cautionary information.*		**Date of manufacture**
IP 20	**No protection from liquids** *Min. NEMA Enclosure rating 1.*	**GTIN**	**Global trade item number**
	Disposal symbol *Indicating separate collection for electrical and electronic equipment, in compliance with 2012/19/EU WEEE directive.*	(01)03830050218318 (10)XX(11)200200 (21)83XXYYY	**Unique Device Identification (UDI) label**
AP	**Category AP equipment** *NOT Anesthesia proofed!*	(01)	**Global Trade Item Number (GTIN)**
	Type B applied part	(10)	**Batch/Lot code**
100-240V~ 50-60Hz 2,0-1,0A	**Electrical requirements**	(11)	**Date of manufacture in YYMMDD format**
Segurança BRTÜV OCP 0016	**INMETRO marking** *The product is compliant with General Requirements for Product Certification (RGCP)*	(21)	**Serial number**

WARNING LABEL: indicating laser radiation hazard and class of treatment and aiming beam lasers.

Figure 2.6: *Warning label*

OptoYag&SLT M Laser System





Serial number of YAG head

Serial number of SLT head

Figure 2.7: *Compliance and warning labels OptoYag&SLT M*

OptoYag M Laser System

Serial number of YAG head

Figure 2.8: *Compliance and warning labels OptoYag M*

OptoSLT M Laser System

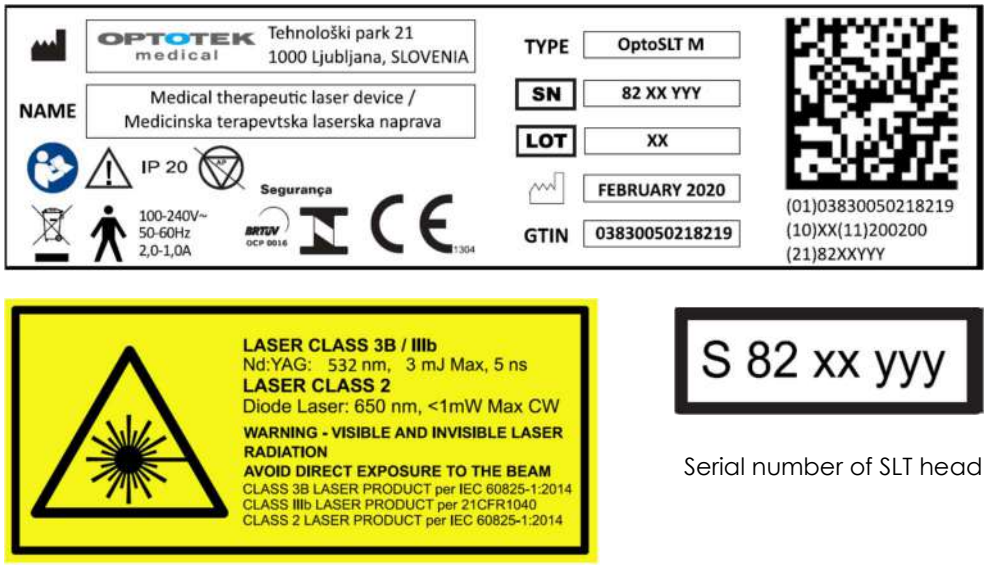
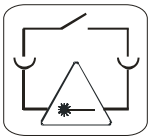
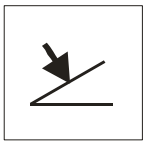
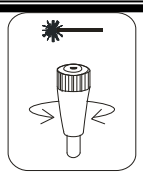


Figure 2.9: *Compliance and warning label OptoSLT M.*

OTHER LABELS:

Label	Description	Applies to:
	**Electrical requirements: Rated power input, rated supply voltage, type of current, rated supply frequency, rated fuses and main ON/OFF switch**	OptoYag M OptoSLT M OptoYag&SLT M
	**Remote interlock & warning light connector**	OptoYag M OptoSLT M OptoYag&SLT M
	**Footswitch connector**	OptoYag M OptoSLT M OptoYag&SLT M
	**Equipotentiality connector**	OptoYag M OptoSLT M OptoYag&SLT M
	**Emergency stop push-button**	OptoYag M OptoSLT M OptoYag&SLT M

Label	Description	Applies to:
	**XYZ joystick and laser trigger button**	OptoYag M OptoSLT M OptoYag&SLT M
	**YAG laser classification and YAG laser aperture**	OptoYag M OptoYag&SLT M
	**SLT laser classification and SLT laser aperture**	OptoSLT M OptoYag&SLT M
	**Caution/Danger label:** **Laser head protective cover label**	OptoYag M OptoSLT M OptoYag&SLT M
	**Console internal connectors protective cover label (front panel)**	OptoYag M OptoSLT M OptoYag&SLT M
	**Use safety eyewear**	OptoYag M OptoSLT M OptoYag&SLT M
	**No pushing** *Pushing against the object is prohibited.*	OptoSLT M OptoYag&SLT M

2.8 Operational safety precautions

The OptoYag M, OptoSLT M and OptoYag&SLT M are safe instruments when correctly installed and operated, and when the safety precautions described in this User's Manual are followed.

Before using the device for the first time, ensure that the equipment is correctly installed and adjusted, and that all safety devices are operational.

All personnel likely to be using or assisting in the use of the laser should read this User's Manual and undertake basic laser safety training.

A laser safety officer should be appointed to be responsible for coordinating all aspects of laser safety.

The following general precautions apply:

- ❒ do not operate the laser unless it is correctly positioned on a level, stable surface;
- ❒ when the system is not in use, remove the key from the power supply console in order to prevent unauthorized use of the laser;
- ❒ do not fire the treatment laser if the aiming beam is not present;
- ❒ check the device according to IEC 60601-1 at least once in 12 months;
- ❒ if the device needs to be moved or relocated during normal use (for instance from room to room), all moving parts of the medical device should be fixed (indicated on the image below) and 2 persons are required to move the device (points where the equipment can be safely lifted are indicated on the image below).

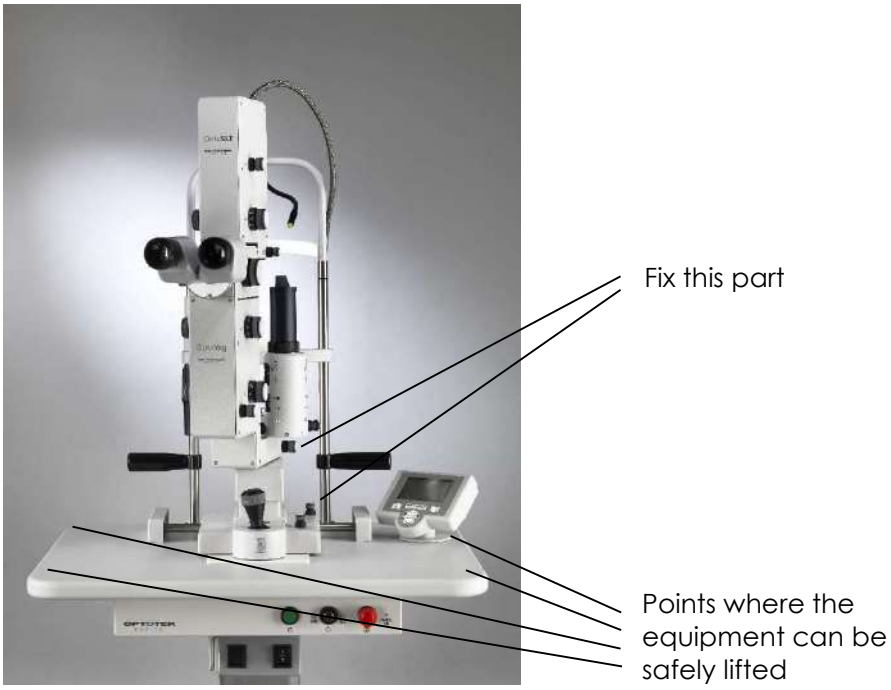


Figure 2.10: *Instruction for safe relocation of the medical device*

3 System description

3.1 System overview

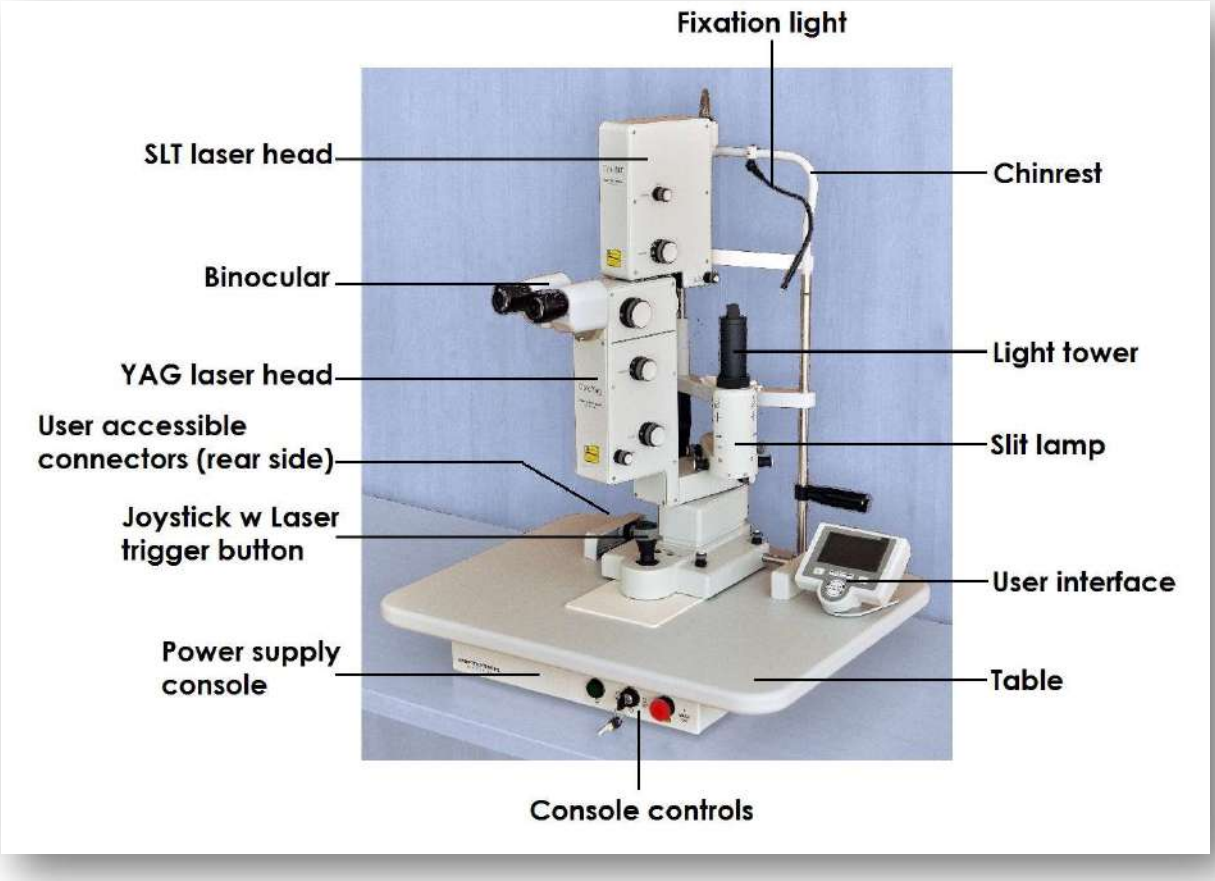


Figure 3.1: *Overview of OptoYag&SLT M **

**** The OptoYag M laser system contains only YAG laser head; the OptoSLT M laser system contains only SLT laser head.***

The OptoYag M, OptoSLT M and OptoYag&SLT M systems are designed to be used by the ophthalmologists in the professional healthcare environment (outpatient offices or operating room environment).

The systems consist of four major sub-assemblies:

- ***Power supply console (OptoYag M, OptoSLT M, OptoYag&SLT M)***
  Laser power supply module
  Control and safety electronics

- **Table with**
  User interface control module
  Chin rest

❒ ***YAG laser head (OptoYag M, OptoYag&SLT M)***

Slit lamp

Integrated YAG treatment laser beam and aiming beam system

Sensors, shutter, safety filters, optics to control and focus the beams

Microprocessor to control the laser head

❒ ***SLT laser head (OptoSLT M, OptoYag&SLT M)***

Slit lamp

Integrated SLT treatment laser beam and aiming beam system

Sensors, shutter, safety filters, optics to control and focus the beams

Microprocessor to control the laser head

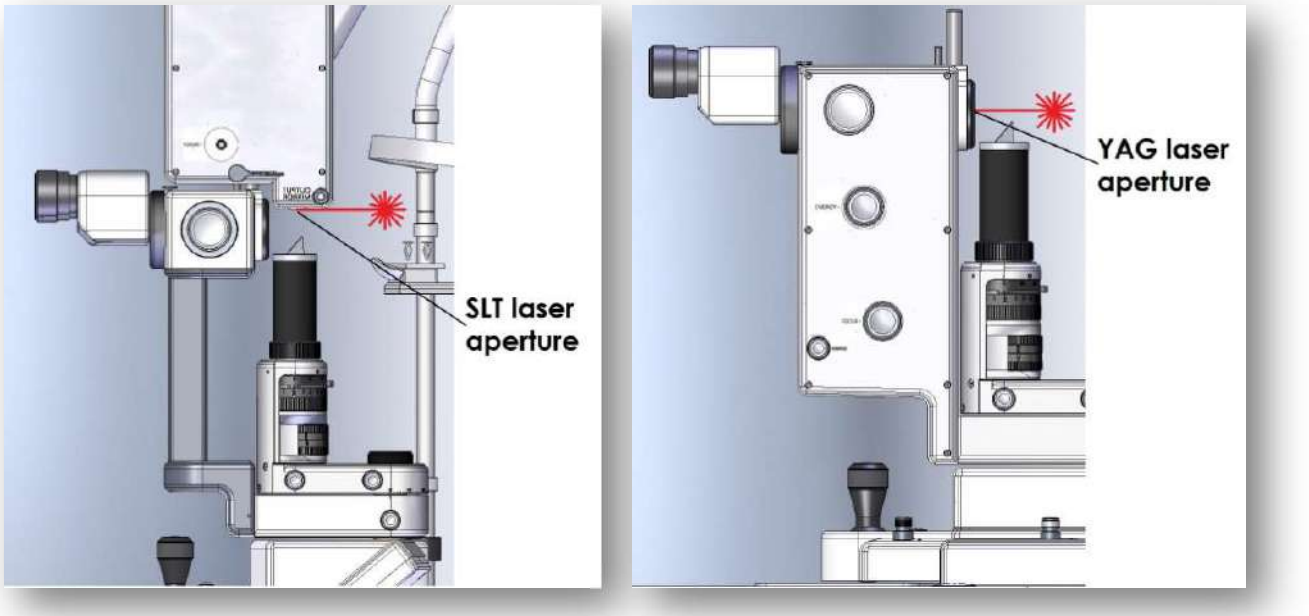


Figure 3.2: *YAG and SLT laser aperture*

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

3.2 Table and motorized lifting column with base

The table is included in the basic set of instrument, whereas the motorized lifting column with base is an optional accessory. Refer to the Chapter 4 "Accessories" for ordering information.

Figure 3.3: *Motorized lifting column with base*

Do not use lifting column with base during the treatment procedure. Turn off the lifting column with base during the procedure.

3.3 Power supply console

The power supply unit is located under the table and provides power to the laser systems, controls the laser systems and provides connections for all system subunits. It comprises mains socket, main ON/OFF switch, power supply and its controls, control electronics, keyswitch, emergency stop button, footswitch and remote interlock connections.

3.4 Power supply console controls

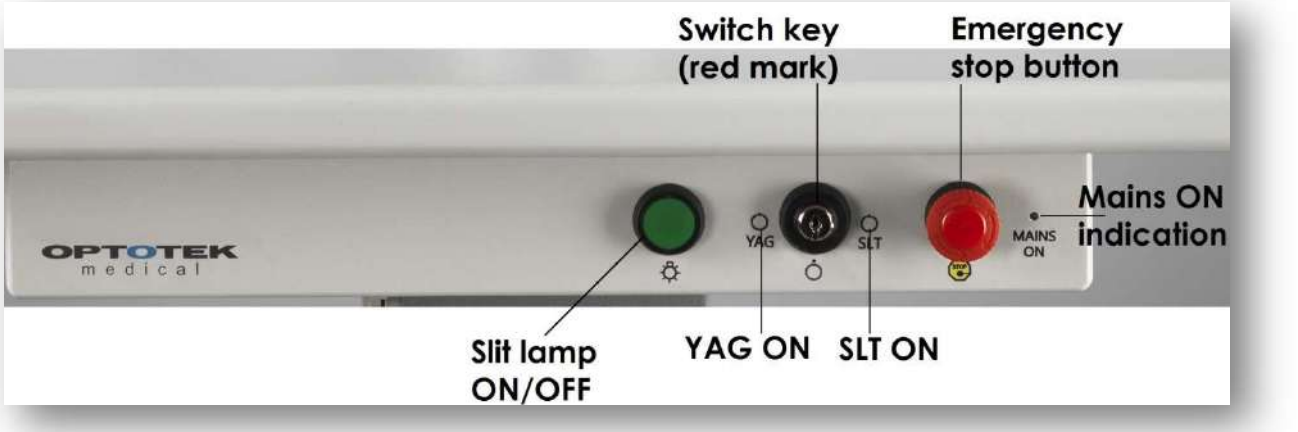


Figure 3.4: *Power supply console controls*

Control	Description
Emergency stop button	A red mushroom type push button. When pressed, it immediately stops the system and eliminates any risk of laser radiation. Rotate it to release it and allow the system operation.
Mains ON indication	Green LED indicates that the mains power connected and main ON/OFF switch is turned on.
e-SlitLight ON/OFF	Press this button to turn on the slit lamp. Green illuminated button indicates that the slit lamp is turned ON. This button allows use of the slit lamp only (without turning on any of the laser heads). When any laser head is activated by turning ON the switch key, the slit lamp turns on automatically.
"SLT ON" keyswitch	The keyswitch is the main power switch. Turn the key to the left to activate the SLT laser head. The key can only be removed in the OFF position.
"YAG ON" keyswitch	The keyswitch is the main power switch. Turn the key to the right to activate the YAG laser head. The key can only be removed in the OFF position.

3.5 User-accessible console connectors

The user-accessible console connectors are located on the rear side of the power supply console.

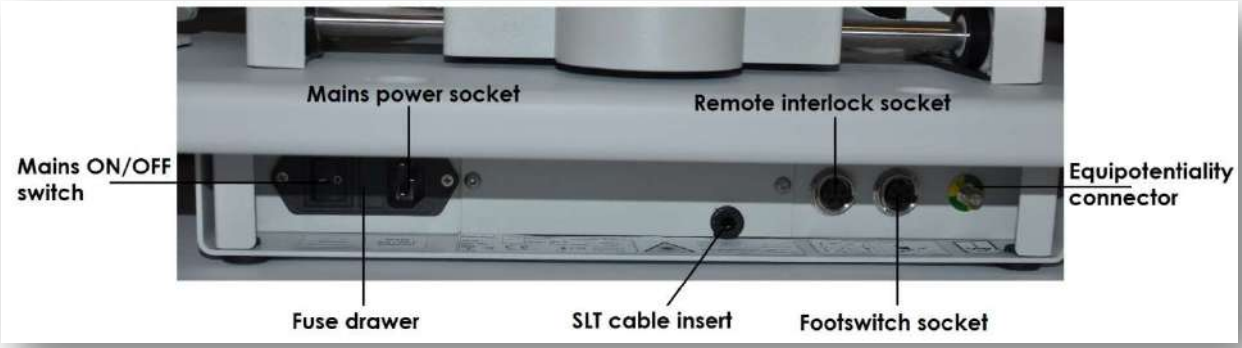
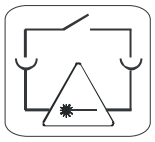
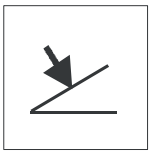


Figure 3.5: *User accessible console connectors*

The end user has the access to the following connectors (refer to the Figure 3.5 for their location on the console):

Connector	Symbol	Description
Mains power connector with the main ON/OFF switch and fuses		Connection to the mains power. Any AC voltage from 100 to 240Vac / 50-60Hz may be used. Current rating of the mains should be at least 10A.
Equipotentiality connector		Potential equalization conductor. For Optotek Distributor use only!

Connector	Symbol	Description
Safety interlock with warning light		The safety interlock allows the operator to install external safety interlock if required. The devices are supplied with a shorting plug fitted to the connector to defeat this interlock.
Footswitch socket		For connection of an optional footswitch laser trigger control.

3.6 Internal console connectors

- ❒ The internal connectors are covered with the protection cover located on the front of the console and must not be accessed by the end user.
- ❒ If the console is opened by the end user, the warranty is voided!
- ❒ Only an authorized Optotek technician during the installation or servicing of the unit should access the internal connectors.

3.7 User interface

The user interface can be placed on right or left side of the tabletop. It contains a microprocessor, graphics liquid crystal display (LCD) and keypad.

The user interface is protected with a durable polycarbonate membrane which protects it and makes it easy-to-clean.

The tactile push buttons beep when pressed in order to alert the operator that a setting has been changed.

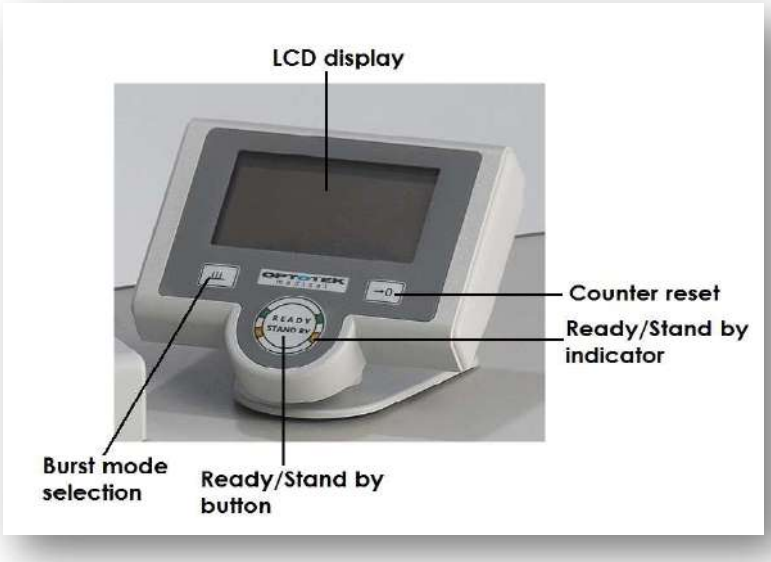


Figure 3.6: *User interface*

3.8 YAG laser head controls

The YAG laser head is fully integrated into a specially designed slit lamp.

Advanced ergonomics provides optimal ease-of-use and minimizes a practitioner fatigue.

The location of laser controls allows easy adjustment of treatment parameters without the need for the operator to move back from the binoculars.

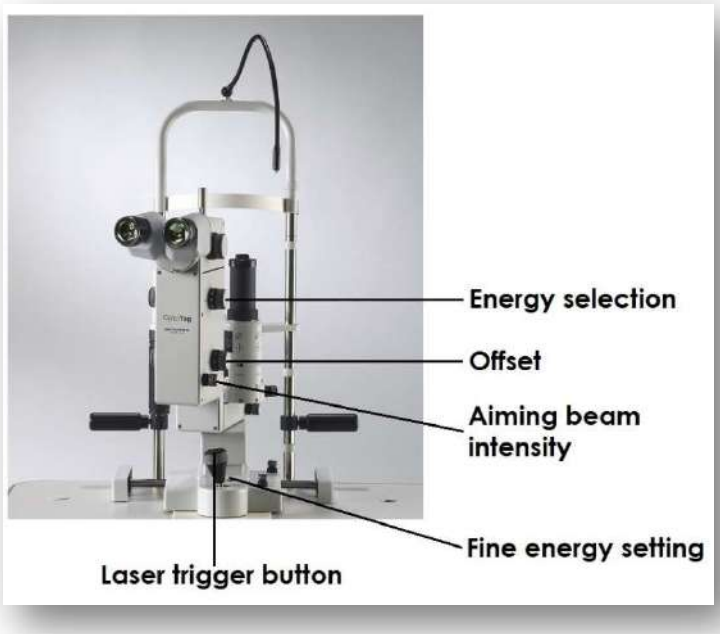


Figure 3.7: *YAG laser head with slit lamp*

The following controls are located on the YAG laser head:

Control	Description
Energy selection	A rotary control on each side of the laser head allows a selection of treatment energy. The selected energy value in mJ is displayed on the user interface LCD.
Offset	A rotary control on each side of the laser head allows a selection of focal shift – offset focus. The focal shift can be set to 0, 150, 300 µm posterior or 150 µm anterior.
Aiming beam intensity	A small rotary knob on the right side of the YAG laser head controls the aiming beam intensity.
Fine energy setting	Fine setting of the selected energy for +10% or -10%.
Laser trigger button	Button on the top of the joystick for triggering the laser pulse.

3.9 SLT laser head controls

The SLT laser head is either integrated into the slit lamp (OptoSLT M) or attached to the tonometer pin of the YAG laser head (OptoYag&SLT M).

The SLT laser head is fixed to the tonometer pin by rotating the Lever handle (refer to the Figure 3.8):

- ❒ Put the Lever handle to vertical (opened) position.
- ❒ Install the laser head.
- ❒ Rotate the lever handle to horizontal (locked) position to fix the laser head.

If the SLT laser head is not in use or tonometer pin is needed for other devices, the SLT laser head can be stored on the SLT laser head rest holder. The holder is located on the side of the lifting column.

- ❒ Remove the SLT laser head cable from the chinrest clips, before moving the laser head from the tonometer pin to the rest holder.

Figure 3.8: *Fixation of the SLT laser head – Lever handle*

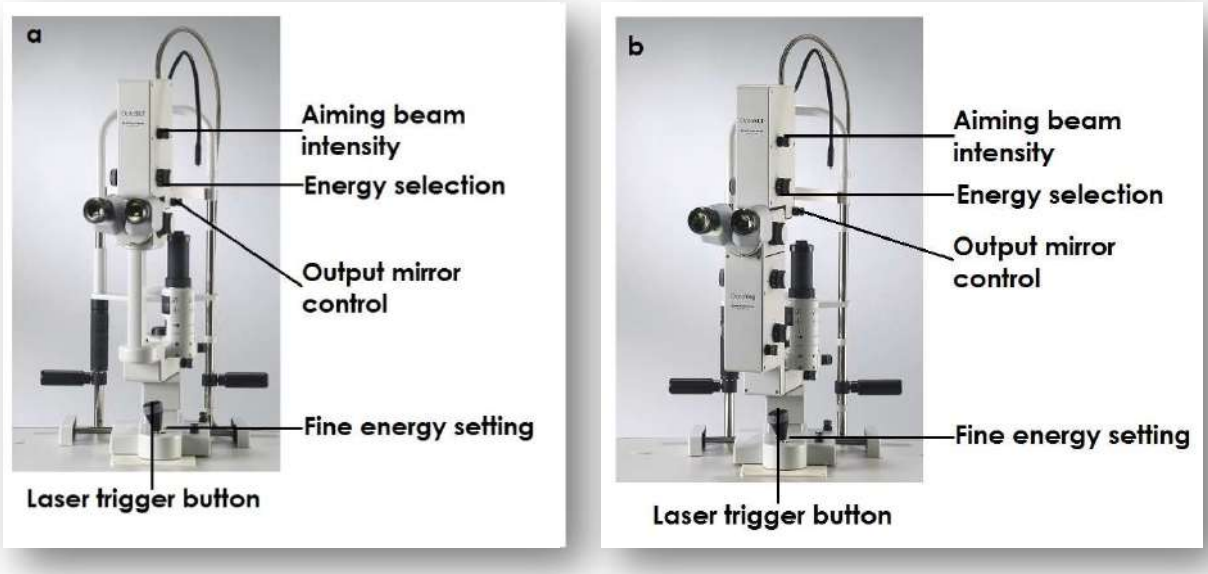


Figure 3.9: *SLT laser head in OptoSLT M (a) and in OptoYag&SLT M (b)*

The following controls are located on the SLT laser head:

Control	Description
Energy selection	A rotary control on each side of the laser head allows a selection of treatment energy. The selected energy value is mJ displayed on the user interface LCD.
Aiming beam intensity	A small rotary knob on the right side of the SLT laser head controls the aiming beam intensity.
Fine energy setting	Fine setting of the selected energy for +10% or -10% .
Output mirror	A rotary control on each side of the laser head rotates the SLT laser output mirror to the working position (refer to the Figure 3.9).
Laser trigger button	Button on the top of the joystick for triggering the laser pulse.
Laser head Lever handle	Fixation of the laser head to the tonometer pin (only in the OptoYag&SLT M).

3.10 Slit lamp controls

The laser systems are combined with two different models of slit lamp. Both models share the same technical characteristics. They differ only in the mechanical construction in order to fit onto the particular system – OptoYag M, OptoSLT M or OptoYag&SLT M.

Both slit lamp models are supplied with fixed magnification of 16 x using 12.5 x eyepieces. A three-step magnification changer is fitted inside the microscope head.

The OptoYag M and OptoYag&SLT M slit lamp incorporates modified microscope head containing the laser optics.

All slit lamp features and controls match the ones of the OptoSLT M slit lamp.

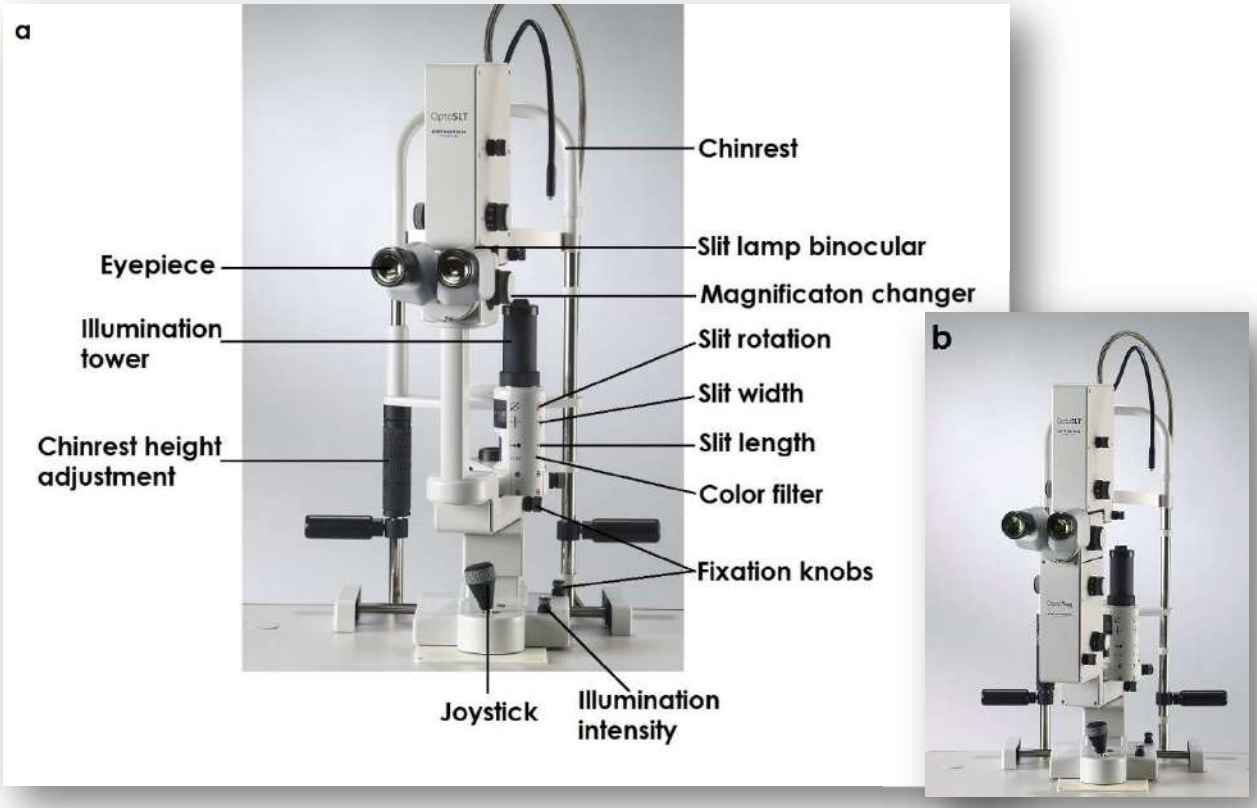
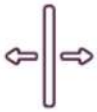


Figure 3.10: *OptoSLT M slit lamp (a) and OptoYag M/OptoYag&SLT M slit lamp (b)*

Slit lamp controls

Control	Symbol	Description
Slit lamp illumination intensity		A rotary control on the right hand side of the slit lamp base. Adjusts the slit light intensity. **Note:** If high illumination is not required, the light should be kept at minimum intensity. The LED temperature is controlled and may lead to automatic intensity reduction.
Joystick		XYZ joystick is used to manipulate the position of the laser head and slit lamp. The push button at the top of the joystick is used to trigger the laser.
Chin rest height		The collar on the chin rest post is rotated to adjust the chin rest height.
Magnification changer	**10 16 25** **6 10 16 25 40** **(optionally)**	A large rotary knob on each side of the laser head is used for the selection of the microscope magnification: 10x, 16x, 25x (6x, 10x, 16x, 25x, 40x optionally)
Slit width		Turned to adjust the slit width.
Slit length		Turned to adjust the slit length.
Color filters	**Filter**    	Bottom wheel button allows the selection of: No filter – LED light Color enhancement filter Blue filter Green filter
Eyepiece adjustment		Diopter adjustment on both eyepieces allows the adjustment of the binocular focus to the operator. The eyepieces are fitted with eyecups that can be folded back if the operator wears spectacles.
Interpupillary distance adjustment		The eyepiece position can be adjusted to the operator's interpupillary distance.

4 Accessories

The following OptoYag M, OptoSLT M and OptoYag&SLT M accessories are available:

Item	Description	Order Code
Footswitch	Medical grade IPX8 foot switch, metal housing	83 5 00 002
Footswitch 2	Medical grade IPX8 foot switch – large housing, plastic housing	83 5 00 400
Warning light illumination laser sign and doorswitch	Illuminated laser warning sign and door interlock switch incl. 10 m cable	83 5 00 300
Safety eyewear	Specific eye protection, wavelength 532 and 1064 nm, CE marked (EN 207). Safety eyewear specification (for both OptoYag M and OptoSLT M): BDY: OD 7+/LB7@532nm; OD7+/LB7@ 1064nm	83 5 00 001
Elbow support	Elbow support – polyurethane, blue	003780
Magnification changer 5x	Optional magnification changer (6x, 10x, 16x, 25x, 40x)	100210615
Focus stick	Focus stick for OptoYag M, OptoSLT M, OptoYag&SLT M	81 5 00 002
Beam splitter 2 plugs	Beam splitter for 2 co-observation tubes	83 5 00 005
Beam splitter 1 plug	Beam splitter for 1 co-observation tube	83 5 00 007
Co-observation tube	Fits both beam splitters	83 5 00 006
Dust cover	For OptoYag M, OptoSLT M, OptoYag&SLT M	83 5 00 003
Chinrest paper (pad)*	Set of 50 pcs	000080
Motorized lifting column with base	For OptoYag M, OptoSLT M, OptoYag&SLT M	L128
Wheel	Wheel for motorized lifting column	

* Applied part (biocompatible).

Use of accessories, transducers and cables other than those specified in this Manual or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

5 Technical description and system features

5.1 Slit lamp

Microscope	
TYPE	Binocular direct vision type
MAGNIFICATION	Selectable, 3 positions: 10x, 16x, 25x (optionally 5 positions: 6x, 10x, 16x, 25x, 40x)
RANGE OF INTERPUPILLARY DISTANCE ADJUSTMENTS	50 mm to 73 mm
RANGE OF EXAMINER'S DIOPTRIC PROJECTION ADJUSTMENT	-8D to +8D
MICROSCOPE OBJECTIVE FOCUS LENGTH	115 mm
EYEPIECE MAGNIFICATION	12,5 x
OPTICAL AXIS HEIGHT	365 - 394 mm
Slit projection unit	
LIGHT SOURCE	White LED
SAFETY CLASSIFICATION	Group 2
SLIT LENGTH	0,3; 1; 12; 2-11 mm; continuously adjusted
SLIT WIDTH	0-12 mm; continuously adjusted
SLIT ROTATION	0- 90°, continuously adjusted
PROJECTION ANGLE	9° to the microscope axis
LIGHT INTENSITY	Electronically adjusted
FILTER	Blue, green, color enhancement
Chinrest	
VERTICAL TRAVEL OF HEAD REST	240 – 310 mm
FIXATION LIGHT	Red LED
Table	
DIMENSION OF THE TABLE	600 x 480 mm
Lifting mechanism with base (optional accessory)	
LIFTING MECHANISM	Electrical, built in motor and power supply
HEIGHT	Min. 685 mm, Max. 935 mm
BASE DIMENSIONS	695 x 450 mm
MAX. LOAD CAPACITY	75 kg
NET WEIGHT	33 kg

Applies to OptoYag M, OptoSLT M and OptoYag&SLT M laser systems.

5.2 YAG laser

Laser head YAG	
LASER SOURCE	Q switched, solid state Nd:YAG
MODE STRUCTURE	Gaussian beam profile
LASER SAFETY CLASS	3B
WAVELENGTH	1064nm
PULSE DURATION	4ns (typical)
REPETITION RATE	Up to 3Hz @ single pulse; 1Hz @ double pulse; 0,5 Hz @ triple pulse
BURST MODE	1, 2 and 3 pulses per burst; selectable; pulse separation of 20µm
ENERGY SELECTION	0,5 to 10 mJ; per pulse; 10 steps selectable
ENERGY CORRECTION	up to +/-10%, selected via buttons on the slit lamp base
MAXIMUM ENERGY	25 mJ@triple pulse setting
SPOT SIZE	< 10 µm
CONE ANGLE	16°
IONIZATION IN AIR	< 4,5 mJ
OFFSET	Selectable: 150µm anterior; 0; 150, 300 µm posterior
AIMING BEAM	Dual beam; 650 nm; continuously variable intensity; Safety class 2; Power < 1 mW (option: 635 nm or 670 nm)
LASER SAFETY FILTERS	Total filtering OD 6 @ 1064 nm
NOHD	7,0 m
COOLING SYSTEM	Air convection
USER CONTROL	Table top remote control with graphics display and keyboard
LASER TRIGGER	Joystick, optional footswitch
DIMENSIONS	125 x 257 x 68 mm

Applies to OptoYag M and OptoYag&SLT M laser systems.

5.3 SLT laser

Laser head SLT	
LASER SOURCE	Q switched, solid state frequency doubled Nd:YAG; 532 nm
LASER SAFETY CLASS	3B
PULSE DURATION	4ns (typical)
PULSE RATE	Up to 3Hz
BURST MODE	Single pulse
ENERGY SETTINGS	0,2; 0,4; 0,6; 0,8; 0,9; 1,0; 1,1; 1,2; 1,5; 2,0; 2,6 mJ
ENERGY CORRECTION	up to +/-10%, selected via buttons on the slit lamp base
MAXIMUM ENERGY	2,6 mJ
NOHD	204 m
SPOT SIZE	400 µm
CONE ANGLE	< 3°

Laser head SLT	
AIMING BEAM	Diode laser; coaxial; 650 nm; continuously variable intensity; Safety class 2; Power < 1 mW (option: 635 nm or 670 nm)
FIXATION TO THE SLIT LAMP	On the tonometer pins of e-SlitLight slit lamp or OptoYag M; moving output mirror in/out of working position; electronic detection of the working position of the delivery system; blocking with the lever
LASER SAFETY FILTERS	Total filtering OD 5,4 @ 532 nm
LASER DELIVERY	Output mirror
COOLING SYSTEM	Air convection
DIMENSIONS	240 x 150 x 60 mm
CABLES TO THE LASER HEAD	From above
USER CONTROL	Table top remote control with graphics display and keyboard

Applies to OptoSLT M and OptoYag&SLT M laser systems.

5.4 Overall system features

Power supply	
TYPE	Medical grade; IEC 60601-1
SUPPLY VOLTAGE	100-240VAC; autoranging
SUPPLY FREQUENCY	50-60 Hz
MAX. SUPPLY CURRENT	2,0 A
MAIN FUSES	T2AH 250 VAC / 5 x 20 mm
SHOCK PROTECTION	CLASS 1, TYPE B (type B equipment provides protection against electric shock by limiting the leakage current and by the provision of a protective earth connection)
Dimensions and weight	
HEIGHT	695 – 730 mm
WIDTH	480 mm
LENGTH	600 mm
NET WEIGHT	23 kg OptoYag&SLT M 21 kg OptoYag M 21 kg OptoSLT M
Environmental conditions – transport and storage	
TEMPERATURE	0°C – 50°C
RELATIVE HUMIDITY	20% - 85% (not condensing)
ATMOSPHERIC PRESSURE	700 hPa – 1060 hPa

Environmental conditions – operation	
TEMPERATURE	20°C – 30°C
RELATIVE HUMIDITY	20% - 85% (not condensing)
ATMOSPHERIC PRESSURE	700 hPa – 1060 hPa

Applies to OptoYag M, OptoSLT M and OptoYag&SLT M laser systems.

5.5 Classification

OptoYag M, OptoSLT M and OptoYag&SLT M fully comply with the requirements of the 93/42/ECC medical directive. They are designed to the generally accepted rules of technology and meet all relevant safety standards. According to 93/42/EEC medical directive, OptoYag M, OptoSLT M and OptoYag&SLT M is classified as follows:

- ❒ **According to the type of protection against electric shock:**
  Equipment energized from an external power source - Class I equipment.
- ❒ **According to the degree of protection against electric shock:**
  Type B applied part.
- ❒ **According to the degree of protection against ingress of water:**
  Ordinary equipment – enclosed equipment without protection against ingress of water.
- ❒ **According to the degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide:**
  Equipment not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- ❒ **According to the method of operation:**
  Continuous operation.

6 Installation

The OptoYag M, OptoSLT M and OptoYag&SLT M are tough and durable instruments, but they contain complex optical and mechanical systems that may be damaged if the unit is mishandled or subject to excessive shock or vibration.

Ensure that the requirements for storage temperature are maintained during storage and transportation (Chapter 5.4).

Optotek is not responsible for any damage caused by mishandling during the use, storage or transportation.

Optical paths of the system may be shifted due to physical shock during the transportation. Transport the system as gently as possible.

The initial installation of the equipment must be performed by an authorized Optotek technician. Installation procedure is described in OptoYag M, OptoSLT M and OptoYag MSLT Service Manual.

The authorized technician has to verify that the illumination, aiming beam and therapy laser beam are at the center of the visual field prior to the first use of the system.

Due to the complexity of the instrument, installation and/or calibration procedures must be performed by a trained and properly qualified Optotek Distributor only!

It is NOT allowed that user himself installs the system (Warranty is voided and Optotek liability ceased)!

It is necessary to fill in Laser system installation record in details and stamp it. A copy of this record must be sent to Optotek within 14 days after the date of installation. Warranty becomes effective after a receipt of the installation record!!!

The authorized technician shall also explain how to operate the system.

6.1 Unpacking the system

Check the content of the package. **Notify the manufacturer or authorized representative of any missing parts!**

The basic set contains:

Item/Description	Qty.	OptoYag M	OptoSLT M	OptoYag&SLT M
e-SlitLight with integrated YAG head	1 pc	✓		✓
e-SlitLight	1 pc		✓	
SLT laser head	1 pc		✓	✓
User interface	1 pc	✓	✓	✓
Power supply console	1 pc	✓	✓	✓
Focus stick	1 pc	✓	✓	✓
Focus stick cover	1 pc	✓	✓	✓
Chin rest	1 pc	✓	✓	✓
Chin rest paper	1 set	✓	✓	✓
Spare main fuse	2 pcs	✓	✓	✓
Rail cover	2 pcs	✓	✓	✓
Mains power cord, EU plug	1 pc	✓	✓	✓
Switch key	2 pcs	✓	✓	✓
Interlock connector	1 pc	✓	✓	✓
Safety goggles	1 pc	✓	✓	✓
Dust cover	1 pc	✓	✓	✓
Thermal paper	1 pc	✓	✓	✓
User's Manual	1 pc	✓	✓	✓
Final Inspection Record	1 pc	✓	✓	✓

6.2 Connection to mains

OptoYag M, OptoSLT M and OptoYag&SLT M are classified as mains operated equipment. Make sure that the mains supply specifications comply with the ones declared in this Manual (compliance label).
Mains plug is considered as disconnecting device. Make sure that mains socket outlet, where the device is connected, is easily reachable by the operator.

To avoid risk of electric shock, the system should be connected to the mains supply with protective earth.

- ❒ Ensure that the main switch ON/OFF is turned off.
- ❒ Connect the mains cable to the system mains socket located on the rear side of the power supply console (Figure 3.5; Figure 6.1).
- ❒ Plug the other end of the mains cable to an electrical outlet.

Figure 6.1: *Mains power supply cable and system mains socket*

Disconnect the system from the mains supply before any maintenance procedure is performed!

6.3 Connection of remote interlock

- ❒ Connect the remote interlock to the safety interlock socket located on the power supply console.
- ❒ If the remote interlock is not connected, "DOOR INTERLOCK" message is displayed on the user interface screen.

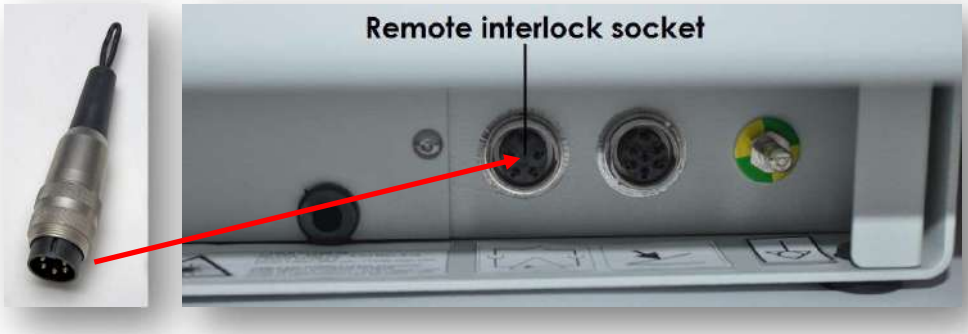


Figure 6.2: *Remote interlock connector and interlock/warning light socket*

6.4 Connection of warning light illumination laser sign and doorswitch

- ❒ The warning light, if used, is connected to the same connector as the remote interlock. Warning Light Illumination Laser Sign and Doorswitch set can only be used with the systems.
- ❒ ***The installation of the warning light should be performed by a trained technician only.***
- ❒ Detailed instructions on warning light installation are provided with the Warning Light Illumination Laser Sign and Doorswitch set.

6.5 Connection of the footswitch

- ❒ The footswitch is available optionally.
- ❒ Connect the footswitch by screwing the footswitch connector screw nut into the "FOOTSWITCH" socket (Figure 3.5; Figure 6.3)

Figure 6.3: *Connecting the footswitch to the footswitch plug*

6.6 Environmental conditions

The device is intended for use in professional healthcare environment – CISPR 11 class A.

- ❒ Do not start the device for at least 8 hours if it has been relocated from the place with a lower (higher) temperature than the lowest (highest) optimal operating temperature.
- ❒ Do not use in rooms or areas with high intensity of electromagnetic disturbances (e.g. RF shielded room of an ME system for magnetic resonance or near active HF surgical equipment).

Refer to the Chapter 5 for optimal operating conditions. Failing to follow those instructions may lead to the system damage!

7 System operation

This chapter describes operational warnings and instructions for starting, operating and shutting down the OptoYag M, OptoSLT M and OptoYag&SLT M systems. It should be carefully read prior to the first use of the instrument.

The instrument must be cleaned and disinfected before treatment.
Refer to Chapter 9 for details.

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

7.1 Starting the device

The following instructions assume the device has been correctly installed, set up and commissioned. It also assumes that all persons attending the treatment area are familiar with all safety instructions and issues as required by safety regulations.

7.1.1 Pre-start checks

Carry out the following checks before using the instrument:

- ❒ Ensure that all persons attending (except the ophthalmologist and patient) are wearing adequate laser safety spectacles;
- ❒ Ensure that the emergency stop button is released;
- ❒ Ensure that the safety interlock, if installed, is connected and the interlock switch is closed.

7.1.2 Laser trigger button and footswitch

The laser can be triggered either by the laser pushbutton on the joystick or by a footswitch (available optionally).

If the footswitch is used to activate the laser:

- ❒ Ensure that it is properly connected to the system (refer to the Figure 6.3);
- ❒ Ensure that it is convenient positioned on the floor;
- ❒ Prevent the accidental operation by other persons attending the treatment.

7.1.3 Starting up

After the pre-start checks, start the system:

- ❒ Connect the device to the mains power supply;
- ❒ Insert the key into the keyswitch and keep it in the OFF position;
- ❒ Turn the power supply ON (main ON/OFF switch);
- ❒ Turn the switch key to the YAG or SLT position.

When the system is turned on:

- ❒ The green e-SlitLight switch/indicator lights to indicate that the system is active.
- ❒ The user interface LCD lights up and displays a message "System initialization".
- ❒ The system then performs a sequence of self tests to check safety circuits and laser.

Do not press any key during the self-test!

- ❒ The "STANDBY" indicator on the user interface is lit up to indicate that the system is in the default "STANDBY" mode.
- ❒ If the **SLT treatment laser** is selected, the user interface LCD displays a message "Warning up – Please wait". The message disappears automatically after 50 seconds. To skip the message, press the RESET button.

It is strongly recommended to wait that the message disappears automatically at least at the initial start up of the system!

- ❒ The user interface LCD indicates the selected treatment laser (YAG or SLT).
- ❒ The slit lamp is activated and available for use.
- ❒ The red laser aiming beam of the selected laser is turned on automatically.

If the system finds any non-conformity during the self-test or operation, the laser beam is disabled and an error message is displayed on the user interface screen.

- ❒ Turn the unit off, wait 30 seconds and turn the unit on.
- ❒ If the self-test passes after the second start up, the condition was just temporary and the system is ready for use.
- ❒ If the error code continues to show up on the display, refer to the Subchapters 10.1 and 10.2 for the list of errors and warning messages.

If you cannot solve the problem, contact your Optotek representative.

- ❒ Fix a disposable chin rest paper on the chinrest. The chin rest paper should be replaced with a fresh one after each patient.
- ❒ The system is now ready to be used.

7.2 Laser emergency stop

In case of emergency, press the red mushroom-shaped emergency stop button shut down the laser.

- ❒ To reset the emergency stop, rotate the button clockwise.
- ❒ Turn the key first to the OFF position and then back to the ON position.
- ❒ Restart the system as described in the Subchapter 7.1.3.

7.3 Normal shut down

To shut the system down in non-emergency situation:

- ❒ Press the READY/STANDBY button to select the "STANDBY" mode.
- ❒ Turn the key to OFF position.
- ❒ Turn the power supply OFF (main switch ON/OFF).
- ❒ Remove the key from the keyswitch to prevent unauthorized use of the system.

If the device is not be used for a longer time, it is recommended to disconnect it from the mains supply, and cover it with dust cover.

7.4 System operation

It is recommended that the steps described in this chapter are done before positioning the patient.

7.4.1 Operating the slit lamp

If only the slit lamp is to be used, turn ON the slit lamp by pressing e-SlitLight ON/OFF switch on the power supply console. Switch green indicator lights up indicating that the slit lamp is active.

When the laser is switched on, the slit lamp turns on automatically.

Figure 7.1: *Slit lamp LCD display*

The LCD screen on the user Interface lights up and displays the following information:

Display	Description
e-SlitLight	Logo e-SlitLight indicates that the system is in the slit lamp mode of operation. All functions of the laser are disabled.
INTENSITY	Indicates the intensity of the slit lamp light source. Rotate the illumination intensity knob (Figure 3.10) to adjust the intensity from 0 (off) to 100% (maximum).
SLEEP MODE PRESS ANY KEY	Slit lamp is in sleep mode. Slit lamp is automatically switched off.

Adjusting the table height (lifting mechanism optional)

The table height is electronically adjustable.

❒ Use the "UP/DOWN" switch on the motorized lifting column to adjust the table.

Adjust the table height carefully in order to avoid any damage to the patient or operator.

To enable both ophthalmologist and patient to be comfortable during the procedure:

❒ Adjust the height of the ophthalmologist's and patient's chairs.

❒ Adjust the table height if necessary.

❒ Adjust the chinrest support by rotating the chin rest height adjustment knob (Figure 3.10).

Adjusting the eyepieces

The eyepieces are fitted with eyecups that can be folded back if the ophthalmologist wears spectacles.

Set the magnification changer to 16 x.

❒ Remove the cover of focus stick receptacle hole (Figure 7.2) and insert the focus stick into the receptacle hole.

❒ Make the adjustment of eyepiece diopter and interpupillary distance in order to obtain the clearest view of the target on focusing stick.

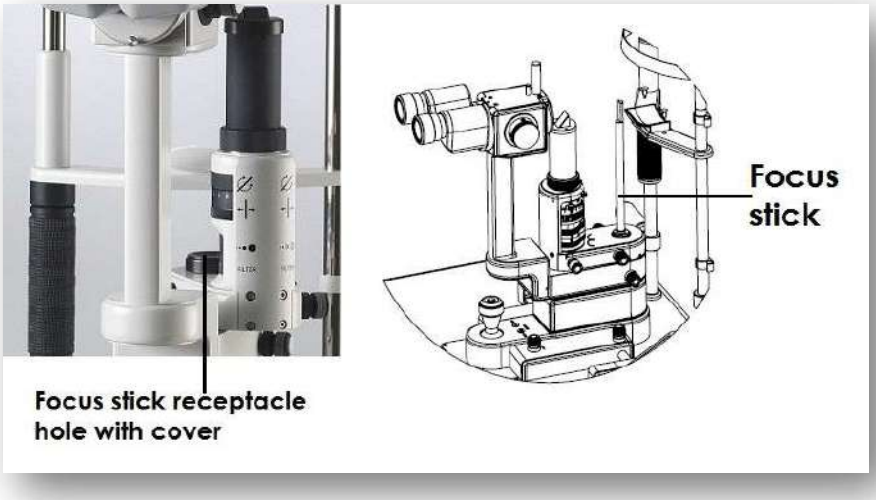


Figure 7.2: *Attachment of focusing rod*

Positioning the slit lamp

❒ Position the slit lamp before the patient is seated, and make fine adjustments afterwards if necessary.

❒ The slit lamp microscope and laser head can be moved backwards, forwards, left and right by manually moving the complete assembly to the desired position.

❒ Make the fine adjustment of position by moving the joystick in any direction.

❒ Rotate the joystick to adjust the height.

Sleep mode

If the slit lamp is not in use for 10 minutes (no keys pressed, no movement is detected), system automatically enters the Sleep Mode. Slit lamp light source intensity is decreased to 0%. When any key on user interface keyboard is pressed, system returns to the "STANDBY" mode.

7.4.2 Operating the YAG laser

When the YAG laser is turned on, the slit lamp automatically turns on. Refer to the Subchapter 7.4.1 for the instructions on how to operate the slit lamp.

- ❒ Turn the switch key to the right position (YAG) to operate the laser system in the YAG treatment mode (refer to the Subchapter 7.1.3).
- ❒ The user interface LCD screen displays the YAG parameters (Figure 7.3).
- ❒ The "STANDBY" indicator on the user interface is illuminated indicating that the system is in the default "STANDBY" mode.

Ensure that the YAG aiming beam is visible!

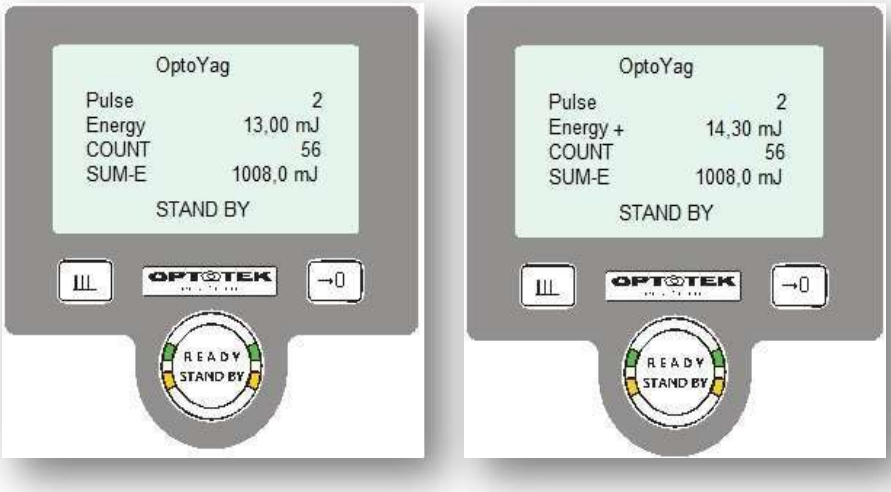


Figure 7.3: *User interface LCD display in YAG laser operation*

The LCD display on the user interface shows the following information:

Display	Description
OptoYag M	The "OptoYag M" sign shows that the system is in the YAG laser mode. All functions of the SLT laser are disabled (in OptoYag&SLT M system).
ENERGY	Laser energy selected by using the energy selection knob is displayed.
FINE ENERGY SETTING (ENERGY +/-)	Energy + /- shows the set energy increased/decreased by 10%. This fine energy setting is performed by depressing fine energy setting buttons (Figure 6.5).
PULSE	Indication of the burst mode: 1, 2 or 3 pulses per burst.
COUNT	Laser pulse counter.
SUM-E	Total energy of the triggered laser pulses.
STANDBY (READY)	Indicates the system mode – "STANDBY" or "READY" mode.

Display	Description
SLIT INTERLOCK	Light tower is in the front of the main objective. Rotate the tower approximately 10-12° either side of the center. The message disappears automatically.
SLEEP MODE PRESS ANY KEY	System is in sleep mode. Slit lamp is switched off. Aiming laser is turned OFF. Press any key to exit the sleep mode.

Setting the energy

- ❒ Rotate the energy selection knob on either side of the laser head to set the desired energy.
- ❒ The set energy in mJ is displayed on the user interface LCD screen.
- ❒ Start the treatment with lower energy and gradually increase its value if required.

Selecting the number of pulses

There are three burst modes available: single, double or triple burst mode. Single pulse mode is a default setting.

- ❒ Select the burst mode by depressing the burst mode selection button on the user interface (Figure 3.6).
- ❒ Each press of this button increases the number of pulses per burst by one.
- ❒ The selected mode is displayed on the screen (Figure 7.3).
- ❒ Press the button in triple burst mode to return to the single one.
- ❒ The energy displayed is the total cumulative energy of all pulses within the burst.

Offset (Focal Shift)

Set the desired offset by rotating the knob located on each side of the YAG laser head (Figure 3.7).

Posterior offset: marked with "**P**" on the knob and adjustable in two steps - 150 and 300 µm.
Anterior offset: marked with "**A**" and allows the setting of 150 µm anterior.
Offset 0: marked with "**0**".

Figure 7.4: *Offset knob*

The pilot beam is blinking when the anterior offset is set. To stop blinking, confirm the anterior setting by triggering the laser pulse or switching the offset knob to "0" or posterior position.

Aiming beam and slit lamp illumination

The aiming beams focus is set accurately when two red spots merge into a single spot. ***Carefully manipulate the joystick until two aiming spots coincide!***

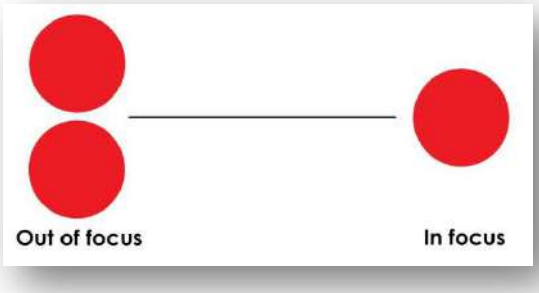


Figure 7.5: *Aiming beam focusing*

- ❒ Set the optimal aiming beam intensity by rotating the aiming beam intensity knob (Figure 3.7).
- ❒ Set also the optimal illumination intensity by rotating the illumination intensity knob (Figure 3.10).

To protect the patient from possible retinal damage, use the lowest practical slit lamp illumination and aiming beam intensity during treatment.

Selecting READY mode

- ❒ Press the Ready/Standby button on the user interface to enter the "READY" mode.
- ❒ If a message "Slit Interlock" is displayed on the user interface LCD, rotate the illumination tower approximately 10 - 12° either side of the center. The message disappears automatically when the illumination tower does not interfere with the main objective.
- ❒ The green laser ready indicator on the user interface lights indicating that the system is ready for performing the treatment.
- ❒ To return to the "STANDBY" mode, press the Ready/Standby button and wait for the standby indicator to illuminate.

Firing the laser

Ensure that the YAG mode is selected before proceeding with treatment. Mis-selection of the laser mode may result in a serious eye damage (applies to the OptoYag&SLT M laser system only).

To fire the laser:

- ❒ Ensure that the patient is positioned correctly.
- ❒ Ensure that the proper treatment parameters are set.
- ❒ Ensure that the laser beam is aimed at the target tissue only.
- ❒ Ensure that the system is in the "READY" mode.
- ❒ Press the laser fire switch - either the laser trigger button on the joystick or the footswitch if connected.

The Nd:YAG laser energy is delivered to the treatment site. The energy delivered is measured and displayed on the user interface LCD.

The device delivers the selected number of pulses after pressing of the laser fire switch. The pulse counter and total energy increments after each treatment pulse. Pressing the reset button resets the counter and total energy.

Sleep mode

If the system is not used for 10 minutes (no keys pressed, no movement is detected), the system automatically enters the sleep mode. Slit lamp is switched off and aiming laser is turned off.

Press any key on the user interface to return the system to the "STANDBY" mode.

7.4.3 Operating the SLT laser

When the SLT laser is turned on, the slit lamp automatically turns on. Refer to the Subchapter 7.4.1 for the instructions on how to operate the slit lamp.

- ❒ Turn the switch key to the left (SLT) to operate the laser system in the SLT treatment mode (refer to Subchapter 7.1.3).
- ❒ The user interface LCD screen displays the SLT parameters (Figure 7.6).
- ❒ The "STANDBY" indicator on the user interface is illuminated indicating that the system is in the default "STANDBY" mode.

Ensure that the SLT aiming beam is visible.

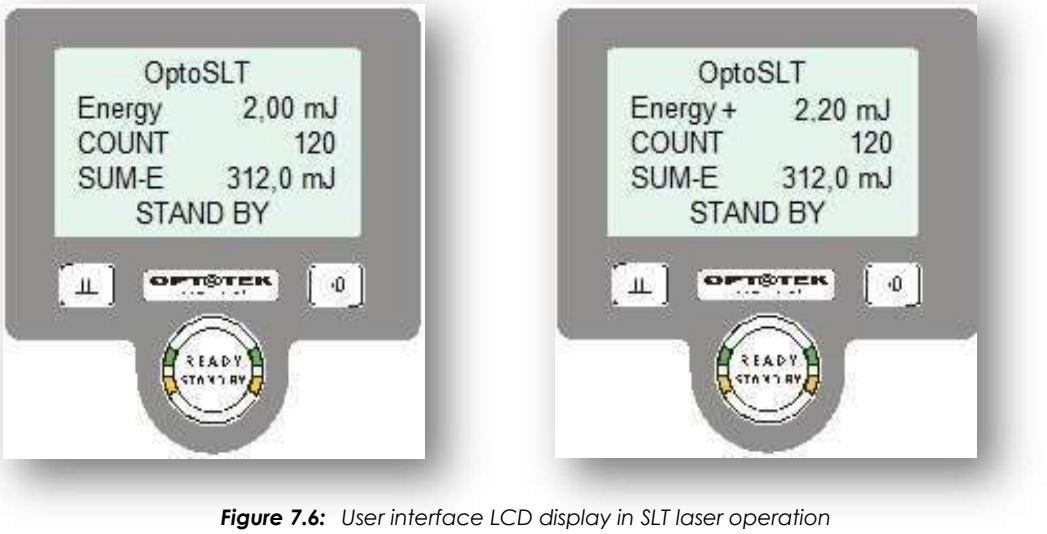


Figure 7.6: *User interface LCD display in SLT laser operation*

The LCD display on the user interface shows the following information:

Display	Description
OptoSLT M	The "OptoSLT M" sign shows that the system is in the SLT laser mode. All functions of the YAG laser are disabled (in OptoYag&SLT M system).
WARNING UP PLEASE WAIT	The SLT laser is warming up. The message disappears automatically after 50 seconds. To skip the message, press the RESET button. It is strongly recommended to wait that the message disappears automatically at least at the initial start up of the system!
ENERGY	Laser energy selected by using the energy selection knob is displayed.
FINE ENERGY SETTING (ENERGY +/-)	Energy +/- shows the set energy increased/decreased by 10%. This fine energy setting is performed by depressing fine energy setting buttons (Figure 3.9).
PULSE	Indication of the burst mode: 1, 2 or 3 pulses per burst.

Display	Description
COUNT	Laser pulse counter.
SUM-E	Total energy of the triggered laser pulses.
STANDBY (READY)	Indicates the system mode – "STANDBY" or "READY" mode.
SLEEP MODE PRESS ANY KEY	System is in sleep mode. Slit lamp light source intensity is decreased to 0%. Aiming laser is turned OFF. Press any key to exit the sleep mode.

Setting the energy

- ❒ Rotate the energy selection knob on either side of the laser head to set the desired energy.
- ❒ The set energy in mJ is displayed on the user interface LCD screen.
- ❒ Start the treatment with lower energy and gradually increase its value if required.

Aiming beam and slit lamp illumination

The aiming beam is fixed in the center of the treatment beam and needs no focusing.

- ❒ Set the optimal aiming beam intensity by rotating the aiming beam intensity knob (Figure 3.9).
- ❒ Set also the optimal illumination intensity by rotating the illumination intensity knob (Figure 3.10).

To protect the patient from possible retinal damage, use the lowest practical slit lamp illumination and aiming beam intensity during treatment.

Selecting READY mode

- ❒ Press the Ready/Standby button on the user interface to enter the "READY" mode.
- ❒ The green laser ready indicator on the user interface lights indicating that the system is ready for performing the treatment.
- ❒ To return to the "STANDBY" mode, press the Ready/Standby button and wait for the standby indicator to illuminate.

Firing the laser

Ensure that the SLT mode is selected before proceeding with treatment. Mis-selection of the laser mode may result in a serious eye damage (applies to the OptoYag&SLT M laser system only).

To fire the laser:

- ❒ Ensure that the patient is positioned correctly.
- ❒ Ensure that the proper treatment parameters are set.
- ❒ Ensure that the laser beam is aimed at the target tissue only.
- ❒ Ensure that the system is in the "READY" mode.
- ❒ Press the laser fire switch - either the laser trigger button on the joystick or the footswitch if connected.

The SLT laser energy is delivered to the treatment site. The energy delivered is measured and displayed on the user interface LCD.

The device delivers a single pulse after pressing the laser fire switch. The pulse counter and total energy increments after each treatment pulse. Pressing the reset button resets the counter and total energy.

Sleep mode

If the system is not used for 10 minutes (no keys pressed, no movement is detected), the system automatically enters the sleep mode. Slit lamp light source intensity is decreased to 0% and aiming laser is turned off.

Press any key on the user interface to return the system to the "STANDBY" mode.

8 Recommended treatment protocol

Optotek does not advise physicians on how to treat their patients. This guide provides the information you may find helpful in establishing your own treatment protocols. Each practitioner should realize that light treatment is not an exact science and although all guidelines are properly followed, problems may occur.

8.1 OptoYag M treatment

The OptoYag M is intended for photodisruption of the eye tissues. Its indications for use include:

- ❒ Posterior capsulotomy (photodistruption of the posterior capsule);
- ❒ Iridotomy (photodisruption of the iris).

The OptoYag M treatments are painless outpatient procedures.

8.1.1 Posterior capsulotomy

Laser posterior capsulotomy (YAG laser capsulotomy) also referred to as secondary cataract is a noninvasive procedure performed on the eye to remove opacification that develops on the posterior capsule of the lens after extraction of a cataract. Posterior capsule opacification is the most common complication after the cataract surgery.
Laser assisted posterior capsulotomy significantly improves visual acuity and contrast sensitivity, and decreases glare.

Contraindications

- ❒ Irregularities of the cornea;
- ❒ Active inflammation in the eye;
- ❒ Extensive corneal dystrophy;
- ❒ Macula swelling;
- ❒ Glass IOLs;
- ❒ Uncontrolled IOP.

Preoperative patient preparation

- ❒ Pupil dilation;
- ❒ Topical anesthesia (Lidocaine eye drops).

Treatment procedure

- ❒ Use CGPL lens (essential for focusing in patients with significant corneal astigmatism).
- ❒ Make a circular or cruciate pattern in the posterior capsule.
  Circular pattern prevents lens pitting the optic in the central visual axis, but creates a large floater. Cruciate pattern minimizes the risk of a large floater, but careful aiming of the laser is required to avoid pitting the center of the lens optic.
- ❒ Aim for the capsulotomy size larger than undilated pupil diameter.
- ❒ Use topical anti-glaucoma eye drops only in high-risk patients.
- ❒ No need to follow-up but inform patients about symptoms of adverse effects.

Treatment parameters

- ❒ Set the offset to P150 (150 µm behind intraocular lens – IOL)
- ❒ *Such setting protects against IOL pitting.*
- ❒ Select a single pulse mode.
  Using double or triple pulse mode may increase the probability of damage to the IOL rapidly.
- ❒ Set the energy to the lowest possible effective level.
  It is recommended that initial energy setting is 1,3 – 1,6 mJ. The energies higher than 5 mJ require extreme caution.
- ❒ Focus the beam in the vitreous body just behind the intraocular lens and the posterior capsule.
- ❒ The procedure requires 15 to 70 pulses (depending on the pattern).

Post-treatment

It is recommended that a patient remains in the office for one to four hours in order to check the intraocular pressure. Topical anti-glaucoma eye drops may be used for a week, if the intraocular pressure increases significantly after the treatment.
Cycloplegic agents to keep the pupil dilated and to prevent spasm of the muscles in the iris, and corticosteroids to reduce inflammation may also be prescribed for up to a week.
The patient can resume normal daily activities after the procedure.

Adverse effects

Although the Nd:YAG laser photodisruption is a safe and effective procedure, it may be associated with some adverse effects:

- ❒ Damage to intraocular implant;
- ❒ Displacement of IOL into eye's vitreous (very rare);
- ❒ Macular edema;
- ❒ Macular holes;
- ❒ Corneal edema;
- ❒ Inflammation of the iris;
- ❒ Retinal detachment;
- ❒ Increased intraocular pressure, glaucoma (usually short-term effect that can be controlled with anti-glaucoma drops).

8.1.2 Iridotomy

Laser iridotomy is a surgical procedure performed to treat angle closure glaucoma.

Contraindications

- ❒ Edematous or opacified cornea;
- ❒ Completely closed angle;
- ❒ Angle closed due to inflammation (uveitis or neovascular glaucoma).

Preoperative patient preparation

- ❒ Pilocarpine - stretches the iris, reduces iris thickness, facilitates perforation);
- ❒ Oral or intravenous acetazolamide - reduces acute IOP spikes after procedure;
- ❒ Topical alpha 2 agonist (apraclonidine or brimonidine) – reduces acute IOP spikes after procedure and decreases bleeding;
- ❒ Topical anesthesia (Lidocaine eyedrops).

Treatment procedure and parameters

- ❒ Set the offset to zero.
- ❒ Set the energy to the lowest possible effective level.
  The energies from to 1 to 6 mJ are most commonly used for this procedure.
- ❒ Focus the beam within the iris stroma.
- ❒ When the opening has been made, enlarge it horizontally to obtain an adequate size (200-500 µm).
- ❒ Patency must be confirmed by direct visualization of the lens through the iridotomy.

Post-treatment

It is recommended that a patient remains in the office for one to four hours in order to evaluate the intraocular pressure. If the intraocular pressure increases significantly after the treatment topical anti-glaucoma eye drops may be applied until the IOP is lowered.
Corticosteroids to reduce inflammation may also be prescribed.
The patient can resume normal daily activities after the procedure.

Adverse effects

Although the Nd:YAG laser iridotomy is a safe and effective procedure, it may be associated with some adverse effects:

- ❒ Increase in intraocular pressure (usually, the IOP spike is transient – 24 hours after the treatment);
- ❒ Anterior uveitis or inflammation within the eye;
- ❒ Swelling, abrasions, or opacification of the cornea;
- ❒ Damage to the cornea endothelium;
- ❒ Bleeding of the iris;
- ❒ Macular edema.

8.2 OptoSLT M treatment

The OptoSLT M is intended for selective laser trabeculoplasty, an advanced treatment of open-angle glaucoma.
Selective Laser Trabeculoplasty (SLT) is noninvasive primary or secondary treatment of increased intraocular pressure. It employs short pulses of specific wavelength that selectively target the melanin-containing cells in the trabecular meshwork while preserving the adjacent non-pigmented eye structures. Low-energy laser irradiation evokes cytokines response what consequently activates the macrophages which clear the damaged cells. Increased trabecular meshwork porosity restores balanced aqueous outflow and lowers the intraocular pressure.

SLT treatment advantages:

- ❒ Equivalent intraocular pressure reduction to ALT (Argon Laser Trabeculoplasty);
- ❒ Minimal damage to the trabecular meshwork;
- ❒ Safe even when repeated;
- ❒ Reduced need and number of medications;
- ❒ Suitable for patients with poor compliance.

Contraindications

The SLT treatment is contraindicated in the following conditions:

- ❒ IOP over 25 mmHg;
- ❒ Reduction of IOP for more than 25%;
- ❒ Juvenile glaucoma;
- ❒ Primary or secondary narrow-angle glaucoma;
- ❒ Inflammatory or uveitic glaucoma;
- ❒ Any disease process or malformation that blocks the angle;
- ❒ Post-traumatic glaucoma.

Preoperative patient preparation

- ❒ A topical alpha-agonist (brimonidine 0,2%) can be used to prevent early postoperative IOP spikes.
- ❒ Topical administration of pilocarpine 2% drop for pupil constriction.
- ❒ Topical anesthesia (proparacaine 0,5%).

Treatment procedure and parameters

- ❒ Use contact SLT gonioscopic lens to focus laser aiming beam to the trabecular meshwork.
- ❒ Start with the energy of 0,8 mJ.
  The energy *may be decreased in eyes with heavily pigmented trabecular meshwork (0,6 mJ)*.
- ❒ Adjust the energy until the treatment endpoint is reached (small "champagne bubbles" are observed).
- ❒ Reduce the energy by 10% and continue without a visible endpoint.
- ❒ Re-evaluate the energy if the trabecular meshwork pigmentation varies in the treatment area.
- ❒ Apply approximately 50 adjacent, non-overlapping spots to cover 180° of trabecular meshwork, or 100 spots to cover full angle circumference (360°).
  Overlapping application of the same number of SLT spots results in poorer IOP response compared with non-overlapping application.
- ❒ The procedure takes 5(180°) or 10 minutes (360°).

Post-treatment

- ❒ After the procedure, patients usually continue to take their preoperative glaucoma medications until the IOP is re-evaluated.
- ❒ Prescribe additional acetazolamid 2x 125 mg p.o. the first day.
- ❒ Non-steroidal or corticosteroid drops are used for for 3-5 days (1 mg/ml dexamethazone 3-4/day).

Adverse effects

The SLT treatment may cause some mild and transient side effects, such as:

- ❒ Transient IOP elevation;
- ❒ Mild anterior chamber inflammation;
- ❒ Mild discomfort during the procedure and tender eyes;
- ❒ Bleeding and hyphema;
- ❒ Choroidal effusion;
- ❒ Macula edema;
- ❒ Corneal haze;
- ❒ Shifts in refractive error (both myopic and hyperopic).

9 Maintenance

The maintenance procedures described hereafter apply to all three models - OptoYag M, OptoSLT M, OptoYag&SLT M.

9.1 Preventive maintenance

The annual preventive maintenance is mandatory. It is administered by the authorized Optotek representative.
The preventive maintenance procedure consists of complete recalibration of the system, and check of the ground resistance and earth leakage current (in accordance with IEC 60601-1).

9.2 Routine maintenance

The devices have been designed to provide trouble-free operation with minimal downtime. As a result, just a few maintenance procedures are required to be done by the user.

There are five routine maintenance tasks:

- ❒ cleaning the system,
- ❒ cleaning the external optics,
- ❒ verifying the aiming accuracy,
- ❒ checking the laser beam mode,
- ❒ arranging an annual maintenance visit.

Protect the system with its dust cover when it is not in use in order to keep the optical components free of dust and other contaminants.

9.2.1 Cleaning the system

The console and slit lamp should be kept clean and free of dust and grime. Cover the system with a dust cover when not in use. Use a cloth dampened with detergent to clean the external surface (except the optics) of the device.

Do not use the abrasive cleaners.
Do not use the solvents to clean the devices.

9.2.2 Cleaning the external optics

The laser head objective lens and the oculars must be kept free of dust, fingerprints and any other contamination otherwise the performance of the laser system may be compromised.

- ❒ Periodically inspect and clean the optics.
- ❒ If any scratch is visible, stop using the system and call your Optotek representative.
- ❒ The internal optics must be cleaned by your Optotek representative only!

Cleaning of the external optics requires:

- ❒ lint free optical tissues (available from a photographic store),
- ❒ cotton swabs or Q-tips,
- ❒ pure or AR grade ethanol or methanol.

Only ethanol and methanol should be used to clean the optics. Do not use them to clean the external surfaces of the console or the slit lamp.

Cleaning procedure:

- ❒ Turn off the system power.
- ❒ Moisten the optical tissue or Q-tip with the solvent and gently wipe it across the optical surface in linear strokes.
- ❒ Use one tissue or one Q-tip per wipe, then discard it, and use a fresh one for the next wipe.

Never use dry swabs or tissues to clean optics. They may damage the optical coatings or scratch the surface.

If any problem occurs during the cleaning procedure, contact your Optotek representative immediately!

9.2.3 Cleaning the areas of patient contact

The areas of patient contact include chinrest, forehead rest, table, and chinrest handles.

- ❒ Thorough cleaning of all patient contact areas is strongly recommended before every new patient in order to exclude the possibility of cross-contamination.
- ❒ To prevent risk of infection, wipe the areas of patient contact with a suitable, hospital-grade liquid cleaning agent (disinfectant) that is non-corrosive, non-toxic and low in residue.
- ❒ Disposable chin rest paper can also be used. The chin rest papers are supplied with the device, but can be ordered separately as well.

9.2.4 Verifying the YAG aiming accuracy

All personnel attending this procedure should wear safety goggles!

Correct optical alignment is critical for accurate aiming of the system. This procedure should be performed at least every three months or when considered necessary by the user.

The procedure steps:

- ❒ Adjust the eyepieces with the help of focus stick as per Figure 7.2.
- ❒ Remove the focus stick.
- ❒ Affix the cellophane (adhesive) tape to the forehead rest and chinrest (Figure 9.1).
- ❒ Attach a piece of photographic paper to the cellophane tape (Figure 9.1).

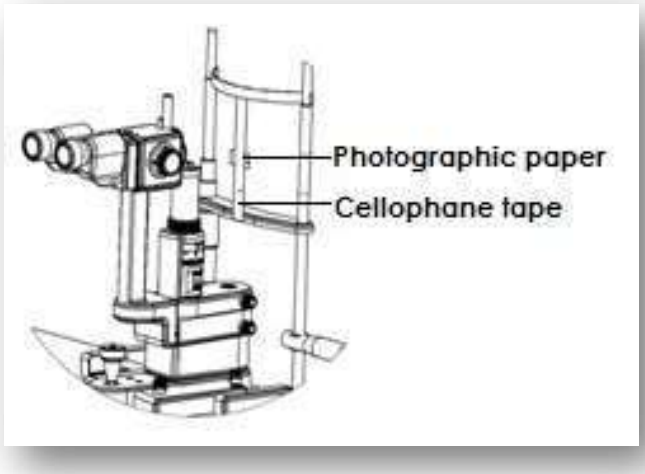


Figure 9.1: *Cellophane tape and photographic paper*

Perform the following procedure:

- ❒ Turn on the YAG laser mode to activate the YAG aiming beam.
- ❒ Adjust the slit width to full circle illumination and low intensity.
- ❒ Position the slit lamp so that the aiming beams converge to form one spot on the photographic paper attached to the tape.
- ❒ Set the posterior offset to "0".
- ❒ Enter the "READY" mode.
- ❒ Select minimum energy and check that the aiming beams are still converged to one spot.
- ❒ Fire the laser once onto the photographic paper.
- ❒ Inspect the burn mark through the binoculars to check that the burn mark on the paper is concentric with the aiming beam spot.
- ❒ Repeat the test if necessary on another area of the photographic paper.

The photographic paper and the focus stick are both included in the basic set of the system, and should be always with the system.

If the aiming spots cannot be made to coincide, do not use the system on patients.

Contact your Optotek representative for system realignment!

If the aiming spot is not present or its intensity is reduced or it looks diffused, the optical delivery system is probably misaligned probably indicates improper working of the system.

Do not use the system on patients!

Contact your Optotek representative for system realignment!

If the aiming beam is not centered in the burn mark, do not use the system on patients.

Contact your Optotek representative for system realignment!

9.2.5 Verifying the SLT aiming accuracy

All personnel attending this procedure should wear safety goggles!

Correct optical alignment is critical for accurate aiming of the system. This procedure should be performed at least every three months or when considered necessary by the user.

Perform the following procedure:

- ❒ Adjust the eyepieces with the help of focus stick as per Figure 7.2.
- ❒ Attach a piece of photographic paper to the focus stick (Figure 9.2).
- ❒ Turn on the SLT laser mode to activate the SLT aiming beam.
- ❒ Adjust the slit width to full circle illumination and low intensity.

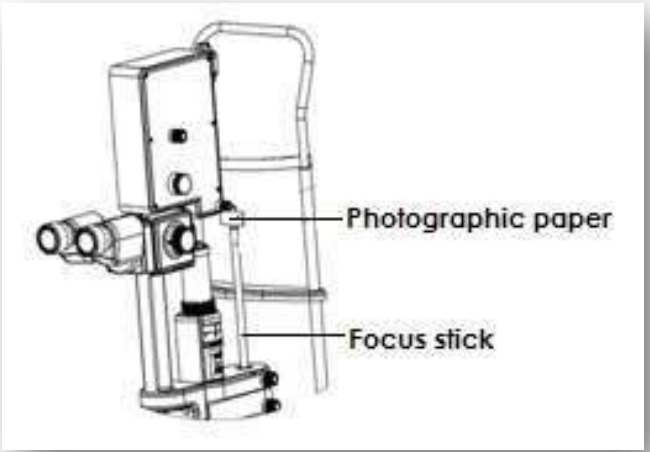


Figure 9.2: *Fixation of the photographic paper to the focusing rod*

- ❒ Enter the "READY" mode.
- ❒ Select minimum energy.

- ❒ Fire the laser once onto the photographic paper.
- ❒ Inspect the burn mark through the binoculars to check that the burn mark on the paper is concentric with the aiming beam spot.
- ❒ Repeat the test if necessary on another area of the photographic paper.

The photographic paper and the focus stick are both included in the basic set of the system, and should be always with the system.

If the aiming spots cannot be made to coincide, do not use the system on patients.

Contact your Optotek representative for system realignment!

If the aiming spot is not present or its intensity is reduced or it looks diffused, the optical delivery system is probably misaligned probably indicates improper working of the system.

Do not use the system on patients!

Contact your Optotek representative for system realignment!

If the aiming beam is not centered in the burn mark, do not use the system on patients.

Contact your Optotek representative for system realignment!

9.3 Verification and calibration procedure

The system must be calibrated whenever any vital module of the system is changed.

- ❒ The system must be calibrated annually. The calibration is usually performed during the annual maintenance of the system.

Calibration must be performed by a qualified Optotek representative!

Adjustment by any other than Optotek trained service engineer voids any existing warranty on the system!

- ❒ Any equipment/tool used to calibrate the laser energy must be calibrated in accordance to ISO 10012 standard.

9.4 Service and annual maintenance

The devices must be maintained, serviced, repaired or modified by authorized persons only.

Contact your local Optotek representative in case of any problems with the device.

Any unauthorized servicing or device modification voids the warranty on the system and ceases Optotek liability.

Contact your local Optotek representative at least once a year to perform a maintenance visit and confirm the correct operation of your system.

Each service or maintenance procedure should be recorded in the laser maintenance/service record contained hereafter.

SYSTEM MODEL: _____

SYSTEM SERIAL NUMBER: _____

Laser maintenance/service record:

SERVICE DATE	AUTHORIZED TECHNICIAN	TECHNICIAN SIGNATURE

The system is programmed to display a warning message requiring the owner to arrange the annual maintenance of the system.

Figure 9.3: *Laser maintenance message*

Inform your local Optotek representative of this message.

Press any key on the user interface to skip the message and continue to use the system.

9.5 Product lifetime

The devices contain no disposable parts. Their declared lifetime is at least seven (7) years from the date of manufacture. The systems are of modular construction therefore the correct operation can be maintained by parts replacement. If the system is no longer in use, it should be disposed as described in the Chapter 9.6.

9.6 Product disposal

The information contained in this Chapter is provided to comply with the European Union Waste Electrical and Electronic Equipment (WEEE) directive 2002/96/EC.

The devices contain no toxic or radioactive elements that would adversely affect a dismantler or the area of disposal. However, the product is largely non-biodegradable and recycling of the base materials is recommended.

Contact the local authorities to determine the correct method of disposal.

The following list indicating the composition of the major elements of the devices assists the recycling of the devices.

Base material	Component parts
Steel	Power supply console / lifting column Stand base Chinrest posts and pillars Axis and bearings
Copper	Wiring
Aluminium	Laser head body Slit lamp body Slit lamp cross-slide Knobs
Processed wood (Particle board)	Table
Plastic	Laser head covers User interface Rail covers
Glass	Optics within laser and optics bench Optics within slit lamp

9.7 Warranty information

Consult your Optotek representative for warranty details!

10 Troubleshooting guide

If any problem occurs during the installation or operation of the system this troubleshooting guide may be of assistance.

Fault	Probable cause	Action required
Does not start up when switched on	Power cable not connected No mains power Emergency stop button is pushed in. Main ON/OFF switch on is turned OFF Blown fuse Protective cover of console internal connectors is opened	Check the power cable Check power appliance Rotate the switch clockwise Turn switch to ON position Check and replace fuses Close protective cover of console internal connectors
Low aiming beam intensity when set at maximum intensity	Dirty optics	Clean optics
Low treatment beam effect	Dirty optics	Clean optics
No slit lamp illumination	Slit lamp illumination malfunction	Contact your Optotek representative!

10.1 Warning messages

Several safety sensors have been implemented to monitor the system. If any sensor detects a faulty situation, a warning message is displayed on the user interface display. The system is automatically locked in the STANDBY mode. After the faulty situation is corrected, the warning message disappears and the system operation returns to normal.

List of warning messages

Display	Cause	Action required
OUTPUT MIRROR INTERLOCK	SLT output mirror not in the correct position	To use the SLT laser: Rotate the SLT output mirror to working position To use the YAG: rotate the SLT output mirror to closed position
OptoSLT **WARMING UP** **PLEASE WAIT** **SKIP**	The SLT laser is warming up. The procedure takes 50 seconds.	Press the RESET (Skip) button to skip it.
FILTER INTERLOCK	ENERGY rotation knob is not in the defined position	Rotate ENERGY knob to the fixed position ("to feel click")
KNOB INTERLOCK	FOCUS rotation knob is not in the defined position	Rotate FOCUS knob to the fixed position ("to feel click")

Display	Cause	Action required
SLT HEAD INTERLOCK	SLT laser head is not attached properly to the Microscope	Attach the SLT laser head properly
SLIT INTERLOCK	Light tower is in the front of the main objective	Remove the light tower
DOOR INTERLOCK	Door interlock switch is opened	Connect the short circuit interlock switch Close room door in case of a door interlock switch
SLEEP MODE **PRESS ANY KEY**	System was not used for 10 minutes	Press any key on the user interface
OptoYag (or OptoSLT) **JOYSTICK** **INTERLOCK** **STAND BY**	The laser trigger button was pressed in the "STAND BY" mode.	The message disappears automatically after 2 second.

10.2 Error messages

The system microprocessors monitor all important system components. If an irregularity is found during operation the user interface is disabled and displays an error message. The footswitch and/or joystick laser trigger button are disabled and the unit defaults to the "STANDBY" mode.

If the error occurs, turn the system off, wait 30 seconds and turn it on again. If the error code disappears and the system functions normally, the condition was temporary and the system may be used as usual. If the same error code appears again, do not use the system.

Contact your local Optotek representative!

The system will not accept operator commands until the fault is rectified. There are no user serviceable components within the laser system.

List of error messages

DISPLAY	PROBABLE CAUSE	ACTION REQUIRED
ERROR_SHUTTER_OPENED	Safety shutter error	Contact your Optotek representative
ERROR_SHUTTER_CLOSED	Safety shutter error	Contact your Optotek representative
ERROR_SHUTTER_ERROR	Safety shutter error	Contact your Optotek representative
ERROR_HIGH_ENERGY	Energy of laser shot was more than 20% above the set value	Contact your Optotek representative
ERROR_LOW_ENERGY	Energy of laser shot was less than 50% below the set value	Contact your Optotek representative
ERROR_PCB	Fault in the safety electronics	Contact your Optotek representative

DISPLAY	PROBABLE CAUSE	ACTION REQUIRED
ERROR_PRISM	Fault in the optical regulation of laser energy	Contact your Optotek representative
ERROR_COMMUNICATION	Fault in the control electronics	Contact your Optotek representative
ERROR_HV	Fault in the high voltage electronics board	Contact your Optotek representative
ERROR_5VD2	Fault in the supply voltage for the safety microprocessor board	Contact your Optotek representative
ERROR_5V	Fault in the supply voltage for the safety electronics board	Contact your Optotek representative
SLIT ERROR **ERROR:** **JOYSTICK** **RESTART THE SYSTEM**	Joystick wires and/or connectors might be damaged.	Immediately cease to use the system and call the Optotek authorized service!

When contacting your local Optotek representative, always quote the mode and serial number of the device!

Record the laser error code in the laser error code record.

Laser error code record:

ERROR CODE	DATE	ERROR CODE	DATE

LASER SYSTEM INSTALLATION RECORD
(to be filled in by a qualified service technician performing installation)

System model: _____

System serial number: _____

Distributor: _____

Person responsible for installation: _____

Date of installation: _____

Installation site (exact address): _____

_____

_____

_____

_____

Distributor:

Full name of responsible person: _____

Signature and stamp: _____

Please fill in this Record in details and stamp it. Send a copy of this record to Optotek latest within 14 days of installation.

The warranty becomes effective upon receipt of this Installation Record.

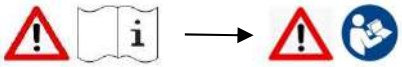
Send a copy of the Record to:

Fax: **+ 386 1 620 46 01**

E-mail: **optotek@optotek.si**

11 User's Manual revision history

Revision	Date	Changes
Revision 1.0.	July 2009	• First draft version release
Revision 1.1.	August 2009	• Revision for "0" production batch
Revision 1.2.	January 2010	• Correction of the Main Label (Class B); Page 27 • Correction of the classification (Class B); Page 35
Revision 2.1.	June 2010	• CMDR Medical Device classification added; Page 8 • SLT laser head fixation level description added; Page 55 • Slit Lamp Color Filter added; Page 58 • Sleep Mode description added; Page 61 to 83 • Laser Installation Record added; Page 88 • Contraindications, Side effects added; page 5 • Cleaning the forehead rest and chin rest; Page 73
Revision 2.2.	November 2010	• Upgrade to OptoYag M, OptoSLT M, OptoYag&SLT M Manual; Cover page, Page 2 • Copy Right added; Page 2 • OptoYag M and OptoSLT M labels added, Pages 20-22 • OptoSLT M Slit Lamp added; Page 45 • New appearance of the main screen; Pages 54 and 56
Revision 2.3	March 2011	• Caution during the self test added; Page 50 • SUM-E description added; Pages 54, 57 • Reset of total energy added; Pages 56, 58 • New warning message added (Joystick Interlock) added; Page 67
Revision 3.0	August 2011	• Figure Table of Contents added; Page 5 • Treatment instructions added; Pages 50-53 • New labels indicating a new batch; Pages 19-23, 35 • Slit lamp menu changed; Page 43 • Warning and error messages changed; Pages 62-64 • SLT automatic doctor filter removed; Pages 37-38 • WEEE Recycling symbol added; Page 61
Revision 3.1	January 2012	• Change in label content; Page 20, 21, 22, 26, 35 • New edition of EMC standard listed; Page 17
Revision 3.2	January 2012	• Subchapter 2.4 "Slit lamp illumination" revised; Page 16
Revision 3.3	April 2012	• New Declaration of Conformity included.
Revision 4.1	March 2013	• New OptoYag M, OptoSLT M, OptoYag&SLT M Model M design described, new labelling; entire document

Revision	Date	Changes
Revision 4.2	May 2013	• OptoYag, OptoSLT, OptoYag&SLT replaced with OptoYag M, OptoSLT M, OptoYag&SLT M; entire document • EN ISO 10993:2009 and EN 62366:2008 standards added; Page 9 and 17 • New EC Declaration of Conformity and CMDR declaration of Conformity added • Sleep mode description changed; Page 44, 46, 47, 49, 50, 51
Revision 4.3	February 2014	• Modification of treatment parameter description (offset P150) on page 52
Revision 4.4	February 2015	• Page 1 and Page 2: Added name of the device • Page 23 and Page 24: New labels with added name of the device
Revision 4.5	July 2017	• Page 9 updated according to latest clinical evaluation • New EC Declaration of Conformity added • New EC Certificate added • New ISO 13485 Certificate added
Revision 4.6	January 2018	• Change of Fixation light color from green to red
Revision 4.7	April 2019	• Compliance to harmonized standards updated. Sections 2.1 (Page 11) and 2.6 (Pages 18,19). • Updated tables "Guidance and Manufacturer's declaration – Electromagnetic Emission" and "Guidance and Manufacturer's declaration – Electromagnetic Immunity", updated safety warning. Section 2.3 (Pages 15, 16). • Corrected NOHD calculation. Section 2.5 (Pages 18, 19). • Updated Safety labels. Section 2.7 (Pages 21-26). • Added instructions for moving the equipment. Section 2.8 (Page 27). • Added warning about lifting mechanism movement. Section 3.2 (Page 30). • Defined applied part. Updated safety warning. Section 4 (Page 37). • Updated tables "Laser head Yag", "Laser head SLT" and "Overall system features". Section 5.4 (Pages 38-40) • Updated environmental conditions. Section 3.1 (Page 28) and Section 6.6 (Page 44).
Revision 4.8	June 2020	• Symbol change throughout the whole document from  • Safety goggles scale numbers updated. Section 2.1 and 2.2 (Pages 10,11,12,18) and 4 (Page 36). • Updated spectral power distribution diagram and spectrally-weighted photochemical source radiances, both phakic LB and aphakic LA. Section 2.4 (Page 16). • Updated OptoSLT M side effects. Section 1.4 (Page 8) and Section 8.2 (page 57) • Standard compliance updated. Section 2.6 (Page 18).

Revision	Date	Changes
		• Updated Compliance and Safety Labels. Section 2.7 (Pages 21-24).