

EXCIMERLASER
ESIRIS
SERVICE MANUAL



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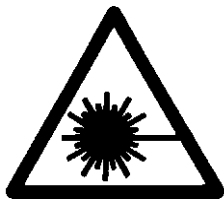
1. Security of Device (Laser beam)

General

The **SCHWIND ESIRIS** is working with a pulsed UV-Laser. The Laser belongs to class 4, which is the one with the highest danger potential. In any case, exposition of eye or skin through direct or scattered laser beams has to be avoided. A professional instrument maintenance - done in the planned intervals - secures that unintended beams can not be exposed of the unit.

Opening of the device is only allowed through trained technicians. All persons, assisting the treatment or attending the procedure have to be informed about danger potentials and have to wear protection glasses.

Besides the high-performance laser, the **SCHWIND ESIRIS** uses three diodelasers as positioning and fixation device. The output of the fixation laser is below 10 μW . Therefore it belongs to class 1, which allows an undefined exposition time of the eye. The positioning lasers are used to adjust the exact working distance to the corneal surface. Their output is 50 - 100 μW . As the beams are aimed in a angle to the eye, an influence at the retina is impossible.



Warnings Laser beam

The laser emits high-performance beams:

Wave lengths:	193 nm
Pulse energy:	max. 8 mJ
Energy density:	800 mJ/cm²

Laser beams with these data are potentially dangerous, but in our case, possible danger is minimised through some details:

- the beam diverges after passing the ablation area, so only in this area a high energy density exists.
- the beams are partially absorbed in the air
- the cornea does not reflect beam during treatment

These effects reduce the energy density of the beam quickly with growing distance to the working area, which is about 280 mm under the beam output opening. In spite of this, the following warnings have to be followed for a safety use:

- **Never look into the laser beam!**
- **Never put your skin into the laser beam!**
- **Wear protection glasses**
- **Make sure, that no reflection devices are placed in the area of the laserbeam**
- **Follow the instructions of the trade association VBG 93!**
- **Persons, not used with the lasers, have to be informed about possible risks!**

Alarm Shields and Type Shield

Beam output is marked with laser warning signs..1.2. Warnschilder

They are looking as following:



	Treatmentlaser	Positionlaser	Fixationlaser
Wavelength	193 nm	633 nm	650 nm
Energy/ Power	20 mJ	< 100 μ W	< 10 μ W
Energy density	800 mJ/cm ²		
Pulse duration	8 ns	∞	∞
Pulse frequency	200 Hz		
Laser class	4	2	1



Accessible Beam Area

The beam area of the device is horizontal down from the output opening to the next surface. Normally this is the patient bed or, in case of treatment, the patient eye. Diameter of beam at the output opening is app. 1,0 mm. In the treatment area, which is 290 mm under the output opening, the beam has a diameter of 1,0 mm. Output and energy density of beam decreases accordingly with increasing distance from treatment area.

Protection Glasses

All persons inside the room (except the patient) have to wear protection glasses according to DIN EN 207, when the laser is working. These glasses must have protection level 7 for beams of 193 nm. The operating surgeon can put-off the glasses, when he looks through the microscope. The glass optics of the microscopes weaken the laserbeam, so that the necessary protection level is achieved. Protection level of glasses depends on maximum existing middle output density (at max. pulse following frequency) or the maximal energy density. These values are $5 \times 10^2 \text{ J/m}^2$.

Working Gas

Danger through the working gas (fluoride 0.106 %, argon 3.33 % and neon 96.56 %) has not to be feared.

The laser head contains only a small quantity of fluoride. It is checked according to the pressure containment regulations. An unintentional output of working gas is very unlikely. Fluoride can be recognised through its pungent smell, long before the concentration will come to maximum allowed values for working places. In such case, open the window, leave the room and call service department of your distributor or directly

Gas containment:

Pressure gas bottle with working gas is stored inside a gas containment. This gas containment is airtight and has a filter, which would absorb the fluoride in case of a leak. For service demands, there is a pressure gas bottle with helium, stored inside the gas containment too.

Declaration of Manufacturer (MPG)

The device has been developed according to the Medical Device Regulations MPG. The named TÜV-office Munich mark: 0123 manufacturer **Co. Herbert Schwind GmbH** is allowed to produce laser devices for medicine purposes and to put them into circulation.

Conformity with the construction authorisation of the device according to the MPBetreibV is ensured under the precondition, that

- delivery is done through **SCHWIND** or authorised distributor
- all service and maintenance works are only performed through authorised personnel
- accessories, consumables and disposable are only allowed, if a completely harmless use (safety-technique) is confirmed through a test of this device performed by an authorised testing authority. This is especially important for patient bed.

2. Description

Specification

Working Laser

ArF-Excimer-Laser

- | | |
|----------------------------------|---|
| • Wavelength | 193 nm |
| • Power (average, beam output) | 2 W max. |
| • Mode | pulsed |
| • Pulse energy (beam output) | 15 mJ max. |
| • Pulse frequency | 200 Hz max. |
| • Pulse duration | 8 ns |
| • Pulse-to-pulse stability | < 5 % |
| • Power density | <1,5 x 10 ⁵ W/m ² |
| • Energy density | 800 mJ/cm ² |
| • Beam diameter (output) | 7 x 4 mm |
| • Treatment area | app. 280 mm under beam output |
| • Beam diameter (treatment area) | 1.0 mm max. |
| • Beam divergence | 2 x 1 mrad |

Pilotlaser

Diodelaser

- | | |
|-------------------------------|-----------|
| • Wavelength | 635 nm |
| • Power (middle, beam output) | < 100 µW |
| • Mode | continued |

Fixationlaser

Diodelaser

- | | |
|--------------------------------|---------|
| • Wavelength | 650 nm |
| • Power (average, beam output) | < 10 µW |
| • Mode | pulsed |

<u>Controlling</u>	<u>Industry PC 586AT (or better)</u>
• Hard Disc	13,6 GB (or more)
• Processor	Pentium III 500 MHz or higher
• Memory	64 MB
• Monitor	12.1", VGA flat monitor
• Interlock	1 opener external
• Monitor output	VGA socket

<u>Cooling</u>	<u>Air</u>
• Cooling Circulation	internal fan

<u>Electrical Connection</u>	<u>3,5 kVA</u>
• Voltage	230 V, 1 phase
• Protection	16 A, sluggish, C-character
• Frequency	50 Hz/60 Hz (switchable)
• Connecting Plug	3 pole CEKON (blue)

<u>Dimensions and Weight</u>	
• Floor Space	see next chapter
• Total weight	appr. 400 kg

Excimer-Laser

Laser principal: Excimer gas lasers are stimulated with an electric pulse in a mixture of rare gases and halogens. The output lifts the rare gas atoms to a higher energy level, so that they react with the halogen molecules and connect, as ArF, XeCl or KrCl. These special molecules, known as excimers, are stable only for a short time. They destroy and put out a high ultraviolet beam. If the gas is arranged in an optical resonator of two parallel mirrors, the laser effect is achieved and light impulses with very high maximum outputs are beamed. The laser gas consumes itself partially during the output and must be changed after 10×10^6 impulses or after 2-3 days.

The 'OPTEX' laser used with the **SCHWIND ESIRIS** is produced by Lambda Physik, Goettingen. It is a very compact unit, which is optimised in reliability and low gas consumption. Above mentioned specifications describe the data of the laser and the necessary voltage connections.



Picture 1: Optex-Laser

Power supply voltage:	230 V AC +/-10 %, 1 Phase
Frequency:	50 Hz or 60 Hz
Power Input:	1.5 kVA
Security for the phase:	6.3 A
Device connections	acc. to IEC standard

Gas Supply

The noble gas mixture **has to** be received directly by **SCHWIND** or the responsible **SCHWIND dealer**, because only by this purity ranks and strictly check criterions are guaranteed. Otherwise damages to the system could be coursed. This is to fix into a Service- and Maintenance-Agreement. The gas bottle will be changed by a **SCHWIND** service engineer/technician or a trained service technician of a **SCHWIND dealer**. If these instructions will not be kept any claims of guarantee and responsibility laps.

Gascontainment:

The Laser operates with premixed PREMIX gas. The capacity of one bottle is sufficient for about 12 months at standard operation (approx. 180 fillings).

Delivery System

The optical system for beam guiding and forming is flanged to the laser at the side of beam output. The beam guide is angled three times to 90°, so that the patient bed can be placed parallel to the laser. Output of treatment beam is horizontally down collinearly with the optical axis of the video control system which is used for centration and focussing.

The treatment area is about 290 mm under the beam output. Focusing of ablation field and the centering at the eye is performed with two positioning lasers and a video camera. At the monitor of the video computer a video picture with crosshair is produced. The ablation field has a maximum diameter of 14.0 mm. Minimal ablation diameter is 1.0 mm. These values as well as the centration of the field at the crosshair can easily be checked, through ablation pulses at a piece of illuminated photo paper or Kodak Wratten Filter.

Diode lasers with low energy are used as positioning laser. Therefore they are directed punctually at the eye in an angle from left and right, so that the points do cross at exact distance of focus. A diode laser beams through the optical axis of the unit onto the eye. This is used as fixation target for the patient. The laser power is below 10 µW, so that a longer lasting illumination at the eye would not cause any danger.

Microscope and Illumination

For exact control of corneal surface a coaxial stereo microscope is used. It allows a coaxial stereoscopic control of the eye, without the control beam path being guided through the working optic of the device. Therefore very good quality of the stereo picture is possible. Abrasion of the epithelium and LASIK can be performed under optimal control conditions. Further the control of treatment result is possible.

The cross hair is only constructed for a magnification of 14x! If another magnification is used this might result in a decentralised position.

For illumination of treatment area, a cold-light lamp is integrated into the unit. This lamp can be adjusted in brightness with a potentiometer and if necessary, it can also be switched-off. The light is directly provided from a ring formed positioning of the lightening end of the fiber below the beam output opening.

Controlling

The system controlling is located inside the device tower besides the patient bed. It includes all voltage delivery units, input fuses and the control computer. Monitor and using keyboard are located at the front-wall of the **ESIRIS**.

The controller can easily interact with the **SCHWIND ESIRIS** through input keyboard and monitor. Inputs into the computer are menu controlled, so that input mistakes can be avoided mostly. Release of treatment procedure is done with the footswitch.

Patient Bed

The patient bed should enable a simple way of exact and stable storing of the patient as well as the adjustment of the treated eye at the ablation area.

Foot Switch

The footswitch is used to release the treatment procedure. This switch has two switch points to avoid unintentional release of pulses. The treatment procedure can be interrupted any time by releasing the footswitch. The program remains active, so the treatment can be continued afterwards by pushing the footswitch again.

Rinsing of Optical Beam Delivery System

Radiation of ArF Excimer laser is 193 nm, and so it is at the outer limit of spectrum area of ultra violet that is air transmitted. Partially absorption through air oxygen lowers the radiation noticeably and ozone is produced. This would damage the optical components, if it would accumulate inside the delivery system. Based on this, it is useable to flood the way of radiation with an oxygen poor gas, which is also good transparent at 193 nm.

For rinsing, nitrogen with a quality of 5.0 has been proved as very good. Nitrogen can be stored and transported easily in pressure bottles, is in a low price limit and non-toxic.

For optimising consumption of rinsing gas, the gas flow is controlled automatically inside the containment of optical system. A flow control checks the nitrogen flow. If the gas is getting empty inside the pressure bottle, the monitor of the control unit displays a message.

Unit can not be used anymore in this case. The pressure bottle with nitrogen has to be changed immediately. To avoid a slow loss of nitrogen through little leaks at the valve of the bottle, it should be closed, while the **ESIRIS** is not in use. Often, the above mentioned message appears, when opening of the valve had been forgotten.

Important note:

Flow of nitrogen must be 8 l/min, in order to guarantee constant ablation values.

3. Installation requirements and preparations

Installation of **SCHWIND ESIRIS** is performed through trained service personnel. To enable a proper installation, some prerequisites have to be fulfilled, which are described below:

Working Room

The room, where **ESIRIS** will be installed, should have a minimum of 3 x 4 m (12 m²). At the outer side of the entrance door, a **laser warning lamp** and the **official laser warning symbol** have to be installed. The warning lamp has to lighten, during the laser is in use. A switch, which interrupts the laser, if the door is opened, can be connected through the interlock input at the device. But this is only recommended when it is guaranteed, that the door is not opened during treatment.

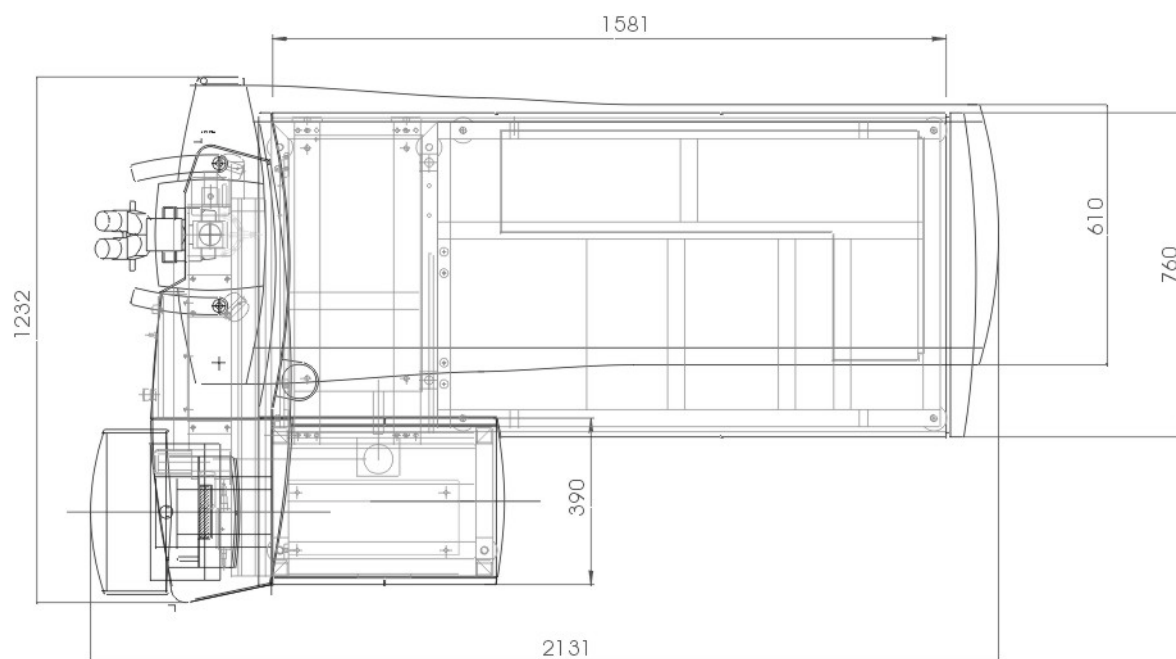
Inside the laser room explosive or inflammable material must not be stored. Near the opening door, protection glasses according to DIN EN 207 have to be available in sufficient quantity. (Protection glasses have to be available in following specifications: D L9 / IL2 calculated by DIN EN 207, according to Laser Vision).

Nitrogen gas bottles, necessary for use of the laser can be stored inside the laser room. They must be fixed, to avoid falling down.

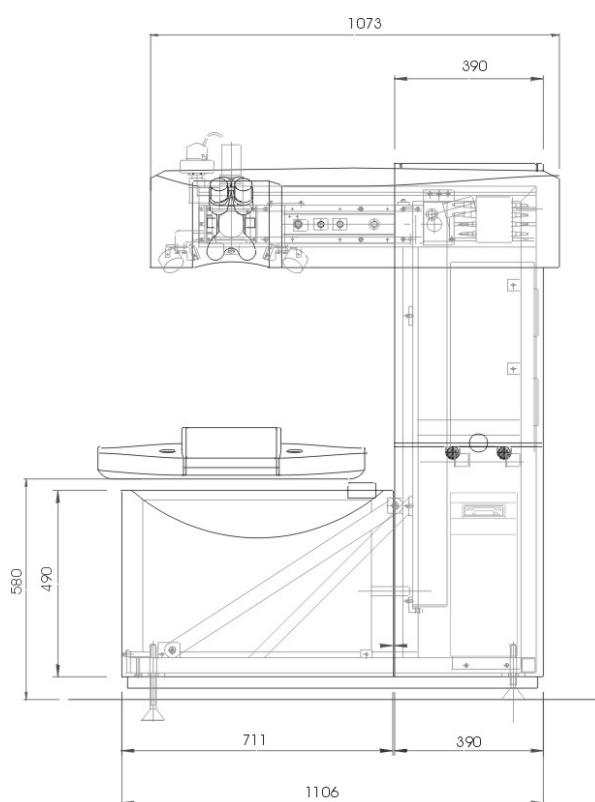
Important note:

Do not use any liquid containing ammoniac to clean the room. Ammoniac vapours attenuate the laser energy and create varying ablation rates and treatment results!

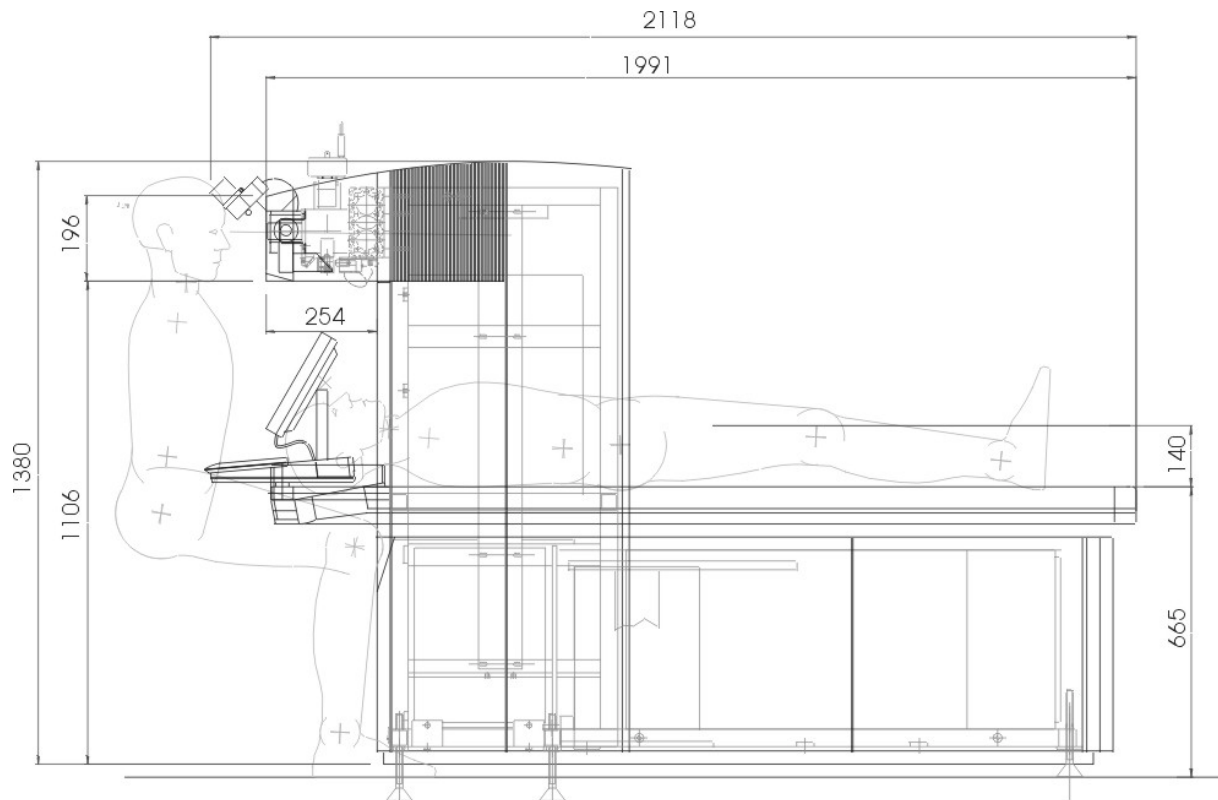
Dimensions ESIRIS



Picture 2: Dimenstions ESIRIS upside



Picture 3: Dimensions ESIRIS front



Picture 4: Dimensions ESIRIS side

Input Requirements

SCHWIND ESIRIS needs as electrical input.

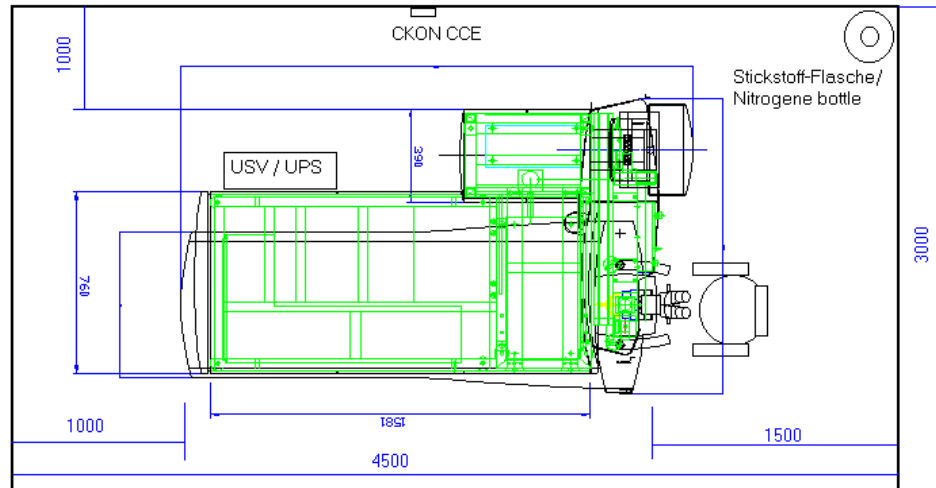
Electric connections**1,2 kVA**

- | | |
|------------------------|------------------------------|
| - Power supply voltage | 230 V, 1 phase |
| - Fuse protection | 16 A, slow; C-characteristic |
| - Frequency | 50/60 Hz |
| - Connections | 3-pol CEKON (blue) |

Installation and room preparations for the installation

Minimum room dimensions (or room requirements)

appr. 3 m x 4m (12 m²)



Picture 5: Room requirements or room dimensions ideally (12 m²)

Requirements for the floor can be seen in above ground plan drawing.

Floor requirements

- Laser system and beam delivery system 250 kg
- Point weight through supporting feet at the laser max. 75 kg
- Base of supporting feet appr. 28 cm² per support
- Patientbed 220 kg
- No. of supporting feet for the laser: 4
- No. of supporting feet for the patient bed: 4
- Door width: min. 80 cm
- Floor covering: PVC or stable, vibration free underground

Installation Requirements

- Stable, unyielding vibration free underground (**no carpet**)

- Power supply for the laser
 Voltage: 1 phase, ~ 230 Volt +/- 10 %
 Current: 16 A
 Fuse protection: Safety switch min. 16A with C-characteristic connections
 CEKON wall plug 230 V / 16 A / 3-pole
- An UPS system (uninterruptable power supply) is necessary (optional to the delivery range of the ESIRIS).
- Nitrogen provision: 50 l – quality 5,0 (99.999 % N₂) min; otherwise the system could be damaged
- 50 l gas bottle should be wall mounted besides or behind the laser.
- Pressure reduce valve at nitrogen bottle with flow control and adjustable flow of 5-10 l per minute (included into the delivery range of the ESIRIS) adjusted at 8 l/min flow
- Darkening shutter
- Air-conditioning in countries with temperatures of more than 25° C or differences of more than ± 10 %
- An air drier is absolutely necessary in countries with an humidity of more than 60 %
- Voltage constant provider (~ 230 Volt ± 10 %)
- The ESIRIS laser is operated with a premix gas mixture, with is stored inside the laser.

Laser warning lamp

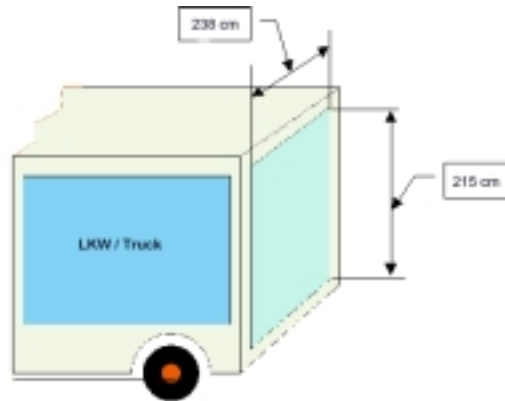
- Possibility to connect a warning lamp at the room wall.
- Warning lamp near the entrance door of the laser room.
- Warning lamps will not be delivered, but there is a possibility of a 24V relay connections with a warning lamp switch connection laser beam output side (interlock).

Dimensions of boxes for the delivery

The delivery consists of three wooden boxes with the following dimensions:

Box 1: 150 x 110 x 180 cm	gross weight:	180 kg	Laser + attachments
Box 2: 220 x 110 x 130 cm	gross weight:	220 kg	bed + attachments
Box 3: 180 x 110 x 114 cm	gross weight:	150 kg	covers + cases

For transport a truck is necessary with a **minimum height of 2,15 m and inside dimensions of 2,38 m**.



Picture 6: Truck Dimensions

During opening of the boxes a trained service technician should be present.

Delivery

The device is delivered in two parts, packed separately: the laser, with the optical system, the patient bed and containment and necessary spare parts, control monitor and keyboard. Packing consists of two screwed wooden boxes. With delivery, the customer has to check if these crates are undamaged.

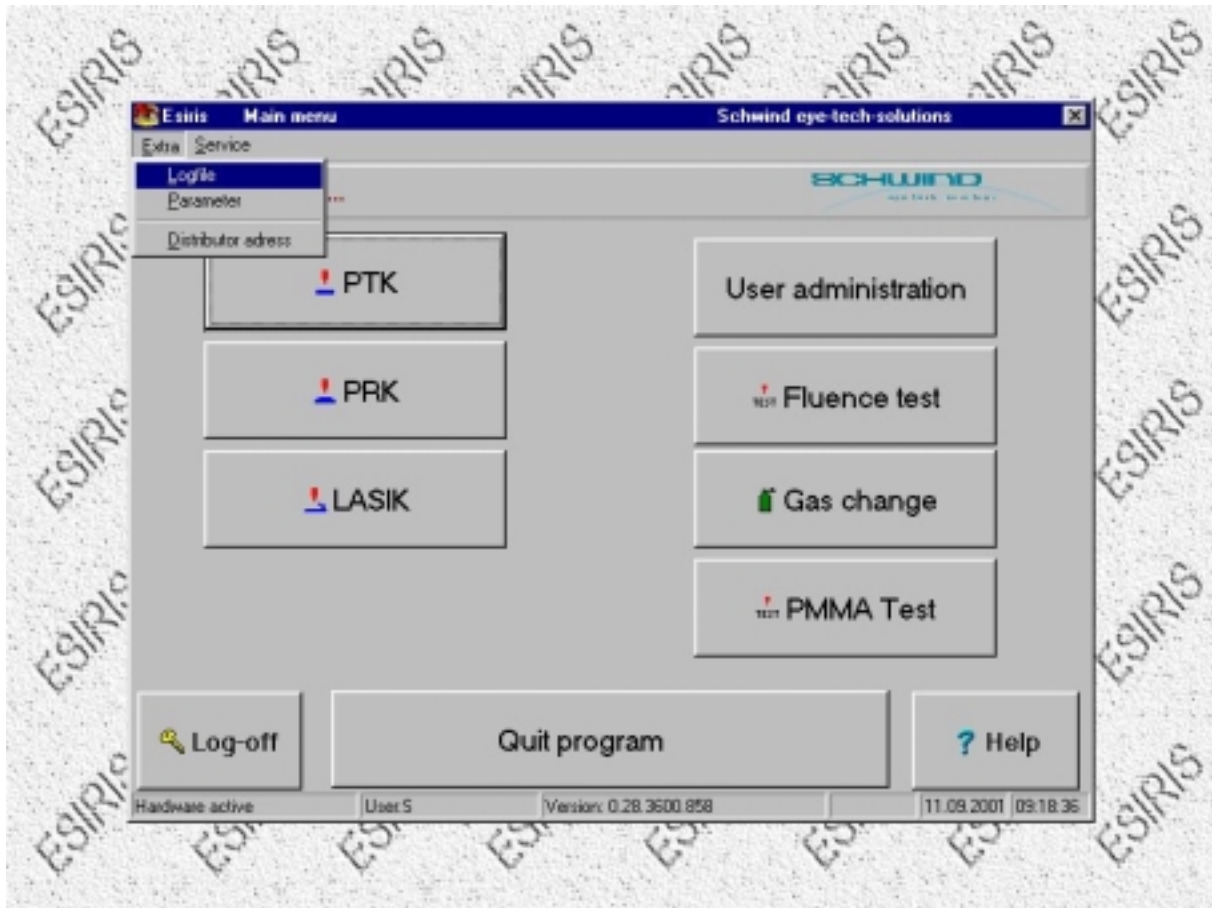
A storage of the boxes outside has to be avoided. It is recommended to unpack the boxes immediately after receipt and to check the goods for damage and completeness. Inform **SCHWIND** or your distributor, that you have received the device, in order to organise visit of a service technician/engineer for the installation.

4. Software description by Service Login

The following chapter gives you a description of the service software functions in the ESIRIS software. By using the service password, the service get following main menu with the pull-down menu **Extra** and **Service**.

Menu Extra

Menu Logfile



Picture 7: main menu

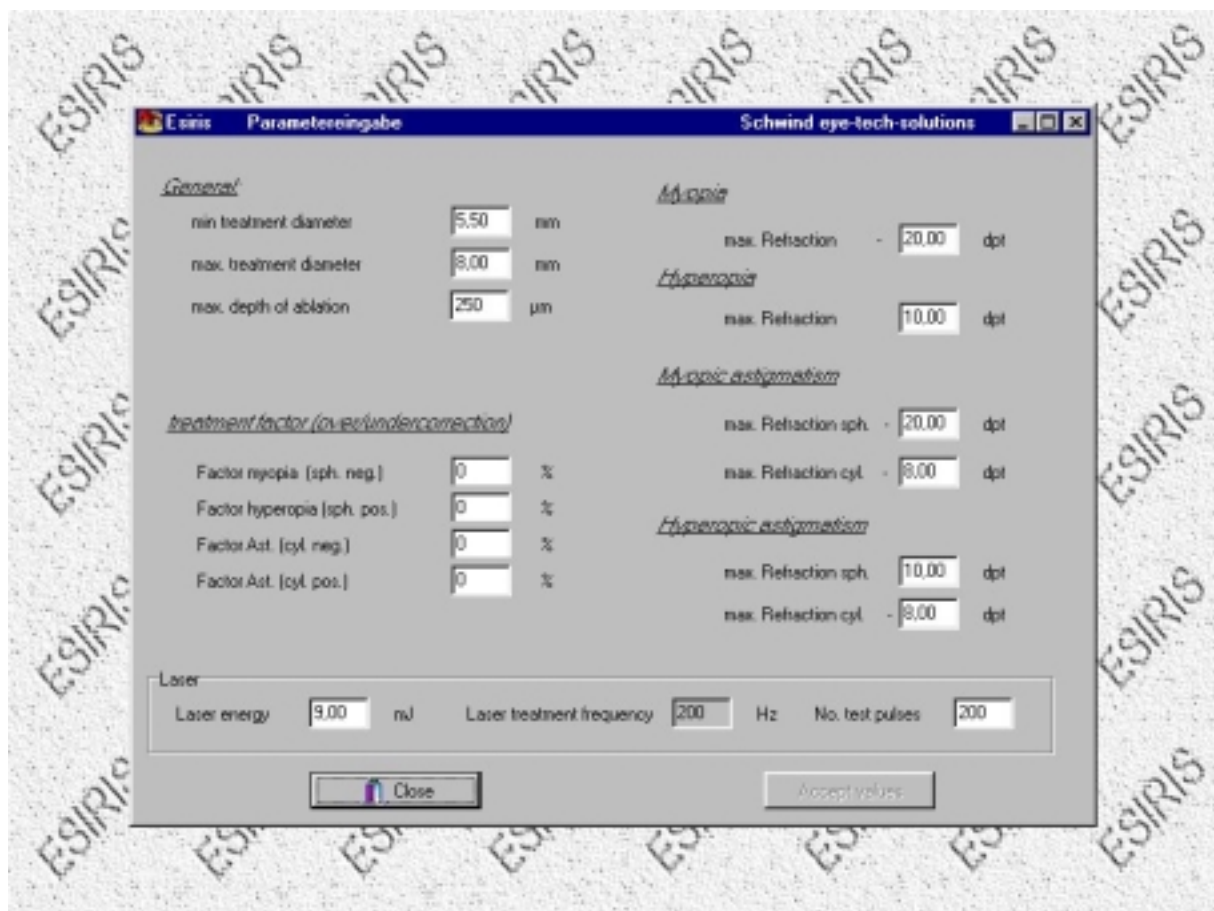
By clicking on the menu point **Logfile**, the technician has the chance to see all error messages and necessary informationen during the last techincal security check. This

is very helpful, because on this way the service stuff gets the complete history of the machine since the installation.

Attention: after 2000 entries the software will automatically reduce the 1500 last old entries in a separate file with the name **logfile+date.bak**. This is a normal text file which can be read with any text editor program.

Menu Parameter

In the parameter menu the service can change necessary parameter for the surgeon, which have an influence of the treatment. By changing these parameters, the technician has to be very careful and has to do the changes only in consence with **Schwind** and the surgeon.



Picture 8: parameter menu

General:

In this section the user can change the minimum and maximum treatment diameter and the maximum ablation depth.

Treatment factor (over/ undercorrection):

If the clinical study shows in some parts over or undercorrections the user has to change here the treatment factors for spherical part for myopia and hyperopia, for the myopic astigmatism(neg.) and the hyperopic astigmatism (pos.) the cylindrical value.

Myopia, Hyperopia, myopic Astigmatism and hyperopic Astigmatism:

On the right side the user can limitate the maximum refraction values for myopia, hyperopia, myopic astigmatism and hyperopic astigmatism.

Laser:

On the bottom of the formular the service can store the laser energy, which is responsible for all treatment methodes.

The laser frequency is only displayed, but not changeable.

The number of test-pulses has the meaning that the service can increase or decrease the number of laser pulses during the necessary tests on photo paper, like scanner test, scanner drift, concentric test and so on. Sometimes, if is it necessary, because the service is using different types of photopaper with different thickness.

Distributor adress

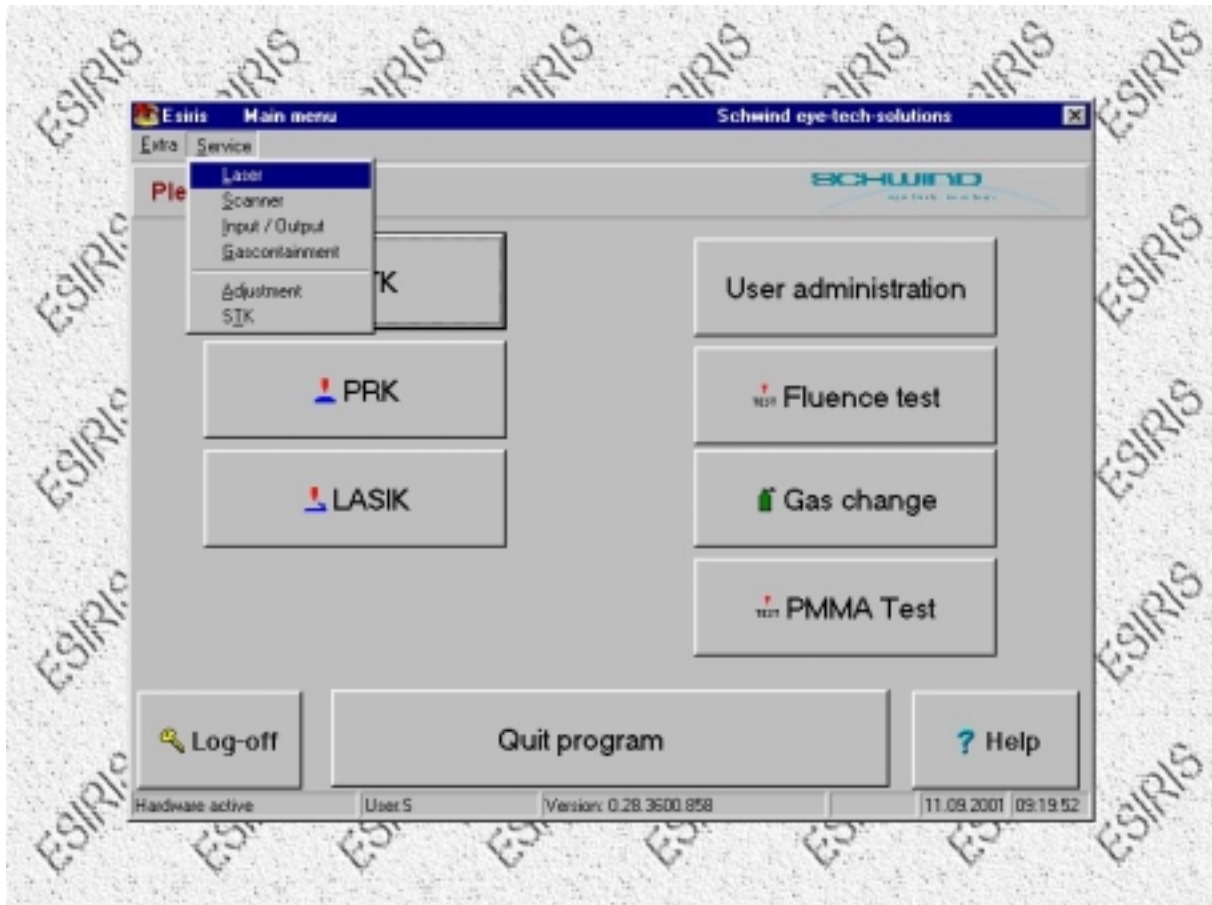
By selecting the menu distributor adress the service can store the adress of the manufacturer **Schwind** or the **distributor**. This is interesting to show the user, who is responsible for gas orders or service cases. Everytime, when something is happening or necessary the software will display the adress on the screen.



Picture 9: Distributor adress

By using the **service** menu in the menu task bar, the service can use several service functions, which are necessary for the adjustment of the laser or to test and check the systems in case of troubles.

Menu Service

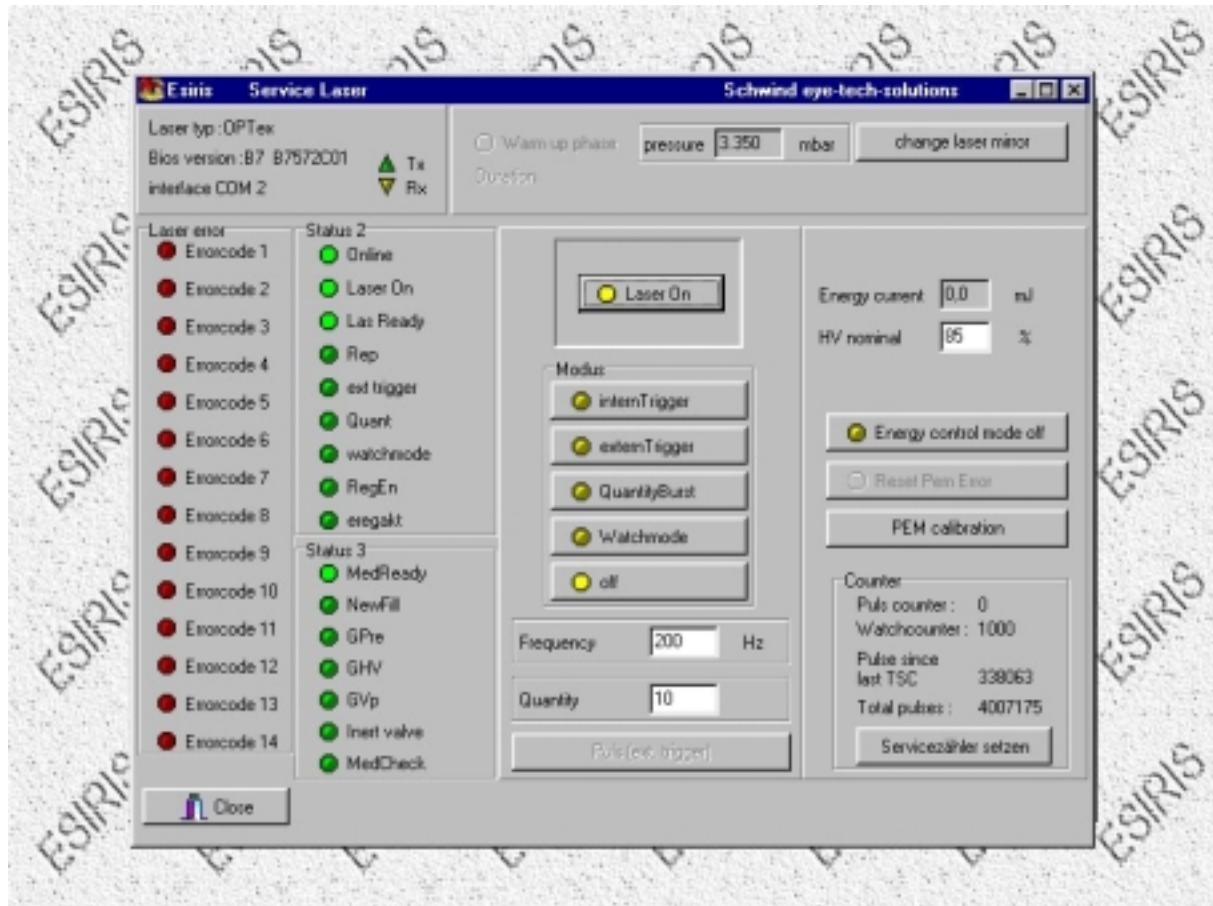


Picture 10: Service menu

In this menu the service can select following items:

- **Laser**
- **Scanner**
- **Input / output**
- **Gascontainment**
- **Adjustment**
- **TSC**

On the next pages all menus will be explained in detail.

Menu Laser:**Picture 11: Laser menu**

On the left side in the top the service can see the laser type, the bios version of the laser and the COM interface. The TX / RX icons are blinking in case of a right connection between the PC and the laser.

Pressure:

On the top the current pressure in the laser tube will be displayed.

Change laser mirror:

By pressing this button the mirror change procedure will be activated. Please follow the instructions on the screen, because this is an automatic function.

Laser error:

In case of laser problems the system will read out the error codes of the laser. The following lines give you a short explanation of the meaning of each errorcode. If the service needs more information, please take a look at the Optex manual from Lambda Physik for detailed information.

Errorcode 1:

Check error occurred (statical error)

Errorcode 2:

Time out error (operation error: laser device is to be switched off)

Errorcode 3:

Laser head chamber open or temperature too high (more than 60 °C)

Errorcode 4:

External interlock circuit open

Errorcode 5:

Electronics chamber open or temperature too high (more than 60°C)

Errorcode 6:

Reservoir pressure out of range (less than 2.9 bar or more than 4.5 bar)

Errorcode 7:

Pressure is not reached in the present time limit (time out error)

Errorcode 8:

Heating circuit error (less than 5.8V or more than 7.5V)

Errorcode 9:

HV charging time exceeded (more than 4.5 ms)

Errorcode 10:

Reservoir pressure too low

Errorcode 11:

Internal energy powermeter error occurred

Errorcode 12:

HV too high error occurred

Errorcode 13:

CPU error occurred

Errorcode 14:

HV temperature error occurred

Status 2 and Status 3:

The Status 2 and Status 3 shows the service the current status of the machine.

Status 2:**Online:**

Laser online

Laser On:

High voltage module activated and ready to be switched on

Las Ready:

Laser ready for operation (high voltage module can be activated)

Rep:

Repetition mode

ext. trigger:

external trigger is activated

Quant:

Quantity burst mode is activated

Watchmode:

Watchmode is activated

RegEn:

Energy Const mode is enabled

Eregakt:

Current energy set value is valid

Status 3:**MedReady:**

Reservoir module is activated

NewFill:

New fill procedure is activated

Gpre:

Premix gas valve is open

GHV:

Laser head valve is open

GVp:

Vaccum pump is switched on and vaccum valve is open

Inert valve:

Inert valve is open

MedCheck:

Laser is in warm-up period

In the center of the formular the user can switch the laser in different modes. To start the laser the user has to press the **Laser On** button. After this it is possible to activate different laser modes.

Modus:**Intern. Trigger:**

Start the internal trigger

Extern. Trigger:

Laser is waiting for external trigger

QuantityBurst:

Number of pulses will be fired

Watchmode:

Laser trigger will be activated by pressing the foot-switch

Off:

Switch of the laser modus

Frequency

In the input mask 'Frequency' the user can change the laser frequency from 1 Hz upto 200 Hz. This setting is no effect of the treatment frequency.

Quantity:

In the input mask 'Quantity' the user can set the number of pulses for the Quantity burst mode.

Energy control mode off / Energy control mode on:

The laser has two control modes. The energy control mode is for the constant energy output, the HV control mode is for the maximum High voltage energy output. The system is using generally the energy constant mode. By pressing the button the user can switch between both modes. Above the current energy or the current HV will be displayed.

In the nominal HV or energy input mask the user can set different values.

Attention: Please change the settings only, when the laser is in standby mode (OFF)

Reset PEM Error:

To reset the internal powermeter error press this button

PEM calibration:

To calibrate the internal powermeter you have to press this button.

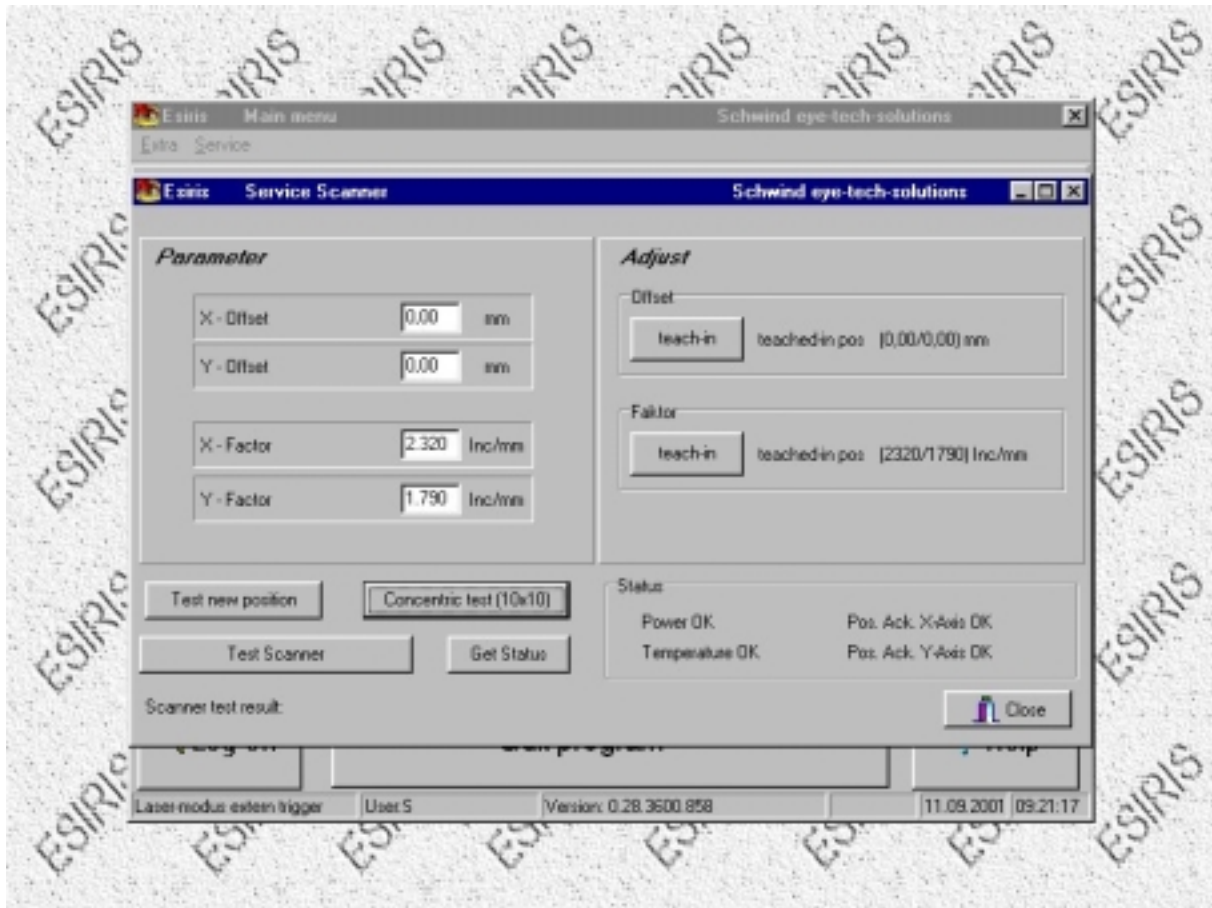
In this case you have to use an external powermeter. The energy value, which was measured the user has to input the value in the input mask.

Counter:

To reset the second pulse counter for the service, press this button.

Menu Scanner:

The menu 'Scanner' has to be used, if the scanning mirror should be calibrated and tested during the adjustment and technical security check.



Picture 12: Scanner menu

In this menu the user has the possibility to set the X- and Y-offset of the scanner. The first X- and Y- offset is responsible for the zero position of the scanner. (Reference position) The second X- and Y- offset is a correction factor to expand the scanning range. **Attention: This has to be checked.**

If the user is changing these parameter, then he has to press the **teach-in** button

Test new position:

For checking the reference position, press this button

Concentric test (10 x 10):

This function has to be used, if the user has to changed the expanding offset. After pressing this button the laser is shooting a cross on the photopaper. After the procedure the user has to check with a lens-meter the distance from one point to the other point and to measure if he has a rectangle of 10 X 10 mm. In case it is not ok, he has to re-check the expand faktor.

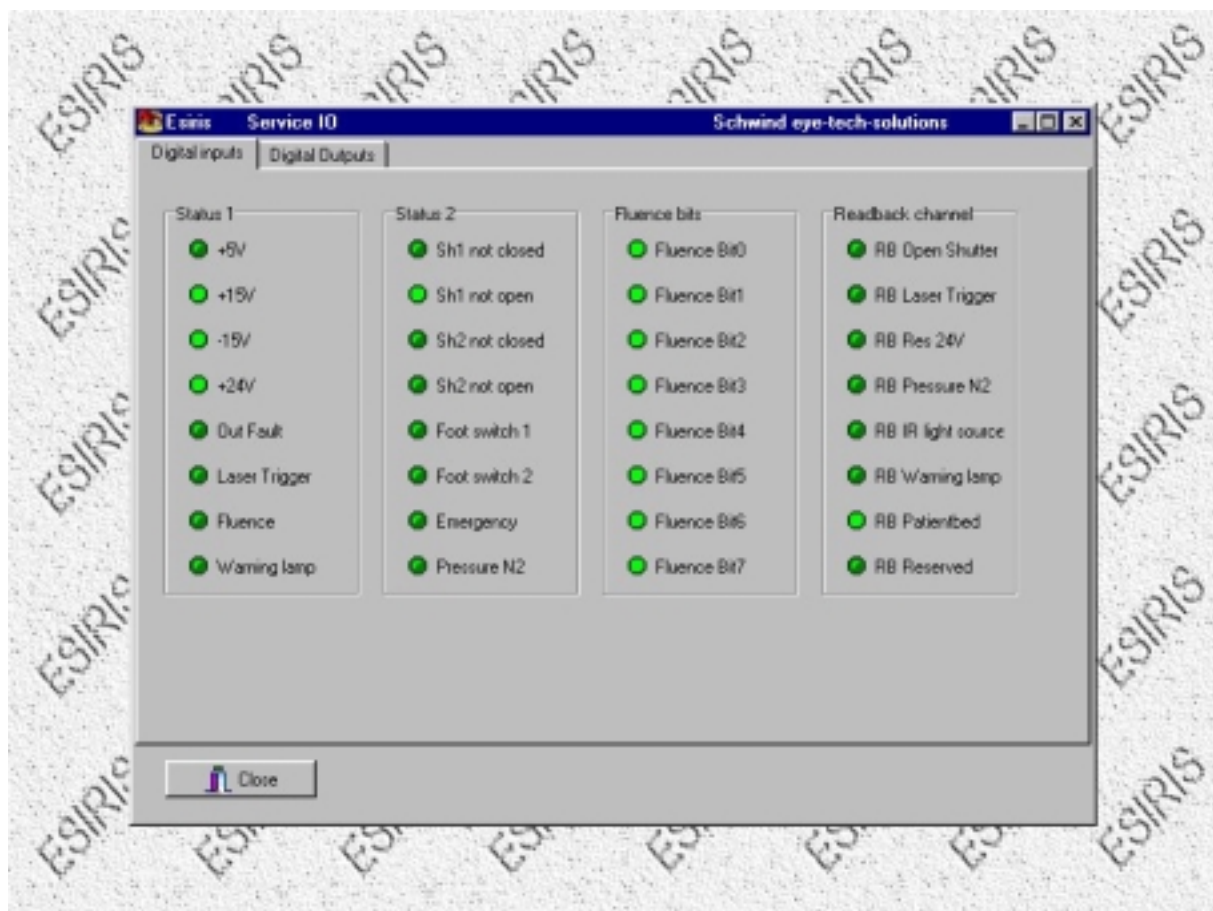
Test Scanner and Get Status:

Both buttons are responsible for internal test. The result will be displayed in the status frame.

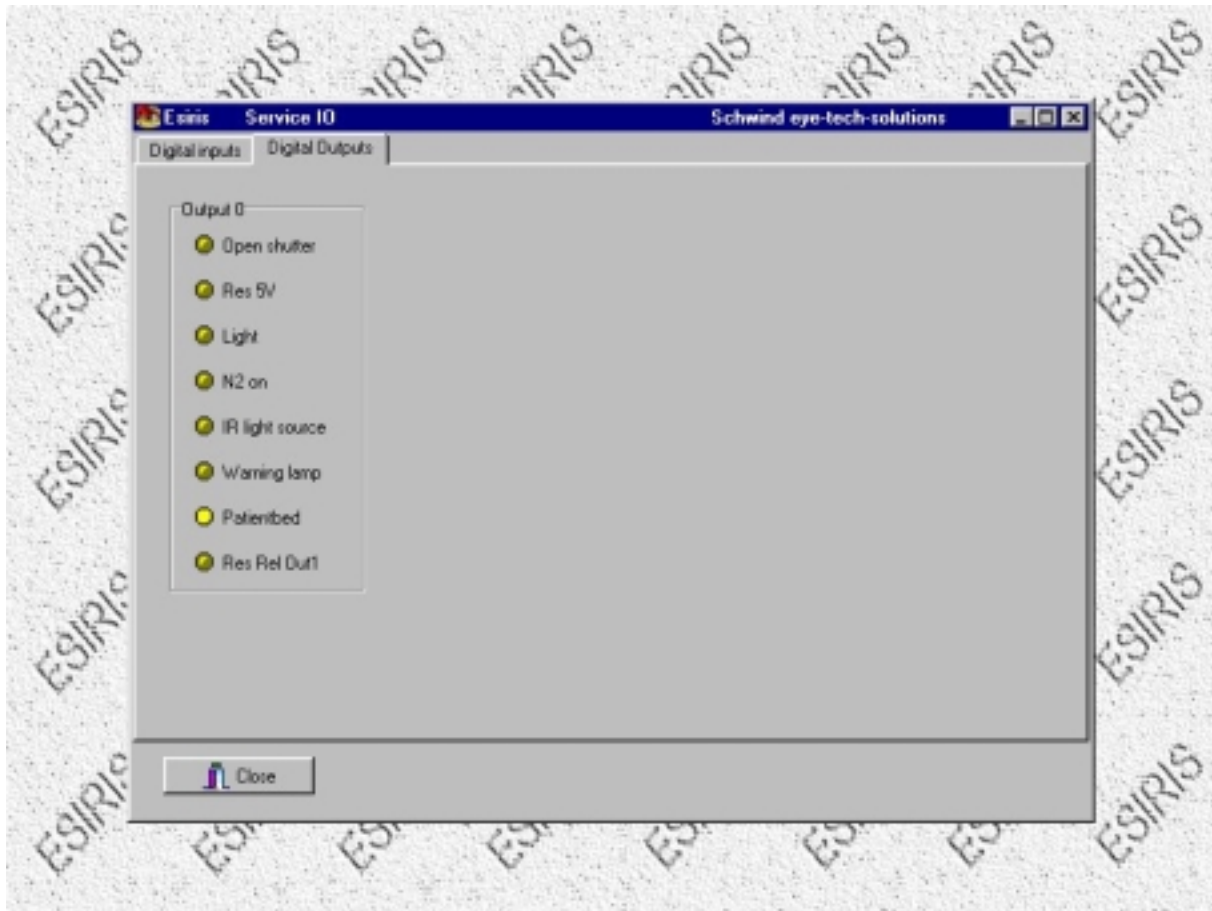
Menu digital inputs / outputs

The input / output window shows the current input status. The outputs can be activated by pressing the lamp icon.

General: light-green lamps show an activity.



Picture 13: Digital input

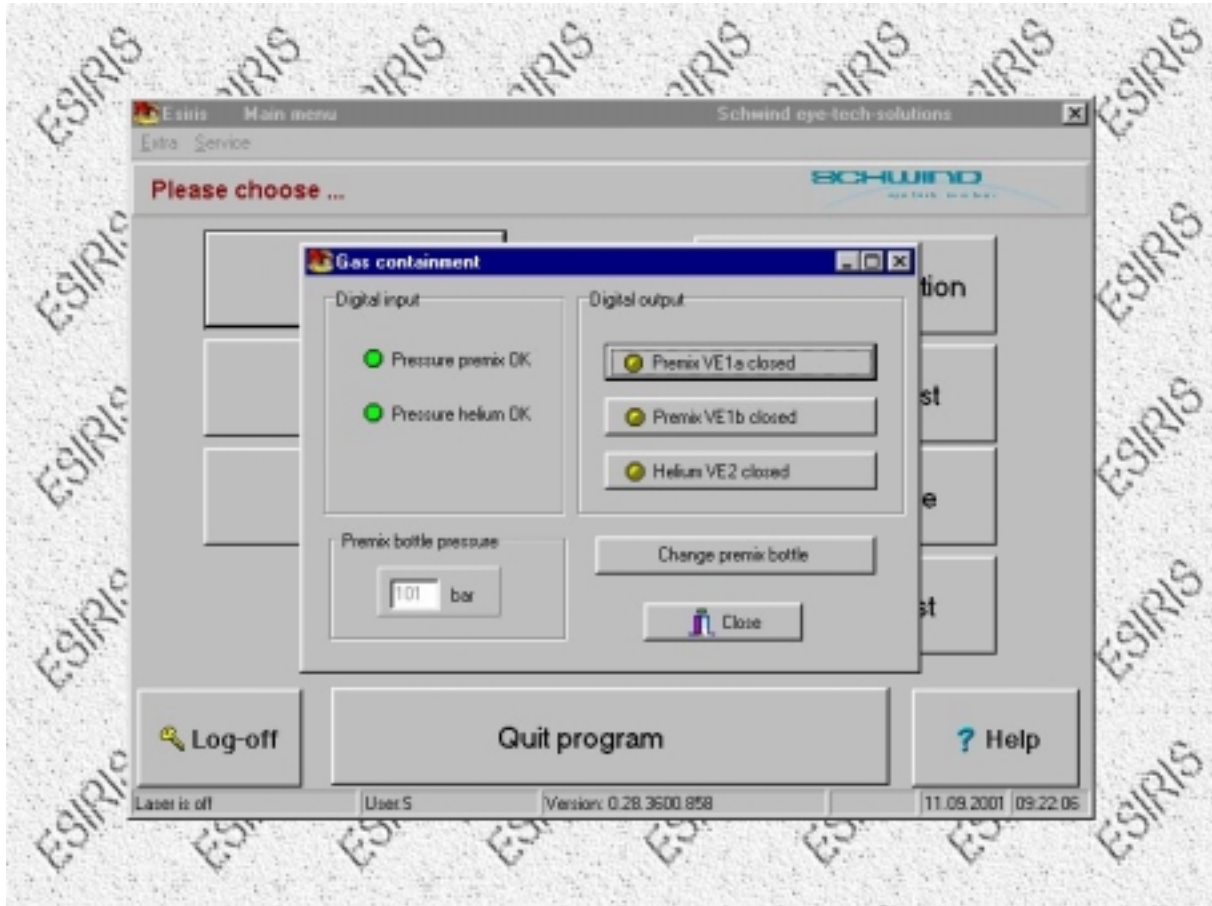


Picture 14: Digital output

The Output window shows the switchable functions. By clicking the lamps, the electronic switch is activated.

Gascontainment:

The gascontainment menu allows the user to switch the gas valves and to do a gas bottle change.



Picture 15: Gascontainment

The digital input window shows the current pressure. If the pressure is OK, the lamp is light-green.

Premix VE1a closed:

Press this button to switch the VE1a valve.

Premix VE1b closed:

Press this button to switch the VE1b valve.

Helium VE2 closed:

Press this button to switch the VE2 valve.

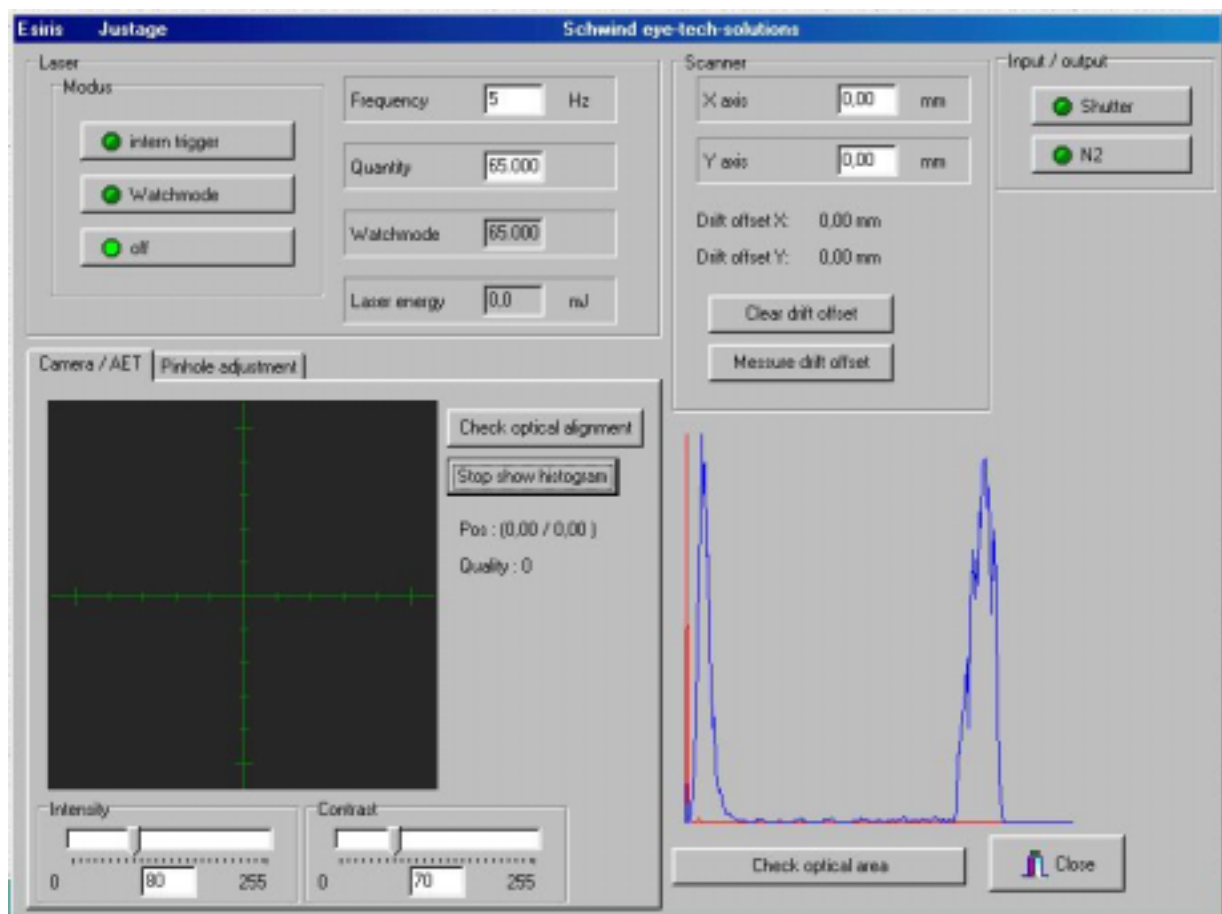
Change premix bottle:

By pressing this button, the gas bottle change procedure will be activated. Please follow the displayed instructions.

The current bottle pressure will be displayed in the premix bottle pressure window.

Menu adjustment:

The adjustment menu was created for the service to make a perfect adjustment of the ESIRIS laser.



Picture 16: Adjustment menu

Laser:

Intern trigger: Switch the laser in the internal trigger mode

Watchmode: Switch the laser in the watch mode

Off: switch the laser in the stand-by mode

Frequency: Set the laser frequency what is necessary

Quantity: Set number of laser pulses for watch mode.

Watchmode: Shows the number of pulses the user had done

Laser energy: Shows the current laser energy

Scanner:

X-axis: set a drift of the scanner for testing

Y-axis: set a drift of the scanner for testing

Clear drift offset: By pressing the button the current scanner drift will be reset to 0/0

Measure drift offset: By pressing the button the scanning drift procedure will be activated.

Input / output:

Shutter: By pressing the button the shutter will be opened

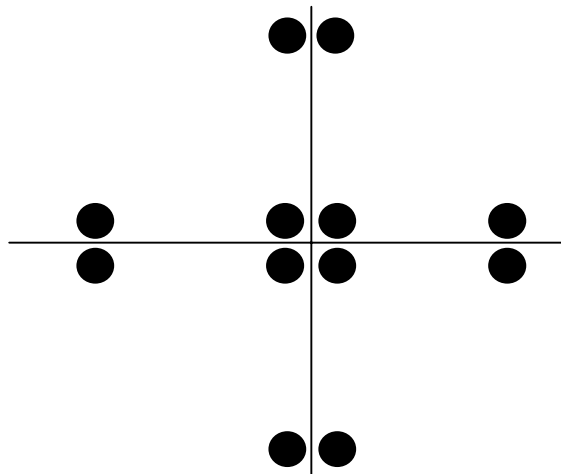
N2: By pressing the button the nitrogene will be opened

Camera / Active Eye-Tracking:

The measurement of the concentric of the video camera the user has to use this menu point. The video image which displays the ablation area has to be checked with the **Check optical alignment** procedure.

Check optical alignment:

By pressing the button the laser will shot following image



Now the user has to check if the cross-hair is in the center and has the same outlook like in the image above.

Stop show histogram:

With this function the intensity and contrast has to be checked. On the right side the user can see a standard histogram which is guilty for the adjustment. The red second histogram has to be overlapped with the standard histogram. By moving the intensity and contrast scrollbar it is very easy to bring both histograms together.

If the user had done this, the alignment of the camera is OK.

If a human eye is positioned in the ablation zone the service can check once again the functionality of the eye-tracking.

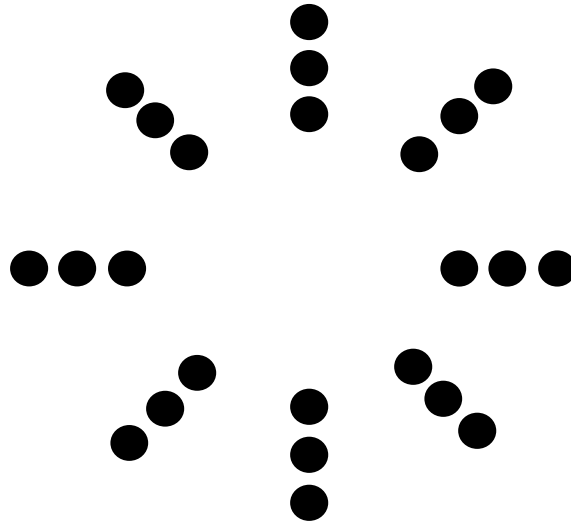
Attention: The quality value should be higher than 120.

The position POS shows the coordinates of the center of the pupil. (compare it with the red cross-hair).

Check optical area:

With this function the service can check the concentric of the scanning mirror.

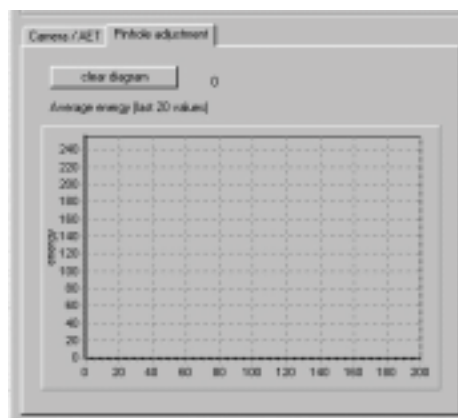
If the user is starting this function, the laser is shooting such profile by pressing the foot-switch.



After this test the user has to check with a lensmeter if he has such profile. If not then the adjustment of the optics has to be checked again.

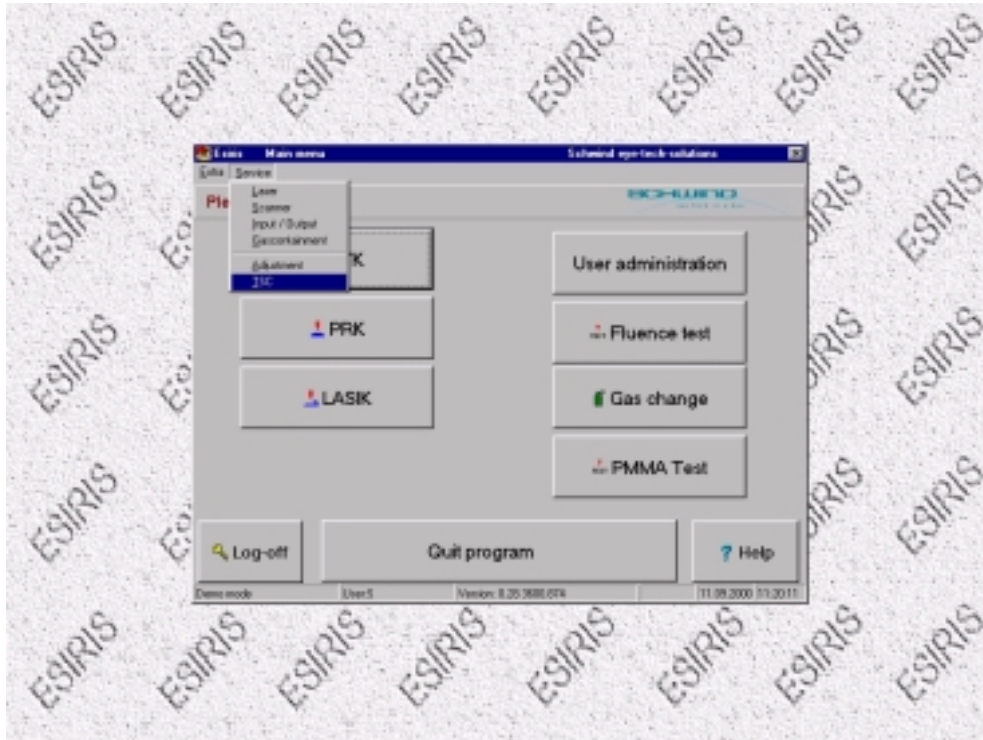
Pinhole adjustment:

By selecting the pinhole adjustment function, the user can check the intensity of the laser beam itself. It is very recommend to do this with this function, because only there the service can be sure that the pinhole is well adjustet. By pressing the foot-switch the laser begins to fire. During the movement of the pinhole the intensity which will be displayed in the histogram shows the maximum what is possible.

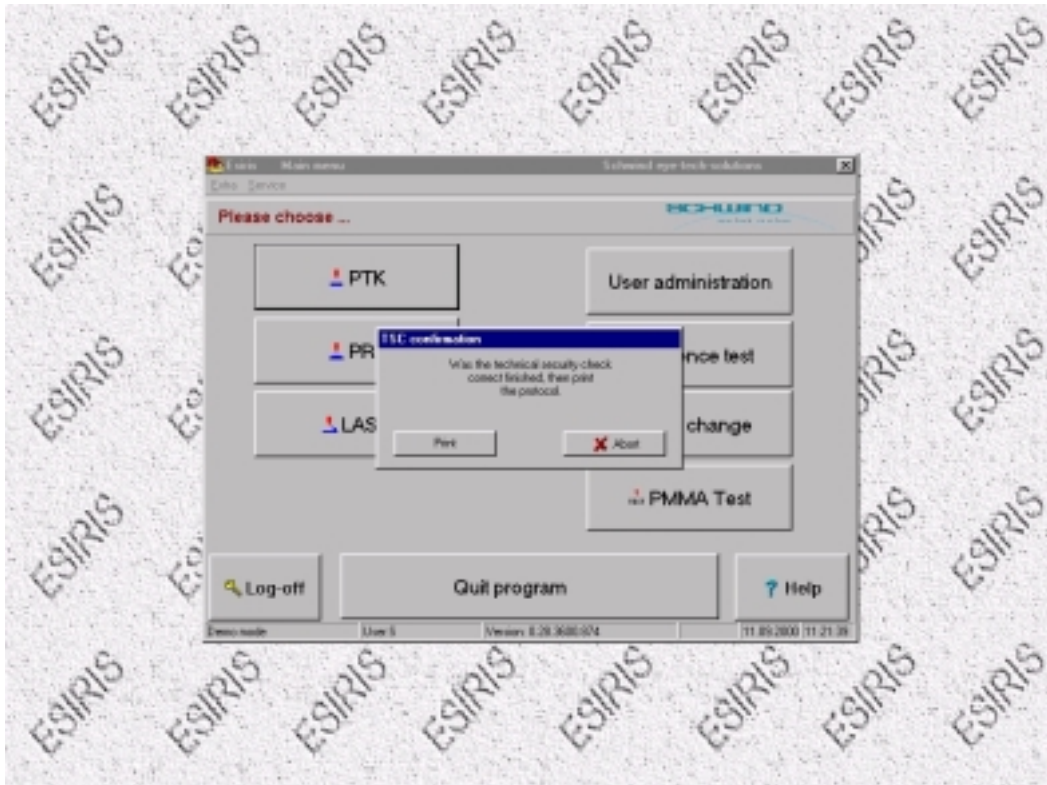


Menu Technical Security Check (TSC)

If the user is selecting this menu, he will be asked if he has done the TSC.



By confirming with the **print**-button a protocol will be printed out.



5. Unpacking and Controlling

SCHWIND ESIRIS is delivered in three separate crates. Remove and store packing material until installation. Check the components for damage and completeness according to delivery list.

The customer is not allowed to perform electrical connection. Disregard would invalid warranty.

Device has been packed properly in perfect condition at factory. Transportation damages are in the responsibility of transporting agent. In case, such damages are recognised during receipt or unpacking, please follow this list:

- In case of outer damage, transporting agent has to check damage and record it at the delivery note.
- Write a report for insurance company with estimated costs.
- In case of inner damage, which could be recognised with unpacking, inform transport agent and follow A) and B)
- Store packing material, until all questions with transport agent and insurance company are cleared

Putting into operation

Installation and instruction according to MDD 93/42 EWG is done through a service technician/engineer from **SCHWIND** or authorised distributor. A not permitted installation, starting or use of the device invalidates warranty. The service technician inspects the room for necessary installations (space, voltage connection, security regulations, and ventilation). He confirms the correspondance at the inspection protocol and connects the system to the power supply. After a system check and after necessary adjustments, he performs examining checks. After installation the device **must not** be transported to another room and there installed and started without getting knowledge to **SCHWIND** or distributor.

Warranty

- Time of warranty starts with operational by handing over and confirmation at the delivery note through the customer.
- Warranty time for **SCHWIND ESIRIS** lasts 12 months
- Warranty includes all defects of the device, caused through defective parts or manufacturing. Further, malfunctions that are not caused through improper use, are repaired under warranty. Further, wilfully damage is not repaired under warranty.
- **SCHWIND** or distributor have to be informed about damages or malfunctions immediately.
- Defective parts have to be returned to **SCHWIND**

6. Dismantling of the ESIRIS-lasers

To prepare the Esiris laser for transportation, you have to remove the patient bed together with the gas containment from the complete laser system.

Before disconnecting the gas tube from valve plugs of the Optex laser, you have to be sure, that no more premix gas is inside the tube.

So please follow the instructions below:

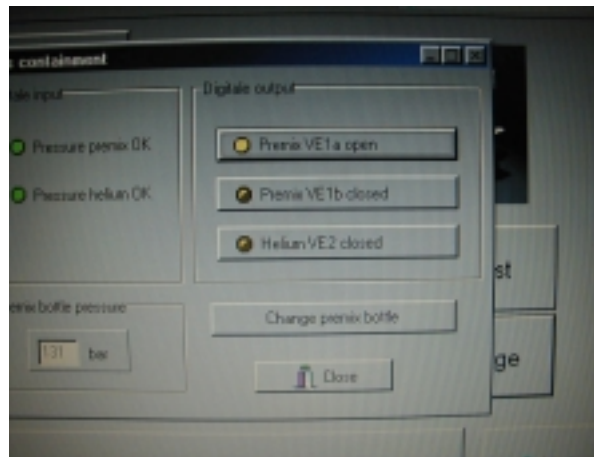
Removal of gas bottles (premix and helium)

Turn on the Esiris laser with the main key-switch and log in with service authority..

1. Choose menu '**SERVICE**' > '**gas containment**'



2. Press button '**Exchange Gas Premix Bottle**'



3. Follow the messages on screen until **'Now you can change the premix bottle'**



4. Now you can press the button **'Abort'** to interrupt the whole premix bottle exchange procedure.
5. Loosen the connection "pig tail" to premix bottle with open-end wrench



6. Mount screw cab onto Premix gas bottle and pig tail.

Hint: By transportation of the laser with air cargo you have to remove the premix gas bottle.

7. Close helium gas bottle valve and loosen the connection "pig tail" to helium bottle with open-end wrench.
8. Mount screw cab onto helium gas bottle and pig tail.

Hint: By transportation of the laser with air cargo you have to remove the helium gas bottle.

9. Close the gas containment

10. Shut down the PC, switch off the system by turning the main key and unplug the power line connection.

Hint: in fact of using an uninterruptable power supply (UPS), switch it off and also switch off the in- and outputbreaker.

11. Disconnect the power cable of Esiris from the UPS.

12. Unplug the optical trigger cable and the optical RS 232 cable from the OpTex laser.



13. Loosen the connection of gas tube to valves of OpTex laser by using an open-end wrench (9/16")



14. Use gyrolock screw cap to prevent Optex valves

15. Use plastic (yellow) screw caps to prevent the gas tube.

16. Connect again the optical trigger cable and the optical RS 232 cable to the Optex laser



6.2 Unplug electrical connections of patient bed, CAN-BUS module and gascontainment

1. Unplug the following electrical connections:

- 24VDC Gas
- 9 pole sub D plug (can Gas M.)
- patient bed (T.)
- RS232 cable for bed control (com 1)
- Remove power cable of patient bed from power socket Esiris



2. Then bring back these cables to stick them to the patient bed
3. Afterwards loosen the screw (13 mm key) of the earthing socket



6.3 Dismantling of optical parts

Dismantling of microscope :

1. Loosen the 4 screws of the microscope base plate (3 mm allenwrench)



2. After removal of the microscope, tighten the screws again with the hands (to prevent them from loosing)

Dismantling CCD camera tower:

1. Remove the 25 pole plug of the CCD camera



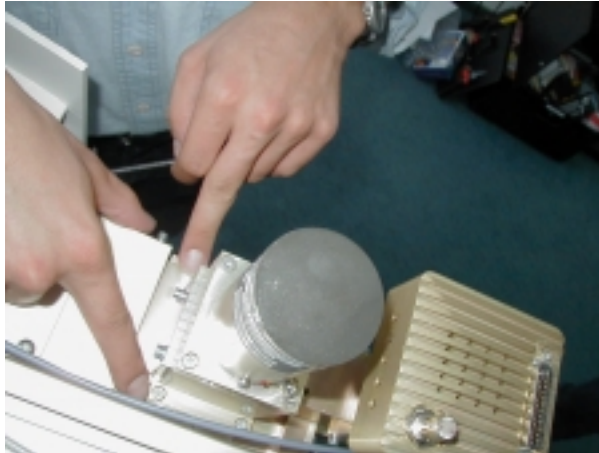
2. Loosen the BNC cable of CCD camera



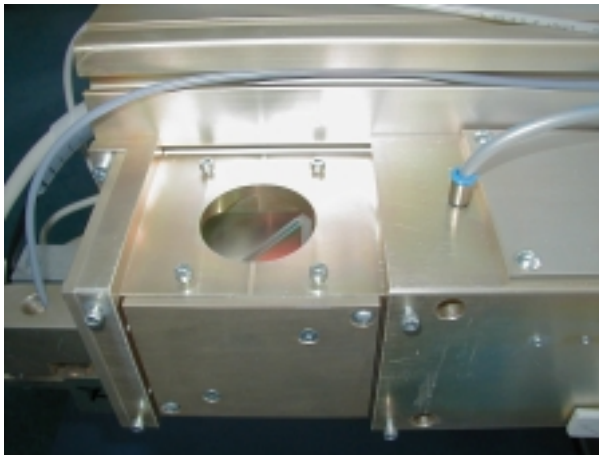
3. Unplug the power cable of the fixation laser



4. Loosen the 4 screws of the CCD camera tower



5. After removal of the CCD camera tower, tighten the screws again with the hands (to prevent them from losing)



6. Cover the opening with tape



7. Protect the CCD camera tower with plastic hood

8. Fixate the cables at the optical arm with tape



Dismantling Scanning mirror

1. Open the electronic box

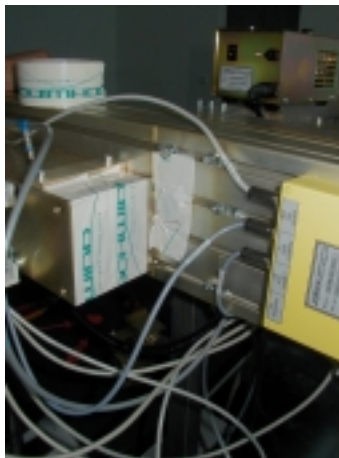
2. Unplug both connections of the galvos



3. Loosen the 4 screws (allenwrench 4mm) of the scanner and hold the scanner with your hands (attention: **do not touch the mirrors mounted on the galvos**)



4. After removal of scanner, tighten the screws again with the hands (to prevent them from loosing)
5. Protekt both beam openings with tape to protect them against dust.



Nitrogen gas cylinder

1. Unplug nitrogen tube at nitrogen management



Dismantle Monitor and Keyboard

1. Loosen the 2 screws at the bottom of the monitor table and remove the cover



2. Unplug the cables for the keyboard and the trackball at the back side of the PC (left: keyboard; right: trackball)



3. Unplug VGA connector and pull both cables to the front of the system



4. Unplug the power cable (12V DC) for the monitor



5. Remove the monitor and the keyboard

6. Dismantle the monitor / keyboard holder with allenwrench (8mm)



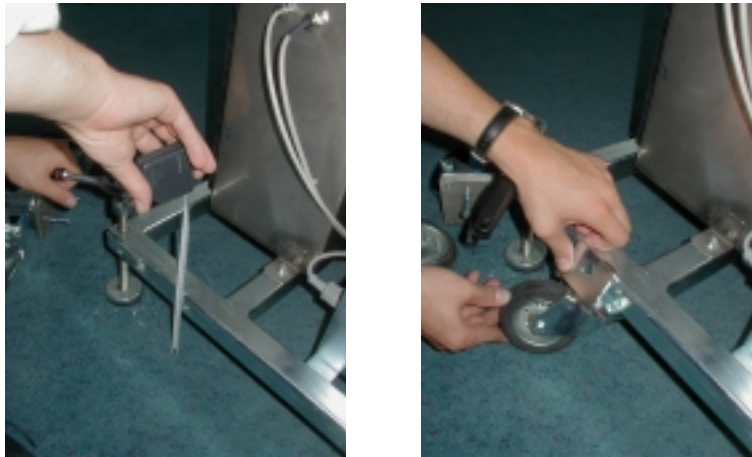
Disconnection of the fluence detector

1. Unplug the fluence cable at the fluence detector
2. Fixate the cable with tape at the system



Dismantling the Patient Bed

1. Screw up the 4 feet to a height of 14 cm from floor to bottom edge of the rack.
2. Fixate the wheels into the allocated drills.
3. After that carefully rolling out of the patient bed to the back.



Dismantling Laser

1. The 4 feet of the laser must be screwed up step by step and not one after the other, otherwise the laser could cant (Danger!!). Screw the feet up to 15 cm distance from the floor to the bottom edge of the laser rack.



2. Fixate the wheels into the allocated drills.

7 Installation of the ESIRIS-Laser

Assembling the Laser

1. Move the laser rack to the correct place in the room. Then screw down the 4 feet of the rack until the wheels rotate free.



2. Unscrew all 4 wheels and put them away.
3. Screw down all the 4 feet step by step, not one after the other, otherwise the laser could cant (Danger!!). Screw the feet down to a distance of 8 cm from floor to the bottom edge of the laser rack.
4. Align the laser rack with a spirit level by minimally moving the feet.

Assembling of the Patient Bed

1. Disconnect the light fibers for lasertrigger and to the RS 232 interface.
2. Move the patient bed carefully to the laserrack until both fit together. Be careful not to snap off the gas pipe!



3. Screw down the 4 feet of the bed until the wheels rotate free, unscrew them and put them away.



4. Screw down all the 4 feet to a distance of 8 cm from floor to the bottom edge of the lasser rack.



5. Align the patient bed with a spirit level by minimally moving the feet. Use the accessible three sides of the rack by minimally moving the feet.

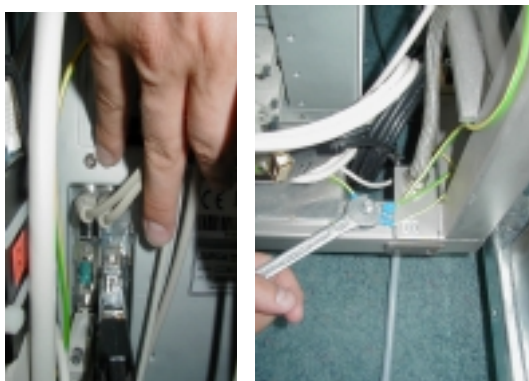


Electrical Connection of Patient Bed, CAN-Bus-Module and Gas-Containment.

1. First put all the cables and light fibers through the laser rack.
2. Connect the following cables:
 - 24 VDC Gas
 - 9-pin Sub-D-Connector (CAN Gas M.)
 - Patient bed (T.)
 - RS 232-cable of patient bed controller to COM2 of the PC
 - put power plug into the socket ledge at the laser rack



3. 3. Anschließend Erdungskabel der Liege am Lasergestell anbringen (13 mm Connect the Ground cable of the bed with the allocated screw at the laser rack (13 mm screw-wrench)



Assembling of Monitor and Keyboard

1. Assemble the metal arm for the table of monitor and keyboard to the laser rack.



2. Build in the monitor and keyboard in the table and thread in the three cables of monitor, keyboard and power supply. Connect the monitor with the according cables. Then fix the cover with the screws.



3. Connect the keyboard to the according jacks at the back side of the PC (left: keyboard; right: mouse). Connect the monitor cable to the according jack at the back side of the PC.



Assembling of the Laser Beam Delivery System

Assembling the Microscope:

Connect the four screws of the basic plate with the laser arm.



Assembling CCD-Camera Tower

1. Remove tape of the cable of the camera tower.



2. Remove dust cover of radiation exit aperture.
3. Remove tape of the camera aperture on the laser arm.



4. Remove the four screws for the camera tower out of the laser arm.
5. Fixate the camera tower with the four screws to the laser arm.
6. Connect the BNC- and the 25-pin SubD-cable to the camera.
7. Connect cable of the fixation-laser.

Assembling the Scanner

1. Remove the tape of both apertures at laser and scanner.
2. Connect scanner with four screws to the laser arm.
3. Connect the cables of the scanner to the cables that come out of the electronic box.



Connection of the Nitrogen Bottle

Pull the nitrogen tube through the bottom plate of the laser and connect it to the nitrogen pressure management.

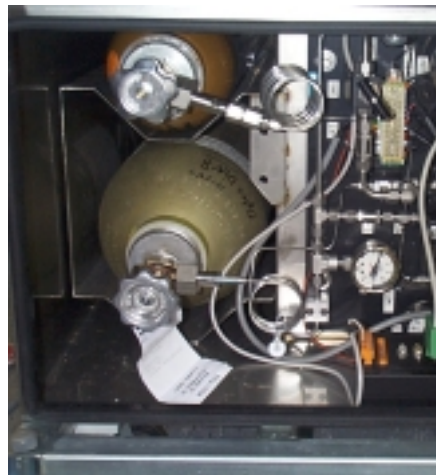


Assembling Fluence Detector.

Connect the according cable to the fluence detector and tighten it.

Connection of the Gas Management to the Optex Laser

1. Remove yellow protection cap from the Gyrolock connector at the gas pipe.
2. Remove yellow protection cap from the valve block of the Optex laser.
3. Connect the gas pipe from the gas containment with the the valve block of the Optex laser and tighten it using the screw-wrench (9/16").
4. Connect light fiber for laser trigger and RS 232 light fiber to the Optex
5. Open the gas containment with the according key.
6. Remove protection caps from the gas bottles and from the pig-tails.
7. Insert the gas bottles into the gas containment and connect the pig-tails to the according gas bottles.



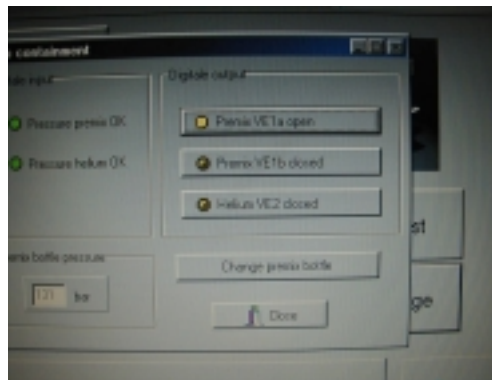
8. Open the bottles.
9. Control all the connections by using the Snoop.

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10. Connect the ESIRIS to the UPS and switch it on with the main key-switch. Log in with service authority.
11. Choose menu '**SERVICE**' > '**gas containment**'



12. Press button 'Change Premix Bottle'



13. Follow the messages on screen until the end of the procedure.

8. Alignment of the ESIRIS

1. Check the laser beam behind the Optex and make sure that the laser beam is central to the first mirror. For the check use fax paper.
2. Remove all optical and mechanical parts of the first optic tube (integrator, 1st lense, pinhole and 2nd mirror). Align the laser beam to the center of the tube opening behind the 2nd mirror.
3. Insert the 1st lense and check if the beam is still in the center.
4. Insert all the other parts into the optical tube (integrator, pinhole, 2nd mirror and all the covers). Pay attention to the lense direction!!
5. Remove the scanner and check if the beam is in the center of the outcoupling hole in front of the scanner. Align the beam by moving the 2nd mirror.
6. If the beam is centered assemble the scanner again.
7. Check the lenses behind the scanner that they are in the correct direction.
8. Select the service login at the PC and follow the messages on the screen for ``Adjustment`` (see chapter ``Service menu/adjustment``).

Appendix

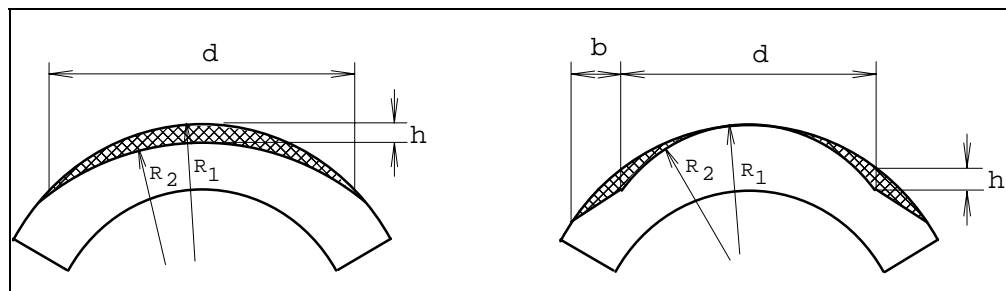
The following appendixes include details of the laser and precise descriptions, which provides the user a better understanding. They are not necessary for ordinary use and so they are not part of user manual.

Appendix A: Calculation Basis

A1. Introduction

For correction of myopia and hyperopia on human eyes, it is necessary to flatten the bounding of the corneal surface or to rise it. If furthermore an astigmatism should be corrected, the bounding of the cornea has to be changed differently in two meridians.

Picture 17: Schematic drawing of corneal correction in



section.

Correction of Myopia $R_1 < R_2$

Correction of Hyperopia $R_1 > R_2$

The areas, treated with excimer laser are darkened.

d = diameter of optical zone,

h = maximum depth of corneal incision

b = width of transition zone at hyperopic correction

R_1 = bending radii of cornea before treatment

R_2 = bending radii of cornea after treatment

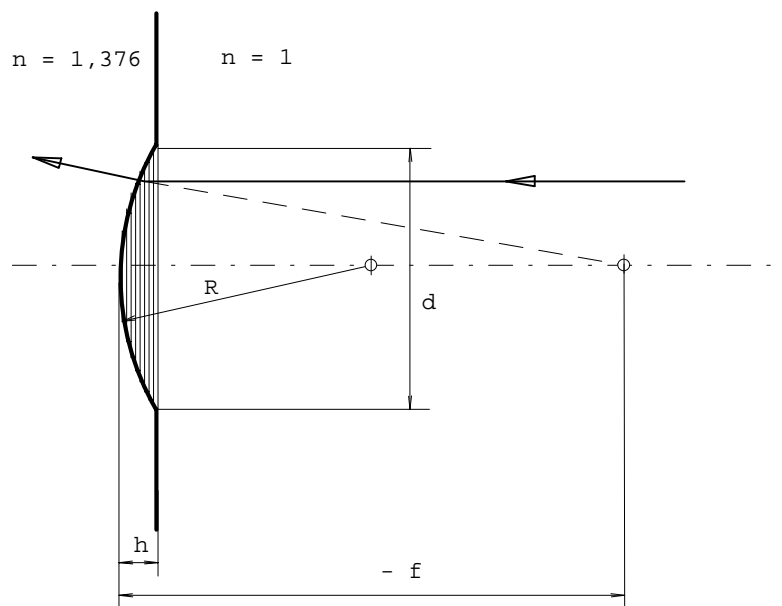
Based on the change of bending on corneal surface, the power of refraction is changed referring to the following formulae:

$$D = (1-n) \times (1/R_2 - 1/R_1)$$

Value for cornea ($n=1.376$) has to be taken for refraction index. Unit for R is (m). Calculation of new corneal contour with above mentioned formulae is very lavish. A great simplification is the assumption of an even surface. In this area a positive or negative lens is made. Consideration of actual corneal bending is not necessary. For adaptation of power density, which influences an area element, to an angle of incidence, it is enough to take the norm bending radii of cornea ($R=7.8$ mm).

A2. Correction of Myopia

Geometric relations at myopia correction under easier assumption of a flat basic area are displayed in picture 3.



Picture 18: Simplified basis for calculation (even corneal surface) for Myopia

An area with negative focal distance is worked in to the basis area. The bending radii of this new limited area results on the following formulae:

$$R[\text{mm}] = (1-n) / D = -376 / D$$

The refractive index of cornea is taken with $n = 1.376$. The requested correction of refraction D has to be taken in diopters [m^{-1}].

For the correlation between diameter of optical zone **d** and the central ablation depth **h** the following formulae is valid:

$$d = 2\sqrt{2hR - h^2} \approx 2\sqrt{2h^x(1-n)/d}$$

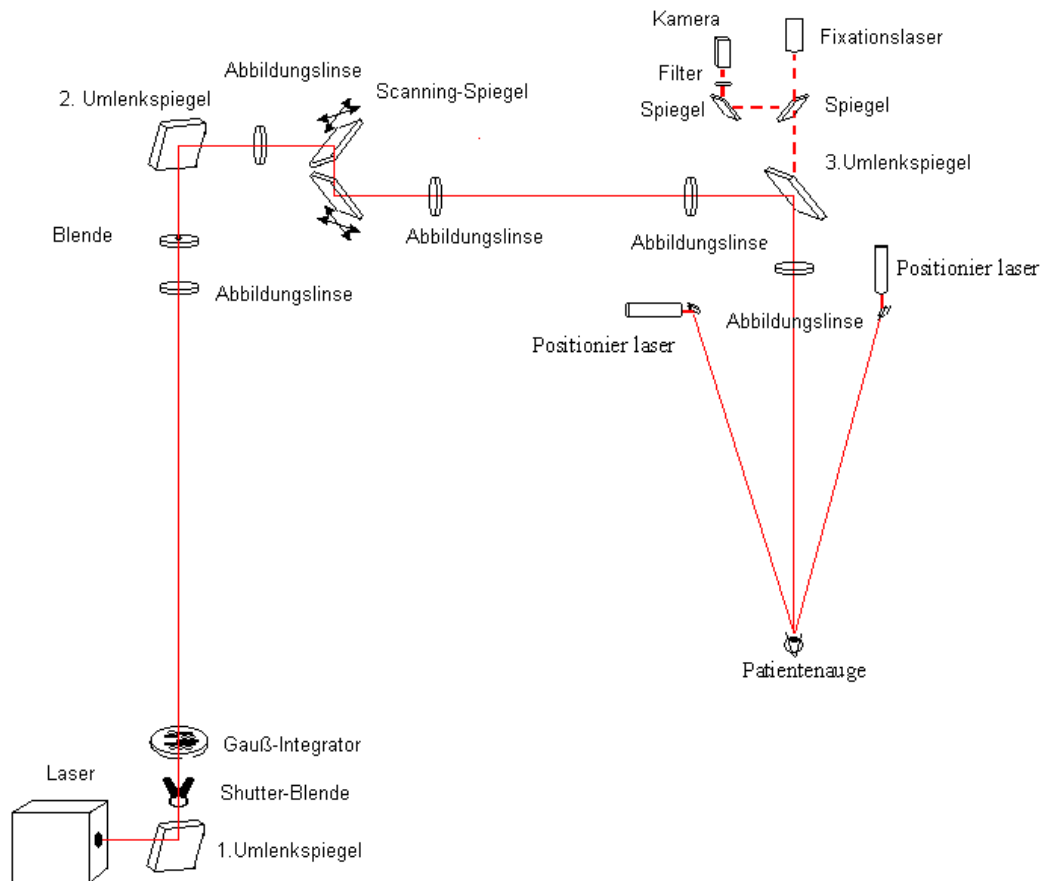
$$d^2 = 8h^x(1-n)/D$$

Diameter **d** of single ablation zones is pre-set through diameter input into the software.

Appendix B: Beam Delivery System

B1. Optical System

The beam delivery system forms the beam of the excimer laser in the requested way and produces radiation areas at the patient's eye with supervised features (diameter, shape and direction). For a wavelength of 193 nm the optical components have to be well transparently. They are made of synthetic quartz glass. The way of beams inside the **SCHWIND ESIRIS** is schematically displayed in the following picture.



Picture 19: 3-dimensional scheme of beam delivery system

The beam output of the laser has a doubled working mechanical shutter after the first bending mirror. Usually, it is always closed. It is only opened, when the operator presses the footswitch. The cross-section of the rough beam, which is emitted by the laser, is 4 x 7 mm. It is formed to a gauss laser profile with an integrator optic. The beam is then deviated by a mirror and comes then to the 2. bending mirror, and is changed to 90°. Through a further lens, which enlarges the beam, the beam comes to a scanning mirror. Then the beam is enlarged through two further lenses until it meets the 3. Bending mirror. From here the beam is focused circularly focused through the last lens to the treatment level and so it comes to the ablation level.

For the several kinds of treatment and there profile the scanning mirror takes over the main task. The single profile parameter are transmitted directly form the software to the mirror and will be worked off.

Through this splitting mirror, the patient eye can be watched with a video camera. An automatic observation of the eye movements enables a quick interruption of the treatment procedure, if the patient leaves the fixation.

A red blinking diode laser is used as fixation target, which can be seen from the patient through the beam splitting mirror. The output of this laser is weakened to an optical power of $< 10 \mu\text{W}$ (laser class 1).

The correct working distance is aligned under control of the operating microscope with two red pilot laser beams, one from the left and one from the right, which are directed to the cornea in an angle. They meet at the cornea at the working distance. As the light spot at the cornea can not be well seen, in practice the light spots at the iris are used. In the working distance these light spots are at the right and left margin of the small fixed iris. With enlarging the distance (driving down the patient bed) the light spots have to move outside. With this fixation of the working distance the patient is moved until the cornea is in the ablation point.

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