SCHWIND
eye-tech-solutions

USER MANUAL (Instruction for Use) TREAT

Original version

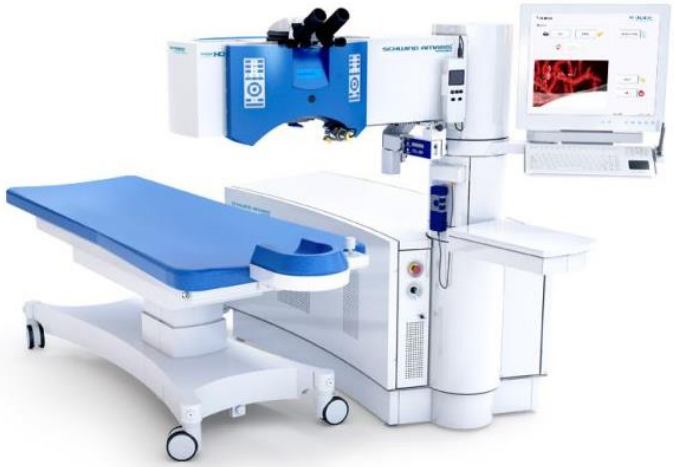
SCHWIND AMARIS

Excimer Laser

SCHWIND AMARIS 1050RS

SCHWIND AMARIS 750S

SCHWIND AMARIS



SCHWIND AMARIS 500E

CE 0483

SCHWIND eye-tech-solutions GmbH Mainparkstrasse 6-10 · 63801 Kleinostheim GERMANY

Dear Customer

Thank you very much for purchasing this medical product and the confidence you have in our company. You have decided on a sophisticated product, which was manufactured and tested under strict quality criteria.

Construction and production fully complies with regulations and requirements which apply to medical products.

Compliance with all effective standards and laws is clearly visible by the CE symbol, which is displayed on the identification label. The CE Symbol stands for conformity with current laws and consequently for security and confidence.

CE 0483

Constant research and development may cause changes in design and scope of supply. Therefore, in individual cases, the figures in this manual might deviate from the delivered product.

If you have any questions or desire further information about your equipment, please do not hesitate to contact us via phone, fax or e-mail. Our team of specialists will be glad to help you. Our address, phone and fax numbers, as well as the e-mail address can be found at the beginning of this manual in chapter GENERAL INFORMATION.

Sincerely,

SCHWIND eye-tech-solutions GmbH

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1 GENERAL INFORMATION

1.1 System Identification Data

Product name: **SCHWIND AMARIS 1050RS**
SCHWIND AMARIS 750S
SCHWIND AMARIS 500E
SCHWIND AMARIS

Device description: **Ophthalmologic laser equipment for corneal tissue ablation, refractive surgery** (refer to chapter **4 Device / System Description**)

Medical device class: **IIb (according to MDR Annex VIII, resp. MDD Annex IX)**

Laser classification: **4 (according to IEC 60825-1:2014)**

Software version: **6.1**

Serial number: Refer to **identification label** of the device(s).

EMDN (European Medical Device Nomenklature): **Z12011001 (Excimer Surgical Laser)**

Basic UDI-DI (All models): **426015714E057-EXCIMER6M**

Unique Device Identification (UDI-DI):

AMARIS Model		UDI Number
UDI-DI	AMARIS 500E	**(01)04260157140219**
	AMARIS 750S	**(01)04260157140226**
	AMARIS 1050RS	**(01)04260157140240**
Complete UDI format:	AMARIS 500E	**(01)04260157140219(11)YYMM00(21)Mxxx**
	AMARIS 750S	**(01)04260157140226(11)YYMM00(21)Sxxx**
	AMARIS 1050RS	**(01)04260157140240(11)YYMM00(21)Rxxx**

CE labelling: CE 0483

Approved device combination: Refer to chapter **4.15**

General Information

System requirements: Refer to chapter **5.2**

Manufacturer: **SCHWIND eye-tech-solutions GmbH**
Mainparkstrasse 6-10
63801 Kleinostheim, GERMANY

SRN (Single Registration Number): **DE-MF-000019049**

Delivery: **SCHWIND eye-tech-solutions GmbH**
or authorized distributor

Current document status: **Version 6.1.11 dated 12-APR-2024 EN**

1.2 Symbols for Warnings, Precautionary Measures and Notes

The following conventions are used in this manual:

WARNING!

This symbol advises the user of serious danger for the patient and the user.

CAUTION

The symbol informs the user that particular care is required for safe and efficient operation of the system.

IMPORTANT NOTE

This symbol provides the user with useful or additional information.

1.3 Notes on the User Manual

The purpose of the user manual is to familiarize the operator(s) of the SCHWIND AMARIS lasers with the design, operating principle, transport, installation, set-up, safe operation, safety notes and the care and maintenance of the medical laser device.

IMPORTANT NOTE

The AMARIS User Manual contains the relevant information for the excimer laser device and the application software only!

Read this User Manual carefully and consider all instructions, as well as safety and warning notes before starting operation of the SCHWIND AMARIS.

However the AMARIS User Manual does not contain all information necessary for the safe and effective operation of the SCHWIND AMARIS as a system combination with the patient bed, the necessary software(s) and/or optional features!

Therefore consider the accompanying documents:

- **User Manual SCHWIND Patient Bed**
- **User Manuals SCHWIND CAM and modules: ORK-CAM and Comparison, PresbyMAX, PTK-CAM**
- **Reprocessing Instruction for re-sterilisable SCHWIND Products**
- **Instructions for Use "Getting Started" for C-eye Cross-Linking or CXL-365 vario**

Please keep the User Manual(s) and all related documents close to the medical device. Allow any user access to the User Manual(s) at all times, store it readily available.

IMPORTANT NOTE

An electronic copy of this user manual can be found embedded in the software. Choose <**Help**> within AMARIS Application software for User Manual access.

IMPORTANT NOTE

If you have any questions regarding any matters, contact an authorized local SCHWIND representative or SCHWIND eye-tech-solutions directly for advice.

Refer to chapter 13 Manufacturer / Technical Support/ Application Support.

IMPORTANT NOTE

The English manual contains the ORIGINAL INSTRUCTIONS, which are legally binding. Translations of these must bear the words **"Translation of the Original Instructions".**

1.4 Scope of Documentation

The scope of documentation of the SCHWIND AMARIS includes the:

Accompanying Documentation "SCHWIND MEDICAL PRODUCTS", consisting of:

- Medical Apparatus Book "SCHWIND MEDICAL PRODUCTS" (EN) or (DE)
- CD/DVD-ROM with Product Documentation SCHWIND AMARIS

Name	Article Number
Accompanying Documentation with Medical Appartus Book	202160x-01 (EN), 202160x-02 (DE)
Product Documentation CD/DVD „SCHWIND AMARIS" (Includes the manuals for SCHWIND SCHWIND AMARIS, Patient Bed, SCHWIND CAM, and the relevant manuals as listed in chapter 1.3., current version)	163430x

1.5 Declaration of Manufacturer

The manufacturer SCHWIND eye-tech-solutions GmbH (SCHWIND) has been authorized by the Notified Body "mdc medical device certification GmbH" (listed at the European Commission with number 0483) to develop, manufacture, distribute and service ophthalmic lasers and accessories for refractive surgery, and medical software for ophthalmology.

Historically, the SCHWIND AMARIS excimer lasers have been developed according to the applicable requirements of the European Medical Device Directive 93/42/EEC, as amended. Since applicability of the Medical Device Regulation (EU) 2017/745 (which replaces the mentioned Directive), it also fulfils the applicable requirements thereof.

CE-Conformity of the devices is declared if and only under the following preconditions:

- Delivery is accomplished by SCHWIND or a distributor authorized by SCHWIND.
- All service and maintenance work is exclusively performed by personnel who are authorized by SCHWIND.
- Accessories, consumables and disposables are supplied by or approved by SCHWIND, or – under solely responsibility of the costumer – their safe operation and interaction is confirmed by an independent accredited testing organisation.

IMPORTANT NOTE

The **Declarations of Conformity** for SCHWIND AMARIS excimer laser can be found on the CD/DVD-ROM "Product Documentation SCHWIND AMARIS".

1.6 Liability of the Manufacturer

SCHWIND eye-tech-solutions does not assume any liability for:

- Injuries to persons, unless caused by gross negligence of the manufacturer.
- Damages of properties.
- Damages / destruction of equipment or software.
- Data loss.
- Financial, legal, commercial and productivity-related disadvantages for the company and the personal user.

Or for the following courses of action:

- Lack of reading this manual completely and carefully before starting operations with the SCHWIND AMARIS.
- Using the AMARIS Application software on computers not officially approved by SCHWIND eye-tech-solutions.
- Lack of understanding the instructions provided in the user documentation, and the explanations provided by SCHWIND's application specialists (otherwise contact SCHWIND's application specialists for further details).
- Lack of observation of any other instructions and safety requirements provided by the user information of compatible devices and accessories for ensuring compatibility and safe operation of the combination between devices.
- Use of any compatible device or accessory without having received adequate inspections and calibrations for proper use and measurement.

- Insufficient training of the user, which can give rise to human errors when using the device with the consequent risk of injury to the patient.
- Use of the equipment by not suitably trained personnel.
- Use of this device for purposes different than its intended use or for its use outside the environment of an ophthalmic surgery.
- Any attempt to alter, modify or manipulate the product in a way not stipulated in the User Manual of SCHWIND eye-tech-solutions.
- Use of the AMARIS Application software or any of its components in different applications.
- Manipulation, alterations or damages to the software or to the device by technicians not authorized by SCHWIND eye-tech-solutions or other third parties.
- Non-observance of the operating notes, warning symbols and safety instructions in this manual.
- Operational error of user.
- Computer virus.
- Excessive force.
- Power failure, voltage fluctuations, electromagnetic interference.
- Inappropriate storage of the data medium (e.g. humidity or temperature influences)
- Erroneous deletion of data by the user.
- Negligence by the user.

1.7 Warranty

IMPORTANT NOTE

The duration of the warranty period for the SCHWIND AMARIS excimer laser system is 12 months.

1. The warranty period begins with the first start-up of the device after signing of the delivery note by the client.
2. Warranty includes all defects of the device caused by defective parts or manufacturing faults. Malfunctions that are not caused by improper use are repaired under warranty. Damage caused by abuse or improper use is not repaired under warranty.
3. The legal warranty applies only to parts that are replaced or repaired by SCHWIND eye-tech-solutions.
4. Damages or malfunctions have to be reported to SCHWIND eye-tech-solutions or to the representative immediately.
5. The damaged parts have to be sent back to SCHWIND eye-tech-solutions. When returning defective parts, please use the original packing or coordinate alternate packing with SCHWIND eye-tech-solutions.
6. Deficiencies that arise from:
   - Non-standard or extraordinary use.
   - Repairs without original parts.

- Incorrect treatment of the device.
- Inspections, services, device modifications or any form of manipulation of the system performed by unauthorized personnel will void the guarantee and will relieve SCHWIND eye-tech-solutions from any responsibility.

7. SCHWIND grants no other warranty, either express or implied, concerning the above-mentioned parts and their documentation. Any implied warranties of merchantability and fitness for the particular purpose are disclaimed.
8. SCHWIND shall not be liable for incidental, consequential, indirect, or special damages of any kind, loss of information or data, or other financial loss arising from or in connection with the sale or use of the product, whether based in contract, tort (including negligence) or any other theory.
9. The above-mentioned exclusion of liability is void if the cause of damage is based on intent or gross negligence. Furthermore, it does not apply to damage due to lack of warranted quality and claims under product liability.
10. Product improvement initiatives based on technological development are not grounds for free-of-charge system upgrades.
11. The General Conditions for Sale, Delivery and Payment of SCHWIND eye-tech-solutions are generally to be considered.

Consider also General Warranty Regulations of SCHWIND eye-tech-solutions GmbH.

1.8 License Agreement

The license agreements realized between the licensee and SCHWIND eye-tech-solutions GmbH are binding.

1.9 Copyright

1.10 Trademarks

All names of other companies and their products mentioned in this manual could be trademarks or registered trademarks.

Quoting of product names is for information only and does not represent any trade mark misuse.

SCHWIND eye-tech-solutions is not liable for the performance or the use of these products.

1.11 How to Access the eIFU

We offer our users an eIFU for accessing the product documentation.

You will receive our SCHWIND product documentation on disc (CD-ROM) as PDF files. This CD/DVD is self-booting. Please observe the enclosed instructions for use **„How to Use CD-ROM/DVD with electronic SCHWIND Instruction for Use"**.

To be able to read the PDF files contained on the CD-ROM, you need a computer with a standard PDF reader. A PDF reader is already installed on the SCHWIND products (SCHWIND AMARIS, SCHWIND ATOS and Workstation).

In addition, you can download the current documents (and previous versions) for your product in the SCHWIND Portal, which you can reach via the following link:

https://www.eye-tech-solutions.com/portal by using your login data (provided by SCHWIND). To access SCHWIND Portal, you may use, without restrictions, any type of browser commercially or publicly available.

This website is fully compliant with the EU General Data protection Regulation 2016/679 (GDPR). Schwind eye-tech-solutions retains personal data for as long as providing services to you or your account remains open. You have the right to access information held about you, ask for correction and/or deletion. After you have closed your account, your personal data related to your account will be deleted unless SCHWIND eye-tech-solutions needs to fulfil legal obligations or regulatory requirements. If you have any question about your right regarding data protection, you may contact SCHWIND Data Protection Officer at datenschutzbeauftragter@eye.tech.net

SCHWIND Portal is available 24/7 under the assurance of the qualified provider and common industry standards.

SCHWIND Portal has been validated to ensure that the probability for occurrence of wrong information on your display is reduced at its acceptable level limit. If you suspect any abnormality when using the portal please contact immediately your service technician (see contact in 13 Manufacturer / Technical Support/ Application Support).

After logging into the SCHWIND Portal, you can select the appropriate instructions in menu Support / Application Support using various filters. New users must first register for the Portal via *Registration for new users*.

It is ensured that when installing new software on the device, the integrated instruction manual is always up to date. You also receive a new CD-ROMs with updated instructions during the visit of our Customer Service department.

For your information, the CD-ROMs only contains instructions in English. The Instructions in other languages are available in the SCHWIND Portal. For safety-related changes in the instructions you will be informed immediately by the SCHWIND company by email.

Upon request, you will receive the paper format of the IFU by mail within in 7 working days – free of charge (see contact in 13 Manufacturer / Technical Support/ Application Support).

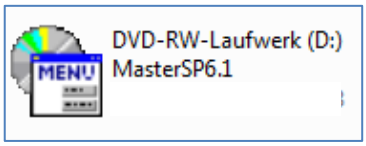
1.12 Using the Product Documentation CD-ROM with the eIFU

To read the SCHWIND **electronic Instructions for use** contained on the "SCHWIND Product Documentation" CD-ROM, perform the following steps:

- Insert the CD-ROM into the disc drive of your computer.
- Double click on the Symbol "CD_Start"

If your **AutoRun** function is switched off and the CD-ROM does not start automatically, please proceed as described below:

- Double click on the desktop on the symbol ***Computer*** (Arbeitsplatz) **or** start the CD-ROM using the Windows (File) Explorer.
- Double click on the CD-ROM symbol:



2 SAFETY

2.1 General Safety Notes

The instructions given in this chapter are to be considered for proper and safe operation of the SCHWIND AMARIS.

The medical device was designed and manufactured in compliance with applicable legal standards and further technical specifications. It is a state-of-the-art product and offers a high level of safety.

This level of safety can only be maintained in practical use of the system when all required measures are taken. It is the obligation of every system user to plan and supervise the performance of these measures.

You will find relevant information in chapter 2.4 Manufacturer's Responsibility and in chapter 2.5 Operator's Responsibility.

IMPORTANT NOTE

Observe all safety regulations, notes and precautions in this User Manual to ensure that the device is operated only in accordance with generally accepted rules of technology and the relevant regulations for medical devices (refer to chapter 2.2 Regulations for Medical Devices.

Observe any other instructions and requirements provided by the user documentation of the different medical devices (especially concerning the operation of the patient bed) to ensure compatibility and safe operation of the combination between devices.

For safety recommendations regarding electromagnetic compatibility (EMC) and restrictions on the use of radio frequency (RF) equipment such as cellular phones, refer to chapter 12.4. EMC Guidance and Manufacturer's Declaration.

This is meant for the safety of the patients, for your own safety and for the protection of the product from damage.

2.2 Regulations for Medical Devices

IMPORTANT NOTE

For safe use of the SCHWIND medical device the **operator** must consider the applicable, normative regulations and directives.

The most important of these are:

1. **Council Directives concerning Medical Devices MDD 93/42/EEC**, as amended. Since applicability of the **Medical Device Regulation (EU) 2017/745** (which replaces the mentioned Directive), it also fulfils the applicable requirements thereof.

   (Regulation valid for EEC countries; please consider corresponding national regulations)

2. **European Directive 2012/19/EEC (waste electrical and electronic equipment – WEEE)**

   (Regulation valid for EEC countries; please consider corresponding national regulations)

3. **European Directive 2011/65/EEC (restriction of the use of certain hazardous substances in electrical and electronic equipment – RoHS)**

   (Regulation valid for EEC countries; please consider corresponding national regulations)

4. **Medical Device Operator Regulation – MPBetreibV**

   (Regulation valid only for Germany and to be observed by the operating company; please consider corresponding national regulations)

5. **Regulation „BGV B2 Laser Radiation" for Accident Prevention by the German "employers liability insurance association "**

   (Regulation valid only for Germany; please consider the valid national regulations)

Further standards are listed in chapter 11 Technical Data.

2.3 Restrictions of Use and Safety Precautions

The purpose of safety precautions and preventive measures is to reduce the possibility of coming in contact with the laser radiation and to avoid other risks.

Please strictly follow the notes listed below:

IMPORTANT NOTE

Device use by trained personnel only!

The use and operation of the AMARIS laser is allowed to persons only, who are authorized representatives of the operator trained by SCHWIND eye tech solutions or by SCHWIND eye-tech-solutions certified representatives, or those persons that received a training from the operator authorized and trained representative. Refer to chapter 2.4.1 Training of User and Operating Personnel.

CAUTION

Service by trained and authorized personnel only!

Only suitably trained and from SCHWIND eye-tech-solutions authorized personnel may perform initial installation, modifications, and service of the SCHWIND AMARIS.

WARNING!

Danger of explosion!

Do not operate the laser system in rooms and areas where danger of explosion exists and in the presence of flammable mixtures!

Consider also the **patient safety** notes in chapter 2.5.1 Patient Safety, **installation notes** in chapter 5 Installation, notes regarding **operation the device** in chapter 6 Device Control and Operation and **notes for maintenance** in chapter 10 Maintenance.

2.4 Manufacturer's Responsibility

Manufacturer and dealer are only responsible for proper operation, reliability and security of the device **when:**

- Service personnel authorized by SCHWIND eye-tech-solutions exclusively carry out transport, installation, initial operation, changes, service and maintenance.
- The power connection in the room in which the laser is operated complies with the legal regulations and technical specifications of SCHWIND eye-tech-solutions concerning the installation.
- The device and equipment is operated in accordance with the specifications in the AMARIS User Manual and accompanying documents.

2.4.1 Training of User and Operating Personnel

As with any technological highly-developed medical device, the operation of the excimer laser requires special training and abilities of the user personnel.

IMPORTANT NOTE

The SCHWIND AMARIS excimer laser may only be operated by specially trained physicians or surgeons who have mastered the functions of the laser and who possess the necessary skills to use it in accordance with the instructions in this User Manual.

Each surgeon has ultimate responsibility for the treatment as well as postoperative measures and follow-ups.

WARNING!

Risk of injury!

Insufficient training of the user can give rise to human errors when using the device with the consequent risk of injury to the patient.

Demand or agree regular training upgrades, whenever you feel that you or your team need further support.

SCHWIND eye-tech-solutions or authorized representative will instruct and train the user personnel in accordance with this user manual.

The completion of training for the responsible AMARIS operators and other persons involved in operation, care, maintenance of the excimer laser, should be documented in the **Medical Apparatus Book**. The maintenance of the Medical Apparatus Book is an obligation of the operating company.

The Medical Apparatus Book is a part of the equipment documentation provided with the AMARIS excimer laser by SCHWIND eye-tech-solutions.

2.4.2 Protective Measures of the Manufacturer

The necessity for personal protection measures of the user against dangerous effects from the AMARIS laser are reduced to a minimum through various measures undertaken by SCHWIND eye-tech-solutions during the manufacturing process of the excimer laser system.

The most important measures are:

Technical design of the excimer laser with integrated safety features, such as:

- Enclosure of the beam.
- Guard against accompanying radiation.
- Mounting of control equipment and control features on the laser housing so that switching on and operating the equipment can be carried out without danger of the laser beam exceeding radiation units.
- An EMERGENCY STOP SWITCH „Laser Stop“ for immediate stopping the laser (refer to chapter 6.6 Control Panel of the Excimer Laser).
- Posting of appropriate warning signs on the equipment against visible and invisible laser radiation (refer to chapter 2.9 Device Labelling).
- Appropriate warning references in the laser software which appear on the screen during laser operation.

Organizational Measures, such as:

- Classification of the AMARIS laser (refer to chapter 4.5 Laser Classification).
- Training courses for user personnel (refer to chapter 2.4.1 Training of User and Operating Personnel).
- Start-up of the AMARIS laser through SCHWIND service technicians (refer to chapter 5.5 Initial Installation / Start-Up).
- Maintenance and service (regular TSC controls) (refer to chapter 10.6 Technical Safety Check (TSC).
- Support of the operator and user by the service department of SCHWIND eye-tech-solutions (refer to GENERAL INFORMATION – Technical Assistance);
- Warranty for the laser systems.
- Providing of equipment documentation as listed in chapter 1.4 Scope of Documentation with safety notes in the User Manual.
- Conformity with the Safety Standards (refer to chapter 2.4.3 Conformity with Safety Standards).

2.4.3 Conformity with Safety Standards

Laser Safety

The SCHWIND AMARIS excimer laser, as a medical laser device, corresponds with the safety requirements of IEC 60601-2-22, "Standard for Medical Lasers" and IEC 60825-1 ”General Standard for Laser Safety".

Safety

Electrical Safety, Mechanical Safety, Functional Safety

The SCHWIND AMARIS excimer laser has been tested for electric, mechanical and functional safety according to the international safety standard IEC 60601-1 (general requirements for safety and performance of medical electrical equipment), and the conformity with the above mentioned standard has been verified.

Electromagnetic Compatibility (EMC)

The SCHWIND AMARIS excimer laser has been tested and found to be compliant with the Standard IEC 60601-1-2 regarding electromagnetic compatibility.

Further information on electromagnetic compatibility (EMC)

Despite adherence to all applicable EMC requirements, malfunctioning cannot be ruled out entirely. This equipment has been tested and found to comply with the limits of IEC 60601-1-2 for medical devices. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates uses and radiates radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity.

However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Relocate the receiving device.
- Separate the equipment by increasing the distance.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected. Consult the manufacturer or field service engineer for assistance.

Note: References to standards are to be understood as references to the respective current edition.

2.5 Operator's Responsibility

In order to ensure the safety of patients and user's personnel as well as the proper function of the device, the operator / user must undertake certain measures as listed in the chapters below.

Consider also the Instructions and notes given in chapter 2.3 Restrictions of Use and Safety Precautions.

IMPORTANT NOTES

All persons who participate in treatments or are present for the purpose of the training must:

- Be enlightened on potential dangers;
- Wear suitable laser eye protection

IMPORTANT NOTES

Please contact responsible authorities and SCHWIND eye-tech-solutions GmbH in case of any non-conform clinical performance of the SCHWIND AMARIS product family lasers and their accessories. The content of a contact notice/form may depend on local legislations, thus the medical institutions may request consulting by local authorities/representatives.

2.5.1 Patient Safety

WARNING!

Risk of injury!

Take care not to injure the patient when positioning or operating the medical device. Make sure that the patient remains calm and relaxed during the treatment.

During movement of the patient bed pay attention **not to wedge** the patient or other persons.

While handling any material which come into direct contact with the patient, precautionary measures must be met in order to prevent disease transmission.

Exposure of the eye or the skin to direct or scattered laser radiation must be avoided in all cases.

After activation and during operation of the medical system pay attention to error messages and warnings displayed on the computer screen.

Do not continue the treatment / measurement, if there is any indication for incorrect processing data or malfunction of the system in order to avoid possible injuries to the patient!

The menu structure is interactive. Do not continue if the display screen is dark or if the visibility/representation is reduced.

Any complication or difficulty in using the device that could generate misunderstanding or ambiguities need to be taken into account to avoid risks to the user and the patient.

Exposure of the eye to slit lamp without aperture or with aperture D10 using powerful light intensity must be avoided.

WARNING

Risk of injury! Persons with pacemakers!

The SCHWIND AMARIS fulfils the requirements of the current editions of IEC 60601-1 and IEC 60601-1-2 for safety and electromagnetic compatibility of medical electrical devices.

Accordingly, the laser should have no influence on heart pacemakers that comply with a device standard compatible with the above-mentioned standards.

However we cannot exclude any influence completely.

Recommendations of the pacemaker manufacturer should also be observed.

Potential electromagnetic radiation can influence functionality of the laser and other medical devices.

2.5.2 Device Safety

- Follow the accident prevention regulations and regulations concerning installation, operation and usage of medical products as listed in chapter 2.2 Regulations for Medical Devices.
- Use the system / medical device only for its intended purpose (refer to chapter 3.1 Intended Use).
- Provide proper and secure conditions for the product.
- Maintain all documentation in good condition and store them with the system / device.
- Make sure that none of the labels on the system are removed or made illegible.
- Request the inspection of the system / medical device at regular intervals (TSC).

2.5.3 Electrical Safety

To ensure the **safety of personnel** and the **device,** the following arrangements must be kept by the operator:

- Only a trained and from SCHWIND eye-tech-solutions authorized technician should perform the service or repair works on the **electrical equipment** of the device.
- Inspect the electrical equipment for proper fitting and connection, damage to cables, lines and housing at regular intervals.
- Disconnect the power supply immediately in case of fire.
- Extinguish fire only with CO_2 or powder extinguisher.

2.5.4 Patient Bed Interlock

For patient positioning, a **patient bed** is supplied with the excimer laser.

WARNING!

Risk of injury! Incorrect ablation results possible!

To prevent unintentional movements of the patient bed during the laser ablation **the patient bed should be equipped with an interlock**.

If no interlock is used to block patient bed movements during ablation, be aware of releasing the foot switch or pressing the emergency stop button if any movements occur.

2.5.5 Laser Warning Lamp and Door Interlock

The laser provides a potential-free relay contact to switch a laser warning lamp, which may be mounted outside the room, e.g. above the entrance door of the laser room. The lamp will automatically switch on when the laser is operating.

Furthermore, it's possible to connect a normally closed potential-free door contact to the laser. The door interlock will stop laser triggering in case of opening the door during laser operation. The door interlock is short circuit by default by means of a short circuit plug at the door interlock input.

IMPORTANT NOTE

Be aware that a door interlock will interrupt the laser treatment every time someone opens the door. This may disturb your treatment sequence and therefore the treatment outcome.

SCHWIND eye-tech-solutions recommend not using the door interlock.

The clearly-defined laser area of the system tolerates absence of the interlock because there is no direct potential risk for persons entering the operation room during laser activity.

However, in some countries national regulations are insistent that a door interlock has to be connected.

IMPORTANT NOTE

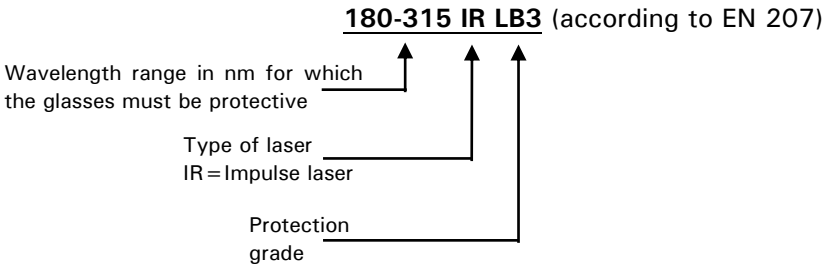
Warning lamps and **door interlock contacts** are not included in the scope of delivery of the AMARIS laser.

Please contact the SCHWIND eye-tech-solutions service department for the electrical specifications and installation notes if you want to connect a laser warning lamp to the laser or to use the door interlock.

2.5.6 Protective Glasses

All persons inside the laser area (except the patient) must wear protective glasses, according to EN 207.

Considering the I/R mode the protective glasses for use with the SCHWIND AMARIS laser systems must meet the following minimum standards:



WARNING

Risk of eye injury!

Never look directly at the laser beam!

Protective glasses must be worn while in the laser area. Non-observance can lead to irreversible eye injury.

Make sure that laser protective eyewear is in perfect condition before use and does not show any indications of damage, such as cracks or scratches in the lenses.

The operating surgeon may remove the glasses when he looks through the microscope. The glass optics of the microscope weaken the laser beam so that the necessary protection level is achieved.

2.5.7 Protective Clothing

Exposure of the skin to direct or indirect radiation has to be avoided. This is achieved e.g. via wearing of suitable work clothing.

2.5.8 Data and Virus Protection

The user is obliged to comply with the according valid data protection acts, in particular, those regarding data transmission to third parties.

The manufacturer guarantees that all SCHWIND products are delivered free of virus or other malware.

By any means, a use of virus- or other malware-infected media (USB-Sticks, SD-cards, external HDD, etc.), which could spread malware to the SCHWIND systems must be avoided.

The user is obliged to regularly check his own computer systems (non-SCHWIND provided hardware) for possible viruses, Trojans, worms or any other malware.

The user is obliged to make updates of his malware-protection software on his own computer systems on a regular basis.

In this regard, SCHWIND eye-tech-solutions will not assume any responsibility for consequential damages caused by intrusion of malware to SCHWIND systems.

CAUTION

Malware infection of medical device(s).

In case of known malware infection of medical device(s), the user shall inform their authorized local SCHWIND representative or SCHWIND eye-tech-solutions promptly.

2.5.9 Data Input

IMPORTANT NOTE

The user must make sure that the data entered are correct.

The user must ensure that the correct patient and the correct eye have been chosen for treatment!

The user shall not rename files after exporting, if needed he shall use the filename entries before exporting.

It must be ensured that only authorized staff has access to the processors / the server.

2.5.10 Protection from Data Loss

SCHWIND eye-tech-solutions GmbH does not assume any liability for a data loss due to non-compliance with the points described in this chapter.

The user can protect their systems from data loss as stated in the following:

- In order to ensure the integrity of the exported data, make sure that the medium where the files are exported finished the saving activities before removing it from device.
- Create back-up files of user's import and export data on virus-free storage media.
- Use diagnostic tools with particular care.

Safety

- Do not install any additional software or non- SCHWIND approved hardware on SCHWIND systems.

IMPORTANT NOTE

The user is obliged to ensure the data storage!

Work with an updated anti-virus software package and ensure that all incoming data are free of virus. Use virus-free storage media for transfer.

It must be ensured that only authorized staff has access to the data carriers.

2.5.11 Protection from Unauthorized Use

When not in use, the excimer laser is to be protected from unauthorized use by removing the key from the key switch.

It is recommended to switch off the system completely by means of the main switch when the system is intended to be not in use for a longer period (refer to chapter 6.4.3 Switch OFF the Device.)

2.6 Dangers Resulting from Laser Operation

2.6.1 Laser Radiation

Radiation from high-performance lasers is potentially dangerous. In our case, however, the following effects as listed below minimize danger:

- The beam diverges after passing the ablation area within a well-defined direction, so a high energy density exists only in that area.
- The beam is partially absorbed in the air.
- The cornea does not reflect the laser beam during treatment (any reflection is only a very weak beam).

These effects reduce the energy density of the beam quickly with increasing distance to the working area, which is about 193 mm under the beam output opening.

For all laser models the laser area is well defined as a cone, starting from the laser aperture underneath the laser arm downward to the floor, as shown in Figure 2-1.

The treatment plane with the focus of the laser beam is approx. 193 mm beneath the laser arm, measured from the laser arm housing.

The area at the floor is limited to a diameter of 130 mm, due to the range of possible scanning of the laser beam.

The **N**ominal **O**cular **H**azard **D**istance (**NOHD**-value) declares the safe distance for which the irradiance falls off below the limit of the maximum permissible exposure (MPE) under ideal conditions.

The NOHD-Value is determined regarding the limits of the IEC 60825-1:2014

The NOHD-value is determined to be 45 centimeters for all AMARIS variants.

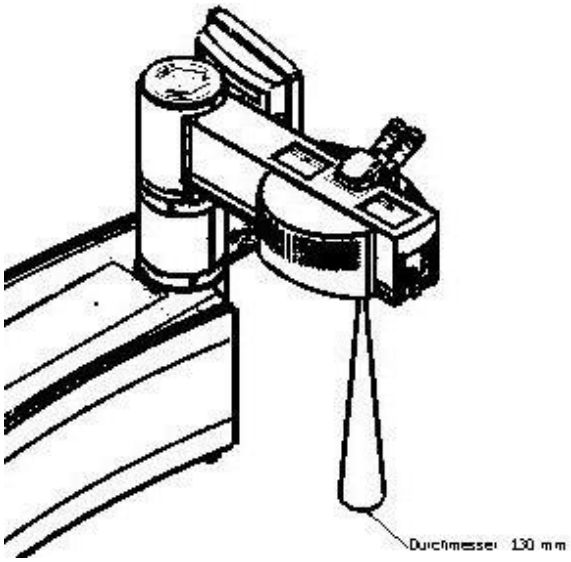


Figure 2-1: Accessible beam area (example AMARIS 750S)

2.6.2 Mirrored Reflection

Ensure that there are no reflective objects in the area of the laser beam, because this may lead to dangerous mirrored reflections.

WARNING!

Reflective objects (like high-gloss polished metal surfaces) in the area of the laser beam may lead to dangerous mirrored reflections.

2.6.3 Ablation Products

With the laser beam the cornea is re-shaped by ablating a small amount of tissue with each laser pulse. To reduce influence of the plume on subsequent laser pulses, the **particle aspiration system** or **plume evacuation system** remove particles and emerging plumes from the surgical plane (refer to chapters 4.10 Particle Aspiration System and 4.11 Plume Evacuation System).

The aspiration system blows the plume from the treatment area, but is not designed to remove the entire plume.

WARNING!

Laser plume may contain tissue particles.

Due to clinical standards it's recommended to wear a surgical mask.

Several studies, however, have shown that the risk of infection caused by the plume is very low.

2.6.4 Working Gas

The active laser medium of an ArF-excimer laser is a premix gas, containing < 0,2% fluorine gas and 1% to 5% argon, buffered in neon. Up to 5% helium may also be included, thus reducing the respective portion of neon.

Possible negative influence from the premix gas is minimal due to the low fluorine concentration.

During the exchange of the working gas in the laser cavity, the old gas is neutralized by a filter and becomes thereby harmless.

The laser head contains only a small quantity of fluorine. It is checked according to the pressure compartment regulations. An unintentional output of working gas is very unlikely. Fluorine can be recognized through its pungent smell long before the concentration will reach maximum allowed values for work areas. If a fluorine gas leak is detected, open the window, leave the room and call the service department of SCHWIND eye-tech-solutions or the service of your nearest distributor.

WARNING!

Risk of injury!

In case of the pungent smell of fluorine gas, open the window and leave the room immediately.

Contact the service department of SCHWIND eye-tech-solutions.

2.6.5 Topic Ozone

During the operation of the laser ozone (O_3) is created by the laser beam (ultraviolet light with a wave length of 193 nm) as interaction with O_2. With extended exposure, ozone can cause irritations of the respiratory system and of the eyes, as well as headache and further side effects. Various studies[1,2] show that pregnant women may be particularly sensitive to ozone exposure. When operating the AMARIS always ensure that the operating environment is sufficiently ventilated, depending on the size of the room.

If the environmental area is not well ventilated, the ozone may accumulate and, as a result, may partly absorb the delivered energy of the laser beam. This may influence patient outcomes of refractive surgery.

[1] Lin Y-T, Jung C-R, Lee YL, Hwang B-F. Associations Between Ozone and Preterm Birth in Women Who Develop Gestational Diabetes. *Am J Epidemiol*. 2015;181(4):280-287. doi:10.1093/aje/kwu264

[2] Salam MT, Millstein J, Li YF, Lurmann FW, Margolis HG, Gilliland FD. Birth outcomes and prenatal exposure to ozone, carbon monoxide, and particulate matter: Results from the Children's Health Study. *Environ Health Perspect*. 2005;113(11):1638-1644. doi:10.1289/ehp.8111

2.7 Electrical Safety - Connection of Devices to External Plugs

To ensure electrical safety, only devices intended for use by SCHWIND eye-tech-solutions (printer, monitor, etc.) may be connected to the external plugs (refer also to chapter 10.7 Components and Consumables).

Additional devices connected to analogue and digital plugs of the system must fulfil EN and IEC specifications (i.e. EN IEC 60950-1resp. its successor IEC 62368-1 for data processing devices, IEC 60601-1 for electrical medical devices).

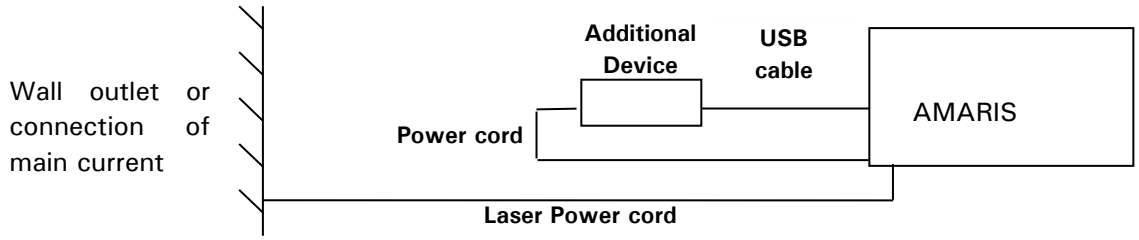
IMPORTANT NOTE

Persons connecting additional devices to signal input or output are reconfiguring the system and are responsible for ensuring that the specifications outlined in IEC 60601-1 are maintained.

Should you have further questions, please do not hesitate to contact the Service Department of SCHWIND eye-tech-solutions.

Additional devices not medically approved, like printers, DVD-recorder or monitors, must be powered via an insulating transformer when connecting them to the laser.

Example 1: Additional Device connected with AMARIS via power cord (recommended)



Example2: Additional device is not connected with AMARIS via power cord.

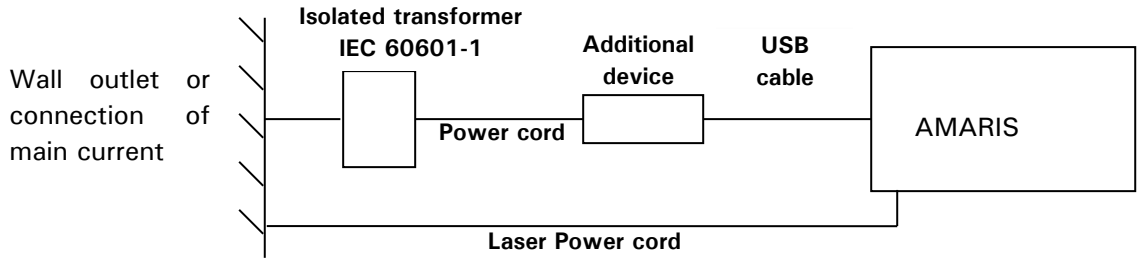


Figure 2-2: Samples of printer connection

Potential Free Power Supply Output

The SCHWIND AMARIS provides a potential free power supply output with 230 VAC, 50/60Hz at three power outlet sockets at the connection plate.

The max. output load for all connected components (e.g. TFT-monitor, patient bed) is limited. Refer to chapter 2.9.3 Connection Terminal Label of the Device.

Main Power Supply AMARIS	SCHWIND AMARIS Type	Max. Load at Power Outlet Socket –X1	Connections of Components to Power Outlet Socket –X1
230V AC from UPS	AMARIS, AMARIS 500E, AMARIS 750S, AMARIS 1050RS	**450VA**	Connection and operation of SCHWIND Patient Bed and monitor is possible.
208, 220, 230,240V AC			
120, 127V AC			
100, 110V AC	AMARIS, AMARIS 500E		
100, 110V AC	AMARIS 750S, AMARIS 1050RS	**20VA**	Connection of SCHWIND Patient Bed only. No connection of other devices to the power outlet socket. For use of SCHWIND Patient Bed, the interlock cable must be installed and Patient Bed must be locked during treatment. 20VA is the standby power supply of the Patient Bed.

Table 1: MAXIMAL LOAD AT POWER OUTLET X1

CAUTION

Do not overload the laser's power outlet socket!

The maximum load for all connected components together must not exceed the value(s) as listed in the Table 1: MAXIMAL LOAD AT POWER OUTLET X1 .

WARNING!

Risk of electric shock!

To avoid the risk of electric shock, the AMARIS must only be connected to supply mains with protective earth.

Risk of reduced level of safety!

Connecting electrical equipment to the multiple socket outlet, effectively leads to creating a MEDICAL ELECTRICAL SYSTEM and the result can be a reduced level of safety. Connect only electrical equipment as approved system combinations specified in chapter 4.15 .

For other electrical equipment than those specified, requirements must be provided that are applicable to a MEDICAL ELECTRICAL SYSTEM. For this purpose contact the manufacturer and refer to IEC 60601-1.

2.8 In Case of Emergency

In chapter 2.6 Dangers Resulting from Laser Operation, dangers are listed which could occur during laser operation. The risk of an emergency is lowered to a minimum by the technical design of the system and the organizational measures taken by the manufacturer (refer to chapter 2.4 Manufacturer's Responsibility).

If a danger for the service personnel and the patient during the laser operation should arise despite the protective measures of the manufacturer, the following steps have to be taken:

Gas leak (laser operating gas)

- Open the windows.
- Shut down the laser system and switch off the device using the emergency stop switch.
- All personnel must leave the room.
- Inform the service department of SCHWIND eye-tech-solutions or the customer service of your distributor (see Service Hotline).

Other dangerous situations

- Switch off the laser system using the **emergency stop switch**.
- Bring the patients and the service personnel in a safe environment.
- Inform the service department of SCHWIND eye-tech-solutions or the customer service of your distributor (see Service Hotline).

Accident situation

In the case of a work accident resulting in injury to the eye or skin from laser radiation of a patient or the service personnel, after carrying out any medical care, a medical professional must perform a thorough examination.

An accident notice is to be submitted to the responsible supervisory authority. A copy of this message is to be sent to SCHWIND eye-tech-solutions GmbH. You will find a sample of the damage report in your Medical Apparatus Book in chapter 9.

Observe the requirements of Standard IEC 60825-1

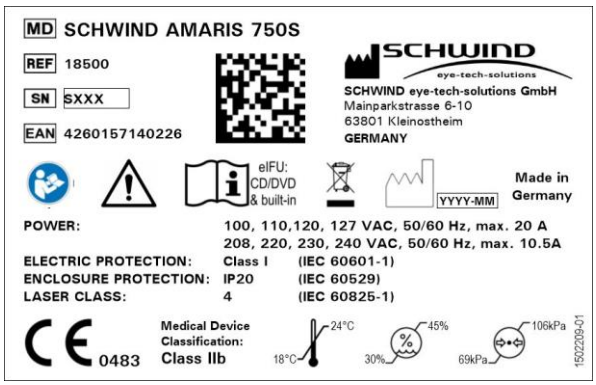
2.9 Device Labelling

2.9.1 Identification Label of the Device

The AMARIS excimer laser is labelled according IEC 60825-1

(Size of labels not actual)

SCHWIND AMARIS 750S



SCHWIND AMARIS 1050RS

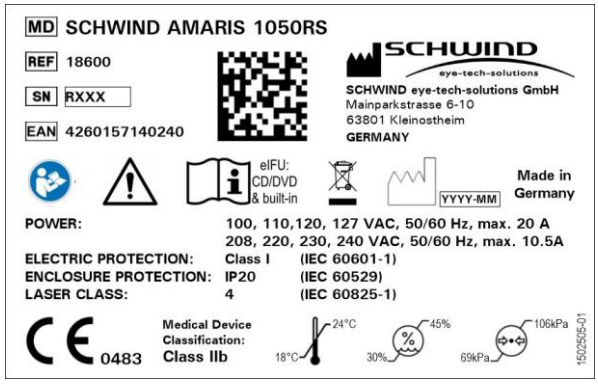
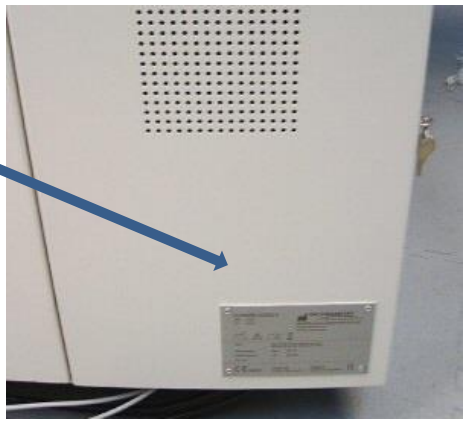


Figure 2-3: Identification labels AMARIS 750S / 1050RS

The identification label for **AMARIS 750S / 1050RS** is placed outside the housing of the compartment door.



SCHWIND AMARIS 500E

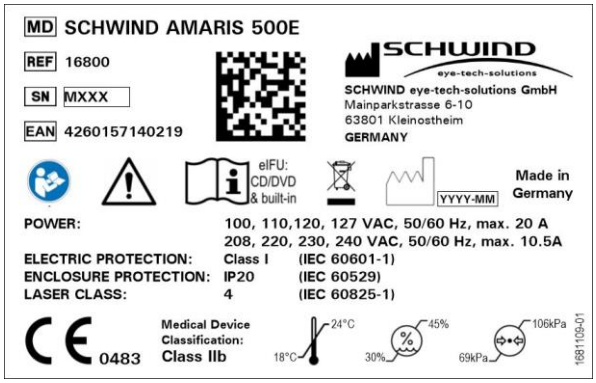


Figure 2-4: Identification label AMARIS 500E

The identification label of **AMARIS 500E** is placed outside the rear side panel.

Safety

Explanation of Symbols

The following symbols are shown in the identification label:

Symbol	Explanation
MD	Product is a Medical Device
SN	Serial Number
REF	Article Number
EAN	European Article Number
	Name of Manufacturer
SCHWIND eye-tech-solutions	SCHWIND Logo
	Read operating instructions
	Consider accompanying documents
 eIFU: Built-in & CD-ROM	Consult operating instructions, electronic Instructions for Use
	Our medical product is labelled with this symbol in accordance with European Directive 2012/19/EEC-(Waste Electrical and Electronic Equipment – WEEE) to indicate that, at the end of its live, it must be disposed separately from other household waste. Please contact your local authority or waste disposal service for the return and recycling of this product.
 YYYY-MM	Date of manufacture
CE 0483	CE mark, confirms compliance with the regulation for medical devices MDD 93/42/EWG, resp. MDR 2017/745. 0483 is the number of the certifying notified body.
	Temperature Range during operation For AMARIS: 18°C – 24°C (see chapter 5.2.4)
	Humidity during operation For AMARIS: 30% - 45% RH (see chapter 5.2.4)
	Athmosperic pressure during operation For AMARIS: 69 kPa – 106 kPa (altitude above sea level 3000 m, see chapter 5.2.4)

2.9.2 UDI-Label

UDI-Label for marking the device and packaging:

Figure 2-5: Example of a UDI-Label Template (for SCHWIND AMARIS 1050RS)

The UDI-Dis for the different SCHWIND AMARIS models are given in section 1.1 System Identification Data. The UDI-Label is placed next to the Identification label.

Explanation of Symbols

The following symbols are shown in the identification label:

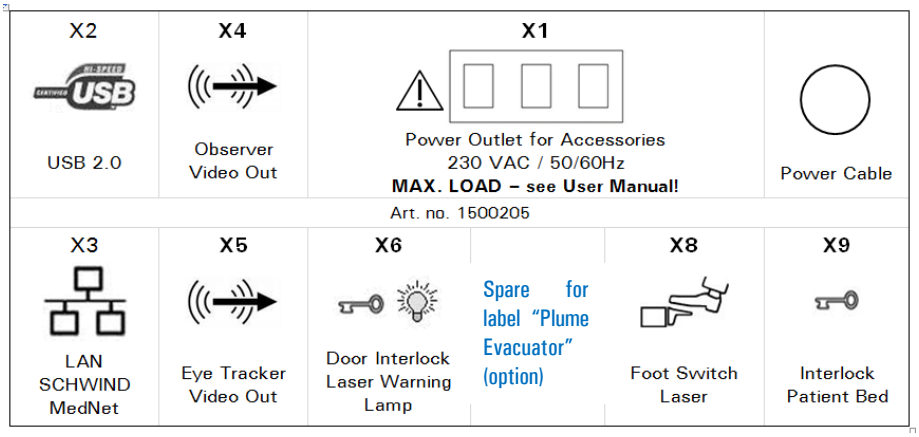
Symbol	Explanation
REF	Article number
UDI	Unique Device Identifier
	GS1 Data Matrix Code

2.9.3 Connection Terminal Label of the Device

The connection terminal label of the manufacturer is placed on the connections terminal of the AMARIS, providing information about the connection types used in the device.

In conjunction with the option Video Extender, the connector "X5" is used as the HDMI output.

SCHWIND AMARIS / AMARIS 750S / AMARIS 1050RS



The label is placed inside the compartment door, see Figure 2-7.

Figure 2-6: Position of "Connection Terminal" label AMARIS 750S/1050RS

SCHWIND AMARIS 500E

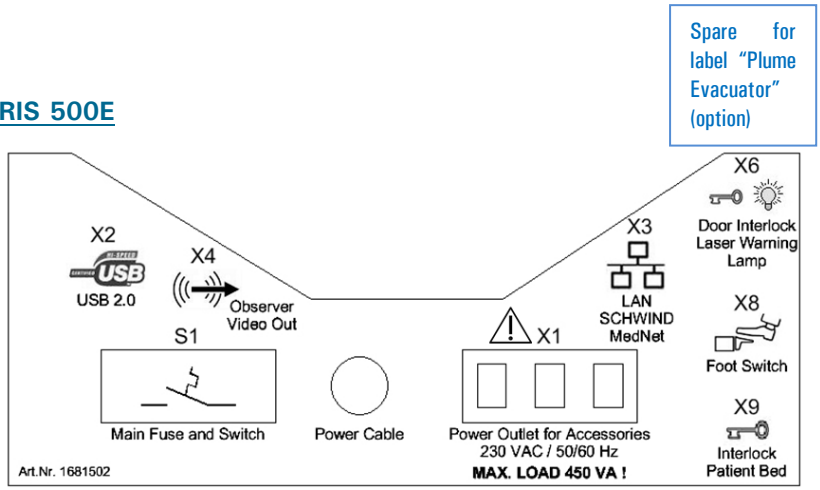
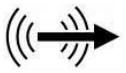
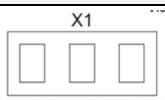
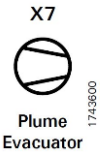


Figure 2-7: Label "Connection Terminal AMARIS 500E"

The label is placed inside the compartment door, see Figure 2-6.

Explanation of Symbols

Symbol	Explanation
	USB 2.0 connection to the panel PC for printer connection USB logo 2.0
	Eye Tracker Video Out. Observer Video Out for connection of DVD recorder and/or external monitor.
	Door interlock and warning light acc. IEC 60601-2-22 for laser safety.
	Foot switch laser Connection of the foot switch to the device.
	Interlock connection for SCHWIND Patient Bed

Symbol	Explanation
	Power outlet socket for components 230 VAC / 50/60Hz[3]
	RJ45 LAN connection
	Safe and efficient operation of the system is required. Refer to WARNING note in chapter 2.7 Electrical Safety - Connection of Devices to External Plugs – "Potential Free Power Supply Output"
	Connection for external Plume Evacuator (option)

2.9.4 Mains Input Label of the Device

The mains input label of the manufacturer is placed near the mains input of the AMARIS, providing information about power configuration of the device.

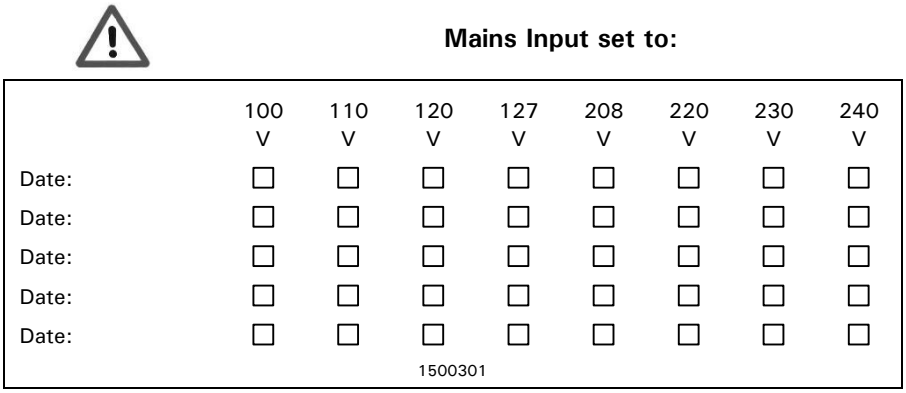


Figure 2-8: Mains input label AMARIS

CAUTION

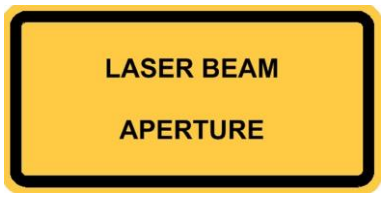
Internally changing the mains supply voltage to other values than the recommended can cause malfunctions of the device.

[3]For max. load of power outlet sockets – refer to chapter 2.7 Electrical Safety - Connection of Devices to External Plugs - "Potential Free Power Supply Output"

2.9.5 Laser Warning Labels

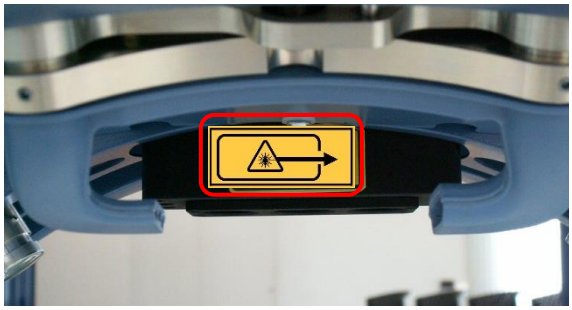
The **SCHWIND AMARIS excimer laser** is marked with appropriate labels:

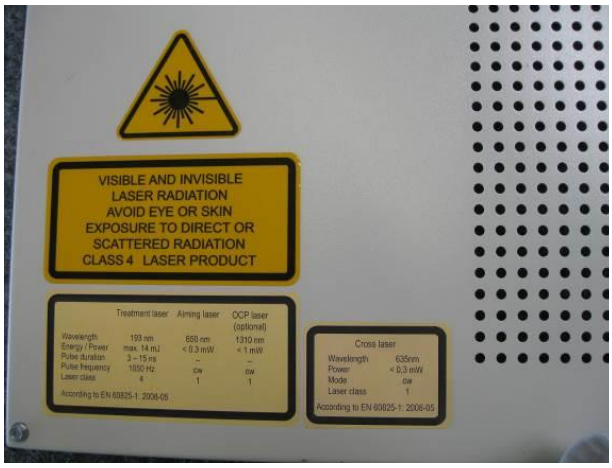
Laser Warning Labels



(alternatively as symbol)

Label is placed on front and back side of the microscope lens.

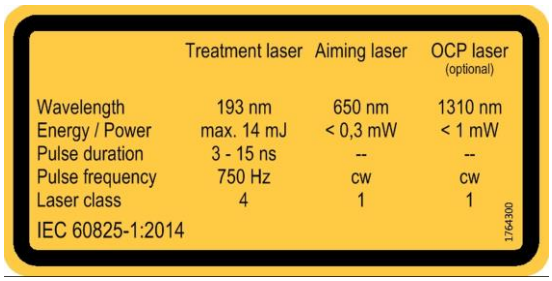




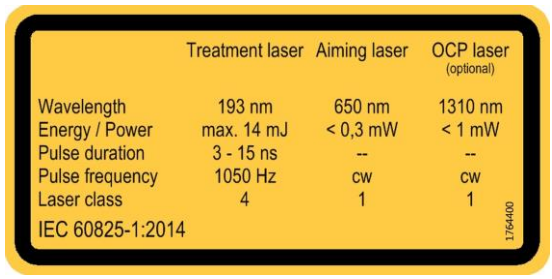
The laser labels are placed on the protective laser housing, outside on the compartment door.

Laser Data Labels

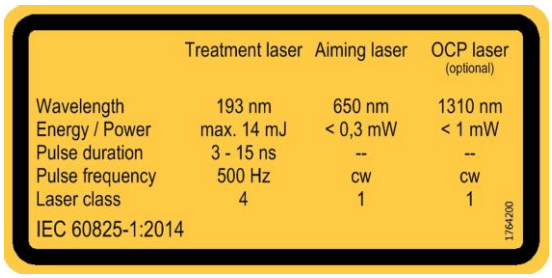
SCHWIND AMARIS 750S



SCHWIND AMARIS 1050RS



SCHWIND AMARIS / SCHWIND AMARIS 500E



Cross laser (optional)

Figure 2-9: Laser data labels

3 INTRODUCTION

3.1 Intended Use

The SCHWIND AMARIS excimer laser is a medical device used in corneal refractive surgery for the correction of ametropia, such as myopia (near sightness), hyperopia (far sightness) and astigmatism through LASIK (Laser [assisted] in situ keratomileusis), surface ablations as PRK (Photorefractive Keratectomy), TransPRK (Transepithelial Photorefractive Keratectomy), LASEK (Laser Epithelial Keratomileusis) or EPI-LASIK treatments. Besides standard treatment modes (correction of SCA - Sphere, Cylinder, Axis), individual data from patients from topographic- and wavefront diagnostic devices can be imported to the laser and used for customized treatments.

Presbyopic treatments (standard and customized) planned with the PresbyMAX module can be performed with the laser as well.

Moreover therapeutical treatments PTK (Phototherapeutic Keratectomy) can be performed with the excimer laser.

The device is used by professional ophthalmologists only, primarily in eye clinics and private medical practices where semi-sterile conditions have to be established.

IMPORTANT NOTE

Device use according to its intended use.

The medical device shall only be used in accordance with the application conditions specified by the manufacturer.

The medical device has to be used by a doctor and a staff specialized in ophthalmology with specific training in the preparation, calibration, and maintenance of the device and components, as well as special training in the use of the same in accordance with its intended purpose. At your convenience, during the first sessions ask for the collaboration of suitably trained personnel from SCHWIND eye-tech-solutions.

Due to the intended purpose, the laser is intended to ablate the following materials:

Human corneal tissue for the refractive or therapeutic surgery; from SCHWIND eye-tech-solutions delivered fluence foil for fluence test and calibration purposes; from SCHWIND eye-tech-solutions delivered photo paper for service purposes and calibration purposes; from SCHWIND eye-tech-solutions delivered PMMA plates for service and calibration purposes;

Consider instructions contained in chapter 2.3 Restrictions of Use and Safety Precautions.

3.2 Disclaimer SCHWIND AMARIS Excimer Laser (initial model)

The SCHWIND AMARIS excimer laser (initial model) manufactured by SCHWIND eye-tech-solutions until August 2010 is equivalent to the SCHWIND AMARIS 750S model but has a repetition rate of 500Hz.

All parts within this user manual referring to the SCHWIND AMARIS 750S / 1050RS are valid for the SCHWIND AMARIS excimer laser as well.

3.3 Contraindications and Side Effects

Below you will find the list of contraindications and possible side effects for refractive photo ablation. However, this list does not release you from the duty to update your own expertise with the latest results from general research in the area of refractive surgery. Review all contraindications according to the relevant literature and the national legislation.

Be sure to fully inform your patient about the risks and benefits of laser surgery during a consultative conversation.

3.3.1 Absolute Contraindications for Refractive Photo Ablation

- Unstable refraction.
- In pregnant or nursing women.
- In patients with collagen vascular, autoimmune or immunodeficiency diseases.
- Severe local infective or allergic conditions (e.g. Blepharitis, Previous Herpes Simplex or Zoster keratitis, Allergic eye disease severe enough to require regular treatment).
- Severe dry eye disease (minor dry eyes are not a contraindication).
- Monocularity or severe amblyopia.
- Cataract
- In patients who are taking one or both of the following medications: isotretinoin (Accutane®) or amiodarone hydrochloride (Cordarone®).
- Other disease patterns determined by the ophthalmologist and/or surgeon to be contraindications.

3.3.2 Relative Contraindications

- Glaucoma
- Diabetes Mellitus
- Inappropriate motivation or unreasonable expectation
- Other disease patterns determined by the ophthalmologist and/or surgeon to be contraindications.
- Age limit (patients should be older than 18 years old).

3.3.3 Direct Side Effects (caused by the laser surgery)

- **Infection and Delayed Healing:**

  There is about a 0.1 percent chance of the cornea becoming infected after PRK/TransPRK, and a somewhat smaller chance after LASIK. Generally, this means added discomfort and delay in healing, with no long-term effects within a period of four years.

- **Undercorrection / Overcorrection**:

  It is not possible to perfectly predict how the eye will respond to laser surgery. As a result, the patient may still need corrective lenses after the procedure to obtain good vision. In some cases, a second procedure can be performed to improve the result.

- **Decrease in Best-Corrected Vision:**

  After refractive surgery, some patients find that their best obtainable vision with corrective lenses is worse than it was before the surgery. This can occur as a result of irregular tissue removal or the development of corneal haze.

- **Excessive Corneal Haze:**

  Corneal haze occurs as a part of the normal healing process after surface ablations like PRK and TransPRK. In most cases, it has little or no effect on the final vision and can only be seen by the doctor through a microscope. However, there are some cases of excessive haze that interferes with vision. As with undercorrections, this can often be dealt with by means of an additional laser treatment. The risk of significant haze is much lower with LASIK than with PRK.

- **Regression:**

  In some patients the effect of refractive surgery is gradually lost over several months. This is similar to an under correction, and re-treatment is often possible.

- **Halo Effect:**

  The halo effect is an optical effect that is noticed in dim light. As the pupil enlarges, the untreated peripheral cornea produces a second faded image. For some patients who have undergone PRK/TransPRK or LASIK, this effect can interfere with night driving.

- **Incomplete Procedure:**

  Equipment malfunction may require the procedure to be stopped before completion. This is a more significant factor in LASIK, with its higher degree of complexity, than in PRK or TranPRK.

3.3.4 Indirect Side Effects (caused by the complete surgery)

- **Flap Damage or Loss (LASIK only):**

  Instead of creating a hinged flap of tissue on the corneal shape, the entire flap could come off. If this occurs it can be replaced after the laser treatment. However, there is a risk that the flap could be damaged or lost.

- **Distorted Flap (LASIK only):**

  Irregular healing of the corneal flap could create a distorted corneal shape, resulting in a decrease of best-corrected vision.

- **Side effects caused by the medication**

- **Dry Eye Syndrome:**

  Postoperative dry eye due to damaging of nerves in the cornea during the flap cut or epithelial removal. This syndrome may last up to three months.

  Even when everything goes perfectly, there are effects that might cause some dissatisfaction. Older patients should be aware that they can't have both good distance vision and good near vision in the same eye without corrective lenses. Some myopic patients rely on their myopia (by removing their glasses or by wearing a weaker prescription) to allow them to read. Such a patient may need reading glasses after the myopia is surgically corrected. Another consideration is the delay between eye treatments. If one eye is being treated at a time, both eyes may not work well together during the time between treatments. If a contact lens is not tolerated on the untreated eye, work and driving may be awkward or impossible until the second eye has been treated.

3.3.5 Residual Risks

Technical design and safety measures reduce any potential risk to an acceptable level and reduce as far as possible following residual risks associated with potential harms and complications caused by treatments using SCHWIND AMARIS product family lasers:

- Risk of a disturbance of the fertility
- Patient discontent
- Loss of treatment quality (refractive outcome)
- Incorrect treatment including insufficient clinical outcome, lost of visus, ablepsia
- Overcorrection, undercorrection or decentration
- Allergy
- Burn, harm of the patient’s eye, retina or skin
- Risk of infection
- Contamination of environment like contamination with fluorine
- Bodily harm of patient, user or third parties
- Penning of the patient, contusion, harm of the patient, user or third parties
- Electric shock

The residual risks associated with SCHWIND AMARIS Application Software are as follows:

- Temporarily reduced vision quality
- Surgeon may be confused while treatment is considered as wrong
- Poor visual outcome like under- or overcorrection, irregular correction
- Incorrect therapy
- Bodily harm of patient or surgery personel

3.3.6 Biocompatibility of Touchable Parts

All touchable materials of the SCHWIND AMARIS are rated as biocompatible. There are no known problems, such as allergic reactions, which might occur by using the product. If you recognize any effects, please contact the Customer Service of SCHWIND eye-tech-solutions.

4 DEVICE / SYSTEM DESCRIPTION

4.1 General Notes

This chapter gives an overview of the SCHWIND AMARIS components and describes in short form the main function units of the SCHWIND AMARIS, the operation and control elements and the available components for all models, the AMARIS 1050RS, the AMARIS 750S and the AMARIS 500E, respectively.

4.2 The Product

The SCHWIND AMARIS excimer lasers are medical high-performance lasers to be applied for the permanent corrections of the various kinds of ametropias and corneal changes of the human eye in refractive surgery.

It offers customized treatment possibilities in refractive surgery such as the correction of aberrations of the human eye and modulations of the cornea.

For ablation the SCHWIND AMARIS uses cold light (wave length 193 nm) and ablates the desired corneal tissue of the human eye very precisely and computer controlled. This is carried out on the corneal surface (PRK, TransPRK) or on the stroma after creation and folding away of a thin flap (LASIK).

The excimer laser represents the latest and most innovative technology for refractive surgery.

4.3 System Overview

The SCHWIND AMARIS excimer lasers consist of the following **default components**:

1. **Optical system** (chapters 4.8, 4.9), which consists of:
   - Optical arm (covered and uncovered)
   - Microscope
   - Beam path
2. **Panel-PC unit** (chapter 6.2)
   - Touch screen
   - Keyboard with touch pad
   - Two (re-)sterilisable pens
   - Pen holder
   - Card reader
3. Electronic-unit
4. Excimer Laser source (chapters 4.5, 4.6)
5. Gas supply unit (chapter 4.7)
6. Partical Aspiration System with double-channel nozzle for AMARIS 500E/750S/1050RS (until July 2017) (chapter 4.10) **or** internal Plume Evacuation System with single-channel nozzle for AMARIS 750S and 1050RS (since July 2017), (chapter 4.11)
7. Eye tracking system (chapter 8.5)
8. SCHWIND Patient Bed (System combination with AMARIS) (chapter 4.12)
9. SCHWIND CAM Treatment Planning software (System Combination with AMARIS) (chapter 8.2)

OPTIONAL Components:

1. Microscope camera set
2. Video System (chapter 4.14.1)
3. Printer (chapter 4.14.2) *

   * A printer (e.g. CANON PIXMA IP7250) *as an option is not available with new laser deliveries since Q3/2020, i.e. discontinuation of this option for new sales.*
4. Slit lamp (chapter 4.14.3)
5. OCP (Optical Coherence Pachymetry) (chapters 4.14.4, 8.6) **

   ***The OCP (Optical Coherence Pachymetry) as an option is not available for laser production since Q3/2023 anymore, i.e. discontinuation of this option for new sales.*
6. 6D – Eye Tracker (marketed for AMARIS 750S and AMARIS 1050RS only) (chapters 4.14.5, 8.5.6)
7. 7D Latency Free Eye Tracker (marketed for AMARIS 1050RS only) (chapters 4.14.5, 8.5.7)
8. Cross laser module (chapter 4.14.6)
9. Advanced Cyclotorsion Control – Static Cyclotorsion Control for corneal Wavefront-guided treatments (SW licence) (chapter 8.5)
10. Advanced Cyclotorsion Control – Static Cyclotorsion Control for ocular Wavefront-guided treatments (SW licence) (chapter 8.5)
11. Advanced Cyclotorsion Control – Dynamic Cyclotorsion Control for online correction (chapter 8.5)
12. SCHWIND CXL-365 vario **or** C-eye(cross-linking)***

    ****The SCHWIND CXL-365 vario/ C-eye (Cross-Linking Kit) as an option is available for specific countries only. The SCHWIND CXL-365 vario is not available with new laser deliveries since Q3/2023 i.e. discontinuation of this option for new sales.*
13. Patient Bed with motorized swivel option.
14. UPS (Uninterruptible power supply) (chapter 4.14.7)
15. Plume Evacuation System, external version for AMARIS 500E/750S/1050RS (chapter 4.14.8)
16. Video extender HDMI (chapter 4.14.9)

Refer additionally to chapter 10.7 Components and Consumables

IMPORTANT NOTE

C-eye Cross-Linking Kit (1871000) vs. C-eye Sliding Unit (1870500).

The C-eye Cross-Linking Kit consist of the C-eye (CXL) device itself and the C-eye Sliding Unit for AMARIS laser.

The C-eye (CXL) medical device – as new order via SCHWIND eye-tech-solutions or already bought by the user / clinic beforehand – can be easily used in conjunction with the C-eye Sliding Unit for AMARIS laser.

Figure 4-1: Sliding unit & C-eye

Figure 4-2: View of AMARIS 750S / AMARIS 1050RS / AMARIS excimer laser with patient bed

Figure 4-3: View of AMARIS 500E excimer laser with patient bed

4.4 System Description

The overall design of the SCHWIND AMARIS 750S and AMARIS 1050RS provides low height of the basic unit with a tower and laser arm for the beam delivery system, which doesn't give the patient the feeling of being crowded by a big machine. The motorized laser arm can be swivelled over the basic unit. Thus, the patient can easily sit and lay down on the patient bed or chair and surgical personnel have no constraints during patient preparation.

The SCHWIND AMARIS 500E is a more compact version with shorter, but higher basic unit and a fixed laser arm. The laser arm can only be swivelled by a service technician for transportation purposes.

The **laser head** operates at a repetition rate of 750 Hz (model AMARIS 750S), 1050 Hz (model AMARIS 1050RS) or 500 Hz (model AMARIS / AMARIS 500E), respectively, with two levels of fluence: higher fluence for speed of ablation and lower fluence for smoothing and finer ablation. The transition between the two fluence levels is made on the fly (Automatic Fluence Level Adjustment).

An **optical system** guides the laser beam through the tower and laser arm onto the treatment plane and forms the 6x3 mm² rectangular sized beam profile of the laser source into a small round spot of 0.54 mm (FWHM) in diameter with super-Gaussian energy distribution.

The active laser medium of the laser source is an argon-fluorine gas buffered with neon and must be changed in periodic intervals, depending on the working or idle times of the laser. In case of too low energy of the laser source, the system requests the user to start a gas exchange. Once started, the gas exchange procedure is fully automatic.

A **1050 Hz eye tracker** ensures that even fast eye movements up to six dimensions are compensated within 3 ms (milliseconds) during the ablation process. While the laser is ablating the eye tracker compensates X- and Y-lateral movements, as well as X- and Y-eye rolling movements. The lateral x-y- movements seen by the eye tracking system are calculated, with the help of an

eye model, into eye rolling. The scanner of the system is moved according to this Rotation Balance with the Eye Tracker.

Changes of the pupil center during the treatment are corrected using additional limbus tracking and pupil center shift control (PCSC) with both SCHWIND AMARIS models.

As an optional feature for all SCHWIND AMARIS models, the tracker can compensate for cyclotorsional eye movements (**5th dimension**), dynamically during the ablation process and statically with reference images taken during diagnosis with corneal or ocular wavefront analyzers. The resulting angle is automatically calculated and compensated in the ablation profile.

As an additional option for the SCHWIND AMARIS 750S and 1050RS models Z- movements (**6th dimension**) can be measured and actively compensated during the ablation process. Moreover AMARIS systems equipped with a **6D- eye tracker** will actively measure eye rolling movements which can be visualized in the treatment screen.

Additionally, the model AMARIS 1050RS offers the option of a Latency Free Eye tracking feature as **7th dimension.**

The eye tracker works with IR-light illumination, thus making it independently from any density setting of the OP-field illumination or room illumination.

The user control of the machine is based on the Windows™ operating system, installed on a Panel-PC with touch screen for sterile use through the application of re-sterilisable pens. The PC can be adjusted to a suitable working position for both surgeon and assistant.

The planning and calculation of any treatment is based on the SCHWIND eye-tech-solutions **CAM software (Custom Ablation Manager)** as an independent software module. Treatments can also be planned at a (diagnostic) device workstation approved by SCHWIND.

The control of the system is based on several local control units and a main control unit, which is a DebianLinux operated embedded PC.

An **operation microscope,** with which the surgeon can observe the patients eye during the whole treatment process, is integrated in the laser arm. The microscope is designed with an optimized stereopsis angle of 14° and equipped with a 5x motorized magnification changer, which can be changed manually or through software control. An external camera can be mounted on the microscope for video observation by additional personnel or for video documentation. For future purposes the microscope is prepared for coupling-in of alpha-numerical or graphical information into one of the eyepieces.

Four high power **white-light LEDs** illuminate the OP field for best visual inspection of the patient's eye with the microscope. The illumination density can be set manually by the user or through software control.

For additional check of the patient's eye, e.g. control of the flap repositioning, an optional **slit lamp** can be mounted on the laser arm.

At the left and the right sides of the microscope are key pads for easy access to the most commonly needed manual settings, such as illumination density, microscope magnification and particle aspiration. Necessary confirmations can be made here or through pressing “OK” software buttons directly on the Panel-PC touch screen. The key pads can be kept sterile by covering them with sterile foils.

As already mentioned, an additional display is installed beneath the microscope, which gives the operator information about the selected magnification of the microscope, illumination settings, treatment progress and instructions for the next treatment step, without the need to turn to the dialog at the Panel-PC.

The **Treatment Assistant Manager (TAM) software module** guides the surgeon safely and comfortably through the entire treatment procedure by using configurable checklists. For each treatment step, settings for the microscope, illumination density, aiming laser, fixation LED and an integrated timer can be predefined and the Treatment Assistant Manager then automatically fixes the desired settings.

SCHWIND AMARIS – the Excimer Flying Spot Laser offers the following benefits:

- Optimal surface quality during the ablation process through high pulse frequency.
  - 500 Hz flying spot (AMARIS 500E)
  - 750 Hz flying spot (AMARIS 750S)
  - 1050 Hz flying spot (AMARIS 1050RS)
- Optimal centering through high speed Eye Tracker.
  - 5D eye tracker (marketed for AMARIS 500E)
  - 6D eye tracker; incl. active z-movement compensation (marketed for AMARIS 750S / 1050RS)
  - 7D eye tracker for latency free eye movement compensation (marketed for AMARIS 1050RS)
- Correction of myopia and hyperopia, with or without astigmatism.
- Pure Astigmatism correction with positive and negative cylinder.
- Optimal security through sophisticated integrated safety features.
- Integrated SCHWIND CAM treatment planning software with ORK-CAM module for aspherical, aberration-free and customized profiles with interface to the diagnostic devices approved by SCHWIND, including corneal and ocular wavefront treatment planning.
- Integrated PresbyMAX module for aspherical, aberration-free and customized profiles for presbyopic refractive surgery.
- Integrated PTK-CAM module for aspheric and refraction neutral PTK (Phototherapeutic Keratectomy) profiles for therapeutic surgery.

4.5 Laser Classification

The SCHWIND AMARIS, AMARIS 500E, AMARIS 750S and AMARIS 1050RS operate with the following lasers (classification according to IEC 60825-1:2014):

- One excimer laser Class 4
- One aiming laser Class 1
- One cross laser Class 1 (optional)
- One OCP laser Class 1 (optional)

4.5.1 Excimer Laser

The wavelength of the excimer laser is 193 nm and is therefore not visible for the human eye.

WARNING!

Risk of injury! Laser radiation! LASER CLASS 4.

Avoid irradiation of eye or skin by direct or stray radiation.

Technical data of the excimer laser are contained in chapter 11 Technical Data.

4.5.2 Aiming Laser and Cross Laser

The aiming laser has a wavelength of 650 nm and the cross laser 635 nm. Both belong to class 1. The laser output is below 300 µW.

IMPORTANT NOTE

LASER CLASS 1

The aiming laser is guided coaxially with the excimer laser beam and thereby indicates the position of the laser in the working plane. Further information about the aiming laser is contained in the chapter 4.6 Laser Description.

Technical data of the aiming laser are contained in chapter 11 Technical Data.

During the ablation process the aiming laser follows the excimer laser beam and therefore indicates the actual position of the laser beam. The aiming beam indicates the center of ablation when the foot switch is not pressed during the treatment. With active eye tracking the aiming laser follows the pupil, including taught-in offsets.

The cross laser serves as an additional aid for positioning the patient.

4.5.3 OCP Laser

The OCP laser has a wavelength of 1310 nm and is therefore not visible by the human eye. The laser output is less than 1 mW.

IMPORTANT NOTE

LASER CLASS 1

4.6 Laser Description

4.6.1 The Main Principle of the Excimer Laser

The high-performance excimer laser is designed for the ablation of human eye tissue.

Excimer gas lasers are stimulated with an electric pulse in a mixture of noble gases and halogens. The output lifts the noble gas atoms to a higher energy level so that they react with the halogen molecules and bond to them, as ArF.

These special molecules, known as excimers (excited dimers), are stable only for a short time. They collapse and emit a high ultraviolet radiation. If the gas is arranged in an optical resonator of two parallel mirrors, the laser effect is achieved and light impulses with very high outputs are beamed.

The laser gas partially consumes itself during output and must be changed when the intended energy level no longer be achieved through adjustment of laser high voltage.

The laser source used with the AMARIS is a very compact unit optimized for reliability and low gas consumption.

The performance data listed in chapter 11 Technical Data prescribe the data of the laser and the necessary voltage connections.

The laser source is designed for a treatment sequence in which the laser fires for max. 5 minutes dynamically (treatment) and “rests” for 5 minutes in a static “standby” mode (OP- preparation before and after treatment).

Besides the high-performance laser of the AMARIS, a visible low-power diode laser is also used as an aiming laser.

4.6.2 Positioning Slit Lights

Two lamps, one slit-shaped and the other cross-shaped, are used to adjust the exact working distance from and the center of the corneal surface. The two beams of the positioning slit lights will be displayed on a curved surface as two white bow shaped patterns.

4.6.3 Fixation LED

The fixation LED is used for fixation of the patient's eye. The fixation LED beam is displayed on a surface as a green, blinking point.

4.6.4 Aiming Laser

The aiming laser is guided coaxially with the excimer laser beam and, therefore, indicates the position of the laser in the working plane. It will also follow the movements of the excimer laser beam during the treatment.

When the eye tracker is active, the aiming laser fixates on the pupil center and will follow any pupil movements.

If the eye tracker cannot recognize the pupil and must be therefore deactivated, the aiming laser then points into the middle of the working plane. Use the aiming laser to center the patient manually. During the treatment, the correct centration can be checked by releasing the footswitch for a short moment. The aiming laser then points back to the center of ablation.

IMPORTANT NOTE

A change of the aiming laser beam can be an indicator of a damaged beam delivery system.

4.7 Gas Supply

The laser operates with pre-mixed, or „ArF-PREMIX“ gas. The capacity of one bottle is sufficient for about 60 fills (30 fills with MLase laser source) at standard operation. After expiration period the gas bottle needs to be exchanged. The gas bottle must be changed by a SCHWIND eye-tech solutions service engineer/technician or a trained service technician of a SCHWIND dealer. Replacement directly by SETS only if there is no certified dealer in the respective country.

The noble gas mixture must be ordered directly from SCHWIND eye-tech solutions or the responsible SCHWIND dealer to guarantee purity levels and strict check criteria.

Otherwise, damage to the system can occur. This is part of the Service and Maintenance Agreement.

A gas change should be carried out when needed. The system will show message in case it is recommended to perform a gas exchange or in case it is definitely required in order to work with the system. Please perform a gas exchange in that case.

During the gas exchange the used gas is guided through a halogen filter to absorb the fluorine.

For additional information regarding the gas exchange – refer to chapter 7.9 Gas Exchange - Excimer Laser.

IMPORTANT NOTE

Failure to follow these instructions will invalidate any guarantee or claim of responsibility by SCHWIND eye-tech solutions.

CAUTION!

Damage of device!

In case the AMARIS excimer laser system is not in operation for a period over **3 months**, please contact the Service Department of SCHWIND eye-tech-solutions.

Do not use any other gas bottles than specified by SCHWIND eye-tech-solutions!

The customer is not allowed to disconnect or connect any gas bottle from or to the AMARIS. Therefore contact the Service Department of SCHWIND eye-tech-solutions or the responsible SCHWIND dealer.

The label is placed inside the laser at the connection terminal.

IMPORTANT NOTE

The **halogen filter** has to be exchanged with every two changes of the premix gas bottle. This is done by a SCHWIND Service technician or other trained personnel only.

The used halogen filter contains toxic agents and should only be disposed of in a professional way in accordance with directives of your location.

4.8 The Optical System

The optical system for beam guidance and forming is flanged and connected to the laser at its output with a protective tube. The beam is turned four times at a 90° angle each time. Output of the beam is perpendicular to the treatment area, coming down axially with the optical axis of the video control system and of the fixation laser, which are used for centralization.

The treatment area is about 193 mm under the beam output housing. Focusing of the ablation field and centring on the eye is performed with two positioning slit lights, a video camera and a microscope. A video image with crosshair is produced on the monitor, which allows easy centring of the pupil.

The maximum ablation field in the focus level has a diameter of max. 14.0 mm.

A fixation LED beams through the optical axis of the unit onto the eye and is used as a fixation aiming point for the patient. The laser power is below 10 µW, which allows prolonged illumination of the eye without causing any damage.

Vacuuming of Optical Beam Delivery System

Radiation of an ArF excimer laser is 193 nm, which is at the outer limit of the ultra violet light spectrum through which air is transmitted. Contact with air (oxygen) noticeably decreases the radiation and ozone is produced. This would damage the optical components if it were allowed to accumulate inside the delivery system.

For this reason, it is necessary to remove, or evacuate, the air from the beam path. The evacuation process occurs automatically after switching on the system during the start-up phase.

4.9 Microscope and Illumination

A coaxial stereo microscope is used for exact control and focusing of the corneal surface. It allows coaxial stereoscopic inspection of the eye without the control beam path being guided through the working optic of the device. Therefore, a very high quality picture is possible.

Abrasion of the epithelium and LASIK can be performed under optimal control conditions. Furthermore, the inspection of treatment results is possible.

The crosshair is aligned and dimensioned for the magnification changer in position 1.0.

Any another magnification could result in a shift of the crosshair. Further function description of the operation microscope is provided in chapter 6.8 Operating of the Microscope.

For illumination of the treatment area, a LED illumination system (see Figure 4-4: LED illumination) is integrated into the unit. This white light illumination can be adjusted in brightness and switched off and on with the illumination control on the AMARIS control panel, if desired. Brightness can be adjusted for best treatment observation combined with short application time.

IMPORTANT NOTE

High brightness can be very unpleasant to the patient, so avoid inappropriate light illumination and reduce time of illumination to treatment time.

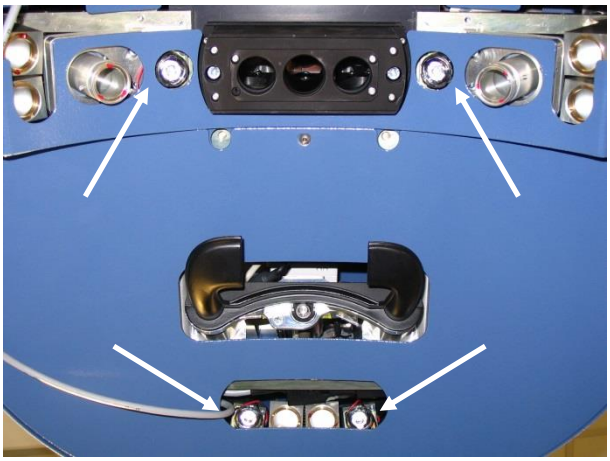


Figure 4-4: LED illumination

4.9.1 Major Components

The major components of the operating microscope are:

- Motor-driven 5 step magnification changer
- 10° to 50° microscope binocular tube

4.9.2 Magnification Changer 5 Step

The 5 step **magnification changer (5)** is motor-driven. The magnification can be changed step-by-step manually by using the appropriate buttons <+> and <—> at the **key pad (5),** or automatically controlled by the software (see Figure 4-5: Components of the operation microscope (example AMARIS 750S).

4.9.3 Microscope Binocular Tube

As a standard, the operating microscope is equipped with a 10° to 50° **binocular tube (1).**

Each **ocular (2)** provides a diopter setting of +5 to -5 D, which can be adapted to the ametropia of the user. For better observation, spectacle wearers should push in the **setting rings (3).**

The pupillary distance (PD) can be set via a **spindle (4)** from 55 to 70 mm. Adjust the PD such that the image is observed by both eyes. Magnification of the microscope is adjusted by **(5)**.

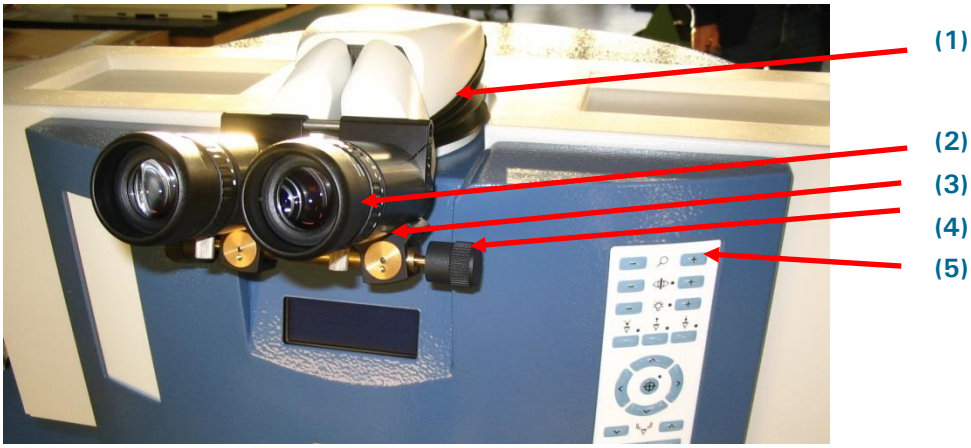
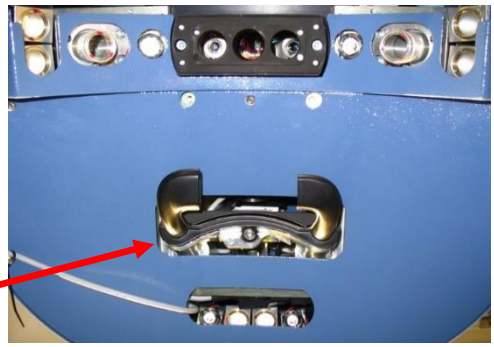


Figure 4-5: Components of the operation microscope (example AMARIS 750S)

4.10 Particle Aspiration System

4.10.1 Description

The Particle Aspiration System is used to remove particles and emerging plumes from the surgical plane during the surgery. The system consists of two tubes which create a laminar air flow above the surgical plane and, therefore, remove the plumes.



The position of the system can be controlled with the respective button on the control panel of the excimer laser (refer to Figure 6-9: Control panel of the excimer laser).

The system is brought into position directly before the laser ablation and is retracted after the laser ablation is finished.

Figure 4-6: Particle Aspiration System

IMPORTANT NOTE

The nozzle of Partical Aspiration Sytem has been used as standard nozzle (double-channel) **until June 2017 in all AMARIS types** (AMARIS 500E/750S/1050RS). **Since July 2017 it will be used in AMARIS 500E only!**

4.10.2 Replacing the Particle Aspiration Nozzles

For replacing the double-channel nozzle for particle aspiration, pull up two metal latches holding the nozzle and drag the nozzle out, than replace it with a new one, refer to chapter 10.3, Maintenance of the Particle Aspiration System.

IMPORTANT NOTE

The **Particle Aspiration System** nozzle with integrated filters is a consumable and **has to be exchanged every 4 weeks**, even if there have been no or few treatments performed, in order to prevent the development of bacteria cells.

The AMARIS Application software has an integrated check and will remind the user to exchange the particle aspiration nozzle if the actual one is older than 28 days.

Refer also to chapter 10.3 Maintenance of the Particle Aspiration System.

IMPORTANT NOTE

It is not allowed to grease or oil the channels of the Particle Aspiration System as evaporated substances may influence the performance of the laser system.

WARNING!

Do not mismatch the nozzles! Risk of under correction!

Do not use the nozzle of the **Plume Evacuation System**! Refer to chapter 4.11 Plume Evacuation System.

4.10.3 Package Labelling of the Partical Aspiration Nozzle

Each nozzle of the Particle Aspiration System is individually packed into a sealed airtight plastic bag. The nozzles are available as a set of quantity 6 only.

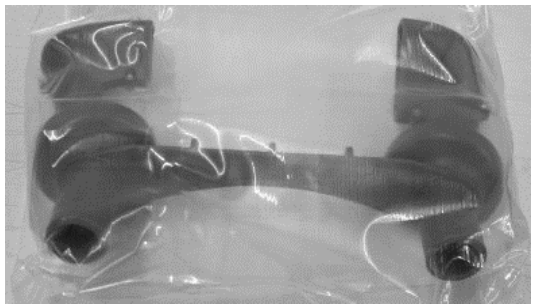


Figure 4-7: Type lable for packaging of partical aspiration nozzles, colour grey, 6 pcs

Symbol explanation:

	The component/unit may be used until: Date [year, four-digit]-[month in two digits], 5 years starting from date of packing.
 28 Days	Period after Opening: After opening the primary packing the product may be used for a maximum of 28 days
	Manufacturer Address
	The product is non sterile
	Reference number (Article-No.)
	Lot-Number, 6-digit number
	Quantity
	Data-Matrix Code. The code consists of the article-no. and LOT-no, separate with ASCII sign 0124 "|" (e.g. 1779401-01|250620).

4.11 Plume Evacuation System

4.11.1 Description

The Plume Evacuation System with the single-channel nozzle is a system for debris removal during the ablation process which can be installed instead of the existing particle aspiration system.
As an alternative to the **partical aspiration system** (refer to chapter 4.10 Particle Aspiration System) delivered with an AMARIS, a high efficacy **Plume Evacuation System** is the default system within the AMARIS 750S and AMARIS 1050RS models **since July 2017**. It will remove particles from the ablation area and reduce the smell during surgery to a minimum and is mounted in two variations:

4.11.1.1 Plume Evacuation System - INTERNAL version

(Standard for AMARIS 750S /1050RS)

The system consists of an **internal evacuation unit** (suction unit) with an **integrated filter**, **tubing** (vacuum hose) and **the single-channel evacuation nozzle** (Figure 4-8), and parts for electrical connection inside the **AMARIS 750S or 1050RS,** available since July 2017.
The internal version of the plume evacuator **is not** available for the **AMARIS 500E.**

WARNING!

Do not mismatch the nozzles!

Risk of under correction!

Do **not** use the **double-channel debris nozzles** together with the Plume Evacuation System!

The Plume Evacuation System must be operated with the **single-channel evacuation nozzle shown in** Figure 4-8.

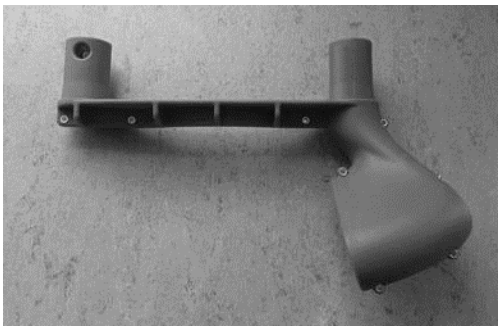


Figure 4-8 Single-channel nozzle for the plume evacuation system

4.11.1.2 Plume Evacuation System - EXTERNAL version

(Option for AMARIS all models)

The system is an add-on kit, which consists of an **external evacuation unit** (suction unit) with **integrated filter** and **tubing** (vacuum hose) and a **special evacuation nozzle, i.e. the single-channel evacuation nozzle (**Figure 4-8**)** (mounted in place of the double-channel debris nozzle), and parts for electrical connection to the AMARIS (all models). The electrical connection is a safe extra low voltage provided by a medical approved power supply.

Figure 4-9: External Evacuation unit with filter and tubing mounted to the nozzle

IMPORTANT NOTE

The **Plume Evacution Sytem** is optionally available for **AMARIS 500E** as **external version only**. Ask SCHWIND eye-tech-solutions or your SCHWIND local representative for additional information.

CAUTION

Before starting a treatment, make sure that the PLUME EVACUATOR is connected properly to the AMARIS and that the louver is not covered.

Pay attention to the sound of the PLUME EVACUATOR to be sure that the blower inside is working during treatment.

4.11.2 Replacing the Plume Evacuation Nozzle

The evacuation nozzles and filter in both internal and external version of the plume evacuation system will be replaced **once a year** by a technician during the regular service visits.

For more details refer to chapter 10.4 Maintenance of the Plume Evacuation System.

4.11.3 Package Labelling of the Plume Evacuation Nozzle

Each nozzle of the Plume Evacuation System is individually packed into a sealed airtight plastic bag.

Figure 4-10: Type label for packaging of plume evacuation nozzle - internal version

4.11.4 Labelling - Plume Evacuator

The plume evacuator of the external Plume Evacuation System is labelled with the following identification label:

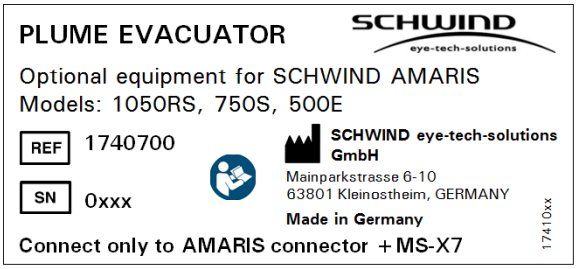


Figure 4-11: Type label for optional plume evacuation system - external version

4.12 Patient Bed

For correct positioning of the patient, a **SCHWIND Patient Bed** is supplied with the laser system.
The patient bed can be operated in combination with a SCHWIND excimer laser as:

1. **Manually traversable (swivelling) bed** (available since May 2011)
2. **Motorized traversable (swivelling) bed** (optionally available from 2012 on)

For use:

- With standard laser devices (e.g. SCHWIND AMARIS 500E/750S/1050RS),
- With other medical devices, e.g. femtosecond lasers if connected to a SCHWIND device,
- In combination with a SCHWIND AMARIS 500E/750S/1050RS laser or with a femtosecond laser to swivel manually between both lasers.

The patient bed can be swivelled through variable angles in steps of 10° from 30° up to 90° and serves as comfortable patient positioning system (refer to chapter 5.2.2, Device and Room Dimensions).

SCHWIND patient bed for AMARIS 750S / AMARIS 1050RS / AMARIS

To position the patient, the patient bed is equipped with a joystick to operate the unit.
The patient bed is connected mechanically to the SCHWIND AMARIS by a **swivel joint.**

IMPORTANT NOTE

For the correct adjustment of the patient's eye to the focal point of the laser, please refer also to chapter 6.10 Positioning Slits.

Ensure that all interlock connections are properly connected.

IMPORTANT NOTE

Trained personal for patient bed alignment!

The patient bed has to be correctly aligned perpendicular to the laser arm of AMARIS excimer laser system. This alignment should only be executed by trained or authorized service personnel.

WARNING!

Risk of injury!

Never use the patient bed for transport of patients!

The patient bed is designed for patients with a maximum weight of 150 kg!

IMPORTANT NOTE

Use only patient beds approved by SCHWIND eye-tech-solutions.

For detailed information concerning the patient bed operation refer to the User Manual (Instruction for Use) of the SCHWIND Patient Bed.

4.13 Foot Switch

The foot switch is used to start the treatment or test procedures. This switch has two switch points to avoid unintentional release of pulses. The treatment procedure can be interrupted at any time by releasing the foot switch. The program remains active, so the treatment can be continued at any time by pressing the foot switch again.

4.14 Optional Features

4.14.1 Video System

The video system is an optional feature and can be ordered separately.The system will include an additional observer camera.

For description and operation instructions of the video equipment please refer to the respective manufacturers/suppliers instruction and operation manuals.

The interface (connection) to the AMARIS laser is described in chapter 2.9.3, Connection Terminal Label of the Device.

The connector for connection of recording or display screen is labelled with **"X4"**. It is a standard BNC connector.

A monitor for display of the camera video is optional available.

Additionally a Video Extender HDMI to connect displays via HDMI directly is available. Please refer to chapter 4.13.11 Video Extender HDMI for detailed information.

Alternatively, a digital video recording system is available when the AMARIS system is equipped with the latest Panel PC version (Onyx Zeus).

Digital video files are stored on the hard disk of the AMARIS panel PC. For description of viewing and external export of video files, refer to chapter 7.11, Printout and Video (Export of Treatment PDF and Video). When using the digital video recording option, external recording devices are not needed in addition.

IMPORTANT NOTE

An additional **video system** (e.g. DVD-recorder or TFT monitor must be placed outside the patient area.

IMPORTANT NOTE

As the free space on the Panel PC hard disc is limited, check it regularly and perform backup of the video files, if necessary. The disk free space is indicated in the main menu of the software.

4.14.2 Printer

IMPORTANT NOTE

If a **printer** is used with the SCHWIND AMARIS via WLAN or USB connection, respectively, the printer must be placed outside the patient area.

4.14.3 Slit Lamp of the Excimer Laser

The integrated slit lamp can be used to check the correct position of the flap after the LASIK surgery. The slit lamp can be switched ON or OFF by pressing both buttons + and — at the control panel at the same time (refer to Figure 6-9). The intensity of the slit lamp light can be adjusted with the respective button on the control panel of the excimer laser (refer to Figure 6-9: Control panel of the excimer laser).

The slit lamp can be moved over the entire working area and turned around its own axis to move the slit over the eye from each lamp position.

To move the slit lamp along the arch, press the lever downwards to release the brake.

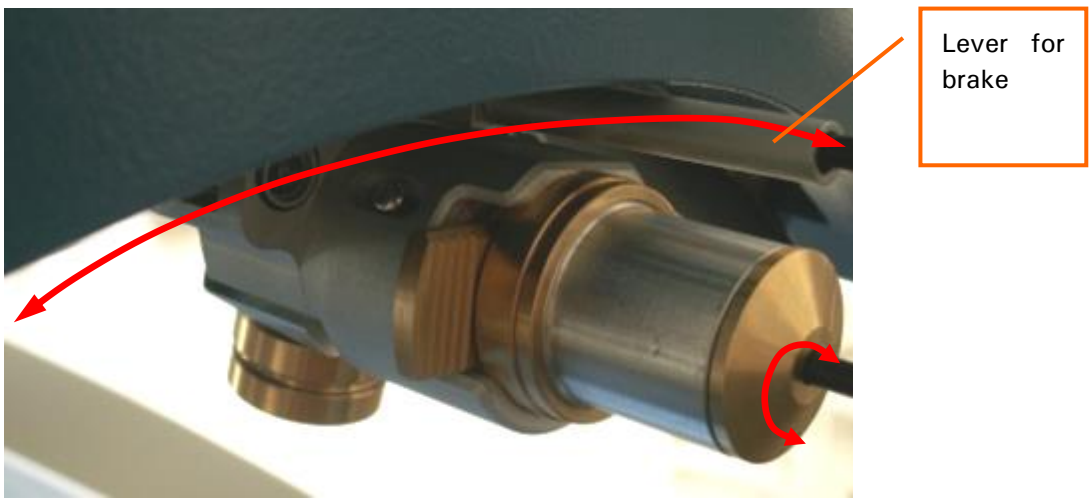


Figure 4-12: Excimer laser slit lamp

IMPORTANT NOTE

The slit lamp will be automatically switched off by the system after **3 minutes**.

There are four types of apertures available which can project different slit sizes, as well as diffuse illumination towards the patient's eye. The different apertures are labelled as:

S (25 μm slit width)

M (50 μm slit width)

L (100 μm slit width)

D (10 mm diffuse illumination

Figure 4-13: Apertures for the slit lamp (sample)

To change the slit size or to change to the diffuse illumination pull out the currently used aperture module and insert the desired module into the slit lamp.

The apertures are kept in a shelf, which is fastened to the laser tower underneath the monitor.

Figure 4-14: Exchange of aperture modules

WARNING!

The new LED is a very powerful light source, so it is very dangerous for the human eye to use higher settings even if there is an aperture with a slit inside the slit lamp. For applications on the human eye it is recommended to use the slit lamp always together with an installed slit aperture. Make sure that slit lamp is switched off before slit aperture is exchanged.

If no aperture is used or the aperture D10 is inside the slit lamp use only very low values of brightness for illumination of the human eye. If higher values of brightness are needed the application time must be reduced to some seconds only.

Dependent on the version of the installed LED the adjustment of the brightness using the buttons on the Manual Control Panel (key pad) of the AMARIS is not working in lower range.

Especially for China settings this not-working-range can be up to 57%.

4.14.4 Online Coherence Pachymetry (OCP)

For the measurement of the corneal thickness during the treatment, an Optical Coherence Pachymeter might be integrated in the AMARIS excimer laser. The OCP option is discontinued for new laser deliveries within 2023.

For details regarding OCP measurements refer to chapter 8.6 Online Coherence Pachymetry (OCP).

4.14.5 6D-/7D-Eye Tracking

As an additional option for selected SCHWIND AMARIS models Z- movements (6th dimension) can be measured and actively compensated during the ablation process. Moreover AMARIS systems equipped with a 6D- eye tracker will actively measure eye rolling movements which can be visualized in the treatment screen.

For details regarding the operation of 6D-Tracker refer to chapter 8.5 Eye Tracking.

The model AMARIS 1050RS is marketed with the option of a latency free (7th dimension) eye tracking additionally. This feature calculates future eye positions to compensate the time delay between the image acquisition and the positioning of the laser beam.

4.14.6 Cross Laser Module

The optionally available integrated **cross laser module** serves as an additional aid for patient alignment to check the patient's head orientation or rotation, respectively. Especially for treatments including cylindrical power or higher-order aberrations WITHOUT having static cyclotorsion control available, the laser helps to ensure that the patient's horizontal axis matches the real x-axis of the laser by projecting a cross over the patient's entire face.

IMPORTANT NOTE

The Cross Laser Module is intended only as an additional aid for better alignment of the patient's head before treatment. The Cross Laser Module cannot replace Static Cyclotorsion Control since rotation of the eye itself cannot be detected.

The laser can be switched on or off with a touch button below the microscope tube. Once switched on, the laser switches off again automatically after a predefined time of either 15, 30, 45 seconds or 1, 2, 3 minutes. The time can be set by a service technician, the default setting is 2 minutes.

The module is only available for the models AMARIS 750S and AMARIS 1050RS.

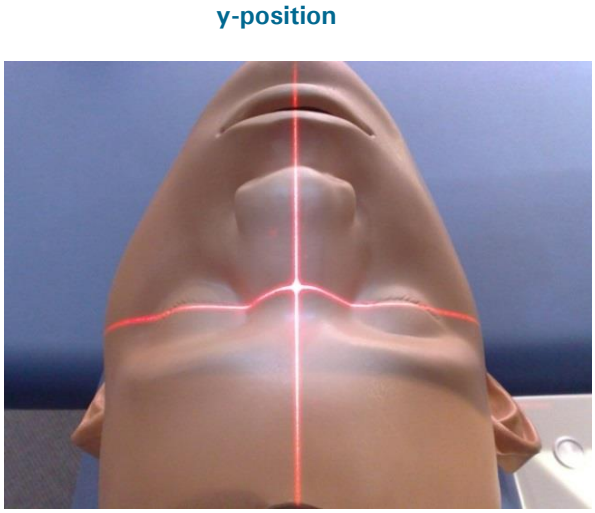


Figure 4-15: Cross laser projected on patient's head

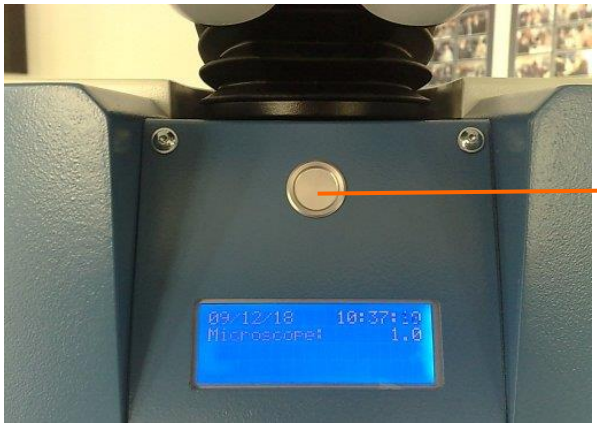


Figure 4-16: Cross laser ON/OFF button

The patient's head should be aligned in such a way that both eyes match with the horizontal line (x-position) of the cross laser module and forehead, nose and chin should match with the vertical line (y-position).

IMPORTANT NOTE

Since the patient's face may not always be symmetrical, the cross laser module cannot guarantee a perfect alignment in all cases and therefore can only be regarded as an additional aid.

4.14.7 Uninterruptable Power Supply (UPS)

CAUTION

The AMARIS should be operated with an UPS (uninterruptible power supply) to avoid treatment interruption in case of power loss.

This is very important, especially in regions or countries with uncertain power supply.

An UPS system is important for safety usage of the system and is necessary to protect against fluctuations and interruptions of the mains supply.

UPS must be connected to power supply around-the-clock (24 hours a day) for battery charge. Use main switch of AMARIS.

Refer additionally to chapter 6.5 UPS - Mains Failure or Power Breakdown.

IMPORTANT NOTE

The UPS must be installed outside the patient area.

The UPS must be considered as an extension of the home or clinic installation and is not a system combination acc. to Article 12 of European Medical Device Directive MDD 93/42/EEC, resp. Article 22 of European Medical Device Regulation MDR 2017/745.

4.14.8 Plume Evacuation System - External

As an option, the aforementioned **external Plume Evacuation System** can be installed in all AMARIS models instead of the previous default system containing the particle aspiration nozzle For a detailed description of the external plume evacuation system refer to chapter 4.11 Plume Evacuation System.

4.14.9 Video Extender HDMI

The Video Extender HDMI is an option, which allows the customer to connect a HDMI-input-Monitor to observe the signal from the observer camera. Pre-condition is the installed Videosystem AMARIS. At customers' site a TV Monitor or a computer monitor can be used. The video signal is provided at the connector plate as a HDMI female connector.

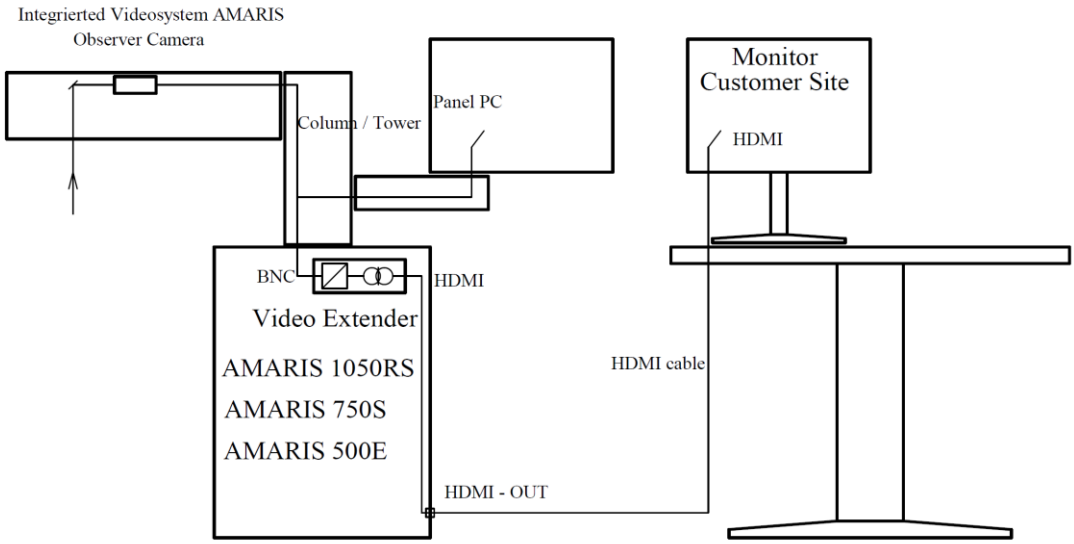


Figure 4-17: Overview AMARIS Video Extender connection

The HDMI output delivers a HDMI signal, which is isolated from AMARIS power supply.

The monitor has to be placed outside the patient area and it can be supplied by external voltage.

The connector is labelled with “X5”

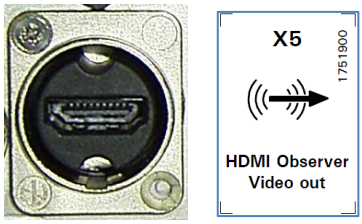


Figure 4-18: HDMI female connector at the main supply connector plate

4.14.10 C-eye Cross-Linking Kit / C-eye Sliding Unit for AMARIS

The C-eye Cross-Linking Kit / C-eye Sliding Unit for AMARIS as optional component is mounted to and can be used in conjunction with SCHWIND AMARIS (all models).The C-eye Sliding Unit makes it possible to easily use the C-eye (CXL) device by manufacturer C.S.O srl in conjunction with a SCHWIND excimer laser. The C-eye Cross-Linking Kit consist of the C-eye (CXL) device itself and the C-eye Sliding Unit for AMARIS laser. The C-eye Sliding Unit can be ordered separately, i.e. without a C-eye (CXL) device, too. The correct working distance of the C-eye device attached to the C-eye Sliding Unit for AMARIS laser is automatically given when the user appropriately adjusts the positioning slits of the SCHWIND excimer laser to patient’s cornea. (Refer to chaper 6.10 Positioning Slits for proper patient eye alignment)

4.15 Approved System Combinations and Optional Accessories / Features

IMPORTANT NOTE

When combining the **AMARIS 500E** / **AMARIS 750S** / **AMARIS 1050RS** excimer laser with a **patient bed** or with **other medical products**, take care to ensure that the combination complies with the requirements of the European Medical Device Directive (93/42/EEC) resp. of the European Medical Device Regulation MDR 2017/745, and of the applicable standards of the family IEC 60601-1 and any other local regulations that may apply. The combination of the SCHWIND AMARIS with other SCHWIND products meets these requirements.

CAUTION

Do not install any devices or software other than those defined in the prescribed system combination as shown in the table below.

Only these are approved by SCHWIND eye-tech-solutions!

SCHWIND does not assume responsibility for any other combinations and the implications of misuse!

The **table** below lists devices for

- **Approved system combination**[1] specified by SCHWIND eye-tech-solutions

  and

- **Approved optional components / features**[2] which are intended for the use with the AMARIS laser system and **may be equipped optionally**

for the respective **AMARIS model** (500E, 750S, 1050RS)

Device	**Class**	**System combination**[1]	**Optional features**[2]
SCHWIND Custom Ablation Manager	IIb	X	---
Patient bed swivelling for the respective AMARIS model (500E, 750S, 1050RS)	I	X	---
SCHWIND CXL-365 vario**	IIa	X	X
C-eye Cross-Linking Kit ** (AMARIS Sliding Unit is supporting act of the C-eye device only, with NO electrical connection between the two devices)	IIb (for C-eye device)	---	X
WLAN-Set for data exchange with workstations (incl. WLAN Access point Dlink and WLAN print server)	---	X	X

Device	Class	System combination [1]	Optional features [2]
Video system AMARIS incl. observer camera	---	X	X
TFT Monitor 19"	---	X	X
OCP Online Pachymetry	---	---	X
Slit lamp	---	---	X
6D-tracking (AMARIS 750S and AMARIS 1050RS only)	---	---	X
Latency-free tracking (AMARIS 1050RS only)	---	---	X
Cross laser	---	---	X
Advanced Cyclotorsion Control for corneal Wavefront guided treatments (SCC)	---	---	X
Advanced Cyclotorsion Control for ocular Wavefront guided treatments (SCC)		---	X
Advanced Cyclotorsion Control Dynamic cyclotorsion control for online correction (DCC)		---	X
Plume Evacuation System (external version)	---	---	X*
Uninterruptible Power Supply (UPS) 3kVA	---	---	X

[1] Approved system combination

[2] **Optional components / features**

***The models except of the AMARIS 500E and available since July 2017 where the plume evacuation system is installed by default.**

*** The SCHWIND CXL-365 vario/ C-eye (Cross-Linking Kit) as an option is available for specific countries only*

5 INSTALLATION

5.1 General Installation Notes

There are no activities by the user necessary regarding the installation of the medical device or software.

Trained service personnel of the SCHWIND eye-tech-solutions or of an authorized distributor perform the installation of the SCHWIND AMARIS and the SCHWIND patient bed.

IMPORTANT NOTE

Please contact your authorized local SCHWIND representative or the Service Department of SCHWIND eye-tech-solutions to organize the installation of the software and/or device.

WARNING!

Risk of injury! Damage of device!

Do not install and operate the SCHWIND AMARIS in rooms, areas where danger of explosion exists and in the presence of flammable mixtures!

Improperly installed cables and lines can smoulder or catch fire.

Live cable ends and components can cause electric shock. To prevent the user or patient from being injured, make sure that all cables are laid in such a way that they are protected against damage and cannot be folded or squeezed.

Do not use portable multiple socket outlets sharing a common grounding cable to connect several devices together with this device to mains.

Do not use multiple cables or any other extension cables. Only the main connection cable delivered by SCHWIND eye-tech-solutions should be used. Otherwise the leakage current of the system could be potentially hazardous to patients!

Misplaced or improperly mounted parts may fall and cause personal injury.

CAUTION

Damage of device!

The SCHWIND AMARIS should not be installed in damp rooms. Avoid dripping, standing, or splashing water near the device.

The device may only be installed and operated in rooms with a compatible electrical supply and in which the electrical installation complies with the relevant national regulations.

Electrostatic processes can damage electronic assemblies.

Consider also the Restrictions of Use and Safety Precautions listed in chapter 2.3 and the information contained in chapter 5.5 Initial Installation / Start-Up.

5.2 Room and Installation Requirements

IMPORTANT NOTE

The detailed **room and installation requirements** for SCHWIND AMARIS excimer laser systems and further technical requirements are listed in the document: **"Room and Installation Requirements for SCHWIND Treatment Devices"**, which is provided by SCHWIND eye-tech-solutions.

5.2.1 General Requirements

1. Avoid direct sunlight, use darkening curtain if necessary.
2. Air conditioning required.
3. Air dehumidifier is absolutely necessary in countries with a humidity of more than 40 %.
4. On the outer side of the entrance door, a laser warning lamp and the official laser-warning symbol must be installed.
5. A switch, which interrupts the laser if the door is opened, can be connected through the interlock input at the system. This is only recommended, however, when it is guaranteed that the door will not be opened during treatment.
6. According to EN 207, protective glasses have to be available in sufficient quantity near the entrance door.
7. Door width: min. 80 cm.
8. Floor covering: **PVC or stable, vibration-free underground**! (No carpet).

IMPORTANT NOTE

Good room lighting is important in the area where laser eye protection is worn. Bright diffused wall surfaces are thereby helpful.

For detailed information reg. the "Vibration characteristics of the floor/ground" please refer to a SCHWIND document **"Room and Installation Requirements for SCHWIND Treatment Devices"**.

5.2.2 Device and Room Dimensions

IMPORTANT NOTE

The following drawings show the room dimensions and positions for SCHWIND AMARIS with SCHWIND Patient Bed. Further room dimensions concerning the combination of SCHWIND AMARIS with SCHWIND ATOS and SCHWIND Patient Bed can be found in the SCHWIND ATOS Instruction for Use.

Keep a distance to wall for service works as specified in the following drawings

Device Dimensions - AMARIS / AMARIS 750S / AMARIS 1050RS

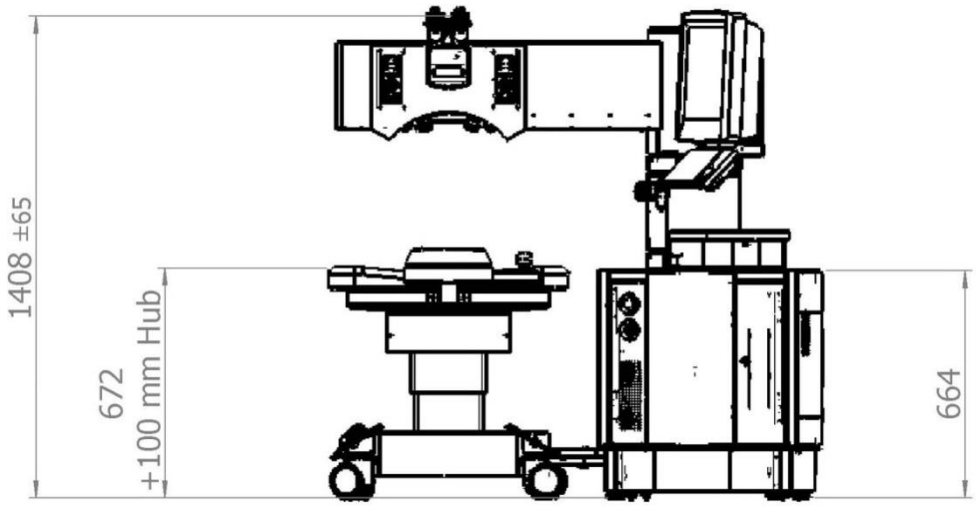


Figure 5-1: AMARIS / AMARIS 750S/ AMARIS 1050RS with swivelling patient bed - front view

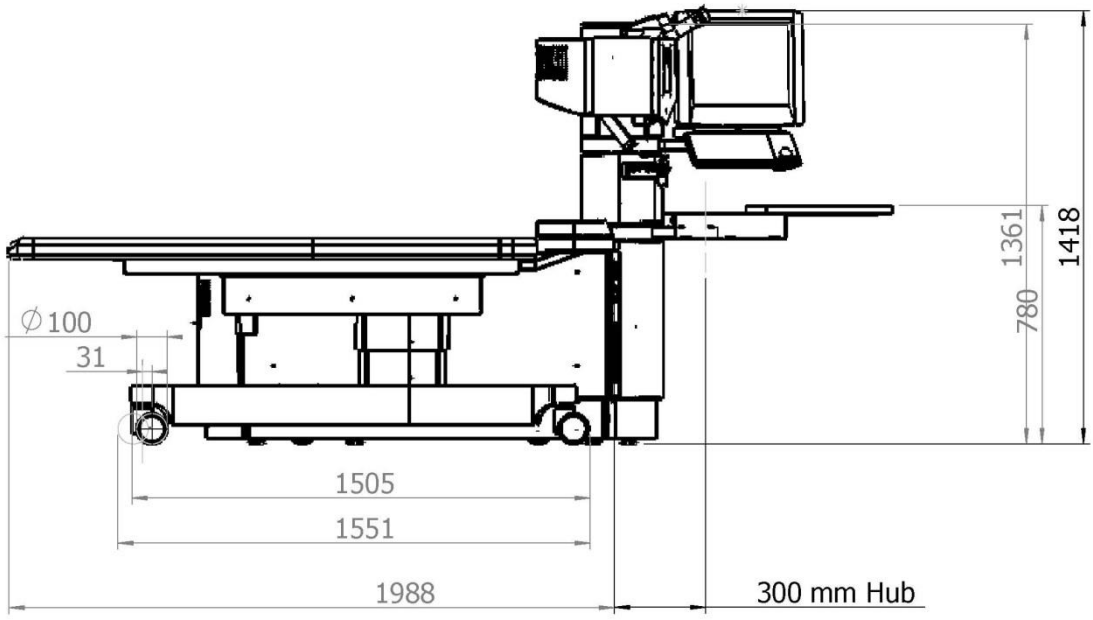


Figure 5-2: AMARIS / AMARIS 750S/AMARIS 1050RS with swivelling patient bed - side view

Room Dimensions - AMARIS / AMARIS 750S / AMARIS 1050RS

All **SCHWIND AMARIS** excimer laser(s) are **designed with a traversable (swivelling) bed** for optionally use with other medical devices. The mechanical end stop for out-swivelling the patient bed can be set in steps of 10°, beginning at 30°, up to 90°.

AMARIS Standard Position

Min. room size:	2300 mm x 3500 mm (approx. 8.0 m²)
Recommended room size:	2900 mm x 3500 mm (approx.10.15 m²

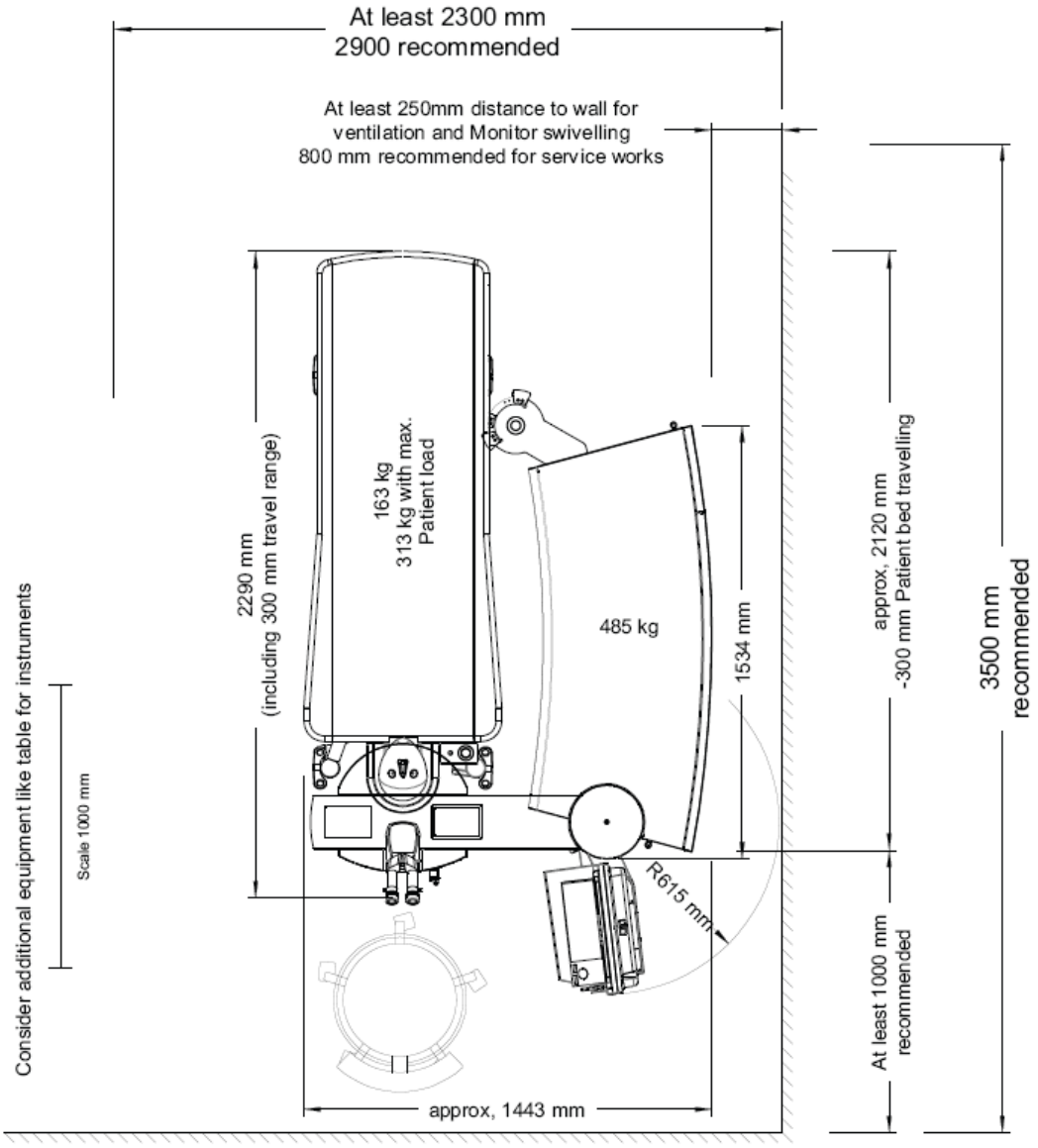


Figure 5-3: AMARIS / AMARIS 750S / AMARIS 1050RS with swivelling patient bed– standard position

Drawing is not shown in actual size

AMARIS Swivelled Position 30°

Min. room size:	2500 mm x 3500 mm (approx. 8.75 m²)
Recommended room size:	3300 mm x 3500 mm (approx.11.55 m²)

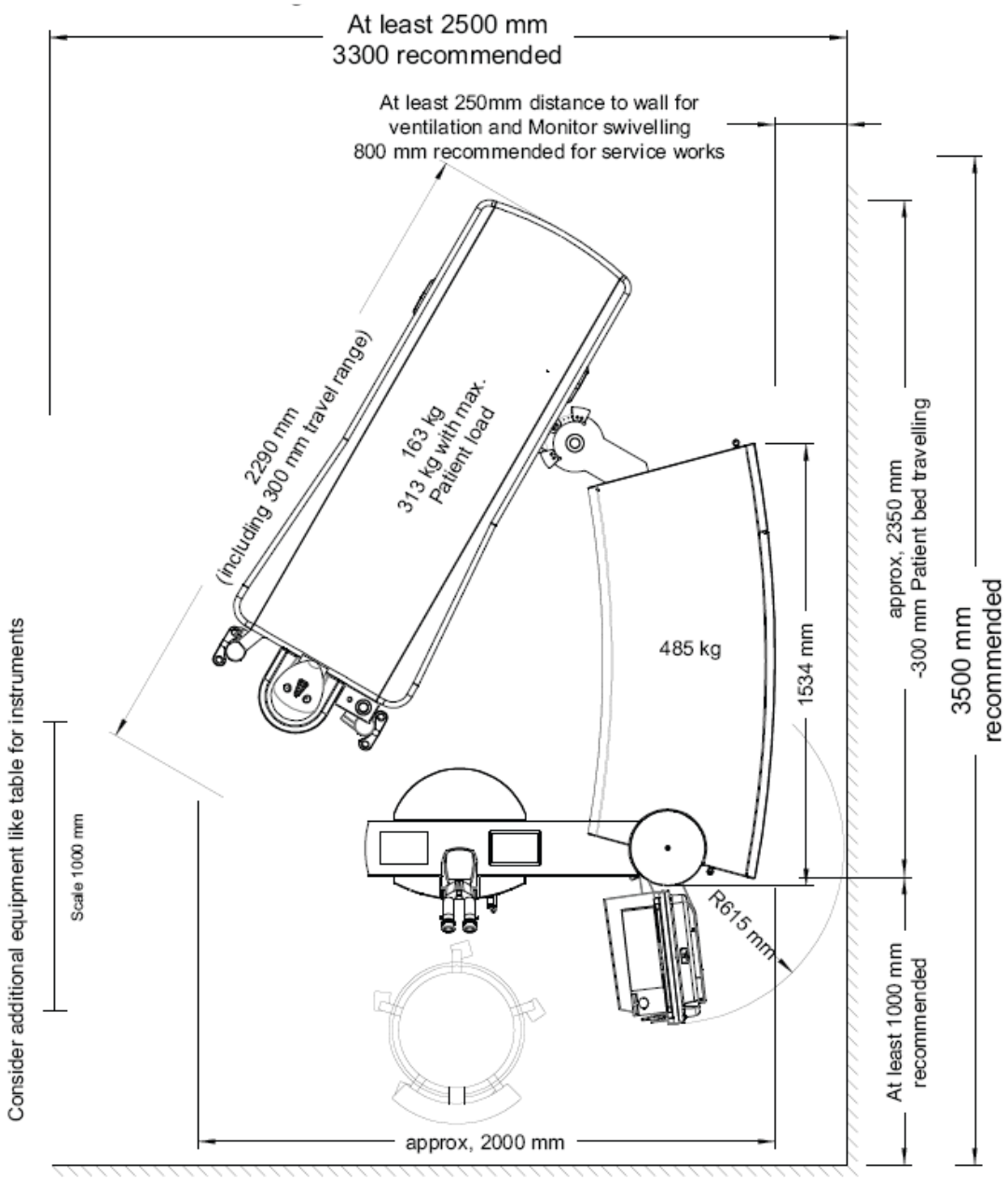


Figure 5-4: AMARIS / AMARIS 750S / AMARIS 1050RS with swivelling patient bed - 30° position

Drawing is not shown in actual size

Installation

AMARIS Swivelled Position 90°

Min. room size: 2800 mm x 3500 mm (approx. 9.8 m²),
Recommended room size: 3600 mm x 3500 mm (approx.14.0 m²)

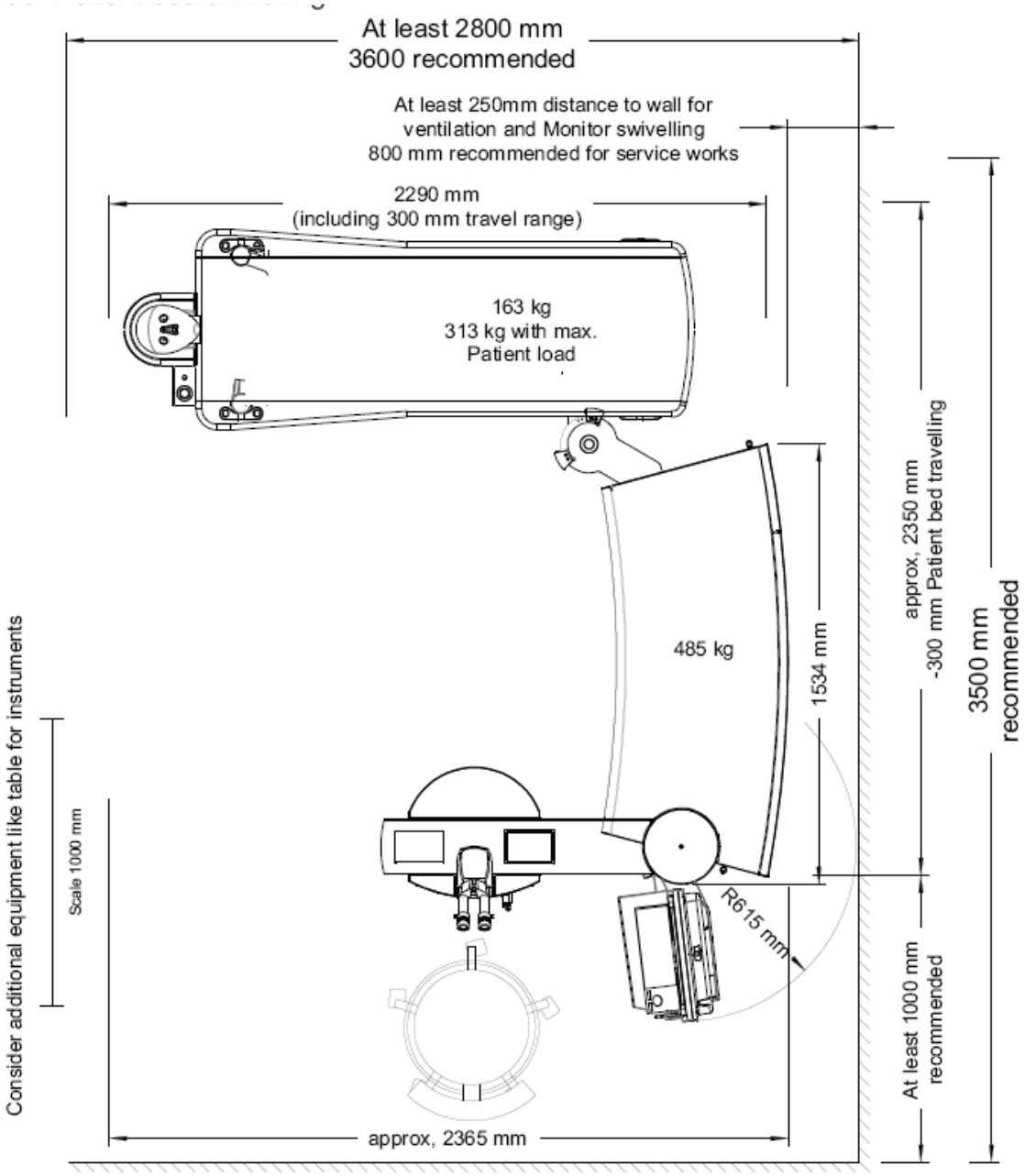


Figure 5-5: AMARIS / AMARIS 750S / AMARIS 1050RS with swivelling patient bed – 90° position

Drawing is not shown in actual size

Device Dimensions - SCHWIND AMARIS 500E

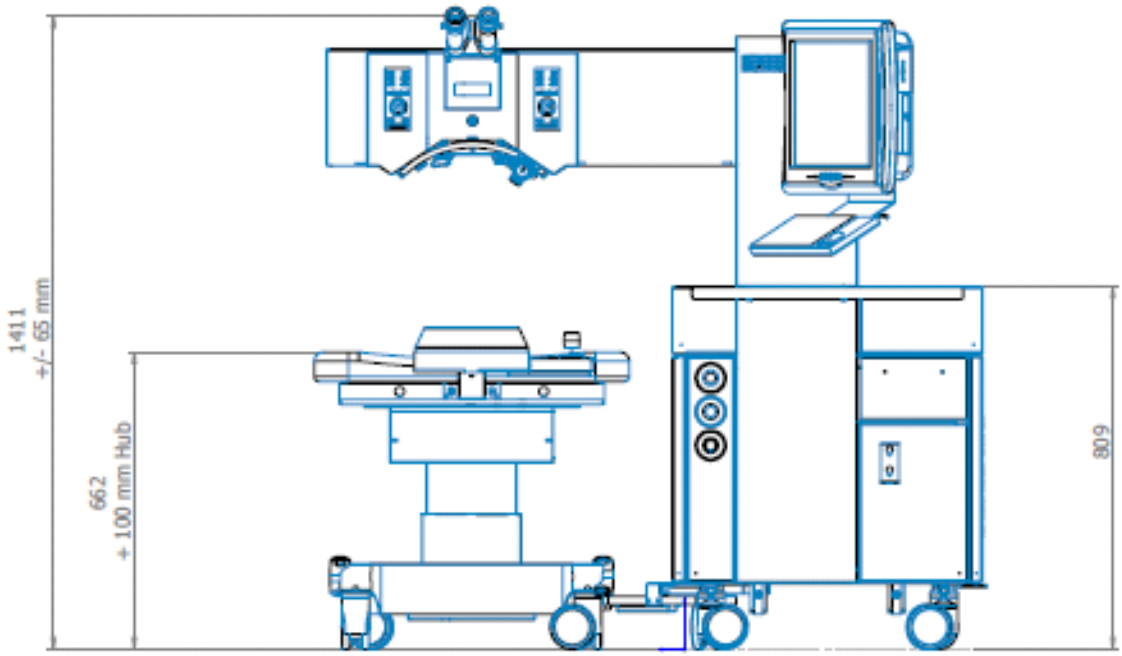


Figure 5-6: AMARIS 500E – front view

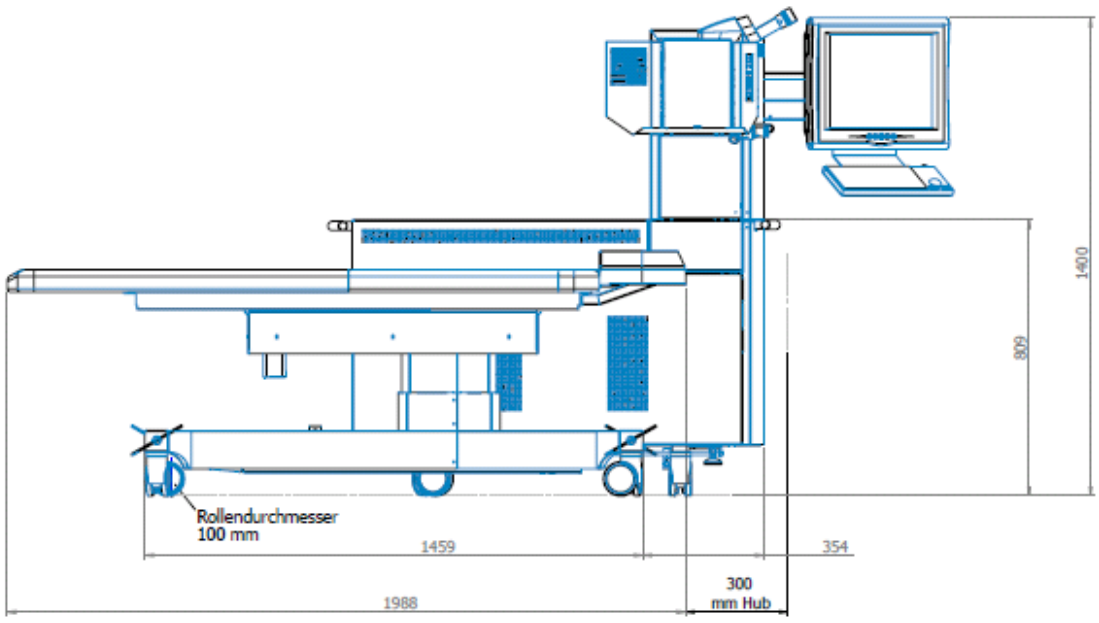


Figure 5-7: AMARIS 500E – side view

Drawing is not shown in actual size

Room Dimensions - SCHWIND AMARIS 500E

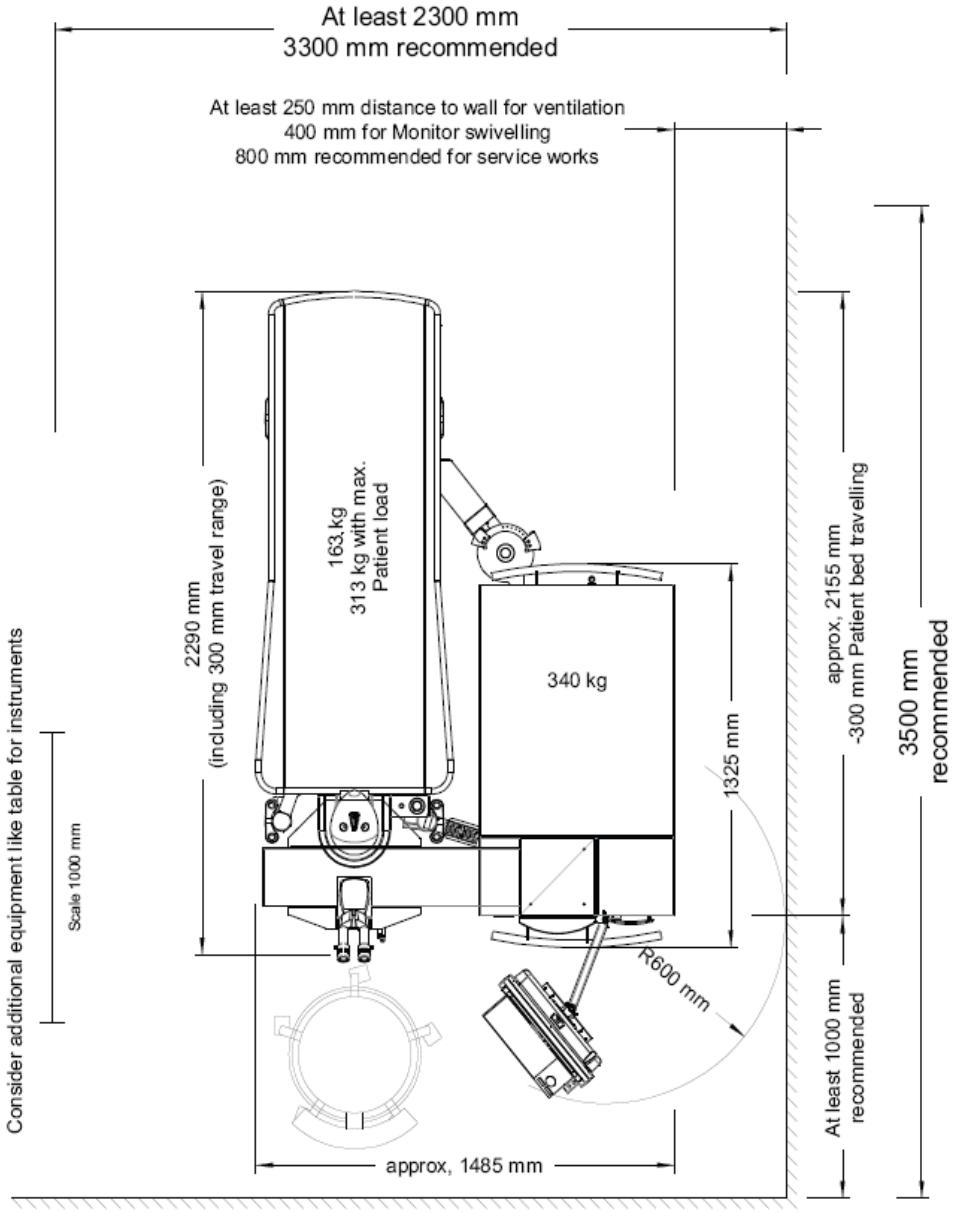
IMPORTANT NOTE

Keep a distance to wall for service works as specified in the following drawings.

AMARIS Standard Position:

Min. room size: 2300 mm x 3500 mm (approx. 8.0 m²)

Recommended room size: 3300 mm x 3500 mm (approx.11.55 m²

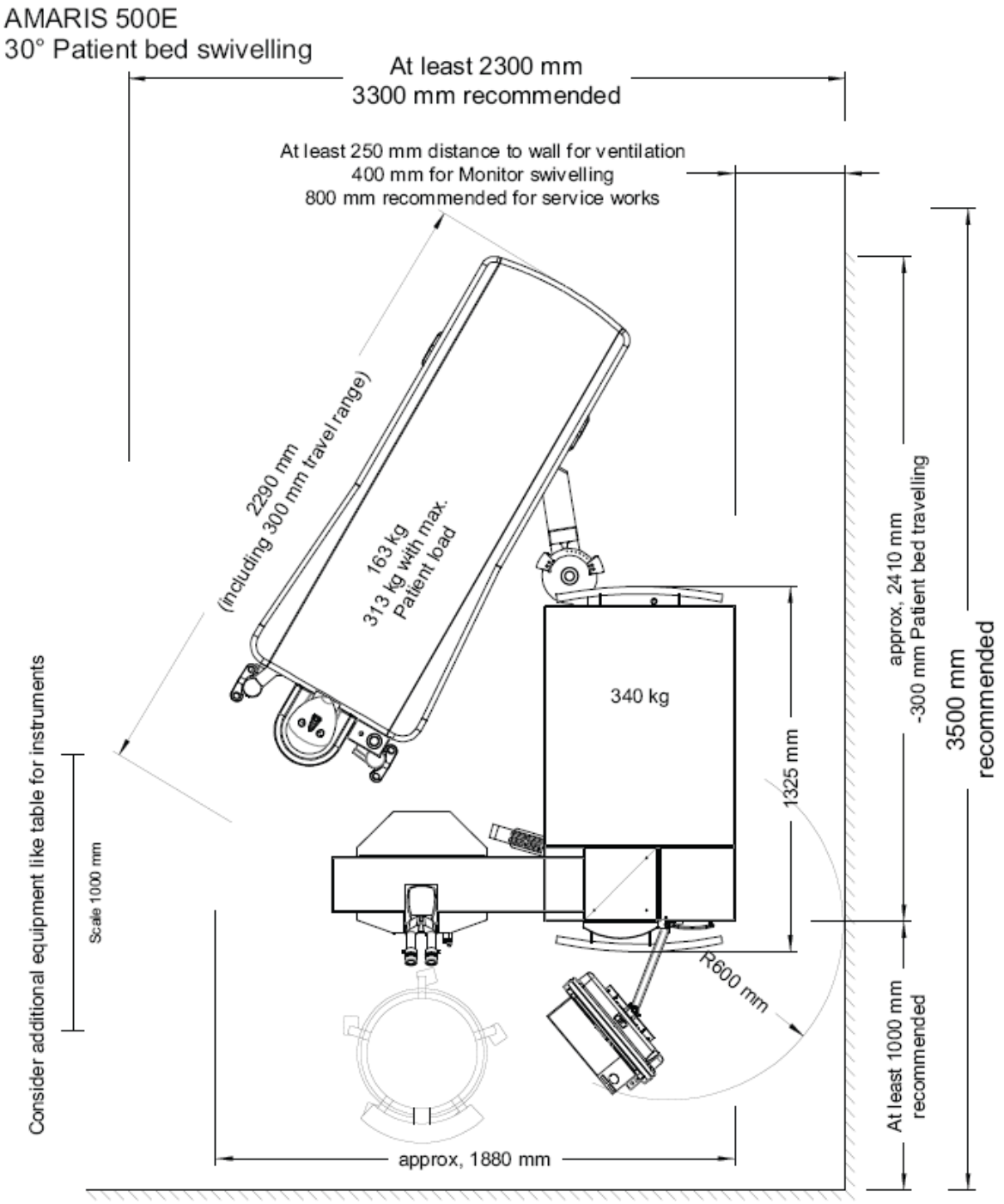


Drawing is not shown in actual size

Figure 5-8: AMARIS 500E with swivelling patient bed – standard position

AMARIS Swivelled Position 30°

Min.room size:	2300 mm x 3500 mm (approx. 8.0 m²)
Recommended room size:	3300 mm x 3500 mm (approx.11.55 m²)



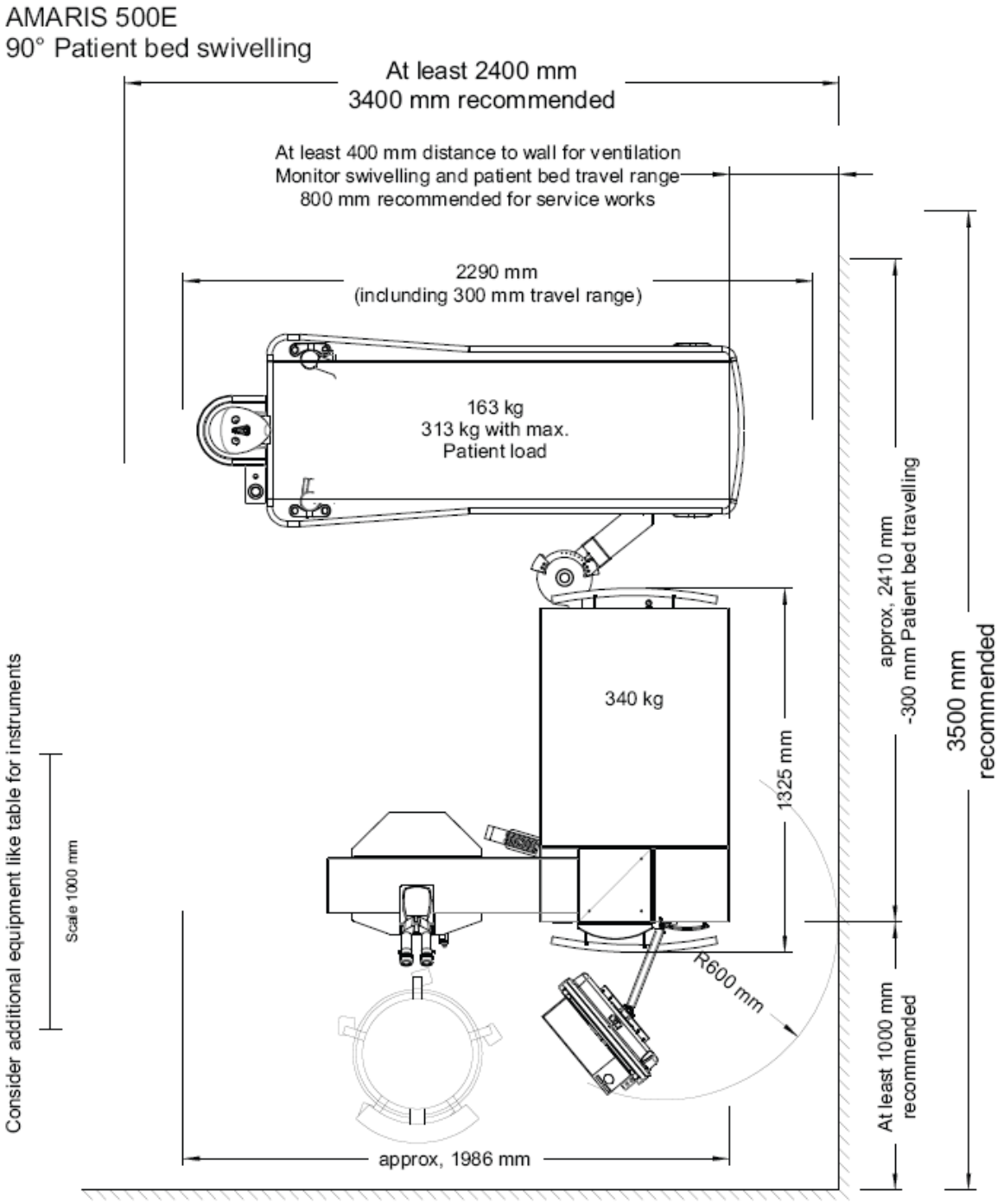
Drawing is not shown in actual size

Figure 5-9: AMARIS 500E with swivelling patient bed - 30° position

Installation

AMARIS Swivelled Position 90°

Min. room size: 2400 x 3500 mm (approx. 9.5 m²),
Recommended room size: 3400 x 3500 mm (approx.12.5 m²)

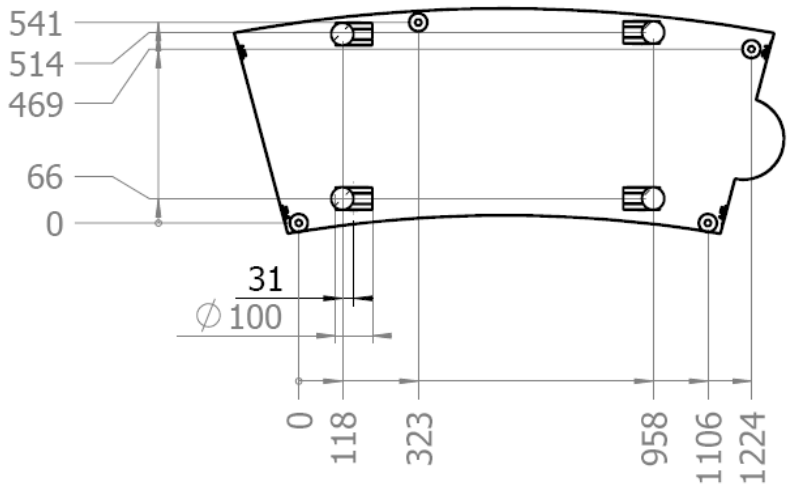


Drawing is not shown in actual size

Figure 5-10: AMARIS 500E with swivelling patient bed 90° position

5.2.3 Arrangement of the AMARIS Laser Feet

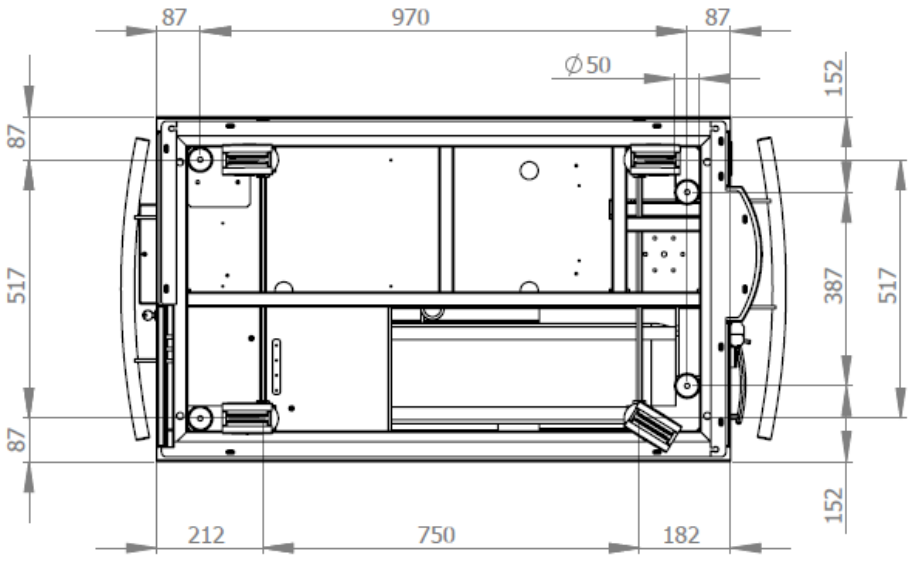
AMARIS / AMARIS 750S / AMARIS 1050RS



All dimensions in mm.

Figure 5-11: Arrangement of AMARIS / AMARIS 750S / AMARIS 1050RS feet

AMARIS 500E



All dimensions in mm

Figure 5-12: Arrangement of AMARIS 500E feet

5.2.4 Environmental Conditions

Air condition:	**Strictly requested!**
Heat load:	**1.5 kWh**
Contaminants:	Minimize dust; No smoking; No volatile cleaning, agents/ detergents (Alcohol, Keton, etc.); No aromatic substances;

IMPORTANT NOTE

The conditions of the operating room lies under the direct responsibility of the user / operator and his quality management system.

The operating conditions shall be established according to standards which are relevant in the respective country.

Room Temp. and Humidity - see Pos. 1 and 2

1. Operation Mode and Standby

Room Temperature Range:	**21°C (70°F) ideal** (range 18°C (64°F) - 24°C (75°F)), Stability ± **2°C** within 2h before starting operation and between fluence test interval.
Relative Humidity:	**40 % ideal (range 30% - 45%)** Stability ± 5% rH within 2h before starting operation and between fluence test interval. **If NO, an air dehumidifier is strictly requested!**
Atmospheric pressure / Absolute altitude of the installation location (height above sea level)**:**	**690 hPa to 1060 hPa** **Max. 3000m** (due to electrical safety)

2. OFF-mode

Room Temperature Range:	**10°C – 30 °C or 50°F – 86°F** Avoid extreme temperature changes.
Relative Humidity:	**15% - 85%** NONCONDENSING! Avoid extreme temperature changes! *See User Information UI_A02-09 "Influence of humidity and condensation on SCHWIND products".*

3. Transport and Storage

Vacuum packaging in wooden box for outdoor transport.

Important: If transport without vacuum packaging, the environmental conditions for **OFF-mode (2.)** are required.

Environmental Temperature Range:	**0°C – 50 °C or 32°F – 122°F** Avoid extreme temperature changes.
Relative Humidity:	**15% - 95%** NONCONDENSING! Avoid extreme temperature changes! *See User Information UI_A02-09 "Influence of humidity and condensation on SCHWIND products".*

IMPORTANT NOTE

If a change in humidity of more than 5% or a change in temperature of more than ±**2°C** is recognized in a shorter time period we recommend performing an additional fluence test.

5.2.5 Installation Requirements

Input Requirements

For the required performance data of power supply for SCHWIND AMARIS, please refer to the data in chapter 11 Technical Data.

5.3 System Software Requirements

5.3.1 SCHWIND CAM Software

- The AMARIS application software and the SCHWIND CAM software or any of its modules must only be used on computers conforming to the requirements established by the IEC 60601-1 standard.
- Furthermore, the SCHWIND CAM software or any of its modules have to be installed and used only on computers officially approved by SCHWIND eye-tech-solutions.
- SCHWIND eye-tech-solutions does not assume any liability for installing or using the SCHWIND CAM software or any of its modules on computers not officially approved by SCHWIND eye-tech-solutions.

Further system requirements for the SCHWIND CAM are listed in the User Manual of the SCHWIND CAM.

IMPORTANT NOTE

External mass-storage devices (e.g. external drive, card reader & memory card or USB-harddisk) may be supplied only via the USB interface of the PC or be operated with a power-supply pack corresponding to the regulation IEC 60601-1 for medical products.

IMPORTANT NOTE

Data carriers like CD/DVD-ROM and memory cards must be absolutely protected from heat, direct sunlight and electromagnetic interference fields!

5.4 Shipping

5.4.1 Scope of Delivery

Description	Article Number
SCHWIND AMARIS Excimer laser (incl. Panel PC and SW): (AMARIS **or** AMARIS 500E **or** AMARIS 750S **or** AMARIS 1050RS)	**16500** (AMARIS) **or** **16800** (AMARIS 500E) **or** **18500** (AMARIS 750S) **or** **18600** (AMARIS 1050RS)
SCHWIND CAM (software with different modules included for refractive and therapeutic treatment planning)	**15585xx**
SCHWIND Patient Bed – manual traversable version	**17275** (AMARIS/AMARIS 750S) **17260** (AMARIS 1050RS) **17250** (AMARIS 500E)
SCHWIND Patient Bed – upgrade to motorized traversable version	**18807**
SCHWIND Product Documentation CD/DVD-ROM "SCHWIND AMARIS"	**16343xx**
Accompanying Documentation "SCHWIND MEDICAL PRODUCTS"	**202160x-01** (en version) **202160x-02** (de version)

5.4.2 Packing of the Shipping Units

The complete shipping unit consists of the laser, optical system, PC and monitor, the device housing, patient bed (optional), as well as components and consumables (refer to chapter 4.3 System Overview).

The several components of the AMARIS are packed separately and can be shipped by air, by forwarding agency or as direct delivery. The delivery by air or by forwarding agency consists of three wooden boxes with the following dimensions:

Box 1 **Laser** (incl. panel-PCmicroscope):
Dimensions: 1820 x 870 x 1590 mm
Gross weight: 670 kg (750S); 560 kg (500E)

Box 2 **SCHWIND patient bed**:
Dimensions: 2280 x 920 x 1030 mm
Gross weight: 355 kg / 377kg

Box 3 Components according to order:
(UPS (if applicable), transformer)
Dimensions: Max. 1280 x1230 x 1250 mm
Gross weight: 250 kg

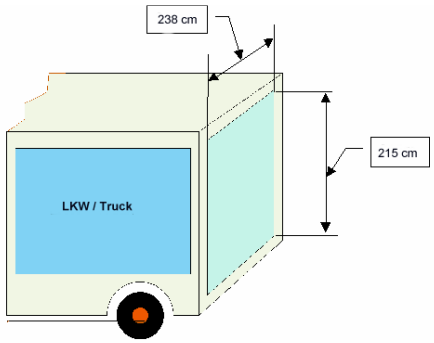


Figure 5-13: Truck dimensions

The direct delivery will be carried out by a small truck.

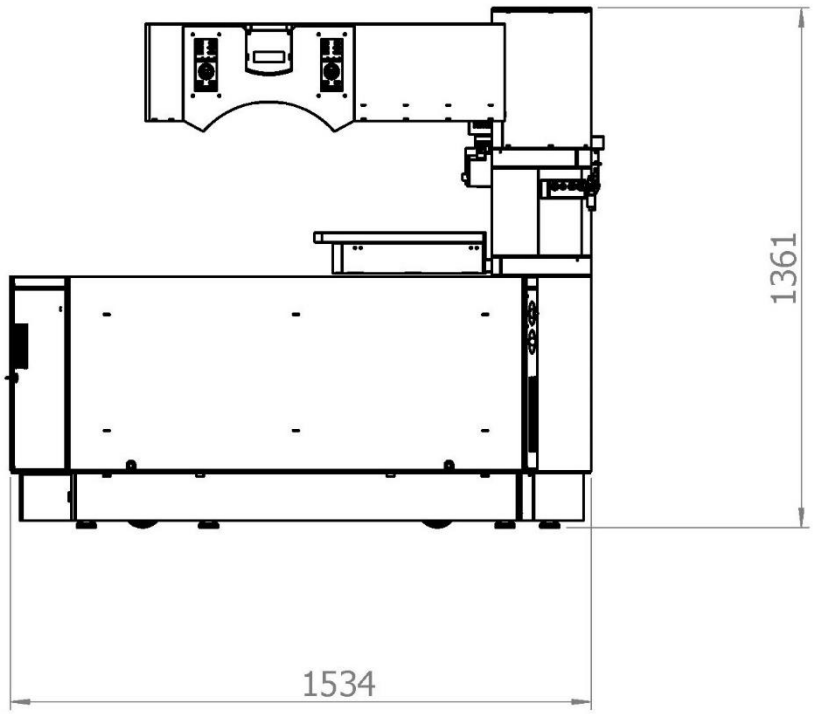
Installation

For the delivery by forwarding agency a truck with a minimum height of 2.15 m and inside dimensions of 2.38 m, with a min. length of 3.50 m is necessary.

5.4.3 Transport Configuration SCHWIND AMARIS / AMARIS 750S / AMARIS 1050RS

The following figures show the side and the top view of AMARIS / AMARIS 750S/ AMARIS 1050RS excimer laser in the transport configuration.

Side view



Top view

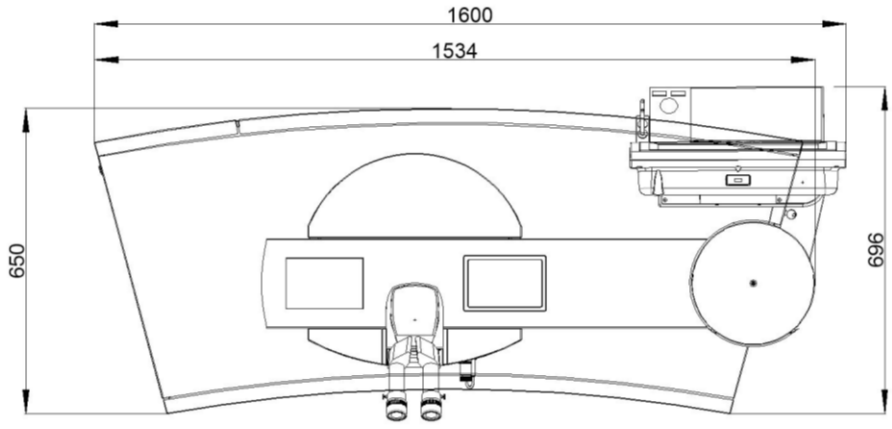


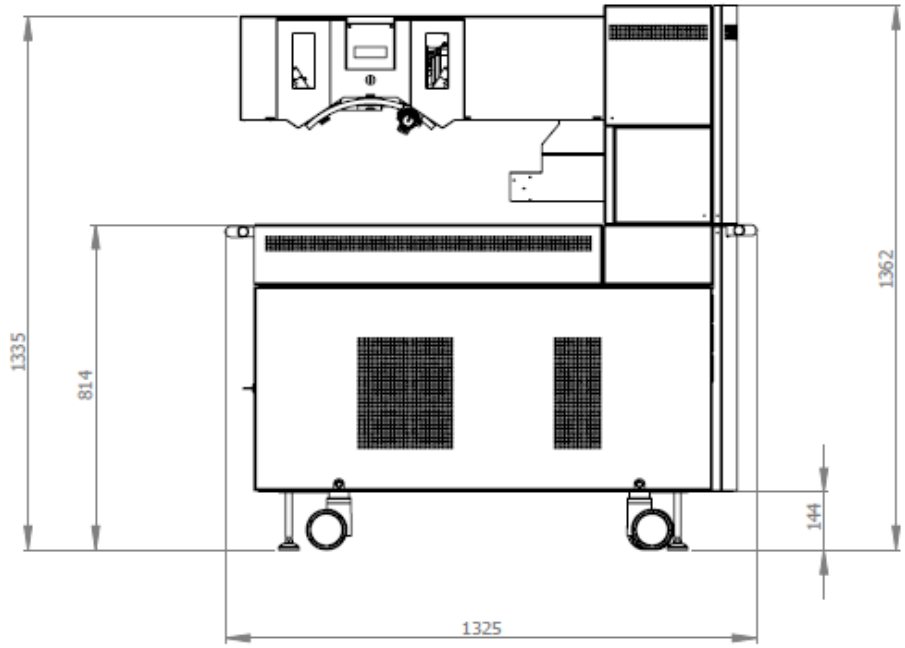
Figure 5-14: Transport configuration of AMARIS / AMARIS 750S / AMARIS 1050RS – top view

Note: The larger dimension only applies if the Panel PC is installed.

5.4.4 Transport Configuration SCHWIND AMARIS 500E

The following figures show the side and the top view of AMARIS 500E excimer laser in the transport configuration.

Side view



Top view

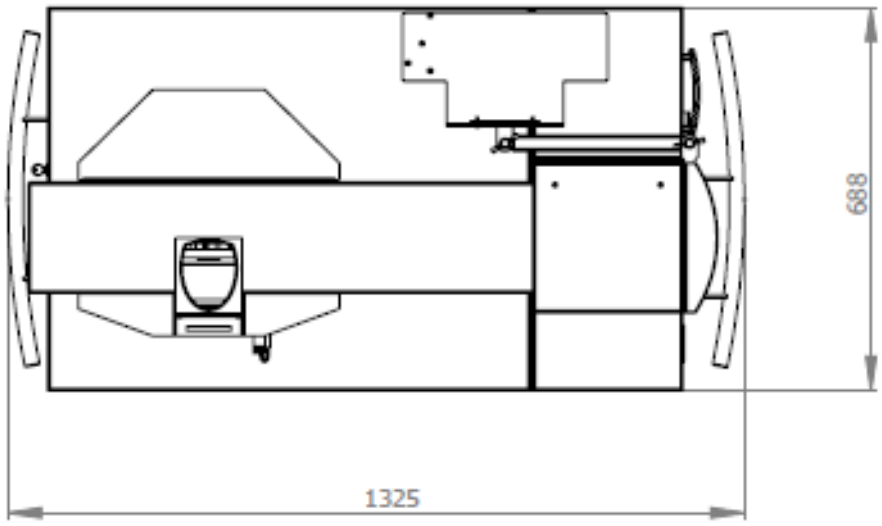


Figure 5-15: Transport configuration of AMARIS 500E

5.4.5 Unpacking and Checking the Delivery

- After delivery of the device units, check immediately for **outside damages** to the boxes and its completeness.
- A service technician of SCHWIND eye-tech-solutions will carry out checking and inspection of the device and its components for damage and completeness according to delivery list.
- If the device or its parts have to be sent back to the manufacturer, please use the original packing material.
- Outside storage of the boxes must be avoided.

IMPORTANT NOTES

The customer is not authorized to unpack the boxes.

Upon delivery of the device, inform SCHWIND eye-tech-solutions in Kleinostheim or your responsible representative in order to organize the installation by our service technicians/engineers.

A service technician of SCHWIND eye-tech-solutions or other trained person has to be present during opening of the boxes.

Store the boxes indoors until installation!

Upon receipt of goods, please note any and all damage, regardless of how minor, and accept delivery only under written conditions!

CAUTION

Damage of device!

Device temperature must be acclimatized for a time period of 4 to 6 hours before opening the vacuum-packaging in order to avoid condensation, which can lead to damage of the device or parts. *(See User Information Note A-02-09 "Influence of humidity and condensation on SCHWIND products").*

5.4.6 Transportation Damages

Transportation damages are the responsibility of the transporting agent.

The packing boxes have been especially designed for best protection of the contents.

The device has been packed properly and in perfect condition at the factory after conclusion of all examinations. If any damages are discovered during or after delivery, please proceed as follows:

1. In case of outer damage, transporting agent has to be informed, to check damage and record it on the delivery note.
2. In any case of damage call SCHWIND eye-tech-solutions or responsible representative immediately to prepare a report with cost estimation for the insurance.
3. If possible, prepare photos of the damaged packing.

Store packing material until all questions with transport agent and insurance company are cleared.

5.5 Initial Installation / Start-Up

Unpacking, initial installation/start-up and instruction in operating the device according to MPG will be performed by a service technician/engineer of SCHWIND eye-tech solutions or authorized Representative.

The service technician inspects the room for necessary installations (dimensions, electrical connection, security regulations and air-condition refer to chapter 5.2, Room and Installation Requirements).

He confirms the correspondence in the inspection protocol and connects the system to the power supply. After a system check and necessary adjustments, he performs operational tests.

CAUTION

Do not perform the initial installation of the software and/or device(s).

The customer is **not allowed** to perform the electrical connection (main supply and interlock) of the device during initial start-up or to perform the initial installation/start-up of the software / device.

Unauthorized starting of installation or use of the device invalidates the warranty.

Trained service personnel of SCHWIND eye-tech-solutions will perform the initial **installation/start-up** of the SCHWIND AMARIS and **connection with a patient bed**, as well as instruction in operating the system.

Please contact the Service Department of SCHWIND eye-tech-solutions to organize the initial installation of the software and/or device(s).

WARNING!

Risk of injury!

While adjusting the SCHWIND AMARIS excimer laser and a patient bed, do not grasp into the motion range of the patient bed. Make sure to keep the wheeling area of the patient bed free of any objects.

Please refer to further installation notes contained in chapter 5.1.

5.6 Relocation of the Excimer Laser System

If you intend to transport the excimer laser to a new location, please inform the service department of SCHWIND eye-tech-solutions or the customer service of your distributor (see Service Hotline).

CAUTION

Damage of device!

The relocation of the excimer laser and the patient bed may only be carried out by service technician of SCHWIND eye-tech-solutions or by SCHWIND authorized personnel.

6 DEVICE CONTROL AND OPERATION

This chapter describes the function of each excimer laser component.

6.1 General Operation Notes

IMPORTANT NOTE

The operation of the SCHWIND AMARIS excimer laser is only allowed by a trained medical personnel.

Before operating the excimer laser, make yourself familiar with the safety regulations (refer to chapter 2 Safety). This serves your personal security and the protection of the product from damage.

IMPORTANT NOTE

Switching ON of the excimer laser and during laser operation, pay attention to any errors and warnings which may be indicated on the computer screen. Should you have any questions, please contact an authorized dealer of SCHWIND eye-tech-solutions or the service department of SCHWIND eye-tech-solutions. (Refer to chapter 13 Manufacturer / Technical Support/ Application Support).

CAUTION

Damage of device!

Do not cover the louvers of the AMARIS system. This could cause overheating of the device during operation.

Before activating any movements of the device make sure, there is no danger of compressive or clamping, neither for patient nor for the user.

WARNING

Danger of explosion!

The excimer laser may not be operated in rooms where danger of explosions exists and is not suitable for use in the presence of flammable mixtures.

Risk of injury!

Use the system only in a room with a compatible electrical supply.

Do not continue the treatment if there is any indication for incorrect processing data or malfunction of the system in order to avoid possible injuries to the patient!

6.2 Control System

The control system is located inside the device. It includes all voltage delivery units, fuses, and the control computer.

You can easily interact with the AMARIS through the **keyboard**, with a **touch pad** and **touch screen monitor** and a re-sterilisable **pen** for the touch screen. Inputs into the computer are menu controlled so that input mistakes can be easily avoided. Release of treatment procedure is accomplished by pressing the foot switch. Secondary functions, such as illumination settings, can be controlled with a key pad beside the microscope. A dot-matrix display gives you additional information about the status of the device.

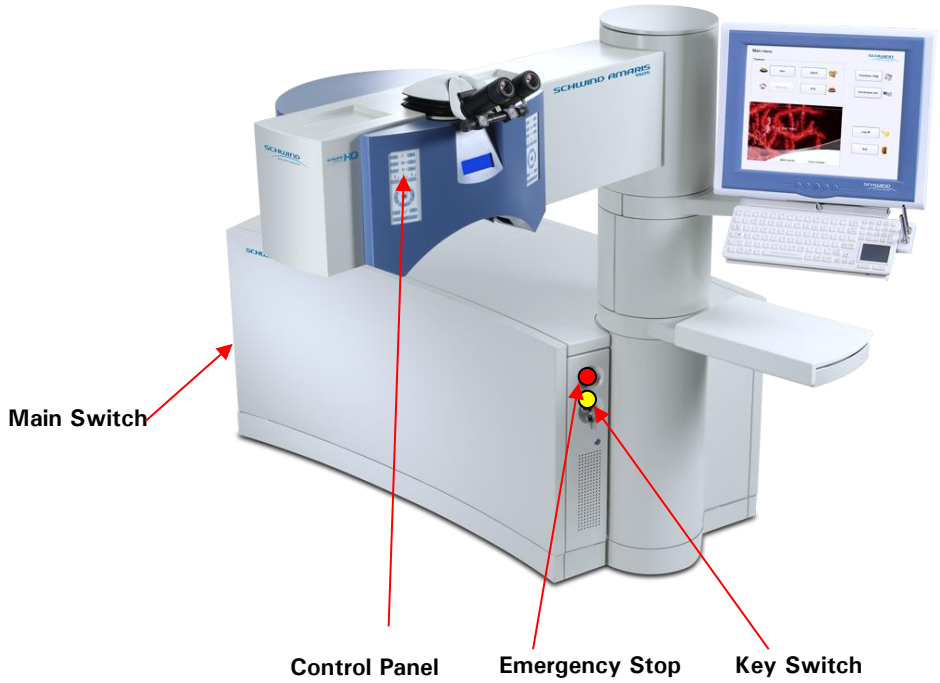


Figure 6-1: AMARIS / AMARIS 750S/ AMARIS 1050RS with key switch and emergency stop

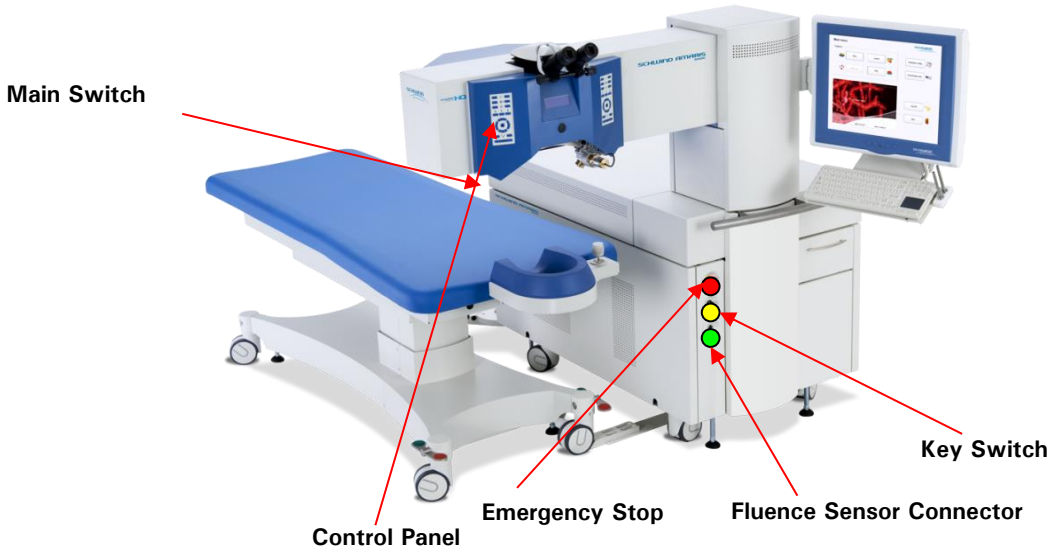


Figure 6-2: AMARIS 500E with key switch and emergency stop

6.2.1 Keyboard with Card Reader, Touch Pad and Re-sterilisable Pen

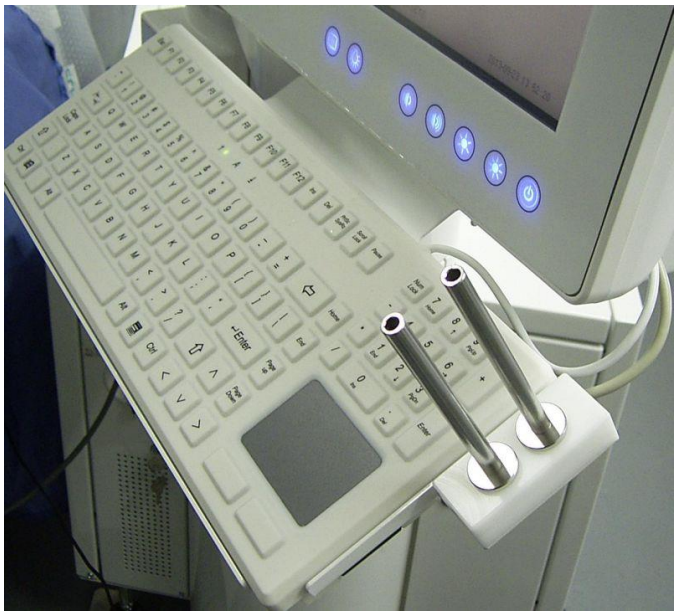


Figure 6-3: Keyboard with touch pad, two re-sterilisable pens and card reader

The re-sterilisable pen can be used to operate the touch screen of the panel PC under sterile conditions. For instructions and parameters of sterilisation please refer to the SCHWIND document “Reprocessing Instructions for resterilisable SCHWIND Products”.

6.2.2 USB Connectors

CAUTION

Damage of device!

Do not remove the cover from the USB port.

Connector shall not be used (for service purposes only).

Figure 6-4: Panel PC ONYX – USB

6.3 Emergency Stop Switch

The emergency stop switch is located left of the laser tower for easy accessibility. If the emergency stop switch is pressed, the laser source and other components will be switched off by the start-up circuit. The control unit and the Panel-PC, however, will remain in power.

To use the emergency switch, simply push the red button.

Release the button by turning it either clockwise or counter clockwise.

After that, switch off the AMARIS with the key switch (**Position Standby**) and switch on the AMARIS with the key switch (**Position Start**).

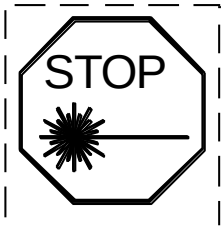


Figure 6-5: Label for laser stop

6.4 Switch ON the Device

6.4.1 Main Switch

The **main switch** is located behind the door of the gas compartment at the backside of the AMARIS base unit.

Open the door to gain access to the main switch.

Be sure that the emergency stop button is not pressed. Otherwise, the system will not start.

Figure 6-6: Main switch

IMPORTANT NOTE

With the main switch switched on, the device is in standby mode, providing power for the start-up circuit.

6.4.2 Key Switch

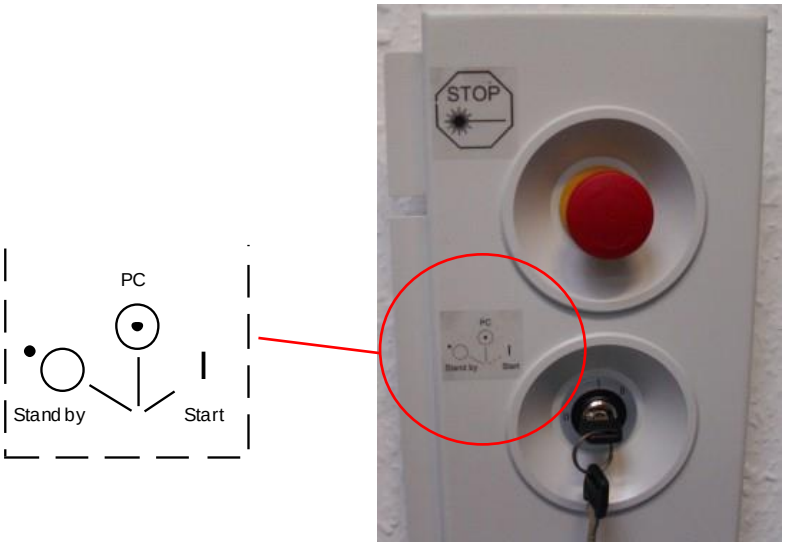


Figure 6-7: Key switch

To start up the device, turn the **key switch** to the "PC" position. The computer and the control system are then switched on. After the boot sequence of the Panel-PC and start of the application software, it is possible to make data entries and to perform treatment planning.

Meanwhile, the control system waits for the key switch "START" position to switch on the components.

Figure 6-8: Key switch positions

IMPORTANT NOTE

With key switch position "PC", it is possible to start the computer system of the device separately.

To start the entire system, turn over the key switch from the "PC" position into the "START" position and let it fall back to the "PC" position. After a few seconds the components of the laser system will be switched on successively.

Based on technical reasons, the unit needs a warm up phase of approx. 5 minutes after starting before the laser can be used. If you try to start a treatment or a Fluence Test within this time, a message will appear: "**Laser still warming up**".

6.4.3 Switch OFF the Device

Close the application software at the Panel-PC and wait until the Windows software is shut down and the screen is black or shows the message **"It's now safe to turn off the computer".**

The system can then be switched **OFF** by turning the key switch to the "STANDBY" position. The device is then in standby mode.

IMPORTANT NOTE

To avoid unauthorized use of the AMARIS laser device, please remove the key from the main key switch when the AMARIS is not in operation.

If the device is intended to be switched off over a longer period, use the **main switch** to shut off the device completely. Otherwise, the standby circuit continues to consume energy.

Switching OFF of an uninterruptible power supply (UPS) is only allowed by a service technician from SCHWIND eye-tech-solutions or an authorized representative.

6.4.4 Disconnection from the Electronic Circuit

Complete separation from the electronic circuit is only possible through:

- Disconnection of the **net connection plug** at the AMARIS device,

Or

- Switching off of the **main switch** at the AMARIS (refer to chapter 6.4.1 Main Switch).

6.5 UPS - Mains Failure or Power Breakdown

Power loss of mains

Power loss of mains is indicated by the repeated sound of a beeper of the UPS. In this case the UPS will automatically resume the power supply of AMARIS for approximately **10 minutes,** for both laser treatment mode and standby mode (no substantial difference in power consumption).

This is enough time to finalize an ablation already in progress. No further ablations shall be started.

The user is requested to stop all activities concerning the AMARIS within 10 minutes and to completely shut down the AMARIS.

IMPORTANT NOTE

In no case should a new laser treatment be started later than 2 minutes after mains power loss.

Please be aware that autonomy of the UPS depends on age and battery condition.

Return of mains power

When mains power returns after failure the user must check the charge condition of the UPS. It is recommended only to start a new laser treatment if charge condition of the UPS is more than 80%.

IMPORTANT NOTE

Charging the UPS batteries takes up to 24 hours.

WARNING!

Risk of incomplete laser treatment!

There is a risk of incomplete laser treatment if charge condition of UPS is less than 80% and mains power fails.

Operation of the UPS

For operation of the UPS refer to the USER Manual for the respective UPS type.

Treatment aborted

In case a treatment was aborted refer to 8.4 Recovery Function.

6.6 Control Panel of the Excimer Laser

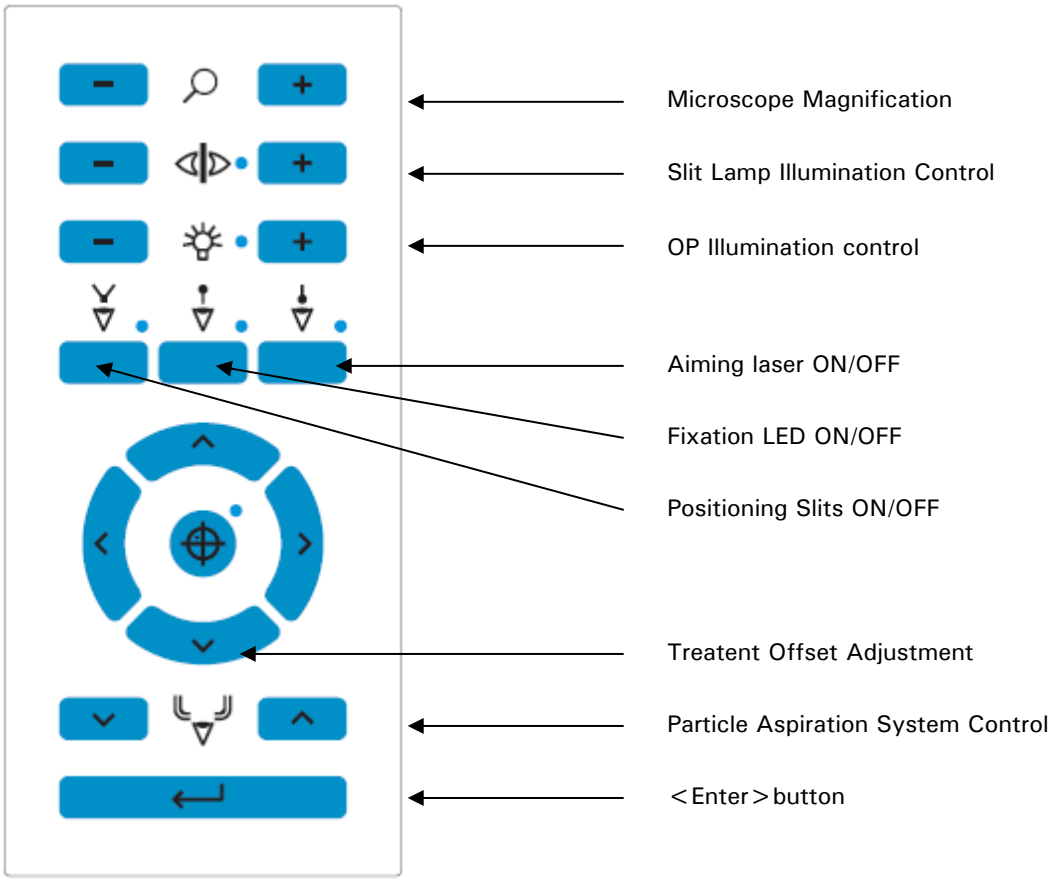


Figure 6-9: Control panel of the excimer laser

Explanation of control elements:

Microscope Magnification: With the buttons <+> and <—> the **magnification** can be changed step by step in both directions.

Slit Lamp Control: The **slit lamp** can be switched ON or OFF by pressing both buttons <+> and <—> at the control panel at the same time and individually adjusted in brightness by using the appropriate button <+> or <—>.

OP Illumination Control: The **OP field illumination** can be switched ON or OFF by pressing both buttons <+> and <—> at the same time and individually adjusted in brightness by using the appropriate button <+> or <—>.

Aiming Laser: A red aiming laser follows all movements of the invisible excimer laser spot. With the button the laser may be switched on or off.

Positioning Slits: On/Off button for the two white light slits used for height adjustment.

Fixation LED:	On/Off switch for the patient fixation target. The patient's eye is offered a blinking target to align on as a “rest position.”
Manual Treatment Offset:	To teach-in a manual treatment offset when the patient is in position under the laser, i.e. to the Purkinje Reflex.
Suction	With the arrow- key the nozzle for particle aspiration or plume evacuation system can be brought into position.
Enter	Various warnings may be confirmed by this key.

WARNING!

Danger of exposure / injury!

The handling and operation of the AMARIS device and control features in any other way as described in this User Manual may cause dangerous exposure!

6.7 Matrix Display

Between the two control panels on left and right side of the laser arm a matrix display shows relevant information regarding:

- Actual date, actual time
- Microscope magnification
- Surgery illumination level (displayed for 3 seconds if illumination is changed) when the laser is in planning/ standby mode.

And information regarding:

- Patients last name, treated eye
- Eye position, microscope magnification
- Treatment progress
- Surgery illumination level (displayed for 3 seconds if illumination is changed) when the laser is in treatment mode.

The value for the eye position (EyePos) gives information about how good the eye is centred. It can reach value between 0 and 100 where 0 means that the position of the eye is out of hot zone and 100 means that the eye is perfectly centred und the laser.

6.8 Operating of the Microscope

The magnification of the microscope can be changed by pressing the accordant button on the AMARIS control panel (refer to Figure 6-9: Control panel of the excimer laser).

Another possibility is to define a pre-selected magnification for each surgical step in the Treatment Assistant Manager (refer to chapter 7.5 Treatment Assistant Manager).

By default, the binocular tube is equipped with 16x eyepieces. Optionally, 10x eyepieces are also available.

General Adjustment

- With the starting rings (6), which can be pulled out or pushed in and fixed by turning clockwise the correct distance for the user can be adjusted.
- Setting of pupillary distance (PD): Via spindle (4) the PD can be set from 55 to 75 mm. While setting the PD, the reticule remains aligned.
- Adjustment of eyepieces (2) (for ametrope persons not using their spectacles): Turn the oculars (3) to the required diopter value.
- Adjustment of eyepieces (2) (for normal sighted persons and ametrope persons wear their spectacles): Turn the oculars (3) to zero.

Focusing

- Set the magnification changer (5) to the smallest magnification.
- Focus the object by matching the height of the operating table.
- Set the magnification changer (5) to the largest magnification. Refocus
- Set the required magnification.

  5 step changer
  4.5x; 7.1x; 11.4x; 17.8x; 28.4x with 16x

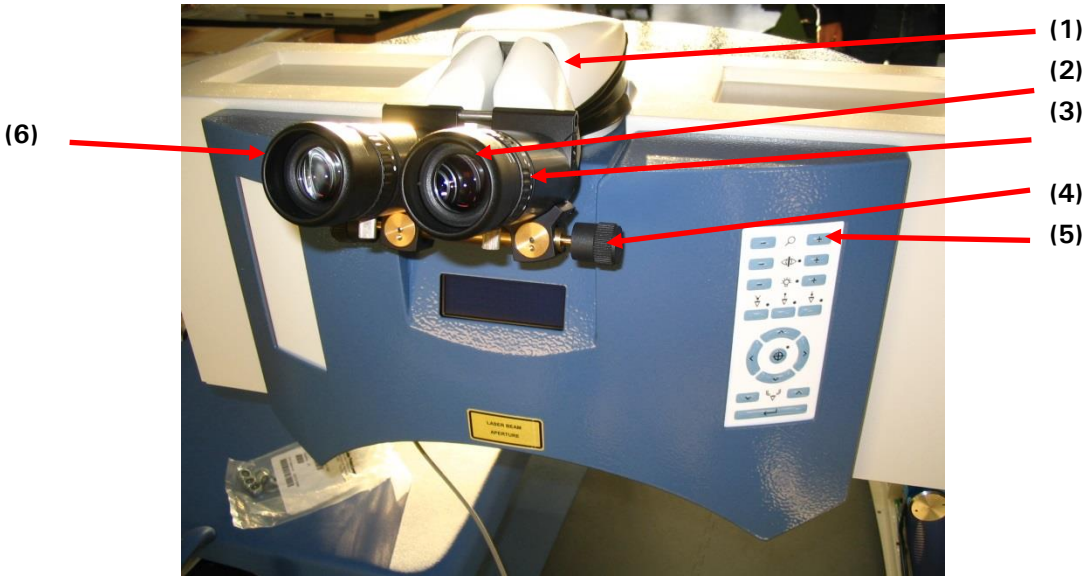


Figure 6-10: Components of the operation microscope (example AMARIS 750S)

6.9 Microscope Crosshair

Depending of the adjusted magnification the circles displayed in the microscope crosshair have the following dimensions:

The dimensions of the circles may differ approx. 10%, depending on the exact magnification.

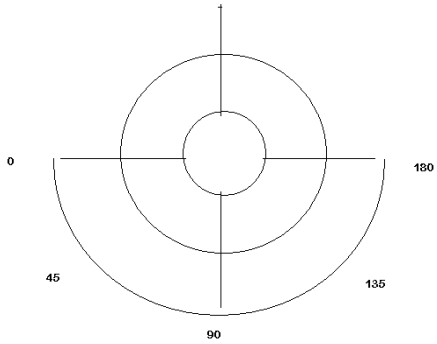


Figure 6-11: Microscope crosshair

Magnification Step	Inner Circle	Outer Circle
0.6	6 mm	14 mm
1.0	4 mm	9 mm
1.6	3 mm	7 mm
2.5	2 mm	4 mm
4.0	1 mm	2 mm

6.10 Positioning Slits

To adjust the correct height of the patient's eye during the treatment, the positioning slit lights are used. The lights consist of a slit and a cross which are generated by LED´s. If the slit lights are switched on they form two bow shaped patterns on the cornea (refer to Figure 6-12: Height adjustment of the excimer laser).

To bring the patients eye in the correct height for the treatment adjust the height of the patient bed by turning the joystick. The two bow pattern on the cornea will converge and finally match in a central point. Tilting of the patient head can be recognized when the area above the central point and the area below the central point have a different size.

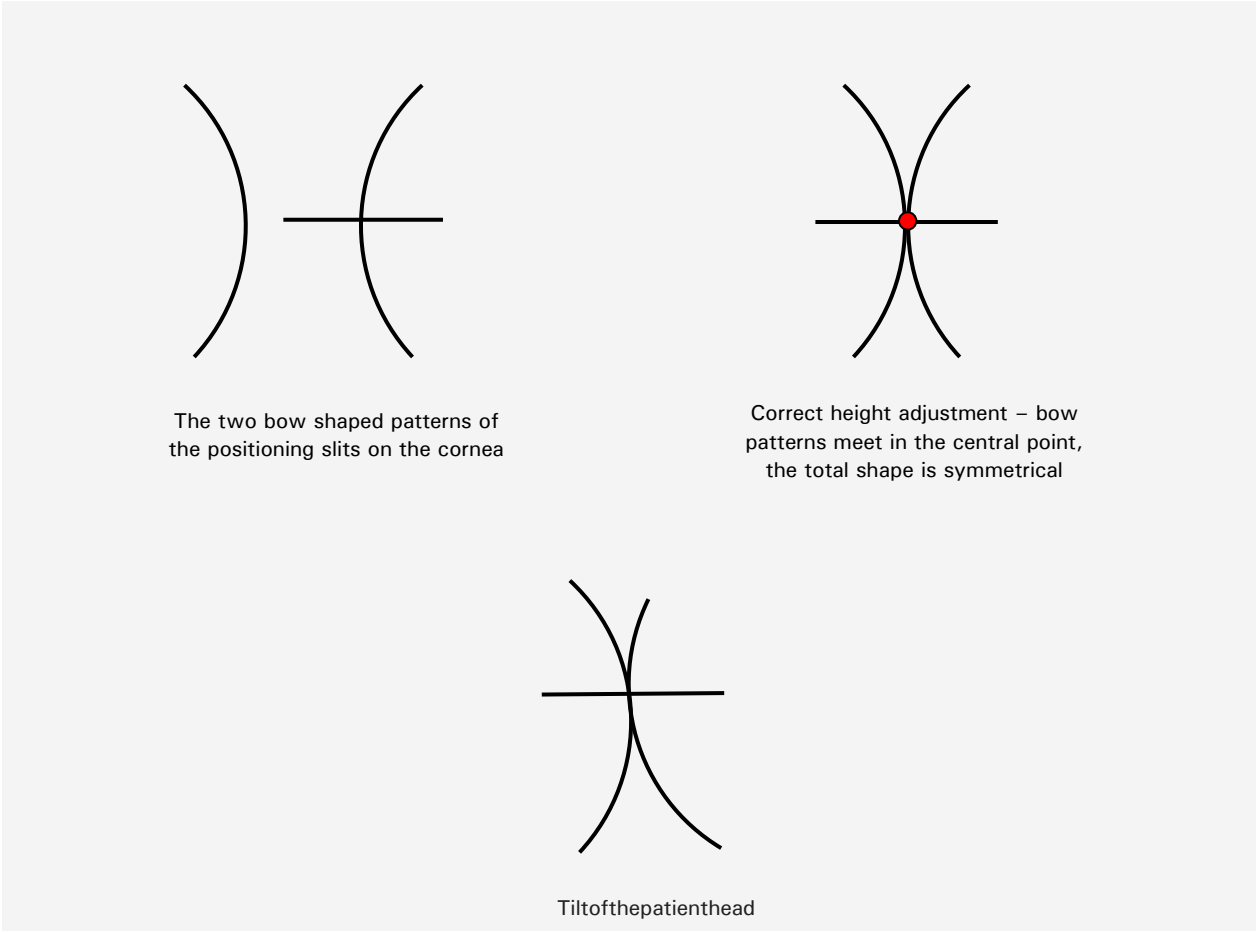


Figure 6-12: Height adjustment of the excimer laser

6.11 Software Managed Operation of the Excimer Laser

To select the desired function in a menu, use the keyboard arrow keys ↑ and ↓, the TAB button or the mouse pointer to the desired menu. The active button will be displayed with a grey highlighted border. Then simply press <**ENTER**> or click with the left trackball button.

6.11.1 User Login

After starting the system, the **Login** menu appears (see Figure 6-13: User Login menu). Enter your user name and your personal password.

6.11.2 Password Input

This password is managed by the administrator (for example, the medical director) and stored in **Password Administration**.

The first issue of the password will be accomplished by specialists / technicians of SCHWIND eye-tech-solutions or the local representative during the handover of the SCHWIND AMARIS. The following figure shows the user **Login** menu:

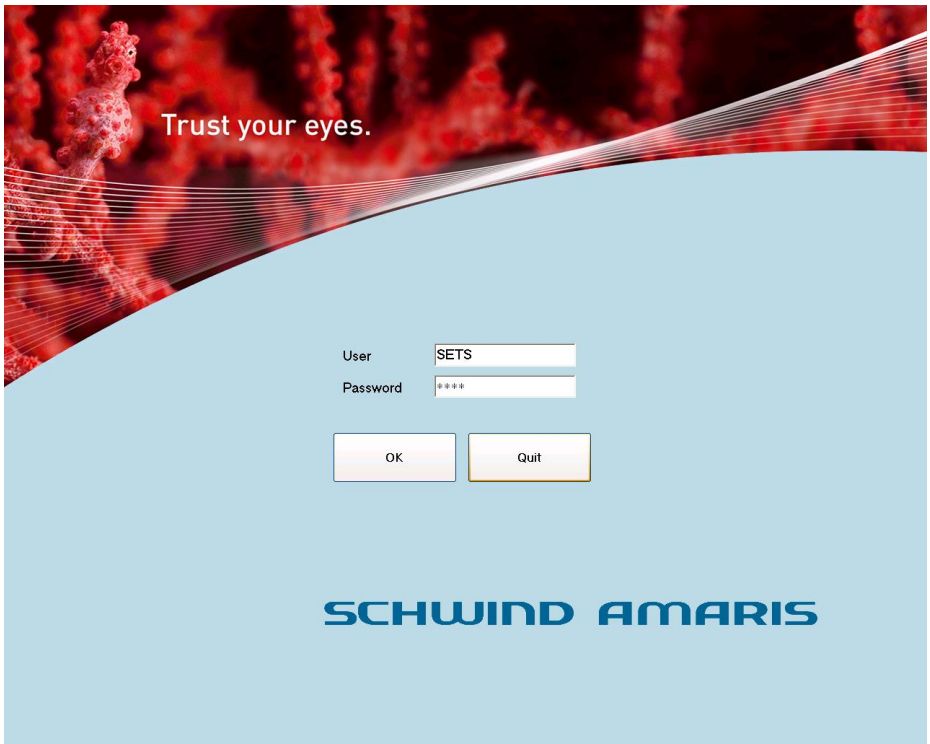


Figure 6-13: User Login menu

6.11.3 Main Menu

After switching on the system, it performs a self-check and runs through a warm up phase, which can take a few minutes.

After login, the **Main menu** appears, see Figure 6-14: Main menu

By choosing one of the buttons from the group **<Treatment> (<New> or <Import>)** you will be able to plan new treatments or to load completely planned treatment files for the laser surgery.

The button **<Recovery>** will only be active if a previous treatment was aborted. By pressing this button a list of aborted treatments will be shown. The treatment which is desired be continued can be selected from the list.

By choosing the button **<Functions>** you can select the appropriate sub-menus to configure and set-up the laser.

The button **<Swivel laser arm>** will allow you to automatically move the upper arm from the treatment position to the standby position (refer to chapter 6.11.4 Movement of the Swivel Laser Arm).

This button is only active in an AMARIS / AMARIS 750S/ AMARIS 1050RS models.

The button **<Log off>** will allow you to change the user.

The button **<Exit>** will allow you to exit the user software and shut down the system.

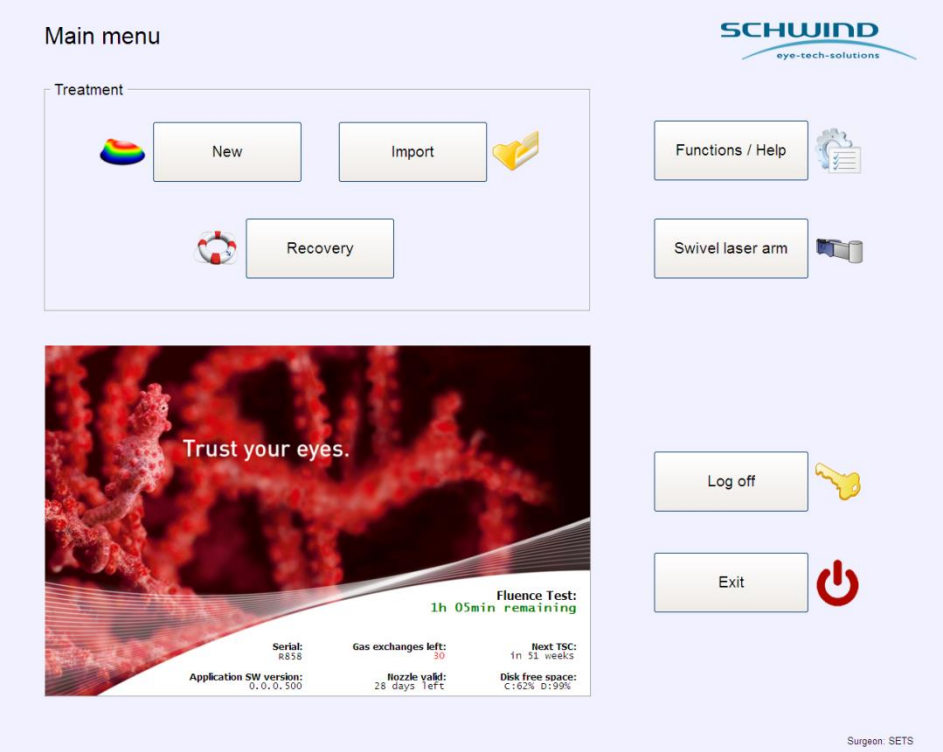


Figure 6-14: Main menu

To select the desired function, use the keyboard arrow keys ↑ and ↓, the **<TAB>** or the mouse pointer to the desired menu. The active button will be displayed with a black border.

Then simply press **<ENTER>**or click with the left trackball button, or directly press the desired button on the screen.

At the lower part of the main menu additional information, such as validity of the fluence test, number of remaining gas exchanges with the actual gas bottle pressure and other system-relevant information is displayed.

IMPORTANT NOTES

For your own certainty all entries should be checked that they have been correctly taken over by the system.

An open menu or a started function can be left by selecting the menu option <**Main menu**> (= Button) and pressing <**ENTER**> or directly on the touch screen

Before each treatment the system performs another short self-check.

6.11.4 Movement of the Swivel Laser Arm – AMARIS / AMARIS 750S / AMARIS 1050RS

The movement of the swivel laser arm is software managed in case of an AMARIS / AMARIS 750S / AMARIS 1050RS model. The SCHWIND AMARIS 500E has a fixed laser arm. Only for transportation purposes the laser arm can be swivelled manually by a service technician.

To move the laser arm in AMARIS / AMARIS 750S / AMARIS 1050RS, the button <**Swivel laser arm**> in the **Main menu** (refer to Figure 6-14) has to be pressed on the touch screen. The following window appears:

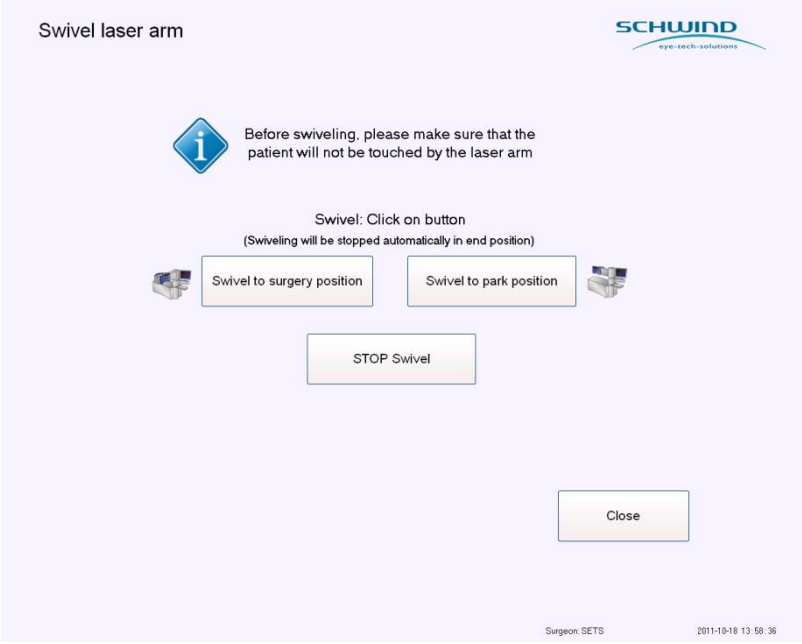


Figure 6-15: Swivel laser arm window

The swivel arm has two end positions: **surgery position** (OP position) and **park position.**

Device Control and Operation

To move the swivel laser arm to the desired position, the appropriate button on the touch screen has to be pressed. The laser arm will then automatically move into the desired position. To stop the movement the button <**STOP Swivel**> has to be pressed.

The treatment and fluence test can be performed only if the laser arm is stationed in the **OP position.**

WARNING!

Risk of injury! Damage of device!

In case of emergency (person or object in the traverse path of the laser arm) proceed as follows:

- Quickly press the <**STOP Swivel**> button , or
- Push against the laser arm with your hand, the arm will stop, or
- Immediately push the <**EMERGENCY STOP**> button.

6.11.5 Troubleshooting

If after the self-test of the system an error message appears:

➔ **Shut down the system, switch off and switch on again, start the program again.**

If the error arises again:

➔ **Inform the service department of SCHWIND eye-tech-solutions or your local representative and describe the error message.**

7 SERVICE PROCEDURES AND FUNCTIONS

7.1 Functions Menu

Determined service procedures are essential for operation of the excimer laser. They can be chosen in the **Functions menu** and they contain the following individual functions:

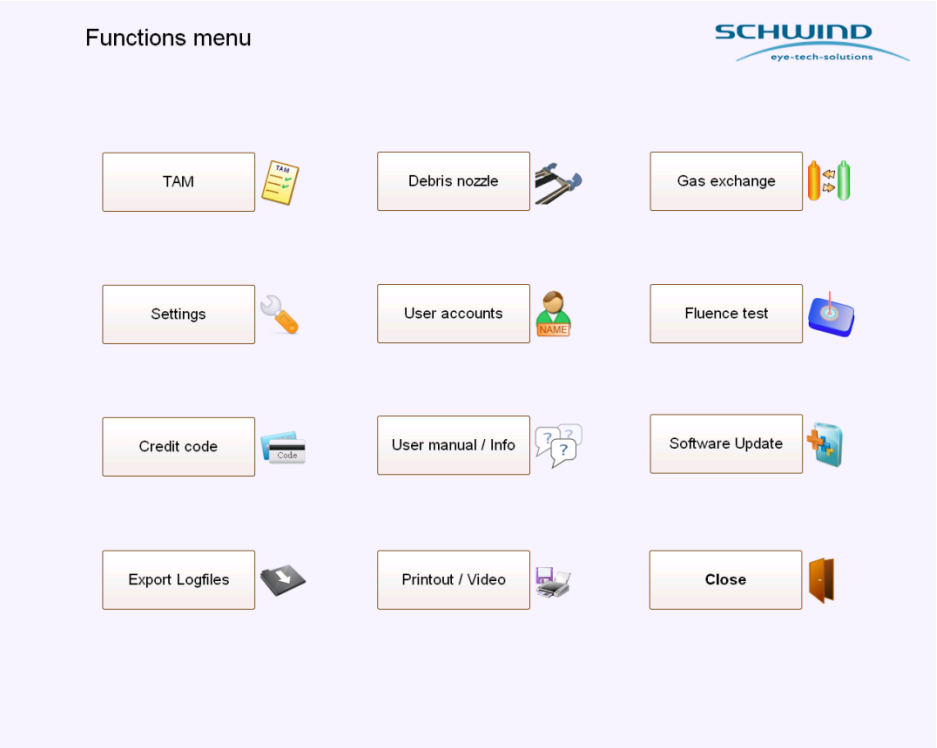


Figure 7-1: Functions menu

- **TAM (Treatment Assistant Manager)**
  To create a treatment workflow model (refer to chapter 7.5 Treatment Assistant Manager).
- **Settings**
  To adjust general settings of the software.
- **User accounts**
  To create and register a new user or to activate new treatments for an existing user (refer to chapter 7.2 Registration / User Accounts).
- **Credit Code**
  To load up new credit files to the system or to see the credit code overview (refer to chapter 7.4 Credit System).

- **Fluence test**
  To calibrate the system.
- **Gas exchange**
  To change the gas fills in the excimer laser tube.
- **Export Log files**
  To export the log and treatment files or to export treatment data to the Datagraph software.
- **Debris Nozzle**
  To enter the serial number of the new particle aspiration nozzle, if the filter was changed.
- **User Manual/ Info**
  To see the User Manual or the Surgical Advice Manual as well as general software information.
- **Printout / Video**
  To export or print, display or export Treatment PDF or treatment videos at any time.
- **Software Update**
  To perform system software updates by loading update files provided by Schwind eye-tech-solutions.

IMPORTANT NOTE

Usually at the beginning of an operation day only the functions Fluence test and eventually gas exchange is necessary.

7.2 Registration / User Accounts

Admin Users (login: admin/admin) have rights to create new users or delete existing users, as well as to influence the default settings and default TAM lists.

Click on the button **<User accounts>** in the **Functions** menu and select among the following points:

- Create new user
- Delete existing user
- Change default Settings
- Change Default TAM
- Close

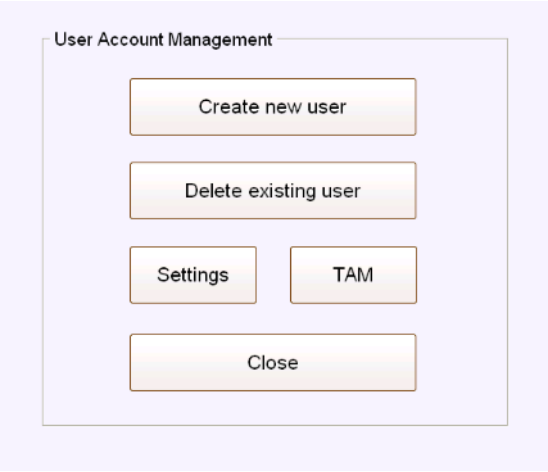


Figure 7-2: User Account Management (Admin User)

During the creation of new users, settings from existing users can be copied using the settings drop down menu.

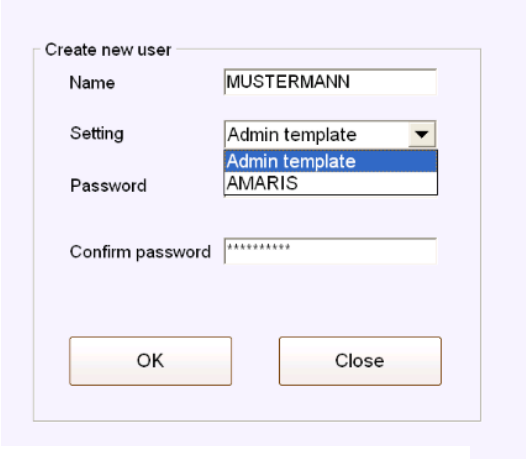


Figure 7-3: Creation of new users

Standard Users have the right to change their own password only.

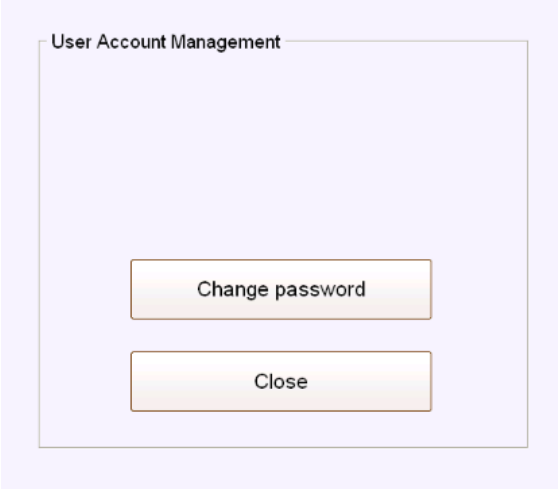


Figure 7-4: User Account Management (standard user)

7.3 Settings Menu

In the **Settings** menu several adjustments concerning different modules of the AMARIS Application software can be made.

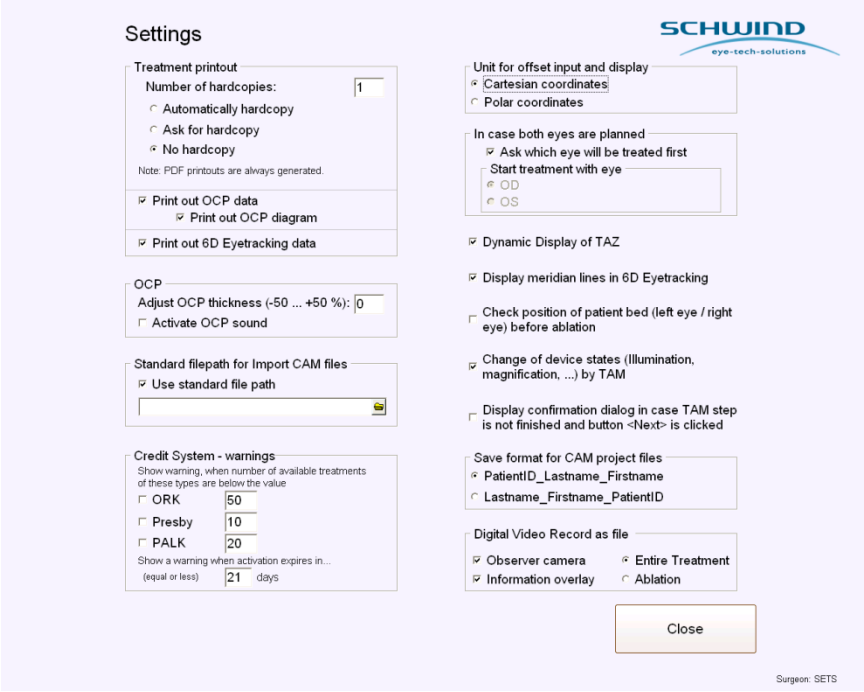


Figure 7-5: Settings menu of the AMARIS Application Software

- Section **Treatment Printout**
  - In this section the user can define if the system shall print a hardcopy (paper form) for the treatment printout automatically, if the system should ask for a hardcopy printout or if there should be no hardcopy printout.
  - In addition the user can decide if the OCP data and the data from 6D-Tracking (Rolling, Z-Axis movements, etc.) shall be printed or not.

IMPORTANT NOTE

After each treatment the treatment printout will be saved as a PDF file. These files can be printed out or exported at any time.

- Section **Unit for Offset input and Display**
  - In this section the user can define whether the treatment offset format, which is displayed in the treatment menu, is polar or cartesian.

- Section **OCP**
  - Under Adjust OCP thickness the displayed value of the corneal thickness in the treatment screen can be decreased or increase in steps of 1% to adjust the value e.g. to the measurement values of an ultrasound pachymeter (maximum and minimum range +50 until-50%).
  - It can be defined if the measured OCP data should be included in the printout and if a diagram of the measured values should be attached.
- Section **Standard file path for Import CAM files**
  - In this section the user can define a standard file path from where imported CAM files shall be loaded.
- Section **Credit System -warnings**
  - Please refer to chapter 7.4 Credit System.
- Section **In case both eyes are planned**
  - In case both eyes are planned the user can select in this section if the system should ask which eye should be treated first or define the eye (OD, OS) with which the treatment will be started always.
- Section **Dynamic Display of TAZ**
  - The dynamic display of the total ablation zone (TAZ) in the eye tracking live image can be activated/deactivated with this option.
- Section **Display meridian lines in 6D-Eyetracking**
  - By activating this field the user can decide if the meridian lines of the 6D-Eytracking which visualize the rolling movement shall be displayed in the Eye tracking live video or not.
- Section **Check position of patient bed (left eye / right eye) before ablation**
  - By activating this field the user can decide if the patient bed position control which checks for the position of the patient bed for treating the corresponding eye is activated or not.
- Section **Change of device states**
  - If this field is activated the system automatically adjusts illumination and magnification settings defined for each treatment step in the Treatment Assistant Manager (TAM). Please refer also to chapter 7.5 Treatment Assistant Manager.
- Section **Display Confirmation Dialog in case TAM step is not finished**
  - If this box is activated, a confirmation dialog is displayed in case the user wants to skip a step of the TAM in the treatment menu.
- Section **Save format for CAM project files**
  - In this section the user can decide if the save format for CAM project files shall be PatientID_Lastname_Firstname or Lastname_Firstname_PatientID
- Section **Digital Video Record as file**

  Digital Video Recording captures video data from the observer camera and writes it to the HDD of the Panel PC. If Video Record is not available (or not possible due to hardware limitations), the options are not displayed.

- User can decide to enable or disable video recording.
- An Information overlay on the recorded video can be set visible which includes patient data (lastname, first name, treated eye, etc. shall be overlayed to the video.
- Video capturing time period can be chosen: entire treatment (start when entering treatment menu) or ablation only.

7.4 Credit System

The available treatment types possible to perform with the AMARIS excimer laser ORK (Optimized Refractive Keratectomy), PTK-KPL (PTK-Keratoplasty), Presby (Presbyopic Treatments) as well as the number of treatment credits for each treatment type, the time period in which the treatments credits are valid and the activation for certain AMARIS options (e.g latency free tracking) are controlled by a credit system integrated in the AMARIS Application software.

For each treatment performed an internal counter will be decreased by one credit. An overview of available credits can be displayed when entering the menu **Functions/Help** and pressing the button **<Credit Code>**.

Normal PTK-treatments (without KPL option) and PMMA-tests are only limited by the time period but free of any credit charge.

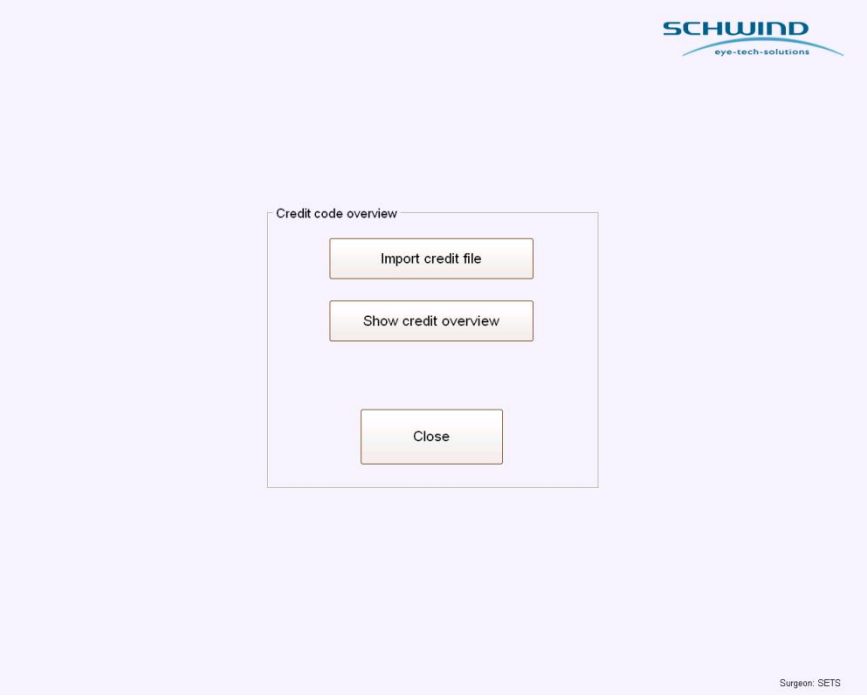


Figure 7-6: Credit code overview

In this menu the user has the possibility to:

- Import a new credit file
- Show the credit overview
- Close the menu

New treatment credits can be imported to the AMARIS Application software by importing a new credit file generated by SCHWIND eye-tech-solutions.

If it should be necessary to import new credits for treatments with the excimer laser system the user has to contact SCHWIND eye-tech-solutions and order new credits via email using the email address codesystem@eye-tech.net.

Important information which is necessary to generate the credit file and which should be included in the mail is:

- Serial number of the AMARIS excimer laser for which the credits should be generated.
- Location where the laser is situated.
- Number of treatment credits which should be generated for each treatment type (ORK, PTK-KPL, Presby) as well as the time period in which the credits should be valid.
- The email address to which the generated credit file should be sent to.

With this information SCHWIND eye-tech-solutions will generate a credit file and sends it to the user. The generated credit files have the following file name:

Laser serial number_ creation date_ creation time.crd

To import a new credit file the user has to copy the received credit file to e.g the SD-Card used for treatment file transfer at the AMARIS excimer laser. This card should be inserted in the memory card drive at the laser.

After that the user starts the AMARIS Application software goes to **Functions/Help→Credit Code** and press the button **<Import Credit file>**.

A windows file open dialog will be displayed and it is possible to select the credit file.

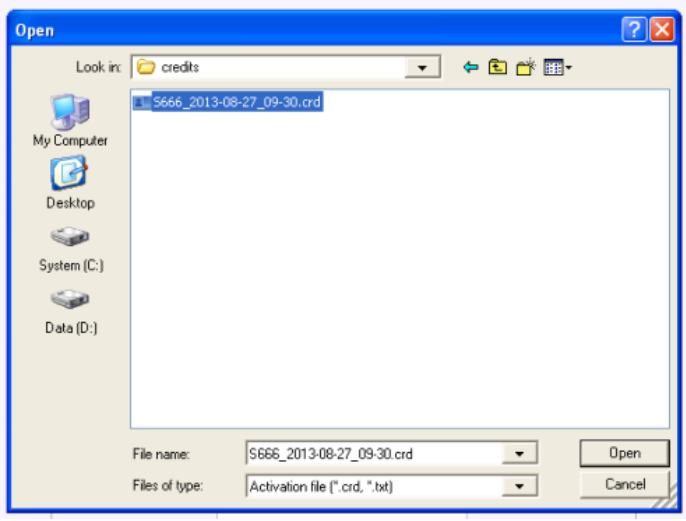


Figure 7-7: Import of a new credit file

After that or by pressing the button **<Show Credit Code Overview>** an overview about the available credits will be displayed.

IMPORTANT NOTE

The new imported credits will be added to the existing credits if the counter value was not zero.

After possible software update at the laser existing credits will not be deleted.

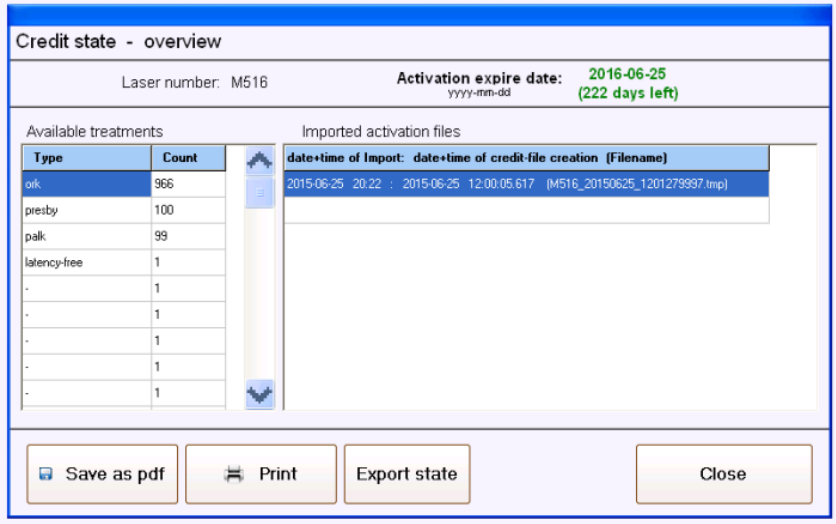


Figure 7-8: Credit code overview

On the left side of the Credit Code overview menu the available treatment types and the number of available credits for each type are displayed.

If there should be any limitation of the available credits in terms of time this can be seen at the top of the window under the point '**Activation expire date'**.

There is also the possibility to print the overview, safe as pdf file or export the current state of credits.

The user can define a number of residual treatments for each treatment type and also a number of residual days after which the credits have expired in the settings of the AMARIS Application software on the bottom left side.

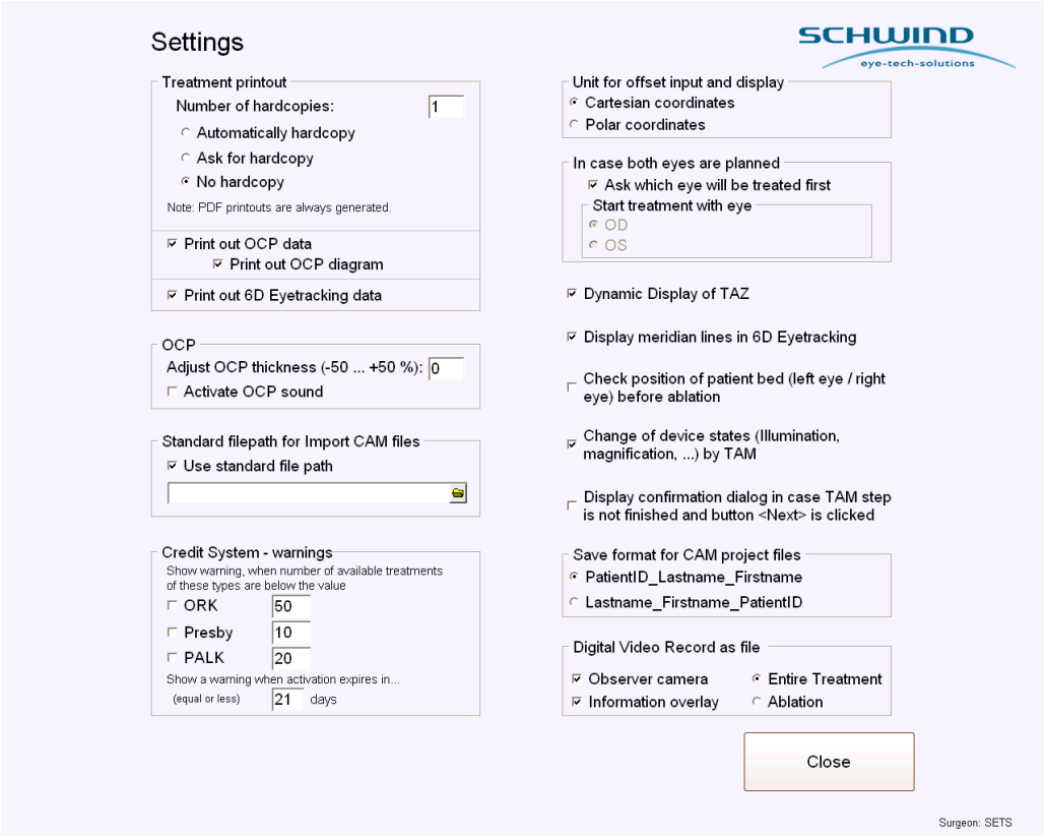


Figure 7-9: Credit system settings in the Settings Menu

It is possible to define for which treatment type a warning message should be displayed, the number of residual credits from which a message should be displayed and the number of residual days from which a warning message should be displayed.

If the actual count of treatment credits or the actual count of residual activation days is below the adjusted values for a warning message. A message which informs the user will be displayed.

IMPORTANT NOTE

The warning messages will be displayed at the login of the AMARIS Application software.

If it is a warning due to residual number of credits an additional warning message will be displayed before each treatment.

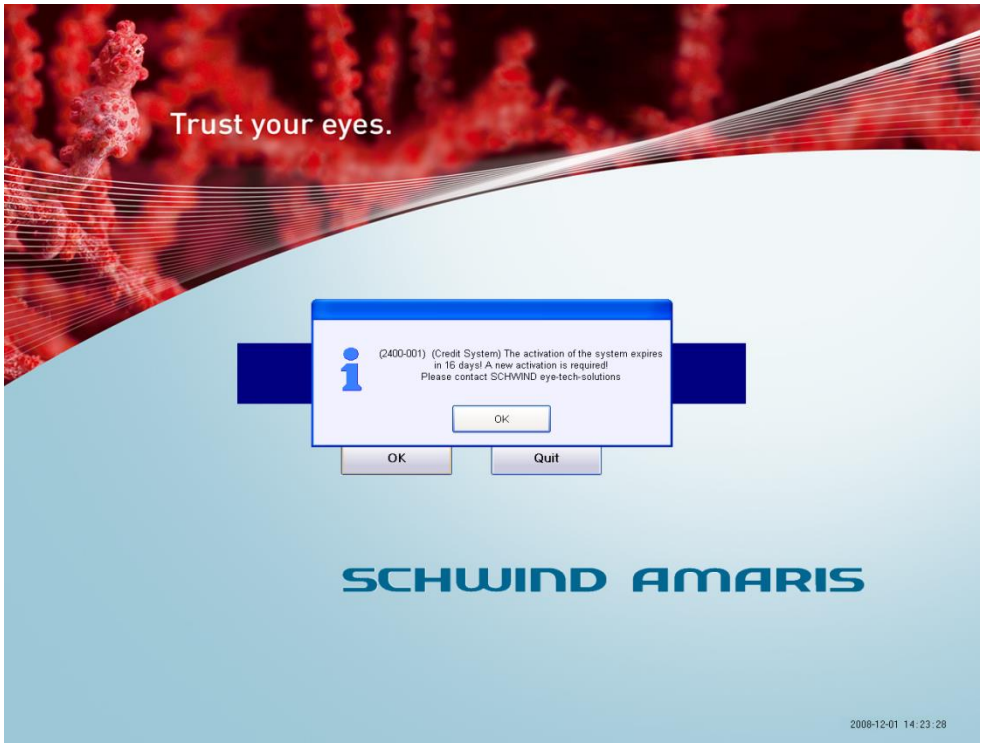


Figure 7-10: Message because of decreasing time of credit activation

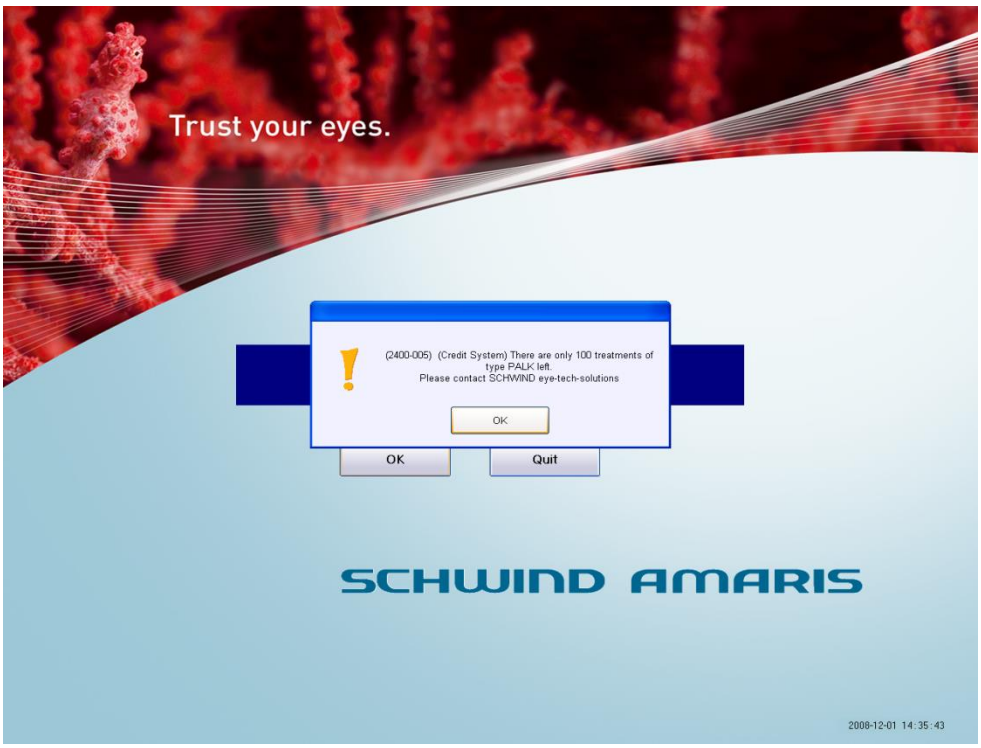


Figure 7-11: Message because of decreasing number of available credits

7.5 Treatment Assistant Manager

The **Treatment Assistant Manager** (TAM) is a helpful tool to standardize the surgical procedures. It offers the possibility to pre-set several standard conditions for the treatment modes like timer settings, illumination, microscope magnification, etc.

Certain default steps like Treatment, SCC and the pachymeter steps cannot be deleted by the user. As a pre-setting, the Treatment Assistant Manager contains a predefined list of surgical steps for the LASIK, PRK, LASEK, FEMTO-LASIK and PTK treatment modes.

IMPORTANT NOTE

For TransPRK treatment the PRK TAM list will be used but the Step Epithelium removal will be skipped automatically as it is a part of the ablation volume and has not to be removed manually.

IMPORTANT NOTE

The treatments steps, which are defined in this menu, are also shown in the treatment menu of the AMARIS software and will guide the surgeon through the procedure.

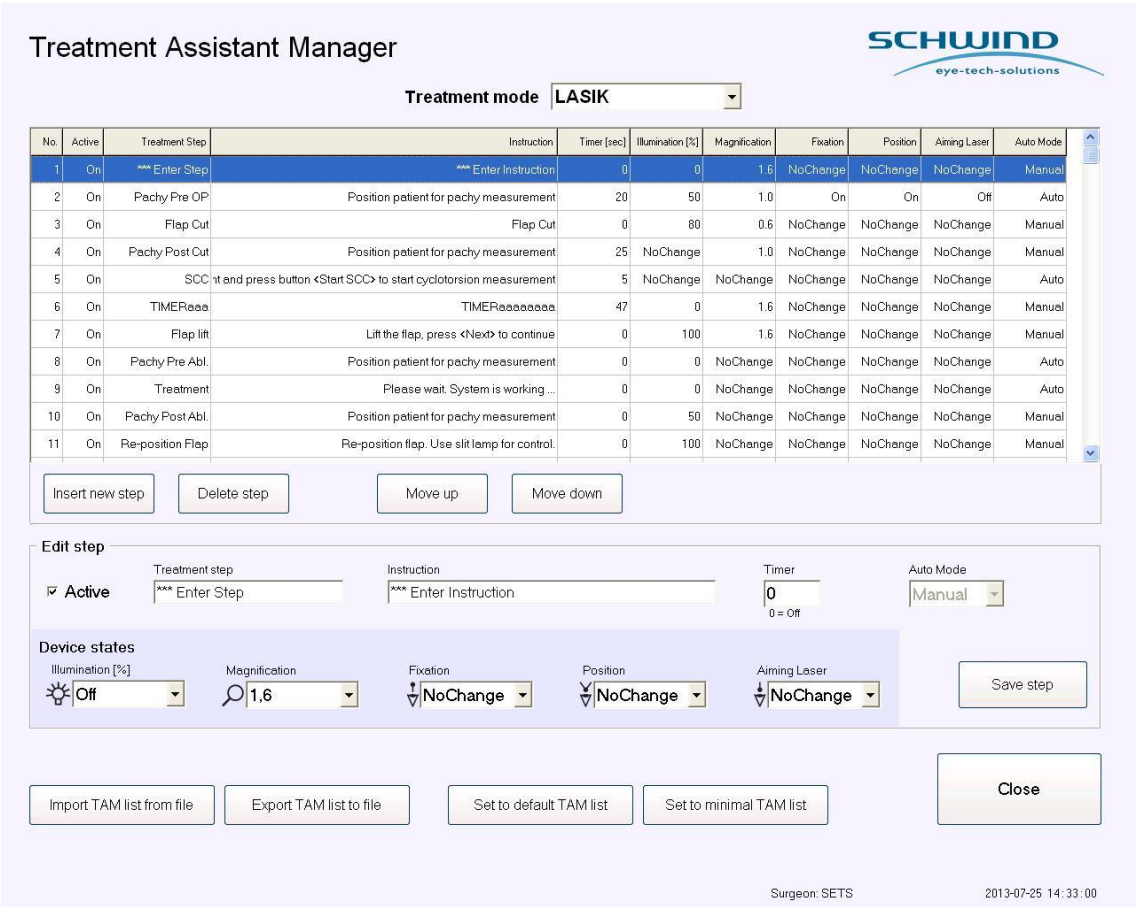


Figure 7-12: Treatment Assistant Manager

7.5.1 Editing the List of Surgical Steps

To edit the surgical steps for the treatment, select the Treatment Assistant Manager <**TAM**> in the **Functions** menu (please refer to 7.1 Functions Menu).

Next, please select the treatment mode for the changes to be applied from the pull-down menu on the top of the menu page. In the list below, the current steps of the procedure with the settings for timer, illumination, microscope magnification, fixation light, positioning laser and aiming are shown.

To change these settings, click on the particular step in the list with the mouse pointer or directly select it by pressing on the screen of the touch display and change the settings for this step with the **Edit step** dialog below the list of treatment steps (refer to Figure 7-13: Edit step dialog). If a step was change the button <**Save Step**> will be surrounded in yellow as a reminder that this step still has to be saved.

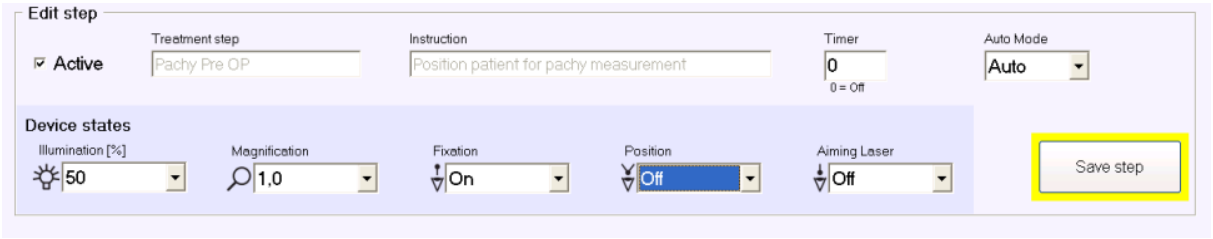


Figure 7-13: Edit step dialog

With the <**Active**>box the user is able to select whether this step will appear during the treatment or not.

To change the name of the surgical step, please enter the desired name in the box <**Treatment Step**>. Instructions, which will be shown during the procedure on the treatment screen, can be predefined for each individual step in the **Instructions** field.

To insert a new surgical step, please select the step in the list before which the new step should be inserted and press <**Insert new step**>. The software will insert a new and empty surgical step.

To delete surgical steps, please select the particular step to be deleted and then click on the <**Delete step**>button.

To move steps up or down, select the particular step and click on the buttons <**Move up**> or <**Move down**> and change the position in the list.

After the changes in each surgical step are finished, press on the <**Save Step**>button to save and apply the changes for the step.

The different lists of surgical steps can be exported and imported by clicking on the buttons <**Export TAM list to file**> and <**Import TAM list from file**> or set to default by clicking on the button <**Set to default TAM list**>.

Pressing the button <**Set to minimal TAM list**>will create a list of surgical steps only consisting of SCC and Treatment.

7.6 Software Update

In case a software update is necessary, this can be performed by the user by pressing the button <**Software Update**> in the function menu.

An update file which is provided by SCHWIND eye-tech-solutions can be loaded by pressing the button < **Select update file and start…** > and the software update process will start automatically.

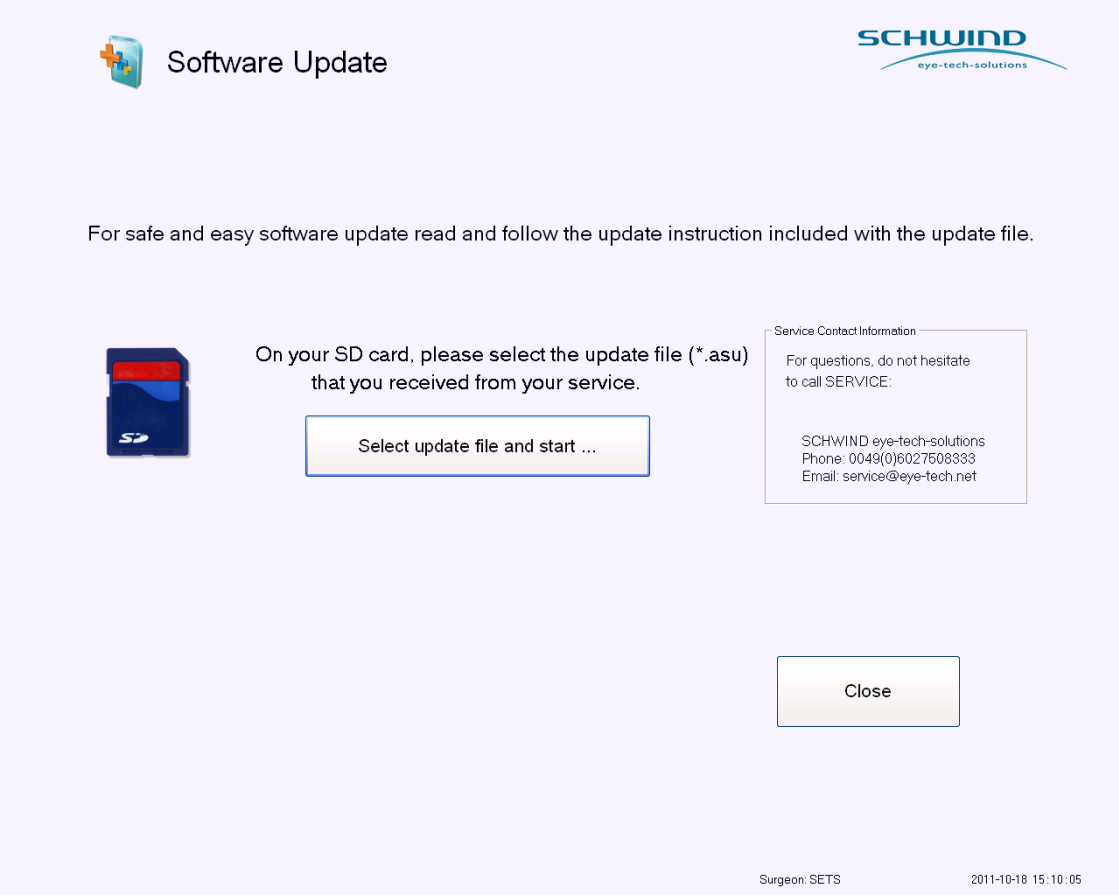


Figure 7-14: Software update

7.7 Fluence Measurement

7.7.1 General

The fluence measurement is used for calibration of the system. Firing the laser onto a special foil carries this out. The system determines the number of pulses required to completely perforate the foil.

The ablation rate is calculated according to predetermined parameters.

The fluence test is the same for all models: AMARIS, AMARIS 1050RS, AMARIS 750S and AMARIS 500E.

IMPORTANT NOTE

The laser itself is able to run at a repetition rate up to 1050 Hz in case of SCHWIND AMARIS 1050RS, 750 Hz in case of SCHWIND AMARIS 750S and up to 500 Hz in case of SCHWIND AMARIS 500E or AMARIS with two levels of fluence for fast ablation with high fluence and smooth ablation for fine-tuning with low fluence. The transition between the two fluence levels is made on the fly (Automatic Fluence Level Adjustment).

Because the laser is able to operate with two different fluence levels the test consists of two steps. The first one is the calibration of the laser under high fluence followed by the calibration under low fluence settings.

After the calibration of the two energies the system will ablate some spots in the centre to calibrate the internal energy sensor. Additionally a Drift Offset test is performed after the fluence measurement to calibrate the Eye Tracking camera.

7.7.2 Connection of the Fluence Detector

Figure 7-15: Connection of the fluence detector at AMARIS / AMARIS 750S/1050RS and AMARIS 500E

IMPORTANT NOTE

Before switching ON the laser, the fluence detector must be connected!
Otherwise the laser has to be restarted to recognize the fluence detector.

When the fluence detector is not in use, it can be parked at the appropriate holder at the housing of the AMARIS.

Figure 7-16: Holder for the fluence detector

7.7.3 Performing a Fluence Test

When should a Fluence Test be carried out?

- At the beginning of each treatment day.
- Every 2 hours – or after a gas exchange.
- After 2 hours, only 2 more treatments are allowed within the next hour.
- If humidity has changed more than 5% or temperature has changes more than **±2°C** during the last 2 hours.
- In case the energy deviation is recognized more than accepted for three times in a row then the system requires a fluence test, independently whether 2 hours after a calibation passed by or not. This can e.g. happen when 3 sequential PTK's for (toric) marking by PTK are applied all with a low amount of laser pulses.

For performing the fluence test, a special test device (fluence detector) is supplied.

The fluence detector consists of a blue metal housing equipped with a fixation device for securing the HS-foil. Inside this holder is a titan dioxide detector which is covered with a sapphire glass that fluoresces when contacted by UV-radiation.

This fluorescent light is detected with sensors and evaluated by the control unit.

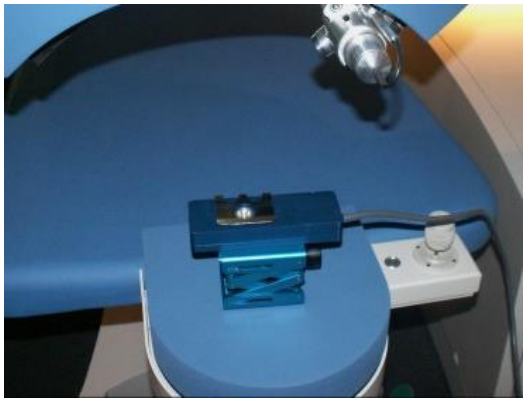


Figure 7-17: Fluence detector with HS-foil – holder

As long as the foil isn't perforated, no laser beam can reach the detector through the glass plate. This means no signal will be transferred to the computer. Upon starting of the perforation, ablation of the entire diameter of the measured quantity of UV light increases continuously until reaching a maximum point. Then the test will be evaluated and finished automatically.

IMPORTANT NOTE

The **HS-foil**, the **photo paper** and the **fluence detector** are **non-sterile parts**. The fluence test and the drift test should be carried out by a **non-sterile assistant**.

To minimize any influences on the measurement the following must be observed:

- Always clamp the **HS-foil** under the flat spring of the fluence detector.
- Clean the glass window of the fluence detector from ablation remains every time before a new fluence test starts and after a fluence test. For cleaning use a special micro fibre tissue which is located in a transparent plastic box in the drawer fastened to the tower (underneath the monitor).
- Carry out the fluence test without interruption, i.e. press the foot switch continuously until the fluence test is completed.
- During the fluence test, the patient bed is blocked and should not be touched.
- Avoid any sunlight in the room during the treatment.
- Such agents could prevent the successfully execution of a fluence test, or result in over-/under corrections during treatment.

WARNING!

Risk of under correction!

Do not use alcohol or other liquids to clean the fluence detector window!

WARNING!

Risk of incorrect test results!

The **HS (High Stability) foil** has an **expiration date** which is indicated on the packaging box. **Take care not to use expired foils, as this could influence the test results.**

Furthermore, the HS-foil is light-sensitive. Store the HS-foil under light-protected conditions in order to avoid quality and conditional changes of the foil.

The photo paper does not have an expiration date, but should, however, also be stored in light-protected conditions to ensure the quality.

To perform the Fluence Test the following steps must be performed:

1. Select the <**Fluence Test**>button in the **Functions** Menu and follow the messages on the monitor.
2. Every 15 fluence tests a message will appear which asks to clean the fluence detector with a micro fibre tissue which is supplied with AMARIS.

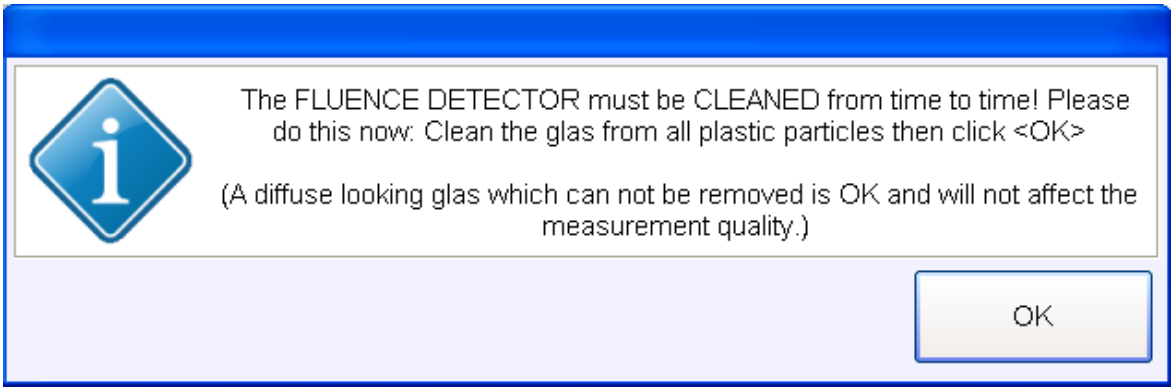


Figure 7-18 : Fluence detector cleaning message

3. Reduce the light in the room. The surgery illumination will be switched off automatically during the test. After having completed the fluence test the illumination will return back to its initial value before starting the calibration.
4. Place the HS-foil under the clamp of the fluence detector.
5. Use both positioning slits to focus and center on the surface of the detector in order to be in the correct plane roughly, then move the bed laterally in order to bring the HS-foil into the ablation area as shown in Figure 7-17, confirm the correct ablation height with the positioning slits while looking through the microscope and fine adjust (if needed).
6. or adjust the ablation height directly on the HS-foil, also using both positioning slits.
7. Check on the monitor that the adjusted position of the sensor is located in the center of the camera picture (live video). Further follow the instruction of the SW. The place where the high stability foil will be perforated during the fluence test is indicated by four green circles. Take care that there is no previously perforated area of the foil at the indicated positions for the new ablations.

WARNING!

Ensure that the sensor is correct positioned and the laser beam will not be exposed onto the clamp of the sensor.

Reflective objects (like high-gloss polished metal surfaces) in the area of the laser beam may lead to dangerous mirrored reflections.

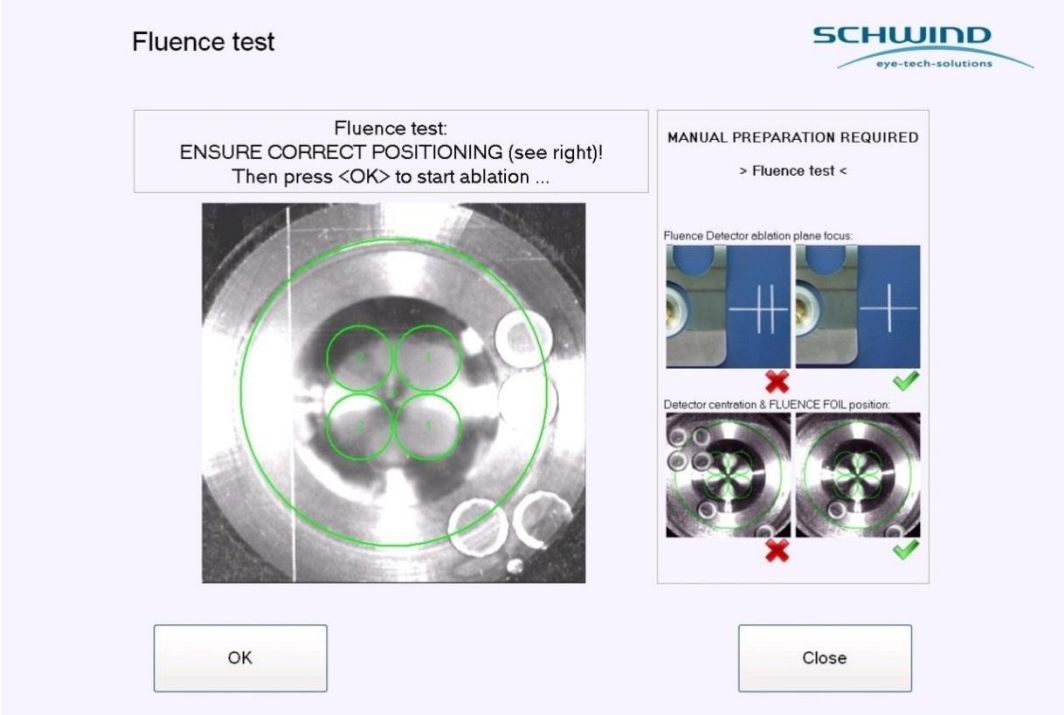


Figure 7-19: Start Screen of the fluence test

IMPORTANT NOTE

The four small pictures on the right side of the SW menu show a correct and incorrect positioning of the high stability foil.

The position where the foil will be perforated is indicated by four small circles, which will rotate from fluence test to fluence test in steps of 90° in order to increase the lifetime of the fluence detector.

8. Bring the particle aspiration system into position.

IMPORTANT NOTE

If the particle aspirator is not in the correct working position it will not be possible to start the fluence test.

9. Wait until the message **"Press Foot Switch"** appears. The foot switch must be pressed down until the system ends the test. The fluence test starts and ends automatically.

WARNING!

Risk of incorrect ablation results!

Take care not to move the fluence detector during the ablation process!

The performance of the fluence test in a way other than described here can lead to dangerous irradiation or under- or over correction.

IMPORTANT NOTE

During the fluence test, the perforation has to be observed via the microscope or the video screen (monitor). The ablated circles should be almost of the size as the green circles indicated the live video image.

Small deviations of the position of the perforation are normal since the ablations are not drift compensated.

After the fluence test a test for determining and compensating of a possible scanner drift will follow.

10. To avoid damage to the foil, it has to be carefully packed after the use.

After the fluence measurements have been performed successfully, the message **"Fluence Test OK"** appears on the screen, (see Figure 7-20)

The fluence measurement procedure is finished.

The measured value for the fluence test will be displayed. The value shows the calculated ablation per pulse at the human cornea in nm as well as the minimum and maximum limit for the high and low fluence.

The actual result will be stored by the software and will be used to calculate the needed number of pulses for the following treatments.

If the test result is negative, treatments cannot be performed with the system.

Press **<OK>** and proceed with the **Drift Offset measurement**.

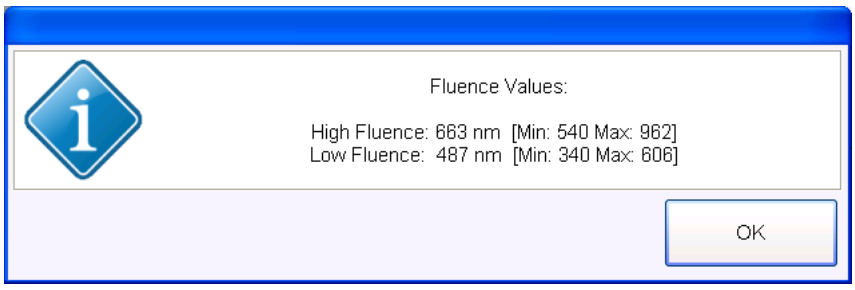


Figure 7-20: Fluence test successfully completed

The **High Voltage Range** to perform treatment with AMARIS / AMARIS 750S/ AMARIS 1050RS or AMARIS 500E is dependent on the laser source integrated in the system.

The parameters for the four possible laser sources are:

Laser source	ESO-500	EXSO-500	EXSO-750/ EXSO-MED	ML-750/ ML-OEM-S1
HV range (allowed)	750 – 1425 V	720 – 1460 V	635-1460 V	530 – 985 V

IMPORTANT NOTE

The currently needed High Voltage and its range will be displayed in the bottom left side of the Fluence Test Menu after successfully finishing the fluence measurement.

Depending on the number of planned treatments it can be useful to have a look on this value in order to perform a possibly needed gas exchange.

7.7.4 Automatic Pre-set Energy Adjustment

If the result of the fluence test is at the upper or lower limit of the valid fluence range, the system will automatically increase or decrease the pre-set energy of the laser source in order to bring the fluence value closer to the default value.

IMPORTANT NOTE

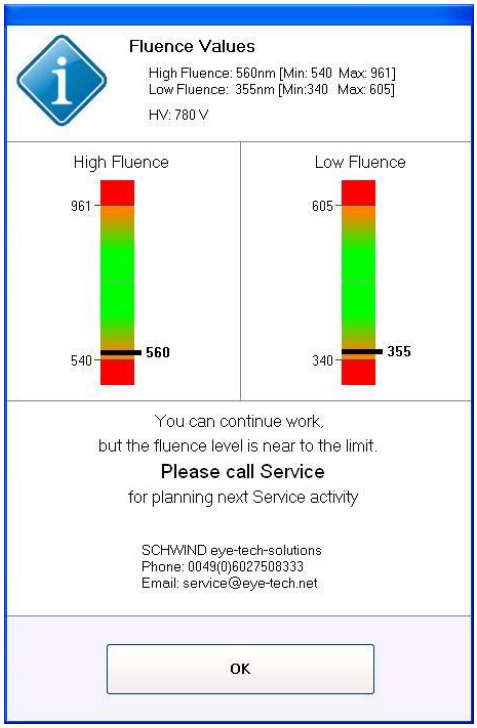
The adjustment of the laser source pre-set energy will take place during the next fluence test only. It is not necessary to repeat the fluence test.

IMPORTANT NOTE

If this message appears it is still possible to work with the laser system, but it is an indication that a service visit for the laser is necessary soon.

In case that the laser source pre-set energy adjustment is at the lower or upper adjustment limit, a message will be displayed explaining the situation and asking to call the service department of SCHWIND eye-tech-solutions to arrange a service visit.

Figure 7-21: Fluence result message/borderline pre-set energy



7.7.5 Troubleshooting – Fluence Test

What to do if:

The first fluence test has not been performed successfully

- Execute a gas change.
- Clean the fluence detector using the micro fibre tissue (refer to Important Note in chapter 7.7.3 Performing a Fluence Test).
- Reduce environmental light.
- Check that the HS-foil is correctly placed.

The fluence test is not successful after a gas change

- Perform another gas change (especially if the laser was not used more than one month, it is usually necessary to do 2-3 gas changes).

The fluence test is not successful despite repeated gas changes

- Please contact the service department of SCHWIND eye-tech-solutions or its local representative.

The third measurement is still not successful

- Please contact the service department of SCHWIND eye-tech-solutions or its local representative.

What happens if?

The fluence test measurement is not successful and/or the time since the last fluence test becomes too long?

- In this case, for safety reasons, the system does not permit any treatments.

7.8 Drift Test

After the fluence test is complete, a drift test has to be performed to check and compensate any possible drifts of the complete optical system. Replace the fluence foil with black photo paper with not changing the horizontal position of the fluence detector. After adjusting the vertical position of the fluence detector with the help of slits as shown in Figure 7-22, start the drift test. Follow the instructions in the fluence test menu.

A small circle with a spot in the center will be ablated on the photo paper. The system calculates the position of the spot in the eye tracker live video and compensates any recognized drifts automatically. The green rectangle indicates the area of interest for the drift measurement.

Take care that there is no previously ablated spot or circle on the photo paper within this rectangle.

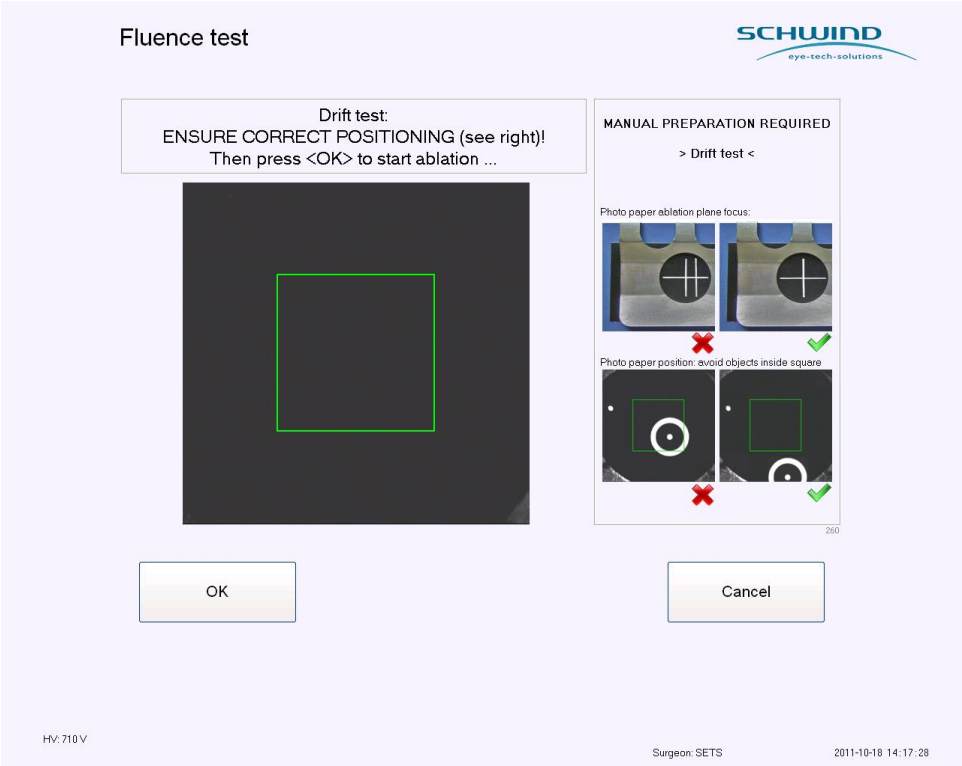


Figure 7-22: Start of the Drift Test Measurement

IMPORTANT NOTE

The four small pictures on the right side of the SW menu show correct and incorrect positioning of the photo paper.

IMPORTANT NOTE

After the circle with the spot in the center is ablated please do not touch the system, since the actual drift measurement is performed by the Eye Tracking system.

After competition of the measurement switch on the aiming beam and check whether the red spot of the aiming beam is concentric with the ablated spot on the photo paper and if the ablated ring has the correct shape.

If the red aiming laser is inside the white ablated spot, confirm the message with <**Yes**> and the drift offset measurement will be valid.

If not, exit the message with <**No**>. If "No" is pressed, the Drift Offset Measurement will be set to not valid and the complete fluence test has to be repeated.

If the aiming beam is still not within the ablated spot after repeating the measurement, the optical alignment has to be checked by a service technician.

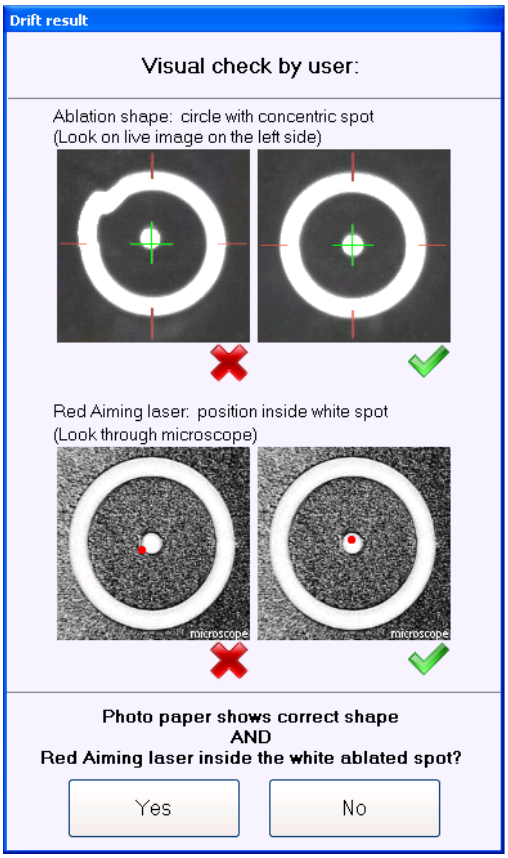


Figure 7-23: Confirmation message 'Drift Test'

IMPORTANT NOTE

After the drift test, the red spot of the aiming beam must be inside the ablated spot on the photo paper.

IMPORTANT NOTE

If the measured Drift Offset is bigger than 400μm, an information message will pop up to inform the user about the situation and instructs to call the service department for further actions.

However, it is possible to perform treatments.

If the measured Drift Offset is bigger than 500μm, a treatment will not be possible for safety reasons.

7.9 Gas Exchange - Excimer Laser

The laser source is a gas filled tube that emits the excimer beam.

IMPORTANT NOTE

The operating time of the gas is limited by the number of released pulses, but also by the time the gas is inside the laser tube.

When is a gas exchange necessary?

- Fluence test cannot be started at all, based on too low energy.
- When the software requires the gas change. In this case the following message is displayed: **"Laser HV is too high."**

IMPORTANT NOTE

The message **"Laser HV is too high"** indicates that a gas exchange is necessary before it is possible to work with the system.

The message **"Laser HV is high"** is also possible but indicates only a recommendation that a gas exchange might be necessary soon.

7.9.1 Performing of a Gas Change

To start the procedure, select the corresponding menu point in the **Functions** menu and press <**ENTER**> button, or directly press the <**Gas exchange**> button on the touch screen. A sub-menu appears, as shown in Figure 7-24: Start of a gas change.

You will be asked to confirm, if a gas change should be performed. To start it, select the button <**OK**>. After that the gas change starts automatically.

After the laser tube is filled up to 7000 mbar with fresh premix gas, the procedure is finished and the following window appears (see Figure 7-25: Gas change).

The gas exchange is now successfully completed.

It is possible to calculate the number of remaining possible gas exchanges by pressing the button <**Calculated Possible Gas Exchanges**>on the right side of the menu.

IMPORTANT NOTE

A system message appears if the gas supply is running short in the gas bottle.

In this case please contact the Service Department of SCHWIND eye-tech-solutions so that the bottle can be exchanged.

The announcement of the possible numbers of gas changes may slightly vary due to small inaccuracies within the range of the sensors.

Please also consider that the last possible gas change is reserved for service.

Changing of gas bottles is only allowed to be carried out by service technicians authorized by SCHWIND eye-tech-solutions.

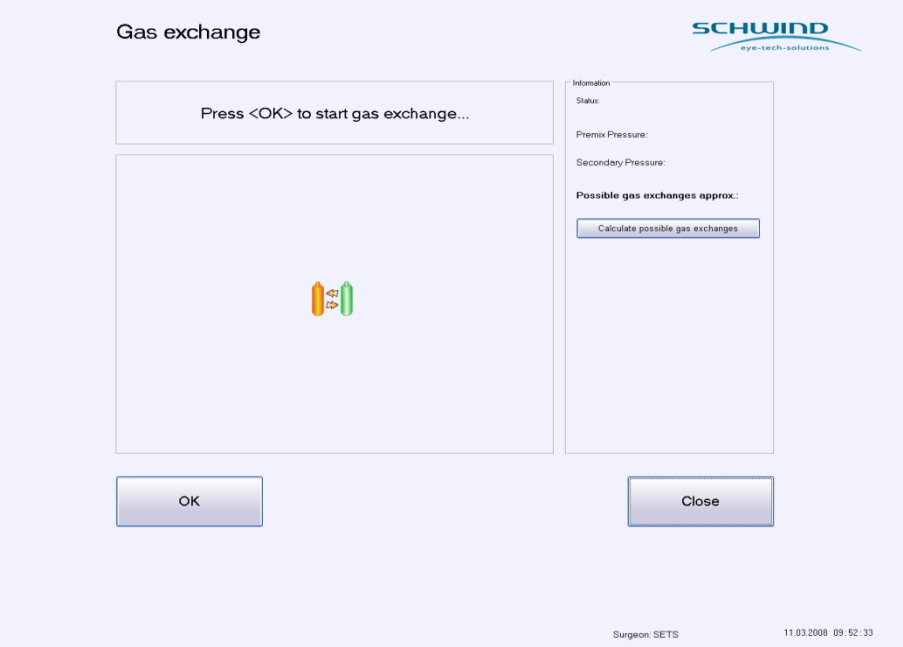


Figure 7-24: Start of a gas change

A new completely filled premix gas bottle is enough to perform around 60 gas exchanges with the integrated ESO and EXSO laser sources and around 30 gas exchanges with the ML laser sources.

Based on the measured High Voltage measured at each Start Up of the excimer laser the system will automatically give a message when a gas exchange is needed or recommended.

It will be not necessary to perform a preventive gas exchange without having the message.

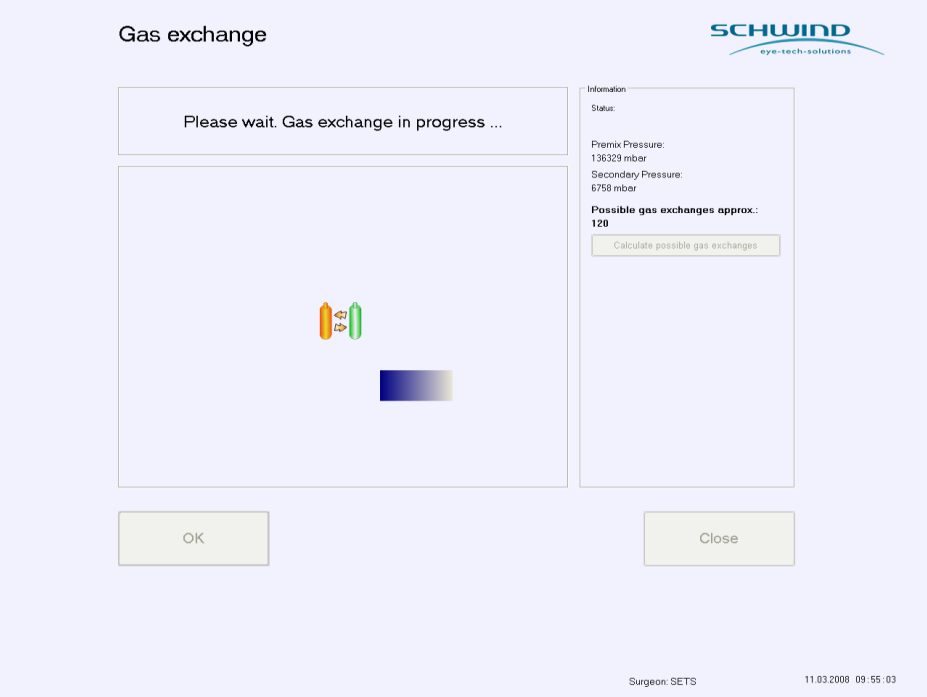


Figure 7-25: Gas change in progress

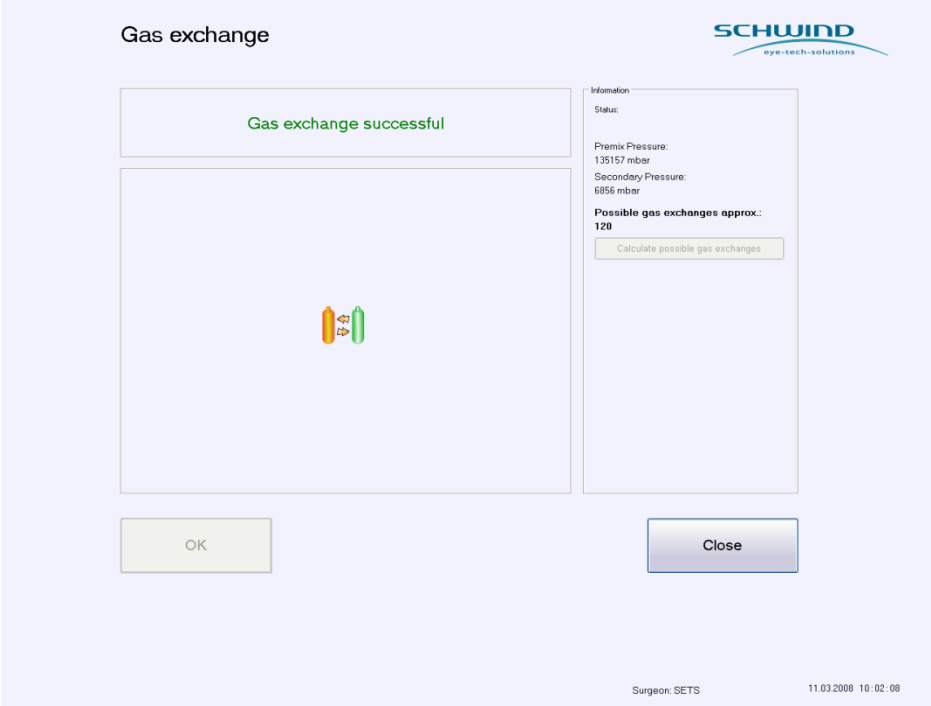


Figure 7-26: Gas change successful

If the menu gas exchange is entered but no gas exchange is necessary an additional message will be displayed (Figure 7-27).

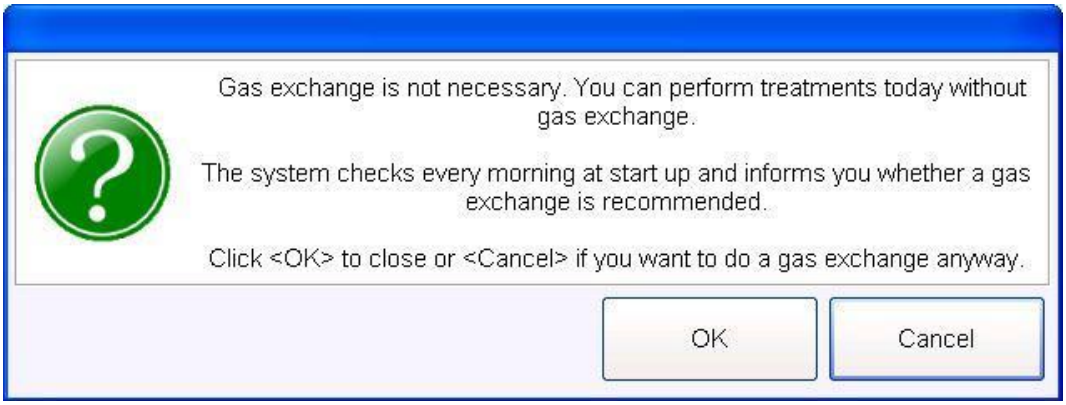


Figure 7-27: No gas exchange needed

7.10 Export of Log File and Treatment Data

In case of system failure caused by a technical defect, it may be necessary to copy the log file and treatment data onto a storage medium and forward the same to SCHWIND eye-tech-solutions. Usually this is done in consultation with the Service Department of SCHWIND eye-tech-solutions or your distributor.

- For this, pressing the <**Export Logfiles**> button activates a submenu
- Please select if you wish to export the system logfiles only or if you wish to export the treatment files and the system log files together.
- In case you want to hide patient data especially when exporting treatment files select the option <**encrypt**> as well.
- The next step is to select the time period for which the files shall be exported and the target drive with the <**Select traget directory**> button. You may use **E: CD-ROM** writer or **the Flash card drive (usually F:\).**
- Click on <**Export**> after selecting the storage medium. The file size and available memory are displayed in this menu again. The selected data is stored by activating the button <**Copy**>. You may send this to the Service Department of SCHWIND eye-tech-solutions.

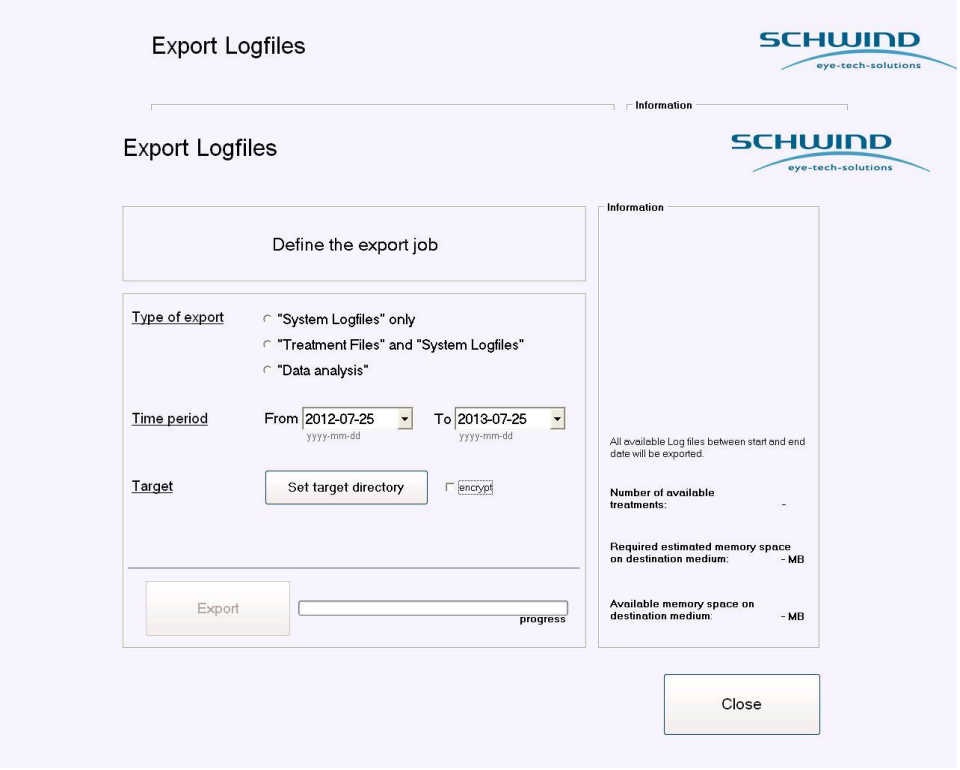


Figure 7-28: Export log files

7.10.1 Export to External Data Analysis Software

In addition to the possibility to export the log and treatments files for the treatments performed with AMARIS there is the possibility to export a file to an external data analysis software (e.g. Datagraph™ - Software, IBRA etc.).

This file will include the patient data and treatment data and can be imported into the Datagraph™ database by selecting the import from AMARIS option.

To export the file from AMARIS the user has to select the **<Data analysis>** option in the **Export Log files** menu. In a next step the start and the end date of the time period from which an export file including all treatments should be generated and the destination where the file shall be saved have to be selected. By pressing the button **<Export>** the file will be generated.

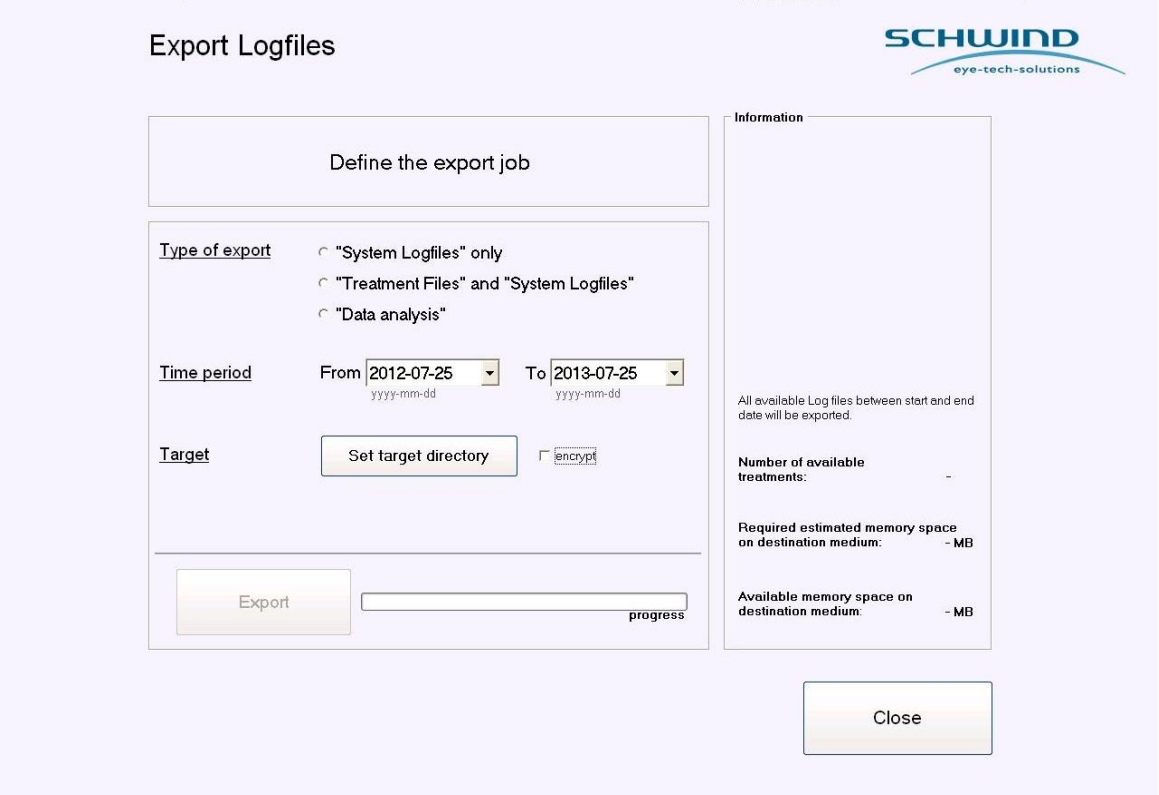


Figure 7-29: Export to external data analysis software

7.11 Printout and Video (Export of Treatment PDF and Video)

Under the sub menu **Treatment Printout** treatment PDF files of the performed treatments can printed or exported at any time.

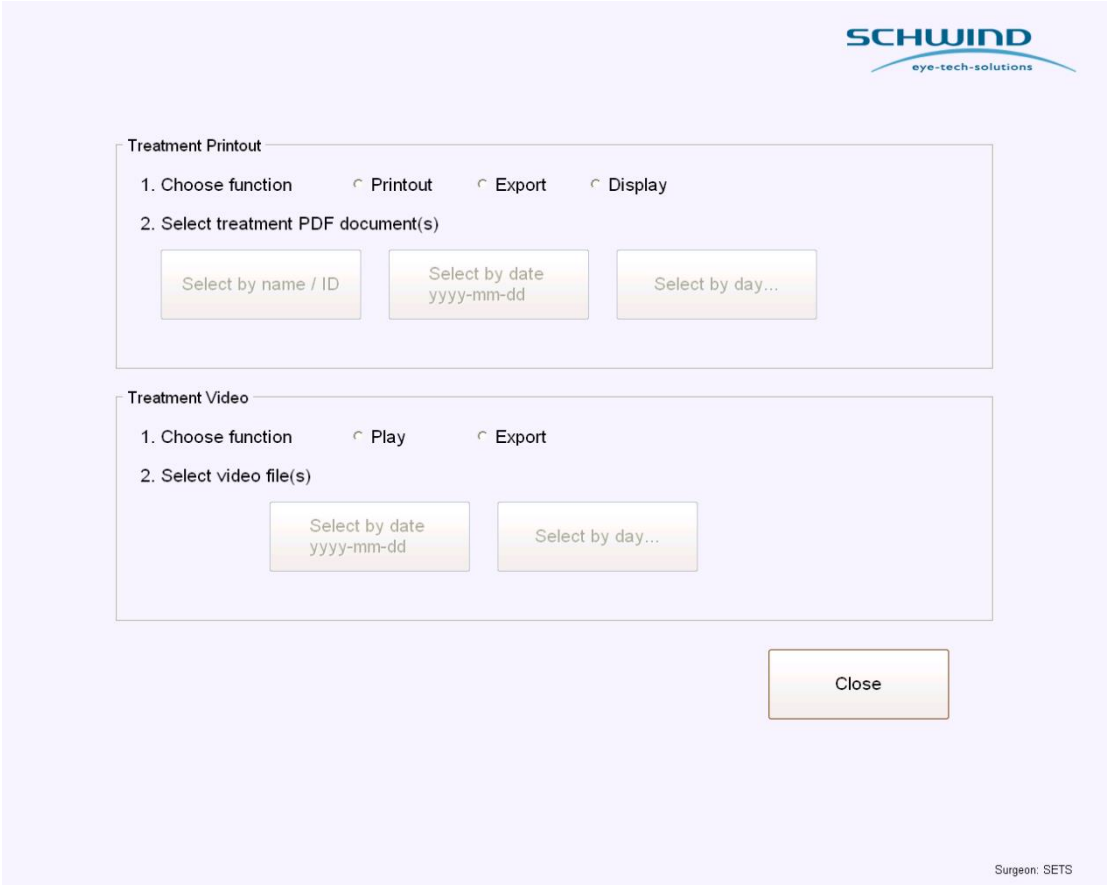


Figure 7-30: Printout and video

The user can select if he wants to printout, export or display the treatment pdf files. It is possible to choose the files for export and printout by Patient Name/ID, to select the file by treatment date or to select all treatments from a specific day.

A dialog will be opened and the file for printout or export can be selected. There will be the option to make a manual selection, to export or print all files from today or to define a time period in which all available treatment files shall be printed, shown or exported.

In case the user wants to print all treatments of the day (e.g. when the treatment day is finished) please select <**Treatment Printout**> and the option <**Select by day**>. A dialogue will be shown (see Figure 7-30, Figure 7-31) in which it is possible to select the specific day.

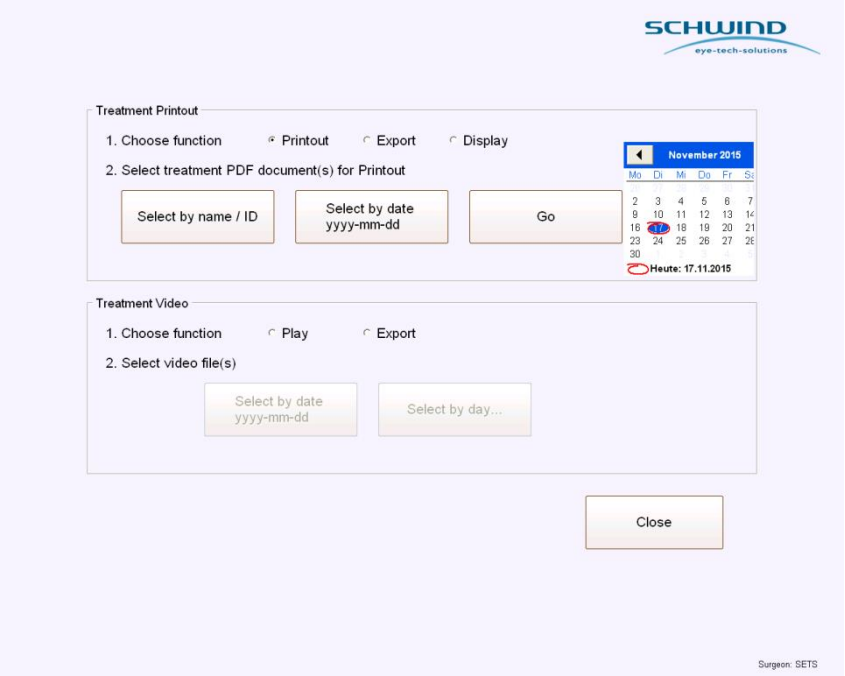


Figure 7-31: Selecting a specific day for printout

When the day is chosen click on the button <**Go**>. In the dialogue which opens now just highlight all treatment pdf and click on “open” for printout.

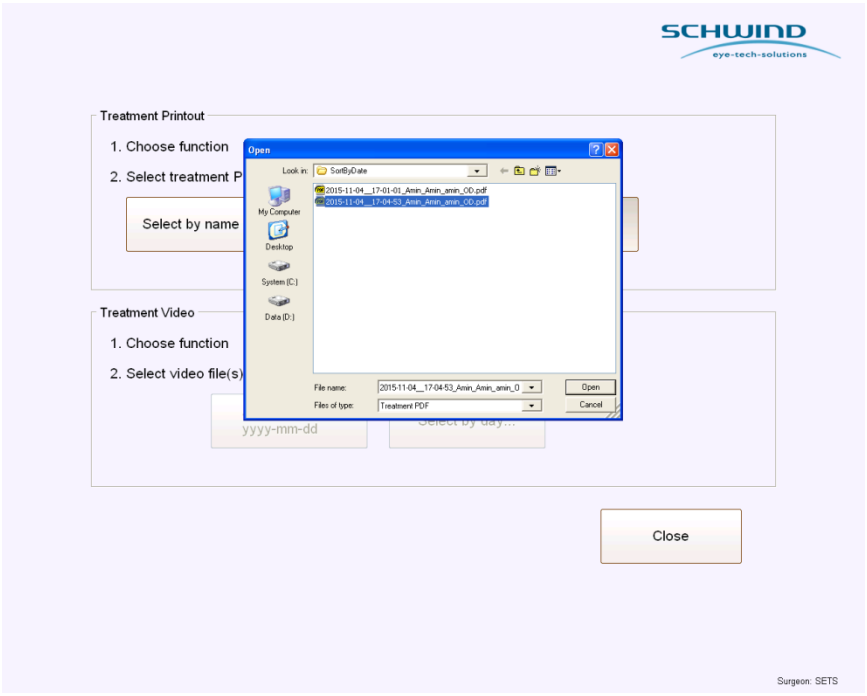


Figure 7-32: Printing all treatment PDF from a specific day

Under the sub menu **Treatment Video** treatment videos of the performed treatments can be viewed or exported at any time.

Figure 7-33: Treatment video

The user can select if he wants to play or export the treatment video files that have been captured. In case the video recording is not possible for your AMARIS or no videos are available, the Video export is not displayed.

It is possible to choose the files for export and play by Patient, by treatment date or to select all treatments from a specific day.

In case the user wants to play/export all treatments of the day, please select <**Treatment Video**> and the option <**Select by day**>. A dialogue will be shown in which it is possible to select the specific day.

IMPORTANT NOTE

In case the hard disk of the panel pc runs out of free space, the oldest video files will be deleted automatically in order to ensure correct function of the panel pc. A back up strategy is the operator's responsibility.

7.12 Treatment Printout

The treatment printout can contain up to two pages, especially when an Online Pachymeter and/or 6D eye tracker is integrated. There are two different printout templates according to the possible treatment types refractive ORK/PresbyMAX and PTK.

On the first page general information, patient data and laser system data will be shown;

- In the section **Patient** relevant patient and input data will be shown;
- In the section **Treatment** relevant parameter and measurement values during treatment will be shown;
- The value "SCC" in the section **Treatment** (see example printout in Figure 7-34) may show either the SCC angle or one of the following statements:
  - n.a. SCC data from diagnostics were not available;
  - n.s. SCC measurement was not successful;
  - n.u. SCC has shown a valid measurements but it was discarded by the user.
- In the section **System Data** relevant parameter regarding the laser system will be shown;
- In the section **Comment** the text comments which were inputted in the SCHWIND CAM or in AMARIS will be shown.

On the second page of the treatment printout relevant OCP and 6D tracking data will be shown;

- In the section **Pachymetry** the values of central corneal thickness measured by the online pachymeter will be shown numerically and in form of a diagram;
- In the section **Eye Tracking 6D** the during treatment measured and compensated values for the z- position of the eye as well as the compensated dynamic x- and Y-Rolling will be shown in form of a diagram.

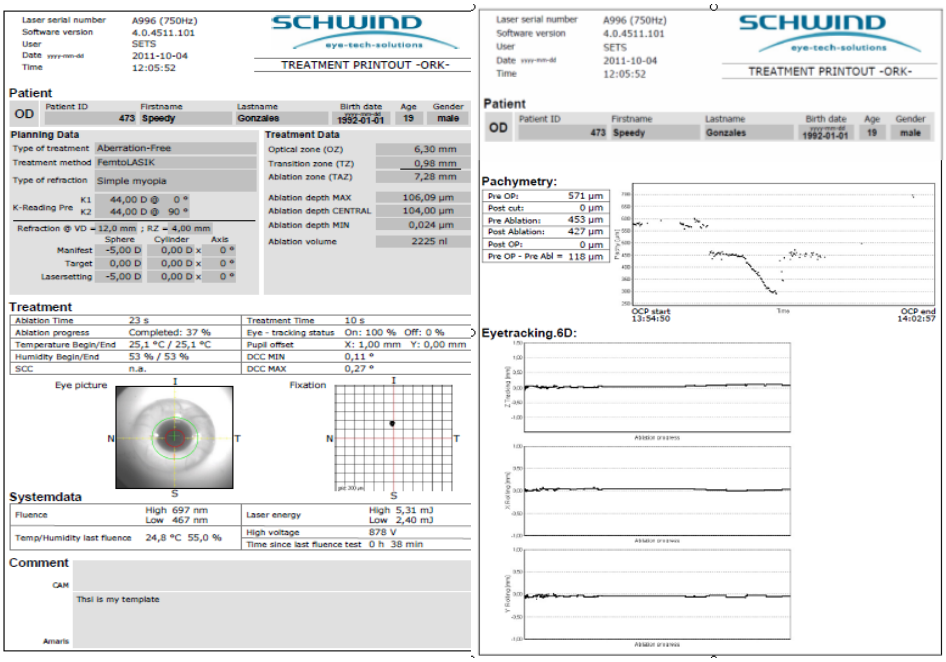


Figure 7-34: Treatment printout ORK page 1 and 2

8 TREATMENT SELECTION

8.1 General

After the **Fluence Test** has been carried out successfully, the appropriate treatment can be selected and the patient data can be entered.

On the left side of the **Main menu** you can select the relevant options <**New**>, <**Import**>, and <**Recovery**>.

After selection of the required treatment, the appropriate sub-menu will appear.

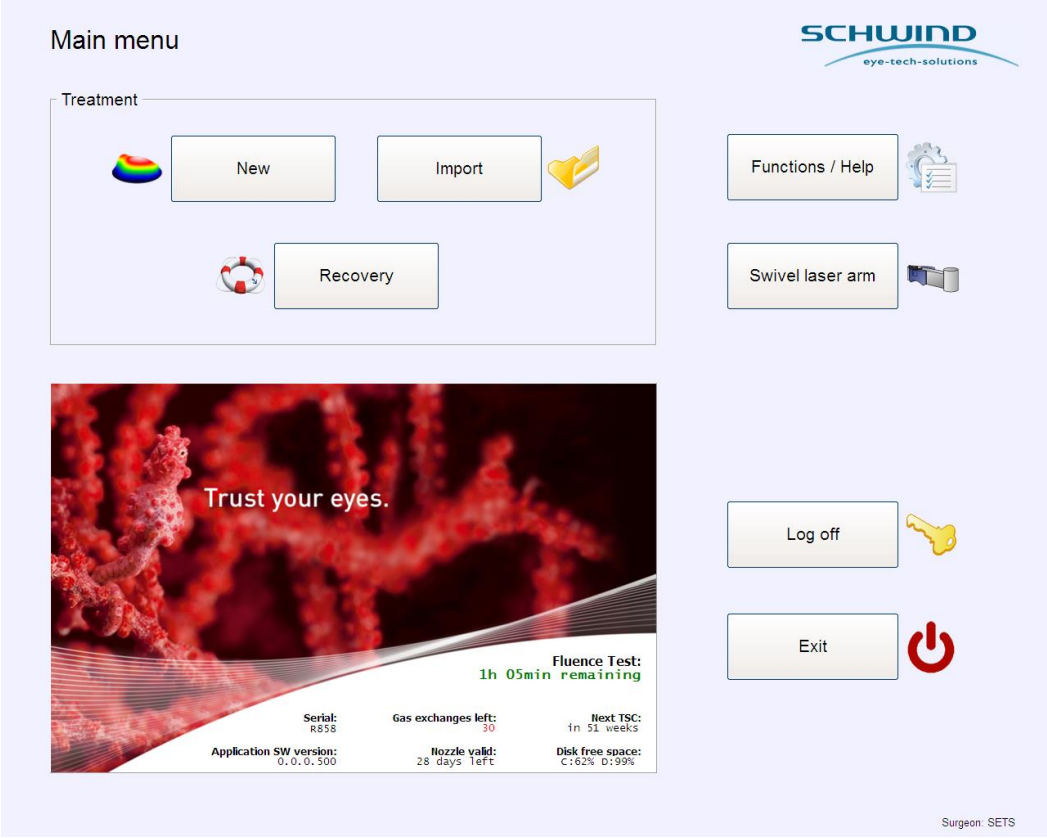


Figure 8-1: Main menu AMARIS

IMPORTANT NOTE

All treatments are planned and calculated with the approved SCHWIND CAM software. Please refer to a separate User Manual (Instruction for Use) of the SCHWIND Custom Ablation Manager and the respective Treatment Planning Guidelines (ORK-CAM, PresbyMAX, PTK-CAM).

8.2 Planning SCHWIND CAM Treatments

The abbreviation **CAM** means **Custom Ablation Manager**. With the SCHWIND AMARIS, all the treatments are SCHWIND CAM guided.

The software consists of three treatment planning modules:

- **ORK-CAM**- the module for refractive treatments,
- **PresbyMAX**- the module for presbyopic treatments,
- **PTK-CAM** with which aspheric and refraction neutral PTK (Phototherapeutic Keratectomy) profiles can be planned. 'KPL' (keratoplasty) option exists for PTK-KPL, i.e. (perforating) keratoplasty in combination with Naumann-Rings by SCHWIND.

IMPORTANT NOTE

This SCHWIND CAM software, especially developed for the AMARIS, is **NOT** part of the AMARIS manual. Please refer to a separate User Manual (Instruction for Use) of the SCHWIND Custom Ablation Manager and the respective Treatment Planning Guidelines (ORK-CAM, PresbyMAX, PTK-CAM).

8.2.1 Planning of new Treatments

By pressing the <**New**> button in the **Main menu** the SCHWIND CAM software will be opened and will allow you to enter all the patient data and type of treatment by selecting one of the modules, e.g ORK-CAM. Please refer to the User Manual (Instruction for Use) of the SCHWIND Custom Ablation Manager and the respective Treatment Planning Guidelines (ORK-CAM, PresbyMAX, PTK-CAM).

After the treatment planning is completed, the summary page (see Figure 8-4) is displayed automatically and the user has the possibility to directly proceed to the treatment screen of the AMARIS software.

IMPORTANT NOTE

The "Summary Page" is only for information purposes and it is not possible to make further changes.

To print out the "Summary Page" press the <**Print**> button.

To select another patient or another eye press the <**Cancel**> button.

To start the treatment, press the <**Start Treatment**> button. The calculation of the shot positions out of the imported ablation volume and the current fluence value of the laser will take a few seconds.

8.2.2 Import of SCHWIND CAM Treatments

By pressing the <**Import**> button in the **Main menu** you will be able to import treatment files which have been created with the SCHWIND CAM software installed on a (diagnostic) device workstation approved by SCHWIND.

A standard path from which the files should be imported can be defined in the general settings Menu of the SCHWIND AMARIS Application software.

If this path is not existent while pressing the button **<Import>** the program will automatically select the path D:\EXPORT_SCHWIND_CAM.

The SCHWIND CAM software will be started automatically and the user will have the possibility to change the treatment parameter.

In the settings of the SCHWIND CAM software the user can define which part of the program the software shall jump to when a project file is opened. You may select **"Patient data input menu"**, "**Main menu**" or "**Summary page**".

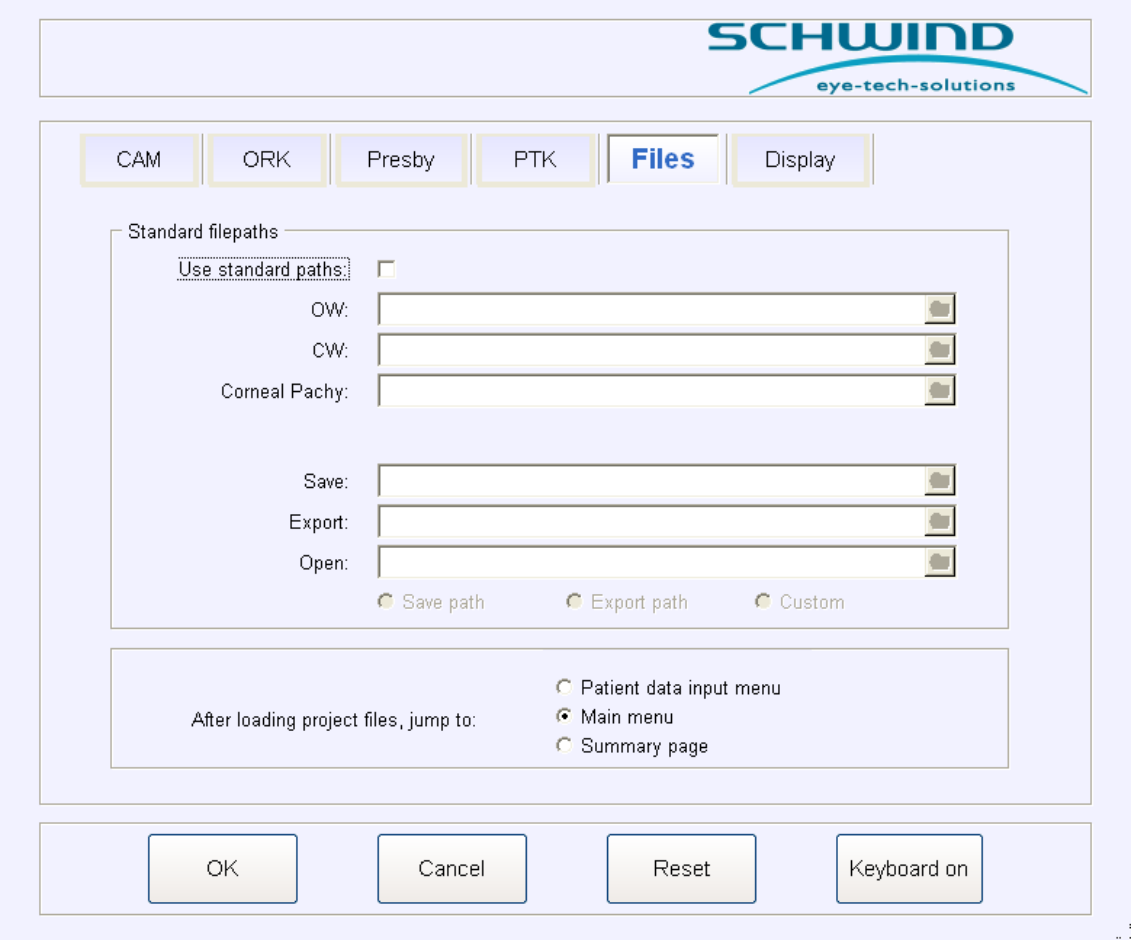


Figure 8-2: Project file loading settings SCHWIND CAM

If for example "Summary page" is selected the software will automatically jump to the summary page directly when a treatment is loaded pressing the button **<Import>**.

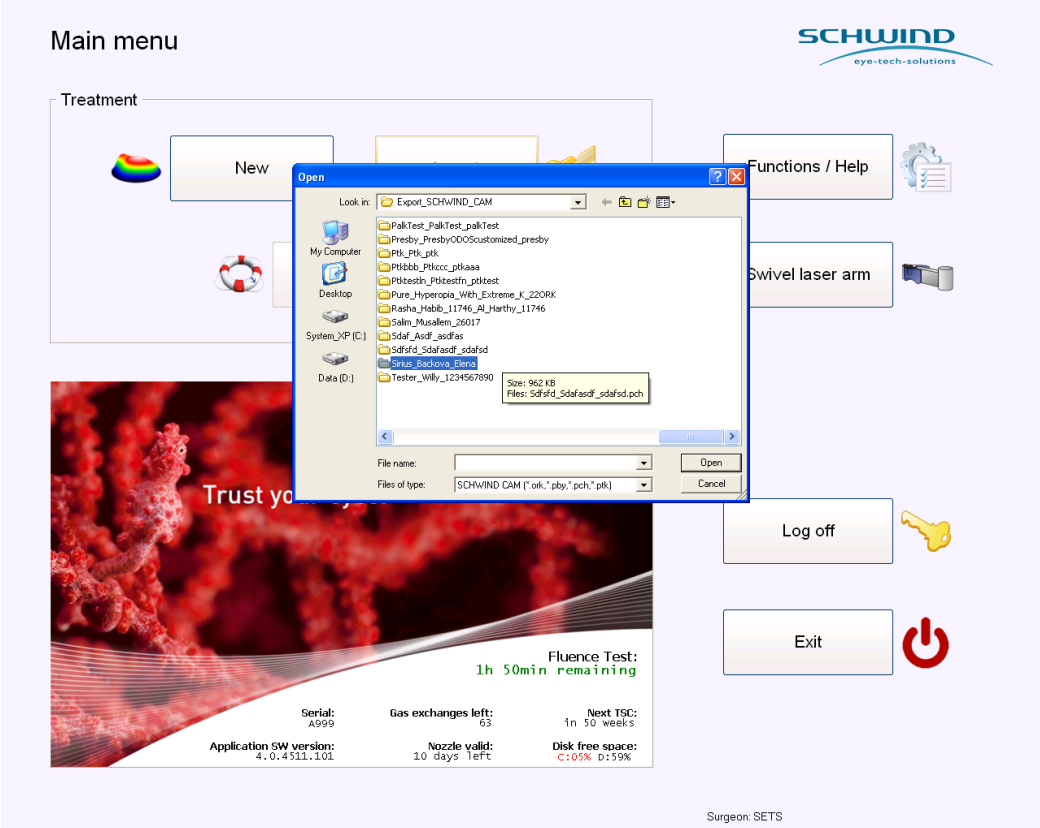


Figure 8-3: Selection of SCHWIND CAM import file (folder)

The reading of the SCHWIND CAM file can take some seconds. Please be patient.

After confirming the input values, the selected part of the software in the SCHWIND CAM settings e.g. “Summary Page” is displayed automatically. This page displays all relevant data of the patient (see Figure 8-4: Summary page).

There is the possibility to directly proceed to the treatment screen of the AMARIS software. By pressing the button <**Cancel**> the user can go back to the main menu of the concerned SCHWIND CAM module.

Treatment Selection

Figure 8-4: Summary page (example)

For more information, please refer to the User Manual (Instruction for Use) of the SCHWIND CAM software and respective Treatment Planning Guidelines (ORK-CAM, PresbyMAX, PTK-CAM).

IMPORTANT NOTE

The “Summary Page” is only for information purpose and it is not possible to make further changes.

IMPORTANT NOTE

Before starting the treatment, make sure that all information is correct and the right patient and eye is selected.

To print out the “Summary Page” press the <**Print**> button.

To select another patient or another eye press the <**Cancel**> button.

To start the treatment, press the <**Start treatment**> button. The calculation of the shot positions out of the imported ablation volume and the current fluence value of the laser will take a few seconds.

Treatment Selection

If the treatment file includes the ablation profiles for two eyes it is possible to always start the treatment with the same eye (OD or OS). The option for which eye the treatment can be started can be set in the settings of the AMARIS Application software.

On the other hand, there is the possibility to define in the options of the AMARIS Application software that there will be a question of which eye the treatment should be started.

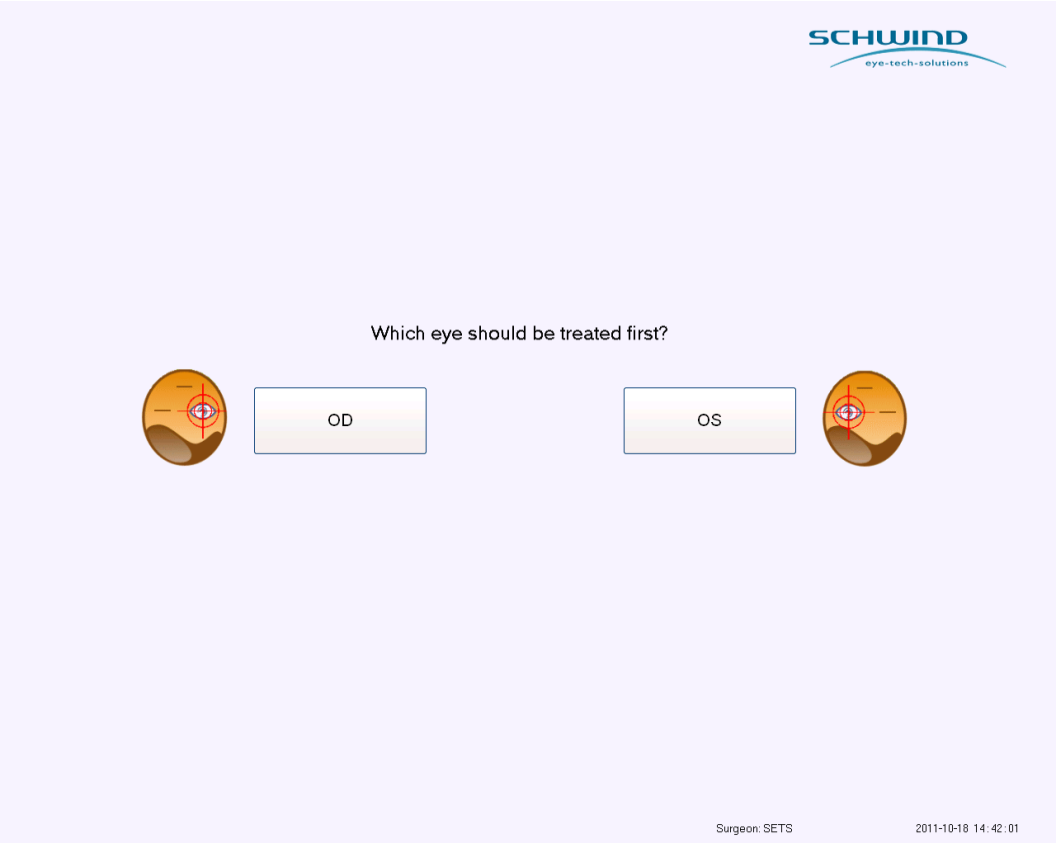


Figure 8-5: Question to start with which eye first

8.3 Performing SCHWIND CAM Treatments

After a new SCHWIND CAM treatment is planned or imported from a (diagnostic) device workstation to perform the treatment and the button <**Start treatment**> at the "Summary Page" was pressed, the AMARIS software will proceed to the treatment menu and the treatment can be initiated after the self-test of the laser has been performed.

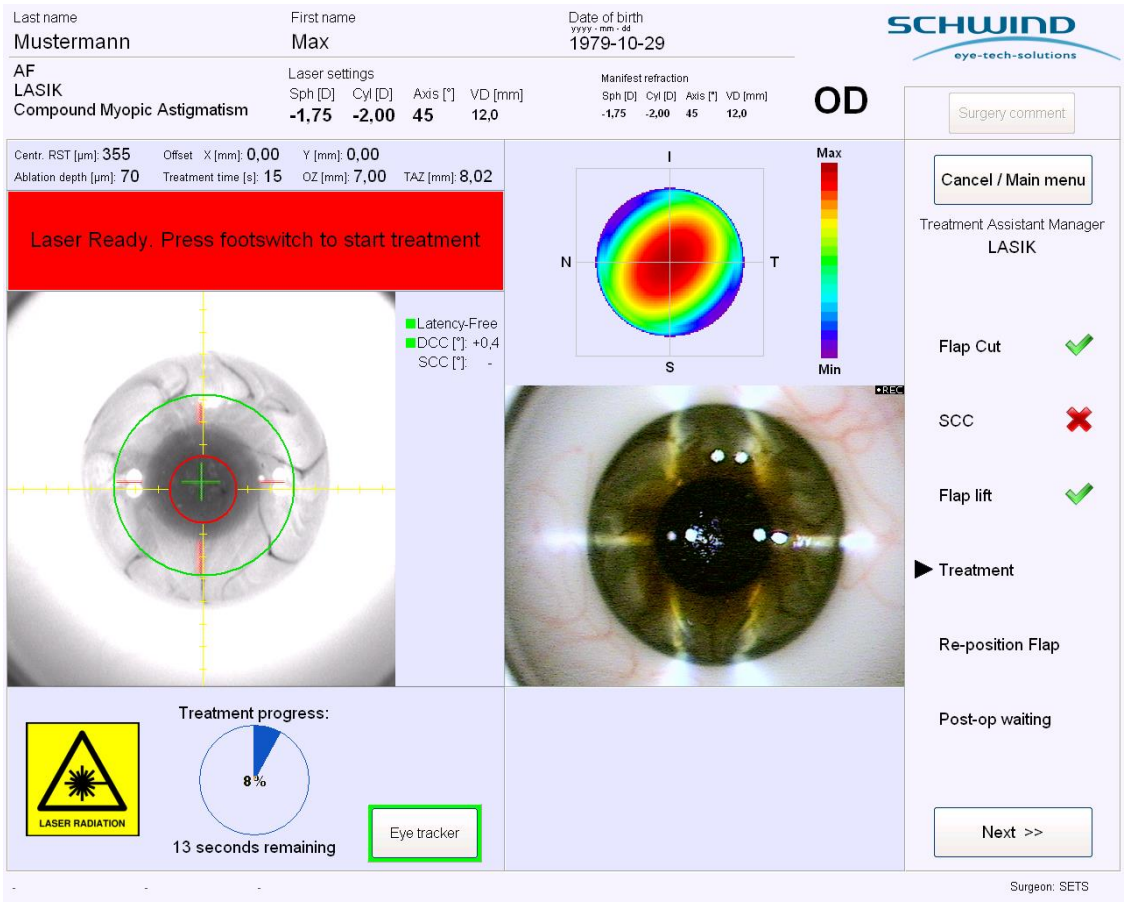


Figure 8-6: AMARIS treatment screen (example)

In the upper left corner of the treatment menu you will find the relevant patient data and treatment information, such as patient name, date of birth, laser settings, manifest refraction, treatment mode and treated eye.

IMPORTANT NOTE

The laser settings may be different from the manifest refraction depending on the entered target refraction.

On the left side of the screen you will find the live image of the eye tracking infrared camera. On the right side of the screen there is a window in which the ablation volume is displayed. Below the eye tracking live image there is a treatment progress window which shows the progress of the

treatment, the live image of the video camera is displayed if this option is installed on the AMARIS system.

CAUTION!

The treatment progress diagram displays the percentage of the already performed treatment. If the laser interrupts the treatment without displaying 100% performed treatment, there is an indication of system failure.

Please contact the Service Department of SCHWIND eye-tech-solutions or its local distributor and export the **treatment log files**.

At the bottom of the treatment menu the possibility exists to set and start a timer by pressing the <**Start timer**> button and to deactivate the active eye tracking by pressing <**Eye tracker**>.

IMPORTANT NOTE

The <**Timer**> button only exists if the timer was activated for this step in the Treatment Assistant Manager (TAM).

The input of a treatment offset is only possible for Aberration-Free treatments in the step **Treatment**.

There is also a section for the optional OCP (Online Coherent Pachymetry) system. By pressing the <**Get Pachy**> button, the corneal thickness values can be stored for every particular step of the procedure.

IMPORTANT NOTE

The functions of the Online Pachymetry can only be used if the Online Pachymeter is integrated into the AMARIS excimer laser.

On the right side of the menu, a treatment assistant is displayed which guides the surgeon through the surgical procedure. The surgical steps, automatic hardware adjustments and messages displayed on the screen can be edited in advance in the Treatment Assistant Manager (please refer to chapter 7.5 Treatment Assistant Manager).

If the option in the Treatment Assistant Manager is set, the assistant will automatically jump to the next step. Otherwise, it is possible to proceed manually to the next step by pressing the <**Next**> button.

On the upper right side of the Menu there is a button <**Surgery comment**> with which free text comments can be input. The comment entered in the treatment screen will be shown on the treatment printout together with the comments which can also be entered in the SCHWIND CAM software.

During the TAM step treatment the button <**Surgery comment**> will be disabled and it is not possible to enter comments during this step.

Treatment Selection

IMPORTANT NOTE

If a digital video recording system is available and activated with the latest Panel PC version, digital video files are stored on the hard disk of the AMARIS panel PC. The video file is initialised and the video starts to be recorded after the first laser pulse is triggered. In case the foot switch is not pressed, the video is not recorded and no warning regarding inactive treatment recording is shown.

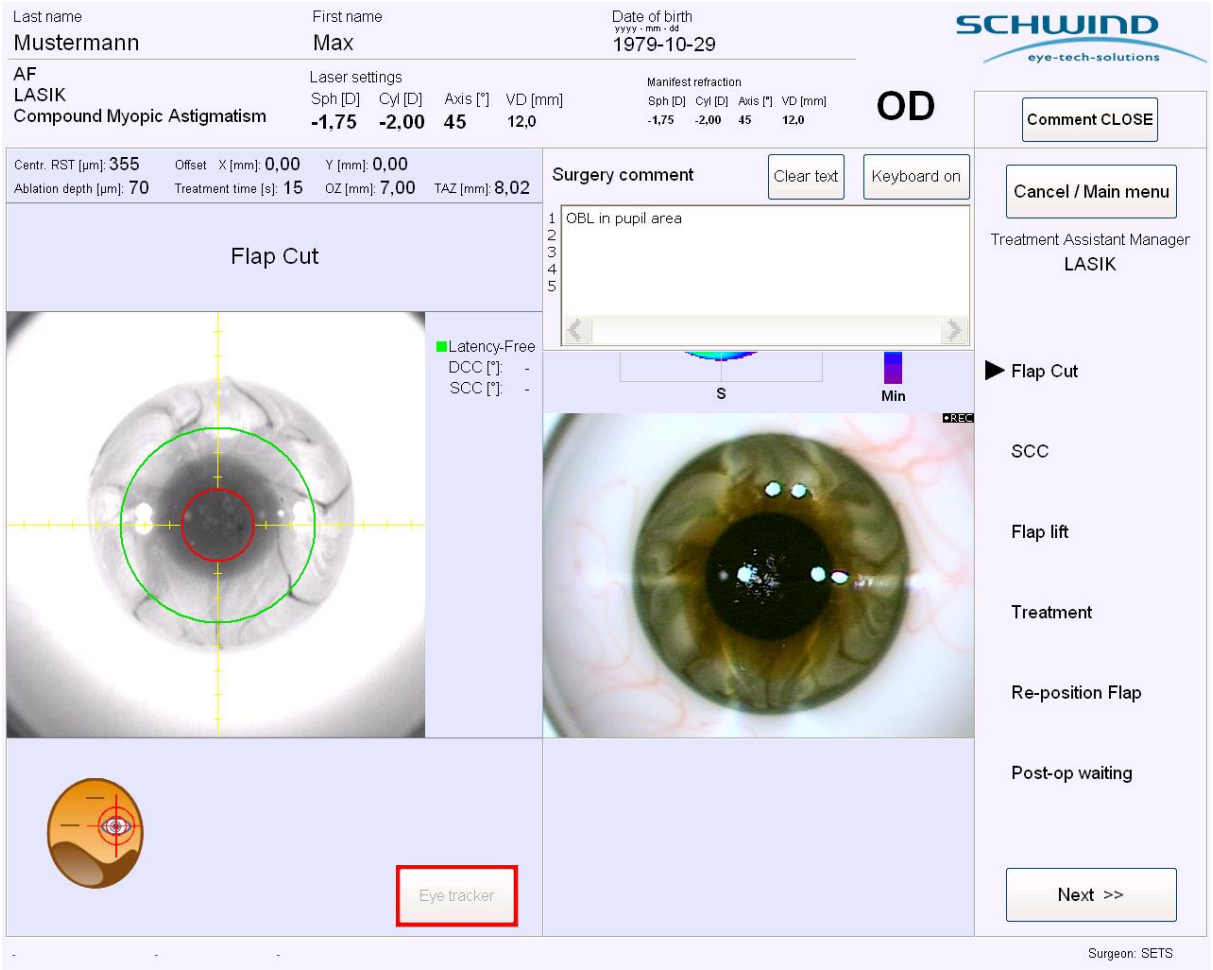


Figure 8-7: Surgery comment

After the treatment has been completed, press the <**Main menu**> button. Now you can print the data.

IMPORTANT NOTE

All transmitted files are labelled with a checksum to avoid transmission errors.

IMPORTANT NOTE

Never remove the storage medium (SD-Card) while data is transferred or during treatment. This may lead to irreparable loss of data. For safety reasons, removal or input of storage media may only be performed in the **Main menu**.

8.4 Recovery Function

In case a treatment was aborted by a technical defect or other reason it can be recovered and continued with the help of the Recovery Function.

The button <**Recovery**> will appear as active as soon as files for a recovery are available. By pressing the button the recovery menu will be opened.

It appears a list of available treatments for recovery and the user can select the treatment to be continued. The maximum number of treatments for recovery is 10.

After the treatment was selected and the button <**Continue Selected Treatment**> was pressed, the application software will start the recovery treatment.

IMPORTANT NOTE

A Recovery treatment is valid for 60h after the abort of the original treatment. After this time it will be deleted automatically from the recovery list.

For a successful recovery of a treatment the actual Fluence value of the AMARIS has to be within +/- 5% of the Fluence level with which the original treatment was performed.

If the original treatment was aborted at less than 5% or more than 95% of treatment progress a message will pop up:

In case the initial treat has used a treatment offset it will also be applicated for the recovery. A new input of a treatment offset will not be possible then.

Treatment Selection

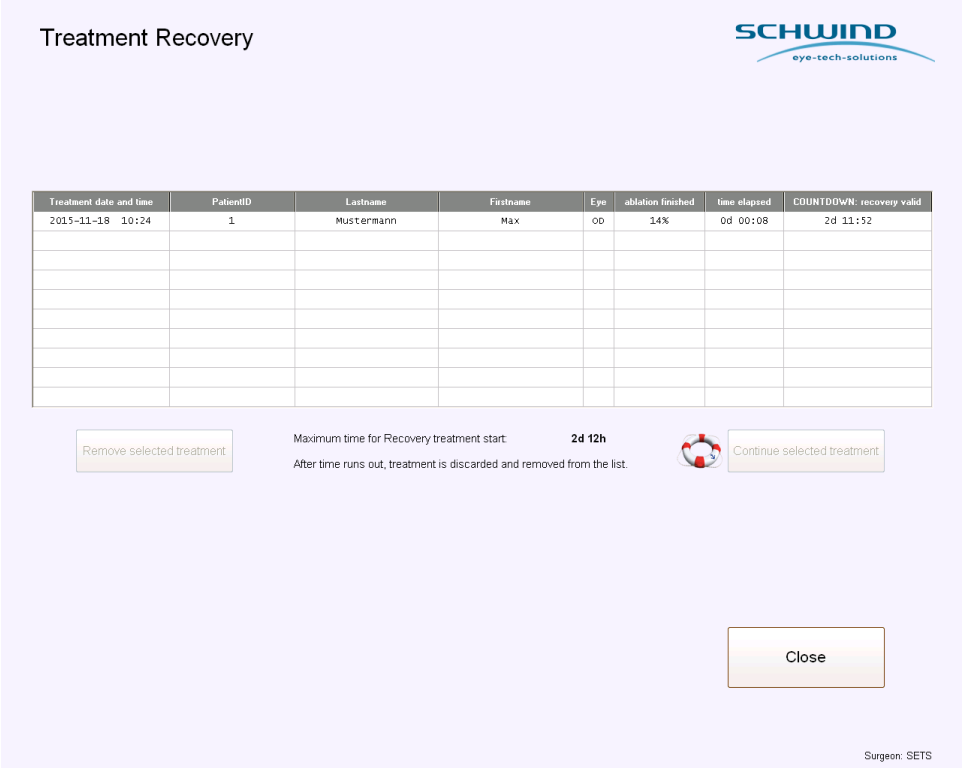


Figure 8-8: Recovery menu

8.5 Eye Tracking

The **EYE TRACKING** is a system, which compensates fast eye movements automatically.

A 1050 Hz eye tracker with simultaneous pupil and limbus detection ensures that even fast eye movements during the ablation process are corrected within 3 ms.

Changes of the pupil center during the treatment are corrected using additional limbus tracking and pupil center shift control (PCSC). Here, the limbus position is not used directly but is used for PCSC and rolling detection. If there is a shift of the pupil center with respect to the limbus due to a change of the pupil size (pupil shift) under different light conditions, it will be automatically compensated. The advantage for the patient: decentration is prevented and no pupildilating medication is necessary prior to treatment. Without the optional 6D Eye Tracking the lateral x-y-movements, seen by the eye tracking system, are calculated with the help of an eye model into eye rolling. The scanner of the system is moved according to this rotation balance with the eye tracker.

In the SCHWIND AMARIS 750S/1050RS models with 6D eye tracking, the rolling of the eye in x and y direction is measured by the tracking system and visualized in the tracking live image.

After the particle aspiration system is brought into treatment position as well as the foot switch is pressed for the first time to start the ablation, the eye tracking initialises and an instant shift of the white meridian lines (if rolling crosshair switched on) and the green crosshair is seen in live image for a short time. It is a normal behaviour and corresponds to the initialisation of the eye-tracker. In case the eye tracking is switched off and on again using the eye tracker button, the eye tracking is initialized in the same way.

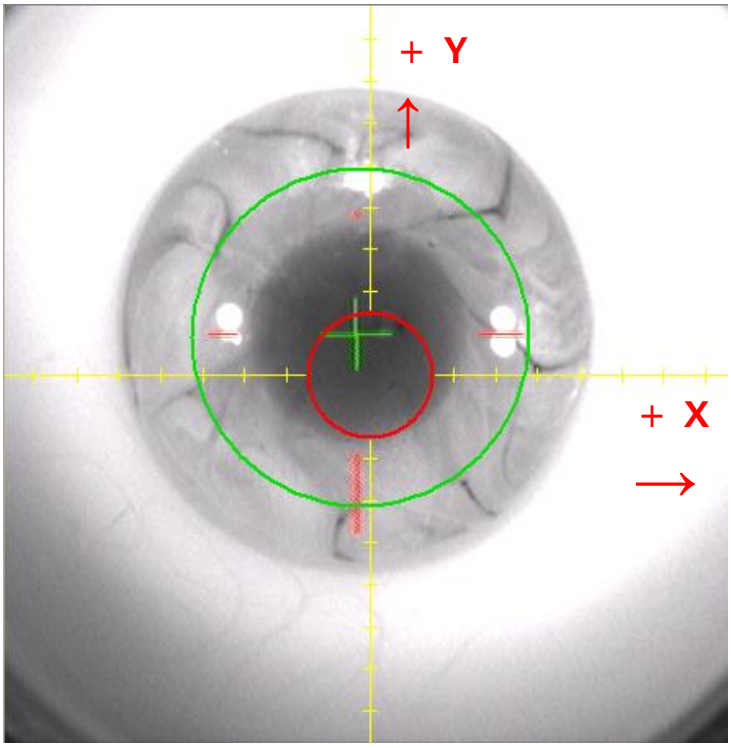


Figure 8-9: Arrangement of the coordinate system for the eye tracker

CAUTION

The arrangement of the coordinate system is displayed in Figure 8-9. Positive values along the x-axis point to the right side of the patient and positive values along the y-axis point in the direction of the patients feet.

The eye tracker calculates the center of the pupil from the live picture. This point of reference is represented on the screen with a **RED CROSS.** The red crosshair indicates the deviation of the pupil center from the center of the beam path by changing the length of its axis.

In case of the asymmetric offset, a **GREEN CROSS** represents the deviation from pupil centre including offsets from Rolling and PCSC (Pupil Center Shift Compensation). The Total Ablation Zone (TAZ) is displayed dynamically as a **GREEN COLOURED CIRCLE** following the position of the ablation center (not displayed) which is equal to the pupil centre (**RED CROSS**).

In case of the symmetric offset, a **GREEN CROSS** represents the deviation from pupil centre including offsets from Rolling and PCSC (Pupil Center Shift Compensation). Here, shift of the **GREEN CROSS** due to a possibly symmetric offset is excluded in this display. The Total Ablation Zone (TAZ) is displayed dynamically as a **GREEN COLOURED CIRCLE** following the position of the ablation center (not displayed) with regard to the pupil centre (**RED CROSS**) and the symmetric offset magnitude of the SCHWIND CAM treatment plan.

Note: In both symmetric and asymmetric offsets the pupil center without Rolling and PCSC is visualized by the **RED CROSS**. The **GREEN CROSS** always denotes the pupil center including offsets from Rolling and PCSC whether the asymmetric or the symmetric offset strategy is selected and does not change its position independently on the offset selection. The offset strategy has an influence on TAZ display within the eye tracker live screen.

Treatment Selection

The display of the **GREEN COLOURED CIRCLE**, **GREEN CROSS** and **RED CROSS** follows the eye movements when eye tracking is active.

The position of the green cross may be different than the position of the **RED CROSS** during treatment, even without entering a treatment offset, due to a possible rolling compensation or because of compensated shifts of pupil center during ablation.

A beam guidance system inside the beam path of the laser steers the excimer beam exactly to the required ablated position. If the ablation center (marked with a **GREEN CROSS**) moves too far (+/- 1.5 mm) away from the center, the system interrupts the treatment.

A message **"pupil is not in hot zone"** will be displayed on the screen, indicating that the patient should fixate again, and asks if the eye tracking should be switched off. If the picture of the pupil is blurred, it is possible that the eye tracker cannot find it.

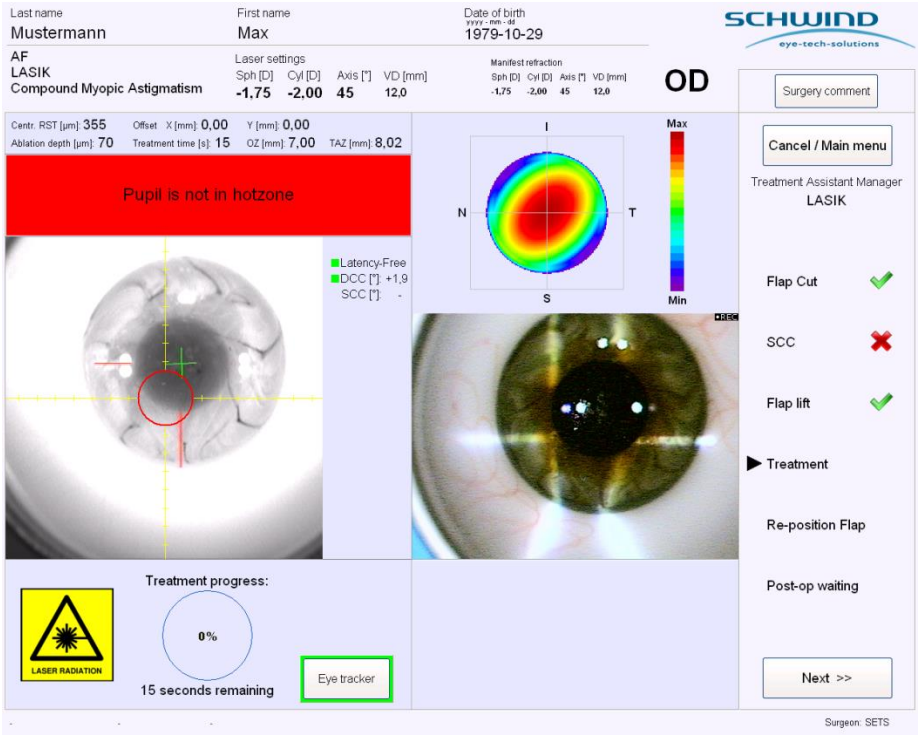


Figure 8-10: Pupil is not in hot zone

IMPORTANT NOTE

During Eye Tracking initialisation the full pupil and limbus have to be visible in the eye tracking image. The focus of the excimer laser shall be adjusted and the patient must fixate. The image should not be influenced by artefacts like opaque bubble layer or bubbles in anterior chamber after cut in Femto-LASIK, draping or other surgical instruments.

After initial eye tracking initialisation and before starting the laser ablation by pressing the foot switch, please subjectively check the correct position of the green cross. It should be located at the pupil center.

The hot zone is marked with a **RED CIRCLE** in the live video.

Treatment Selection

The software releases the laser for treatment only if the **GREEN CROSS**, which marks the center of the ablation, is within the range of the **RED CIRCLE.**

IMPORTANT NOTE

If the eye tracking is active, the <**Eye Tracker**> button is surrounded by a **green border**.

If there is a bad tracking signal or the pupil is out of the eye tracking range, the button will be surrounded by a **red border**. The laser treatment is interrupted.

As soon as the center of the pupil can be detected again or is again in the treatment area with the foot switch pushed, the treatment continues immediately from the interrupted position.

Very short interruptions in the way of milliseconds are barely noticeable; merely the sound of the laser pulse may change slightly.

It is possible to switch OFF the eye tracking completely during the treatment by pressing the <**Eye tracker**>button. A message will appear in which the user has to confirm the deactivation of the eye tracking system. The eye tracker may be switched off in cases when the eye pupil is irregularly shaped, i.e., it is non-round and therefore, its detection becomes not possible. For example, it may be difficult to detect the pupil, or maybe it is not clinically advisable, of patients with congenital or gained eye defects, etc, coloboma of the iris. Please note, that the detection of the pupil is possible if the pupil diameter varies in the range between 1,5 mm and 8,5 mm. If the pupil diameter is less than 1,5 mm or exceeds 8,5 mm, a corresponding message appears informing about the pupil not being found (see Figure 8-11).

Figure 8-11: Message "Pupil not found"

For all the aforementioned cases, when the eye-tracker is switched off, the user should ensure a proper centration and a stable monitoring of the patient eye. For a centration reference the surgeon may use the red circle seen in the live image of the eye tracking infrared camera on left side of the AMARIS treatment screen (Figure 8-9).The patient pupil and the red circle must be concentric to each other during the whole ablation.

WARNING

Incorrect treatment results!

Opaque bubble layers or bubbles in anterior chamber caused by femtosecond laser application, iris naevi, etc. located in the pupil area or surgical instruments covering the limbus area may have negative influence on the successful and correct eye tracking initialisation. Please check and confirm the correct initialisation subjectively and restart the tracker manually, if necessary. Please take into account that in this case the pupil center will be found as a new value and may differ from the previously measured value. Therefore, it is recommended first to check that the infrared reflections and the pupil are not covered.

IMPORTANT NOTE

If the eye tracking system was switched off during the treatment, pressing the <**Eye Tracker**> button again can reactivate it.

The system will then start to measure the eye position again. If the Eyetracking is active, the eye tracker button will be surrounded by a **green border**.

If the eye tracker cannot recognize the pupil and must be deactivated, the aiming laser can be used for centration of the patient (refer to chapter 4.5.2, Aiming Laser, for detailed description).

It is also possible to center the pupil to the yellow cross in the eye tracker live video.

8.5.1 Eye Tracking Coordinates Orientation

The orientation of the values displayed in the diagrams is explained in Figure 8-12: Eye tracking orientation.

- With reference to eye tracking center (black colour)
- With reference to the patients eye (red colour)

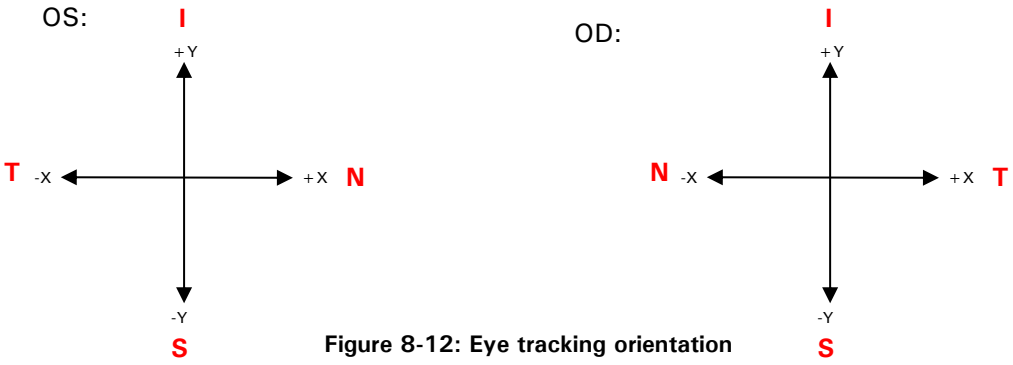


Figure 8-12: Eye tracking orientation

IMPORTANT NOTE

Orientation for DCC and SCC Values:

- Positive numeric value → rotation counter clockwise
- Negative numeric value → rotation clockwise

8.5.2 Eye Tracking Quality

To avoid problems with the **eye tracking** system during ablation, there are some parameters the user should check before pressing the footswitch of the excimer laser.

There are two variants for the infrared illumination of the AMARIS:

1) Version with six LEDs (until May 2022):

The infrared illumination for the AMARIS eye tracking system is provided by **six (6)** LEDs located at the bottom side of the laser arm (Figure 8-13).

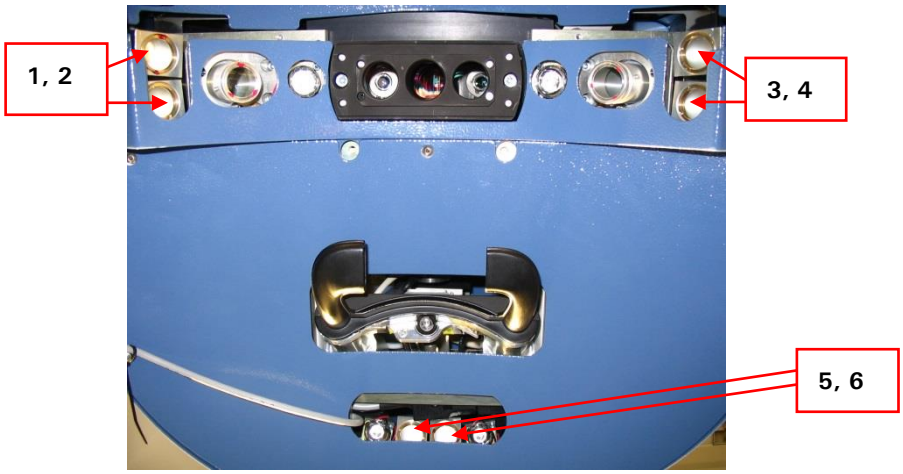


Figure 8-13: Infrared LEDs for eye tracking system (until May 2022)

2) Version with four LEDs (starting June 2022):

Starting in June 2022, the AMARIS is provided with improved IR-illumination-LEDs. Instead of **six** IR-LEDs only **four** IR-LEDs are necessary for functional and reliable eye-tracking. The irradiance of the IR-illumination is the identical value as the previous version.

The infrared illumination for the AMARIS eye tracking system is provided by **four (4)** LEDs located at the bottom side of the laser arm (Figure 8-14).

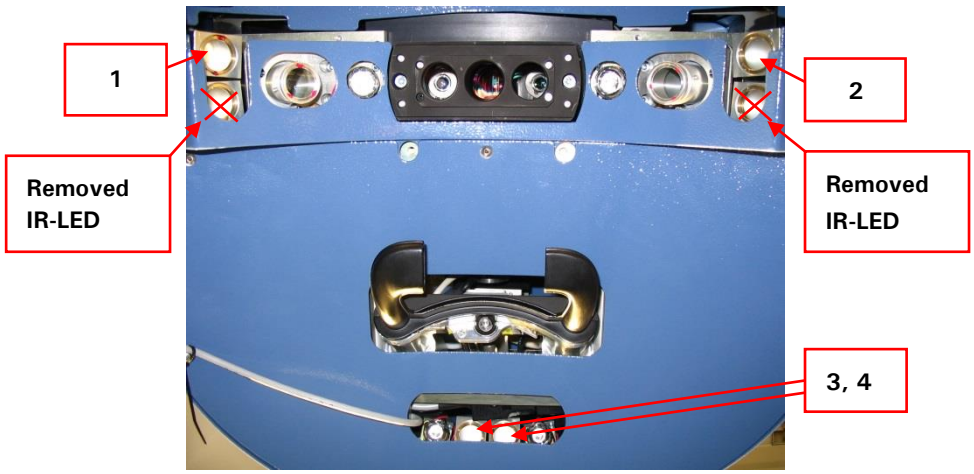


Figure 8-14: Infrared LEDs for eye tracking system (starting June 2022)

The internal eye tracking camera of the AMARIS excimer laser detects the infrared light reflected from the cornea and generates the eye tracking live image needed for pupil, limbus and cyclotorsional detection.

IMPORTANT NOTE.

Covering or blocking the light from some or all infrared LEDs during the treatment may influence the quality of the eye tracking image.

During treatment, some of the infrared LEDs may be blocked due to various reasons such as:

- **Prominent nose of the patient**
- **Improper positioning of the patient's head**
- **Surgical draping during the procedure.**

This results in decreased quality of the eye tracking image and may cause, in worst case, unnecessary longer treatment times than expected since the laser may stop for a short moment if the quality of the live image is insufficient.

Furthermore, a bad contrast image might have an influence on the limbus detection, as well as on static and dynamic cyclotorsional controls.

IMPORTANT NOTE.

We kindly ask to check the quality of the eye tracking live image before pressing the foot switch to ensure a secure and uneventful treatment.

An extended treatment time of more than 10 seconds (e.g. the center of ablation goes outside the hot zone) may cause dehydration and result in over-ablation. Shorter extended treatment times should not have relevant clinical effects as cornea thinning or overcorrection.

The quality of the eye tracking image can be checked by the user before the surgery by checking if all infrared reflections from the LEDs are visible in the eye tracking live image, as displayed in the following figures.

Treatment Selection

1) Version with six LEDs (until May 2022):

In a good quality live image (Figure 8-15) all six infrared LEDs, forming three reflection areas, each consisting of two reflections from the LEDs, are visible. Sometimes the two neighbouring reflections melt into one slightly larger and typically oval reflection.

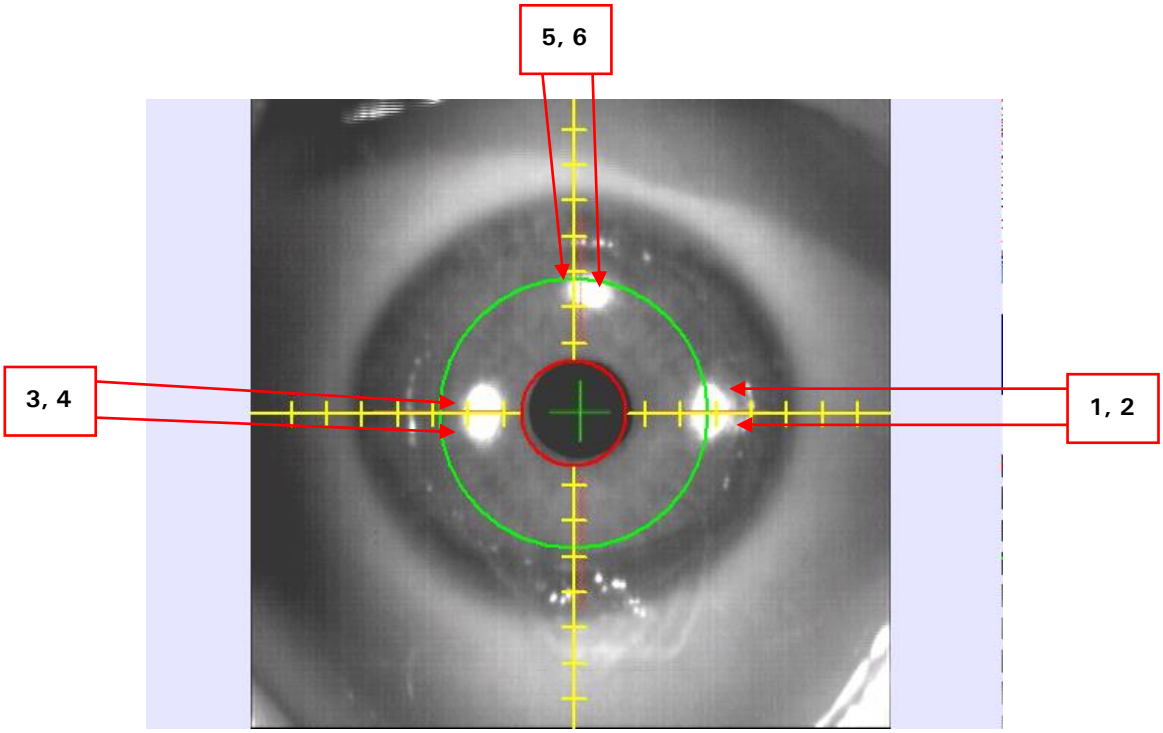


Figure 8-15: Good eye tracking contrast (until May 2022)

Although the reflection of LED no.1 is weakened, there are six reflections visible on the cornea and the live image has a good contrast.

IMPORTANT NOTE.

At least **four (4)** out of the six infrared reflections have to be visible in the live image to ensure good image quality in a 5D tracking version. In a 6D tracking version all reflections have to be visible.

Treatment Selection

Bad quality live images (Figure 8-16) can be recognized, because there are less than four infrared reflections visible on the cornea and the overall contrast of the image is bad.

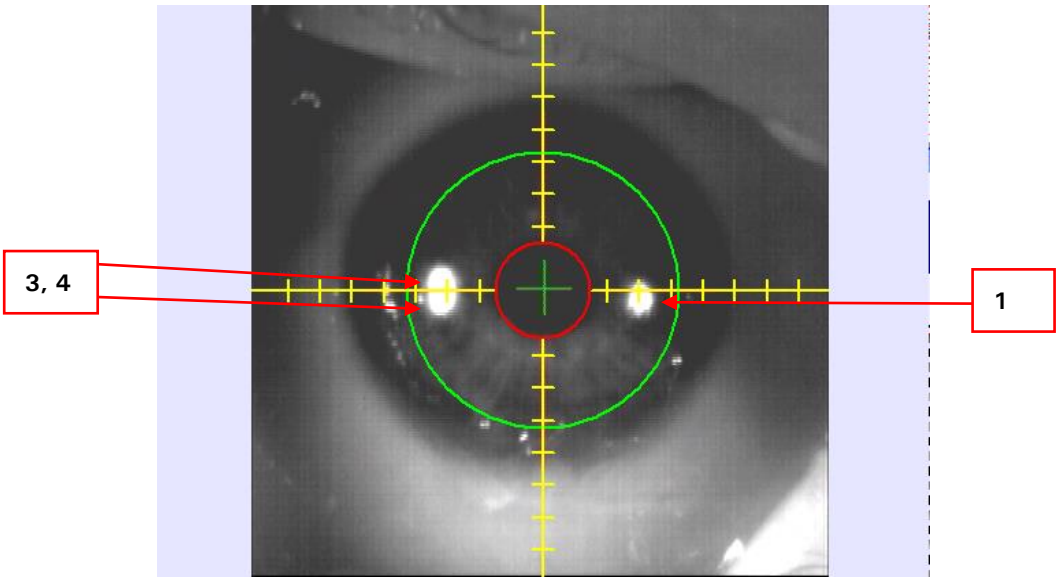


Figure 8-16: Poor eye tracking contrast (until May 2022)

2) Version with four LEDs (starting June 2022):

Within a good quality live image (Figure 8-17), all four infrared LEDs are represented in three reflection areas. The side reflections are represented by one LED on each side and the rear reflection area consists of two reflections from the LEDs (no.3 and no.4).

Sometimes the two neighbouring reflections merge into one slightly larger, and typically oval, reflection.

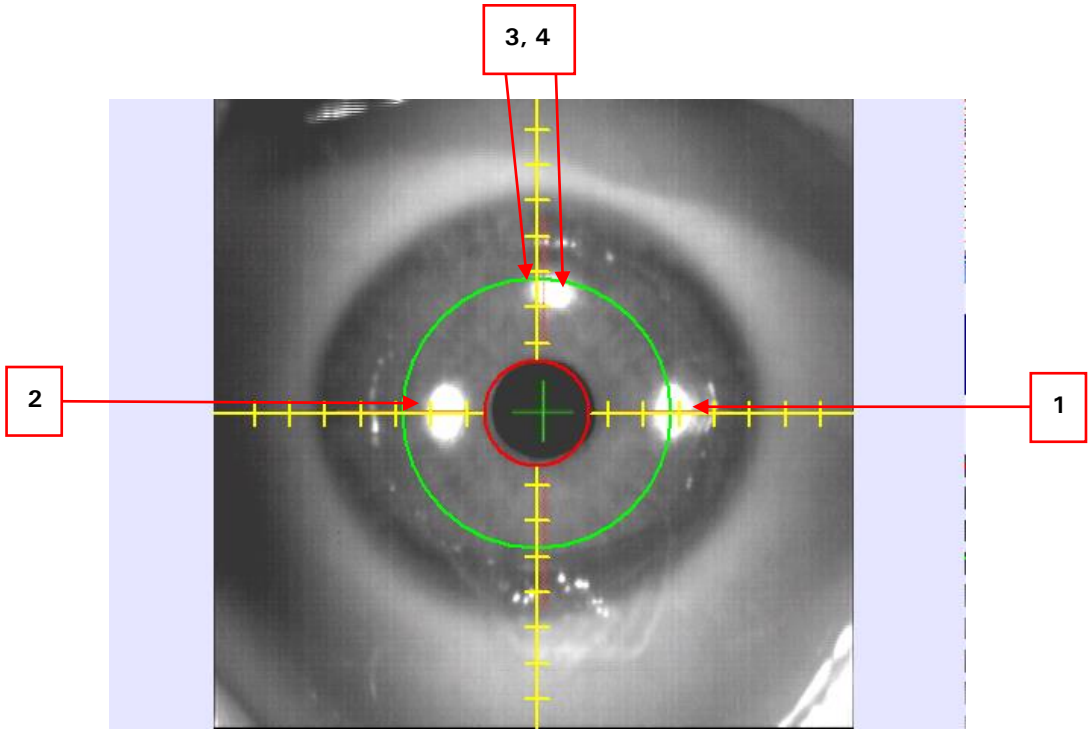


Figure 8-17: Good eye tracking contrast (starting June 2022)

Although the reflection of LED no.3 and/or no.4 is weakened, there are reflections visible on the cornea and the live image provides a good contrast.

IMPORTANT NOTE.

At least **three (3)** out of the four infrared reflections have to be visible in the live image to ensure good image quality in a 5D tracking version. In a 6D tracking version all reflections have to be visible.

Bad quality live images (Figure 8-18) can be recognized, because there are less than three infrared reflections visible on the cornea and the overall contrast of the image is poor.

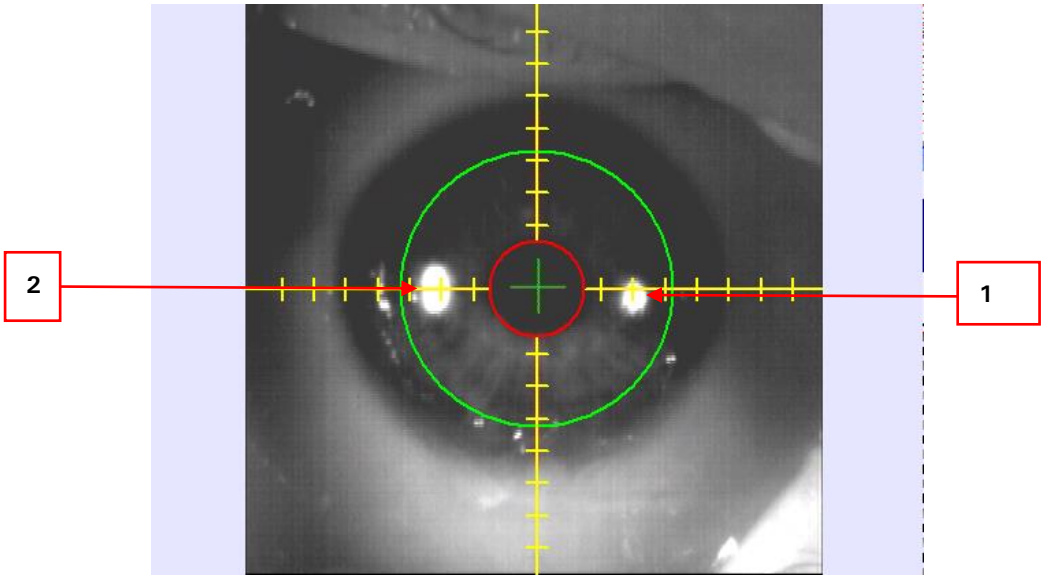


Figure 8-18: Poor eye tracking contrast (starting June 2022)

IMPORTANT NOTE.

In case of a bad eye tracking live image, the user should check the position of the patient's head or the surgical draping to minimize the effect on the infrared illumination.

8.5.3 Static Cyclotorsion Control

The **eye tracker** has the possibility to compare the patient's eye with reference images taken during the diagnosis with the Corneal Wavefront Analyzer Keratron Scout, SCHWIND SIRIUS or SIRIUS+, SCHWIND PERAMIS, or SCHWIND MS-39, in order to acquire the cyclotorsional offset of the eye between the diagnosis and treatment. The pupil size shall not differ more than 30% compared to the diagnosis image. The resulting angle is automatically calculated into the ablation profile. This correction of the cyclotorsional movement of the eye between upright and supine position of the patient is called Static Cyclotorsional Correction (SCC).

The static cyclotorsional measurement is started with pressing the button <**Start SCC**> which appears below the eye tracking live image if the Treatment Assistant Manager is at the Step SCC (Static Cyclotorsional Control).

Treatment Selection

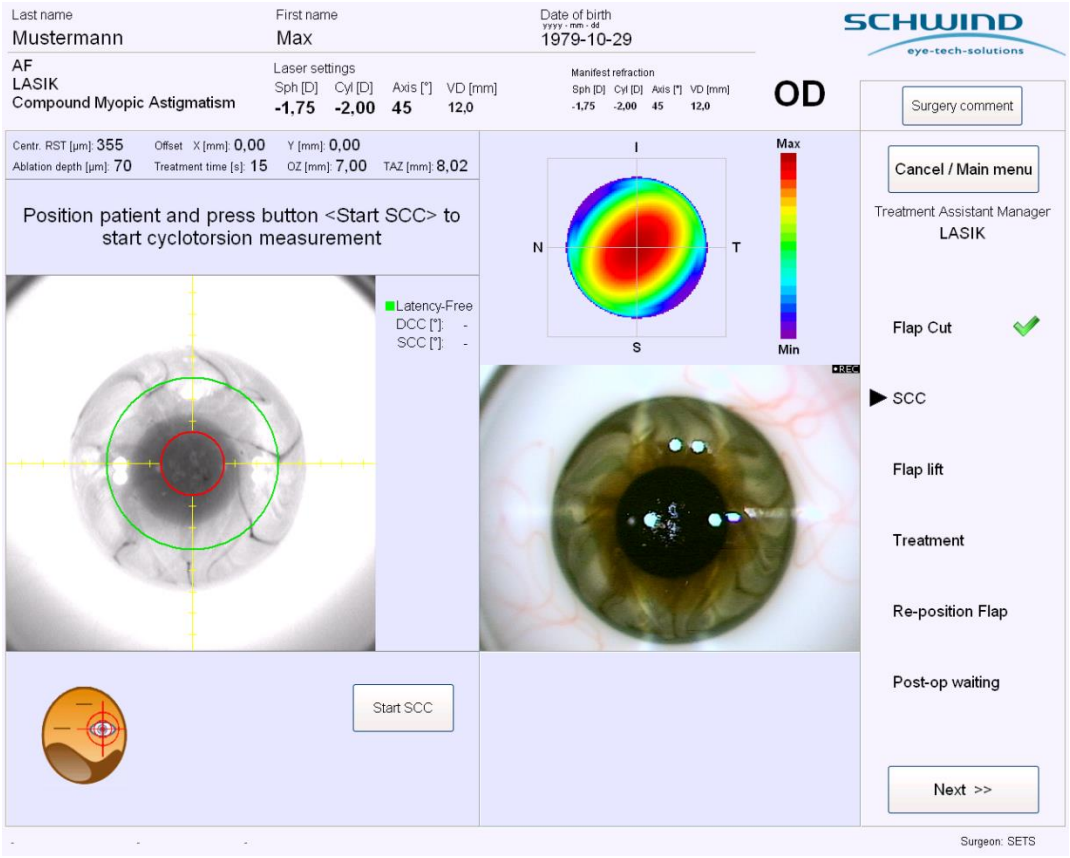


Figure 8-19: Static Cyclotorsional Correction

If the pupil size between reference image and eye tracking live image differ too much from each other, the **Automatic Pupil Size Control** of the AMARIS will adjust the surgery illumination of the laser automatically until the pupil size is equal.

If necessary the positioning slits and the red aiming laser will be switched off also but turned on again after the measurement was successful or if it was aborted by the user.

IMPORTANT NOTE

To ensure correct operation of the Automatic Pupil Size Control, it is recommended to dim the lights in the operating room and not to administer dilating eye drops.

If the patient's eye is not correctly centered, a message appears above the eye tracking live image telling in which direction the patient should be moved to acquire a proper image. The SCC measurement starts automatically as soon as the eye is within correct range of position. In case the message „Pupil not found“ is displayed, make sure that the pupil is centered and visible for the eyetracker and start the SCC measurement again with click on the button “Start SCC”.

As a result of this measurement, a report is displayed in which the reference image, taken at the diagnostic device workstation and the actual image, taken by the eye tracker, are displayed.

The measured cyclotorsion is displayed below these images. The user has the possibility to accept the measured torsional angle, to cancel the measurement or to start a new measurement.

Treatment Selection

If the measured static cyclotorsional angle is accepted the ablation profile will be rotated accordingly and the value of the angle is displayed in the **SCC** field above the eye tracker live image. The cyclotorsional angle is considered to be positive when counter clockwise.

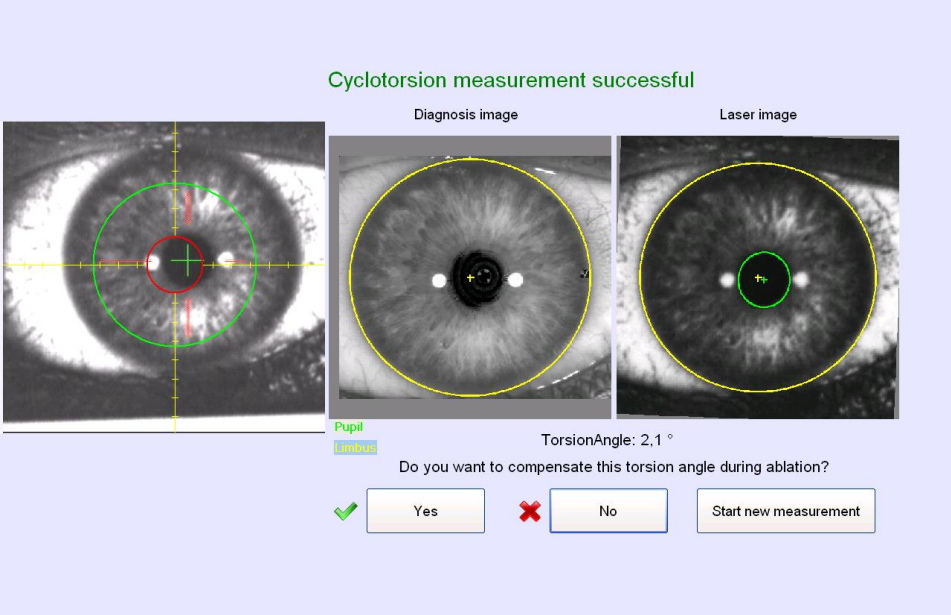


Figure 8-20: Result – Static Cyclotorsional Correction

IMPORTANT NOTE

Orientation for DCC and SCC Values:

- Positive numeric value → rotation counter clockwise
- Negative numeric value → rotation clockwise

In case the measured cyclotorsional angle is larger than 5° there is an additional message displayed which asks to repeat the measurement in order to confirm the result.

If the result of the new measurement differs not more than +/- 2.5° from the original result the measurement can be accepted. If the difference is larger it is recommended to discard the result and to proceed with the treatment without SCC.

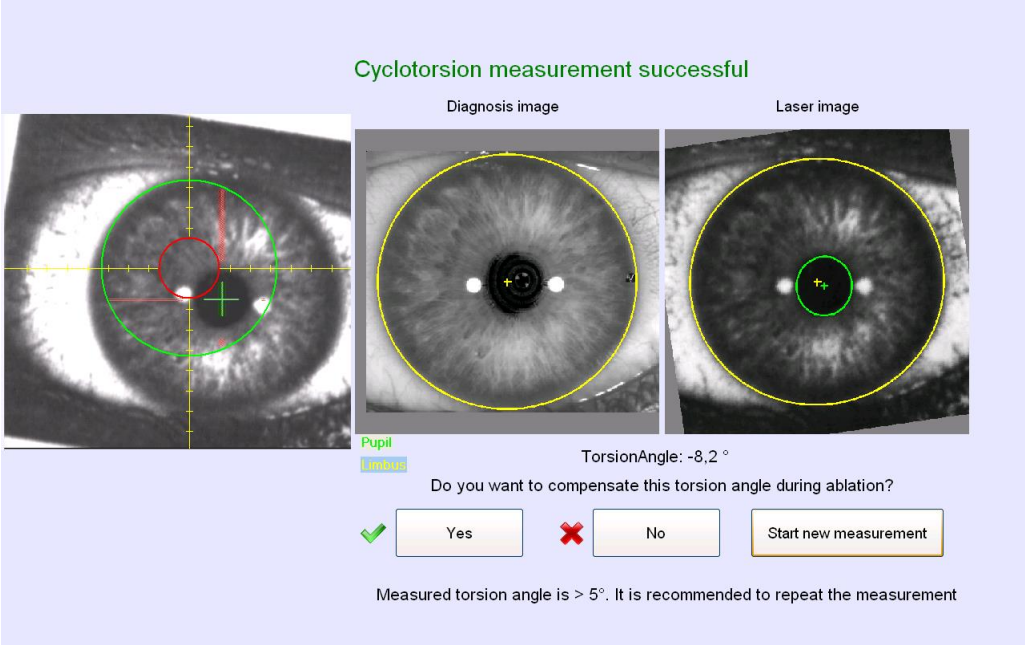


Figure 8-21: SCC result bigger 5°

IMPORTANT NOTE

If a new measurement is started and the patient's eye is no longer in the correct position, the algorithm will return to the treatment menu of the AMARIS Application software and will display a message above the eye tracking live image, indicating in which direction the patient should be moved to acquire a proper image.

As soon as the eye is in the correct position, the measurement will be continued automatically.

Treatment Selection

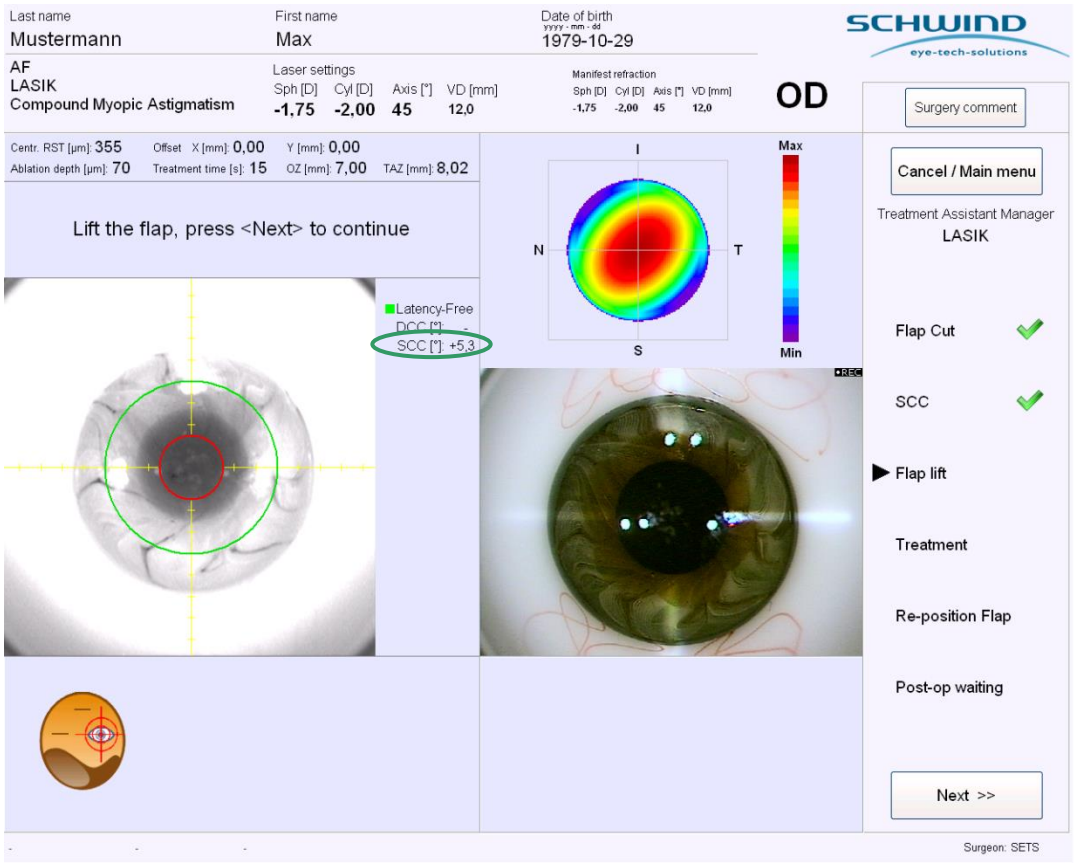


Figure 8-22: Result – Static Cyclotorsional Correction

IMPORTANT NOTE

The measurement range for the Static Cyclotorsional Correction is ± 12.5 degrees.

The SCC measurement is based on significant points in the upper part of the human eye, for example blood vessels or structures of the iris.

It means the AMARIS system starts to search from the edge of the pupil to the periphery of the iris including the limbus. The eye tracker searches for each significant reference point in the measurement range.

If those points are similar to OD and OS the SCC measurement can still provide an offset angle. This is NORMAL.

Please note that the SCC measurement can't be used to detect the correct eye.

To proceed with the treatment procedure after the static cyclotorsion measurement was successful, please lift the flap now and bring the particle aspiration system into treatment position.

8.5.4 Dynamic Cyclotorsion Correction

The cyclotorsional movement of the eye during the surgery is corrected with the Dynamic Cyclotorsional Correction (DCC). A reference image is captured by the eye tracking system at the beginning of the ablation process.

During the procedure the eye tracker captures images of the iris and blood vessel structures in the sclera, calculates the amount of cyclotorsion and corrects the profile accordingly. This process is called Dynamic Cyclotorsional Correction (DCC).

The reference image for the Dynamic Cyclotorsional Correction is taken when the eye tracker is initialized for the first time, shortly before the ablation in the **Treatment** step of the Treatment Assistant Manager. The Dynamic Cyclotorsion Control starts automatically.

IMPORTANT NOTE

The flap lift should be performed directly after the static cyclotorsion measurement was completed and before the particle aspiration system is brought into treatment position to ensure correct initialization of the DCC function.

The time frame between Static Cyclotorsional Correction and initialization should be as short as possible to avoid unnecessary dehydration of the eye and to ensure correct initialization of the DCC function.

If the eye rotates during the treatment the profile will be rotated accordingly. The measured and corrected cyclotorsional angle is displayed in the **DCC** field on the right side the eye tracker live image. For reliable DCC measurement the limbus diameter shall be within the range of 10.0 ± 0.2 mm – 13.6 ± 0.2 mm and the pupil diameter shall be within the range of 1,5 mm – 6 mm ± 0.2 mm. After Start of the DCC measurement, the pupil size shall not change more than 30%.

In addition, the green cross, which indicates the ablation center in the eye tracker live image, will be rotated to show that a dynamic cyclotorsion is measured.

If the Dynamic Cyclotorsion Correction cannot calculate an angle, due to missing structures or exceeding the measurement range, the last measured angle will considered for the treatment but will be decreased to 0 degrees if no new valid torsion angle can be measured.

If during an AMARIS treatment the eye-tracker is switched off, then the SCC and the DCC information will be lost/ignored and the treatment will continue without any SCC or DCC compensation. If later on during the same treatment the eye-tracker will be turned on again, the original SCC value will be used to compensate and the DCC will start with the new reference from the moment of turning on the tracker again.

The green crosshair then rotates back to 0° in this case. If a valid DCC angle can be captured again this value will be considered for the treatment.

IMPORTANT NOTE

The measurement range for the Dynamic Cyclotorsional Correction is approximately ± 7°.

Depending on the quality of identifiable structures this can vary between ± 6° to ± 8°.

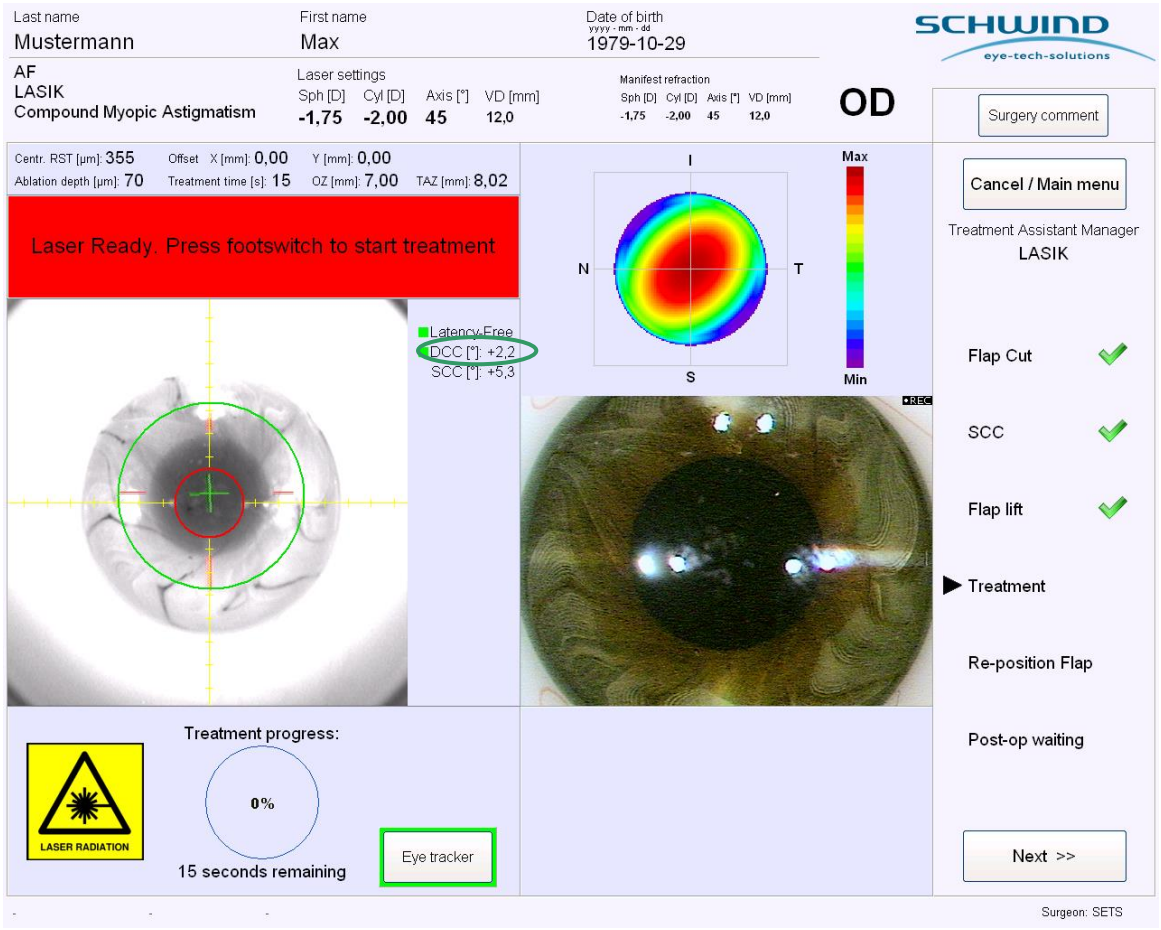


Figure 8-23: Result – Dynamic Cyclotorsional Correction

An AMARIS system can be ordered with one or both of the features. If both features are included, the laser is equipped with Advanced Cyclotorsional Correction (ACC).

8.5.5 Manual Treatment Offset

If no numeric treatment offset was input in the SCHWIND CAM software during treatment planning and an Aberration-Free or PTK treatment is performed it is also possible to use the aiming laser to teach-in an offset by using the arrow keys on the control panel. The aiming laser moves in 10μm increments in the respective direction of the pressed key.

It is still possible to input the **manual treatment offset** after the debris removal system has been brought into surgery position and the eye tracking has initialised.

After having started the ablation (foot switch was pressed), it is no longer possible to enter or to change manual treatment offsets.

Treatment Selection

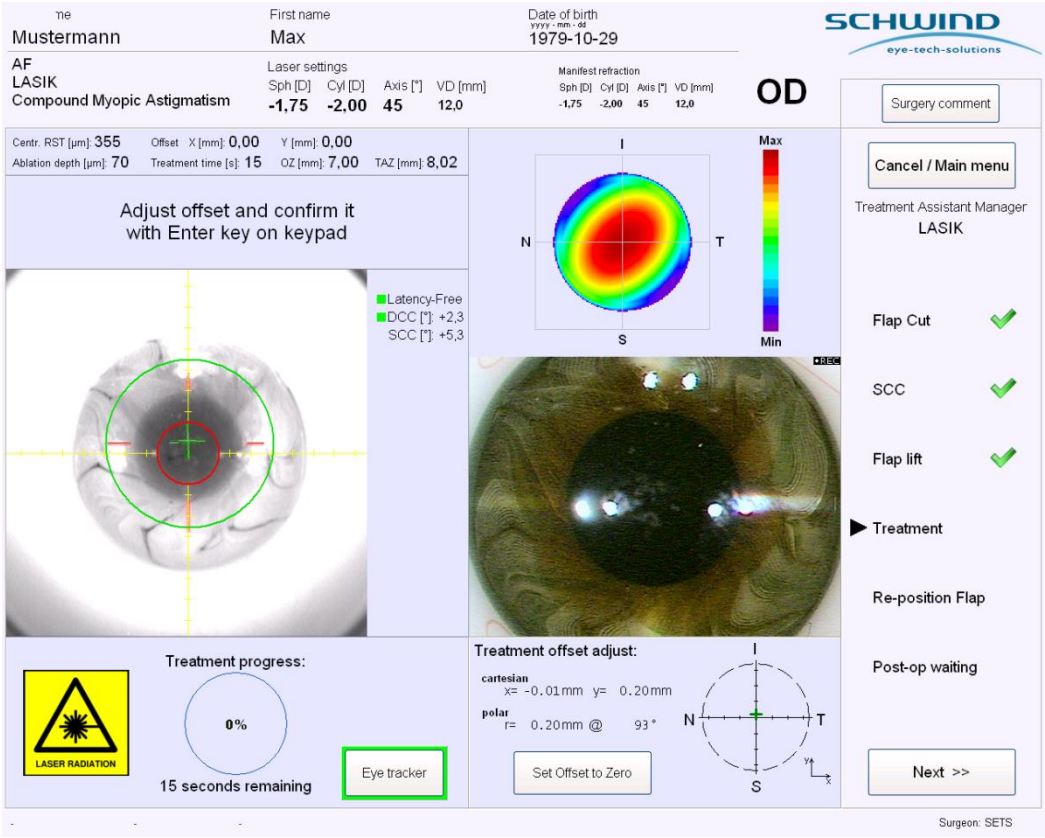


Figure 8-24: Manual treatment offset input

While adjusting the **manual treatment offset** the actual offset value will be shown in a separate window which pops up at the lower right part of the treatment menu. It will be shown in both cartesian and as well in polar coordinates.

This input must be additionally confirmed after conclusion of the procedure by pressing the **<Enter>** button on the control panel. If the manual treatment offset is taught in, the values will be displayed above the eye tracking live image in the treatment screen of the AMARIS Application software.

The **manual treatment offset** can be set back to zero by pressing the key **<remove manual treatment offset>** on the control panel at the laser arm in the middle of the arrow keys or by pressing the button **<Set offset to Zero>** in the offset window which pops up during adjustment of manual treatment offset. This is only possible as long as the ablation has not been started.

IMPORTANT NOTE

For customized treatment it is not possible to enter a manual treatment with the arrow keys.

Numeric treatment offsets in the SCHWIND CAM can be applied for all types of treatments including customized ablations.

IMPORTANT NOTE

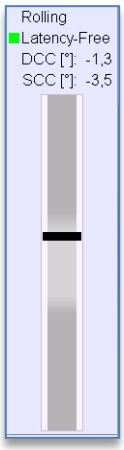
The **GREEN CROSS** remains visible and symbolizes the center of the ablation. The **RED CROSS** shows the center of the pupil.

In chapter 8.5.1 the orientation of the coordinates is explained.

8.5.6 6D Eye Tracking

For the AMARIS / AMARIS 750S and AMARIS 1050RS a **6D Eye Tracking** functionality is optionally available. In addition to the standard 5D Eye Tracking system which actively compensates for lateral movements (vertical and horizontal displacements, 1st and 2nd dimension), Rolling movements (caused by a tilting of the head or of the eye, 3rd and 4th dimensions) and rotations around the visual axis (static and dynamic cyclotorsion, 5th dimension) the 6D Eye Tracking will also actively compensate for displacements of the eye along the z-Axis. The Z-Tracking information will be displayed in form of a slider on the right side of the eye tracking live video during treatment. Additionally rolling movements of the eye will be visualized optionally by white meridian lines inside the eye tracking live video.

The hot zone in z-direction (altitude) is +/- 1,5mm. In case the altitude of the cornea is out of the hot zone range, the ablation will be interrupted and followed by a message informing about the position being out of the hot zone range. The 6D tracking option may be disturbed by a change of recognisability during the ablation, for example by covering partly the patient eye by a sponge for hinge protection. In case the Eye Tracker fails to recognise the z-position of the eye, the ablation proceeds with the last valid z value, i.e., the last recognisible value. In this case the colour of the slider changes to grey (see Figure 8-25). If afterwards the altitude of the patient eye is recognised again, the ablation is proceeded with a new valid value. The same scenario is also valid for eye rolling, i.e., the coverage of the eye will result in the use of the last valid values for the 3D, 4D and DCC tracking options.



The circular LASIK sponges are also not recommended during the treatment because the inner edge of the sponge may be detected as limbus. Moreover, wrong pupil centroid shifts can be detected.

Figure 8-25: Z-Tracking slider

IMPORTANT NOTE

The display of the white meridian lines which visualize rolling movements can be activated or deactivated in the general settings of the AMARIS Application software.

Treatment Selection

Figure 8-26: Treatment screen with 6D Tracking (exemplary illustration)

IMPORTANT NOTE

To achieve a good 6D Eye Tracking quality a successful limbus and iris recognition is very important. At least 80% of the limbus and the iris have to be detected.

Too intensive hinge protection may have an influence on the tracking quality.

IMPORTANT NOTE

For the rolling and z-axis detection nasal and temporal tracking information is more important, therefore nasal hinges may have an influence on the rate of successful 6D information detection.

The 6D Tracking may be lost in case of a nasal hinge. Standard pupil tracking will be always available and the treatment can be performed.

8.5.7 7D Eye Tracking (Latency Free Tracking)

As an unique feature of the SCHWIND AMARIS 1050RS the functionality of 7D Eye Tracking is implemented here to compensate for the eye tracking system latency.

The AMARIS eye tracking system is a very fast image processing system with a camera frame rate of 1050Hz. However, it takes up to **3 ms** to process each image and settle the scanners to the correct position. Within this time the patient's eye may move further on.

With increasing Repetition Rates from the LASER systems the effect of this delay is even magnified, as an increased number of shots will be placed wrongly. It is clear that if the cornea is static or if the delay time approaches zero then no negative effects would be expected. Nevertheless, in the real case, moreover considering also the nature of the different eye movements, the 7D tracking functionality is a good possibility to minimize those errors.

On the basis of known eye positions at earlier time points during treatment, a mathematical model estimates where the eye will be in the future (for following pulse), and the scanners are already sent to (or close to) that position. This virtually enables a latency-free ablation process.

In essence, some past measured values are utilized and processed with simple mathematical operations to give an estimate of the future eye positions.

At the time of receiving eye-tracking information (which actually corresponds to the past, because of eye-tracker latency), AMARIS already knows after which time interval and to which corneal locations the next pulses are planned to be triggered.

There are several future eye positions calculated. When this is done, the system checks how long time until the very next pulse must be triggered. The scanners will be sent to this position, and wait there idle for the trigger signal, and immediately thereafter the scanners will be sent to the calculated position for the next pulse. Then new eye tracker data are collected and the process is repeated iteratively.

Thus, the eye position for each pulse will be calculated at least 2 times (and 1 time confirmed from the past), yet should the newest position be available just short time before the next pulse shall be triggered (shorter than the latency time of the scanning system plus laser source), then the system does not request an update of the scanner positions, and the scanners remain on the previously calculated position for this pulse.

IMPORTANT NOTE

The 7D tracking functionality will effect all other 6 dimensions in form of a real time offset.

8.6 Online Coherence Pachymetry (OCP)

For the measurement of the corneal thickness during the treatment, an Optical Coherence Pachymeter is optionally integrated in the AMARIS excimer laser.

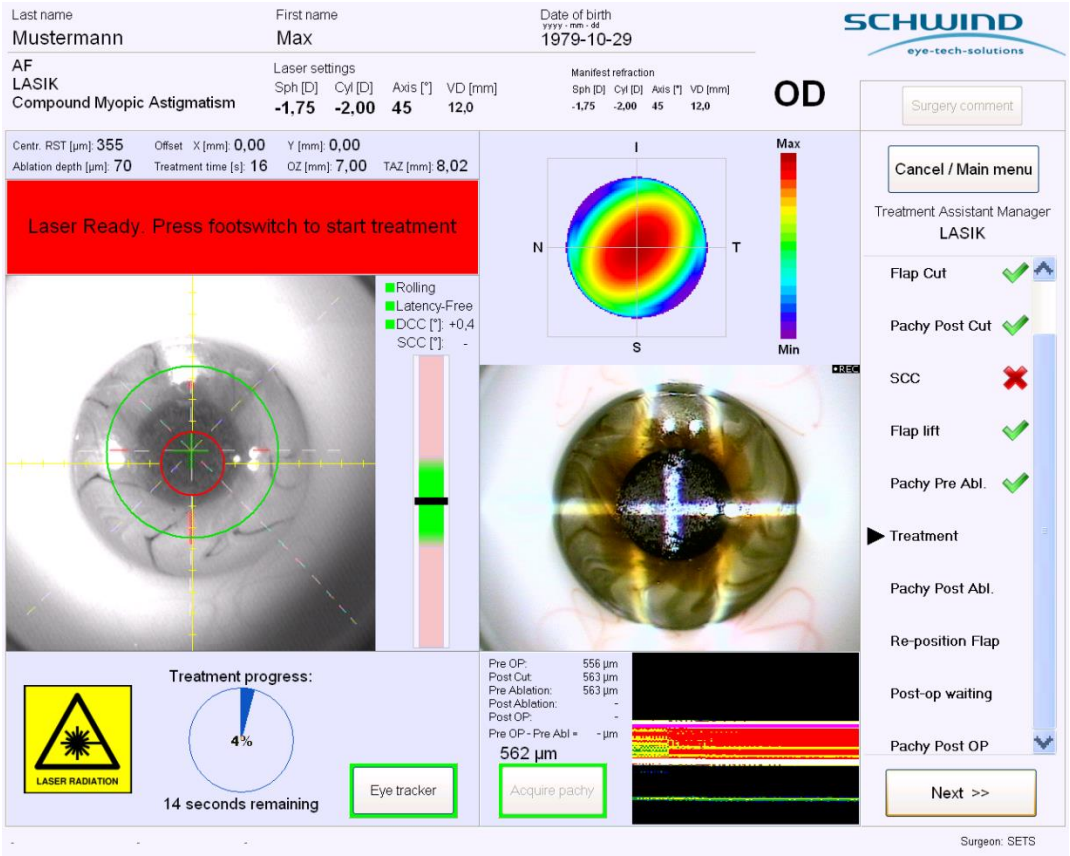


Figure 8-27: Online Coherence Pachymeter

The section for displaying the measured corneal thickness and the raw signal from the OCP in the treatment screen of the AMARIS Application software is on the right side of the screen just below the live video image.

The values are updated with a frequency of 1 Hz and a summary of all measured values during the treatment appear on the treatment printout in the form of a diagram.

Steps for pachymetric measurements during the treatment can be defined in the Treatment Assistant Manager. To save the pachymetric values during these steps, the **<AquirePachy>** button has to be pressed or the measurement will be saved automatically if the step is defined as auto under Auto Mode in the treatment Assistant Manager. (Please refer also to chapter 7.5 Treatment Assistant Manager for detailed information).

During the treatment the system will additionally save a pachymetric value every second. These values are displayed in the form of a diagram on the treatment printout after the laser treatment.

The Online Coherence Pachymeter is ready for measurement and displays the corneal thickness values automatically when the patient eye's lateral position is centred and in focus. (Please see to adjust to the correct focal point).

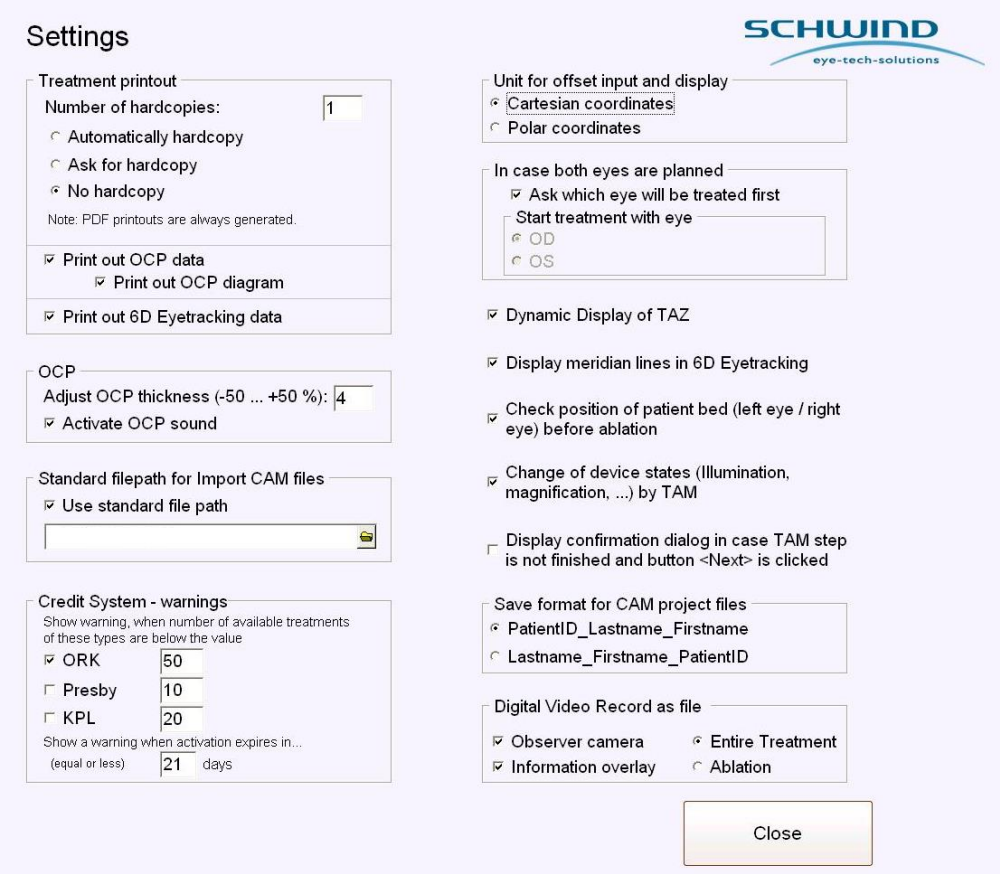


Figure 8-28: Online OCP setting in the Settings menu

In the **Settings** Menu of the AMARIS Application software the following **Settings** for OCP can be defined:

- **Adjust OCP Thickness**
  - The displayed value for the measured corneal thickness can be changed with this option to make the displayed value equal to other devices. (E.g. ultrasound pachymetry). The displayed value can be adjusted by entering a positive or negative percentage between +50% and -50%.
  - By default this value is set to +4%
- **Printout OCP Data**
  - The user can define here whether the printout contains OCP information or not.
- **Activate OCP Sound**
  - With option, a sound can be activated which helps the user to find the focus for the pachymetric measurement more quickly.
  - If no signal is detected there is a sound with a low frequency. With increasing signal quality the frequency of the sound is getting higher and higher and if the measurement was successfully taken there is a special sound which indicates that.

IMPORTANT NOTE

The Online Coherence Pachymeter (OCP) is an option for both models of the AMARIS.

8.7 Timer

The **Timer** function in the **Treatment** menu can be used for several applications. For example it is a useful tool when alcohol is applied to the cornea for several seconds or when there is a certain waiting time after the flap is placed back in the LASIK procedure or to determine the exact waiting period between the flap flushes and the removal of the lid speculum.

The time can be adjusted in steps of +/- 5s by pressing the <+5> or <-5> buttons. Default values can be predefined for each treatment step within the Treatment Assistant Manager configuration. In addition the desired start value can be inputted via the keyboard.

Pressing the <**Start timer**> button starts the count down. The area of the timer will be highlighted in green when the timer is activated.

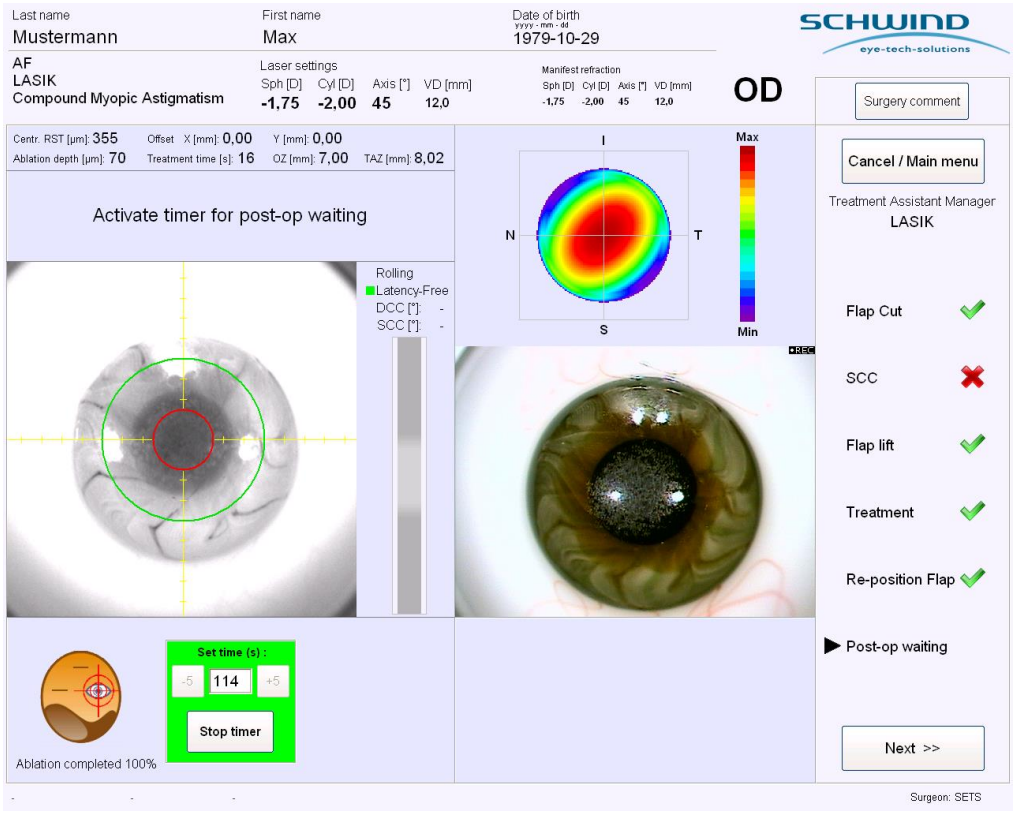


Figure 8-29: Timer function

IMPORTANT NOTES

With the **Timer** function it is only possible to start a count down.

A **Stopwatch** function is not possible.

The Timer will only be available if it was activated for this step in the Treatment Assistant Manager.

9 CLEANING AND MAINTENANCE

9.1 General Notes

WARNING!

Damage of device! Danger of short circuit!

Power must always be OFF during cleaning, disinfection or sterilization the excimer laser, its components or control elements!

Disconnect the patient bed from power supply before and during manual cleaning and disinfection!

Cleaning and disinfection when device is not switched off can lead to damage of the device and / or to personal injury by a short circuit.

CAUTION

Energy impairment of the laser beam! Damage of device!

To clean the SCHWIND AMARIS, its parts and components, the SCHWIND Patient Bed and the treatment room do not use any liquids containing ammoniac or alcohol.

Do not disinfect your hands near the excimer laser.

Before applying disinfection liquids, please check the ingredients of the agent in order to exclude that alcohol or ammonia is included.

If necessary contact the manufacturer of the liquid.

Ammoniac and alcohol reduce the energy of the laser beam and can cause varying of treatment results.

CAUTION

Damage of device!

Do not use ether, acetone or aggressive detergents on painted surfaces! They can damage the surfaces of the device or damage the medical device itself.

Apply only cleaning and disinfection solutions that are intended for medical instruments.

Pay attention to expiration date of cleaning and disinfection solutions.

After opening, use solutions within the time frame recommended by the manufacturer.

Do not use solutions with visible contamination.

Do not use abrasives, scrapers or brushes for cleaning! This can lead to reduced precision of the parts and to unforeseen damage.

The parts and components are highly precise and sensitive instruments. They should be handled with special care.

Never immerse the parts or components into a solution!

During cleaning pay attention that no liquid cleaning agents or water enters into the system, part or unit.

All parts or components must be cooled to room temperature before use.

Allow the device to dry before operating!

WARNING!

Health hazard for surgical staff and patients.

Omission of effective pre-processing influences treatment results and endangers the health of OP personnel and the patient.

Contact with patient secretions and/or processing solutions can endanger your health.

- ➔ Therefore, always wear prescribed protective equipment during pre-processing.
- ➔ Make sure that the cleaned parts do not come in contact with the patient.

9.2 Cleaning of Non-Sterile Parts

The manual cleaning procedure will be applied for the following AMARIS parts, components and units for all models:

- AMARIS housing
- Patient bed
- Touch screen and keyboard with touch pad, control panel, control elements
- Operating microscope
- Fluence detector
- Slit lamp
- Nozzle of particle aspiration system or plume evacuation system

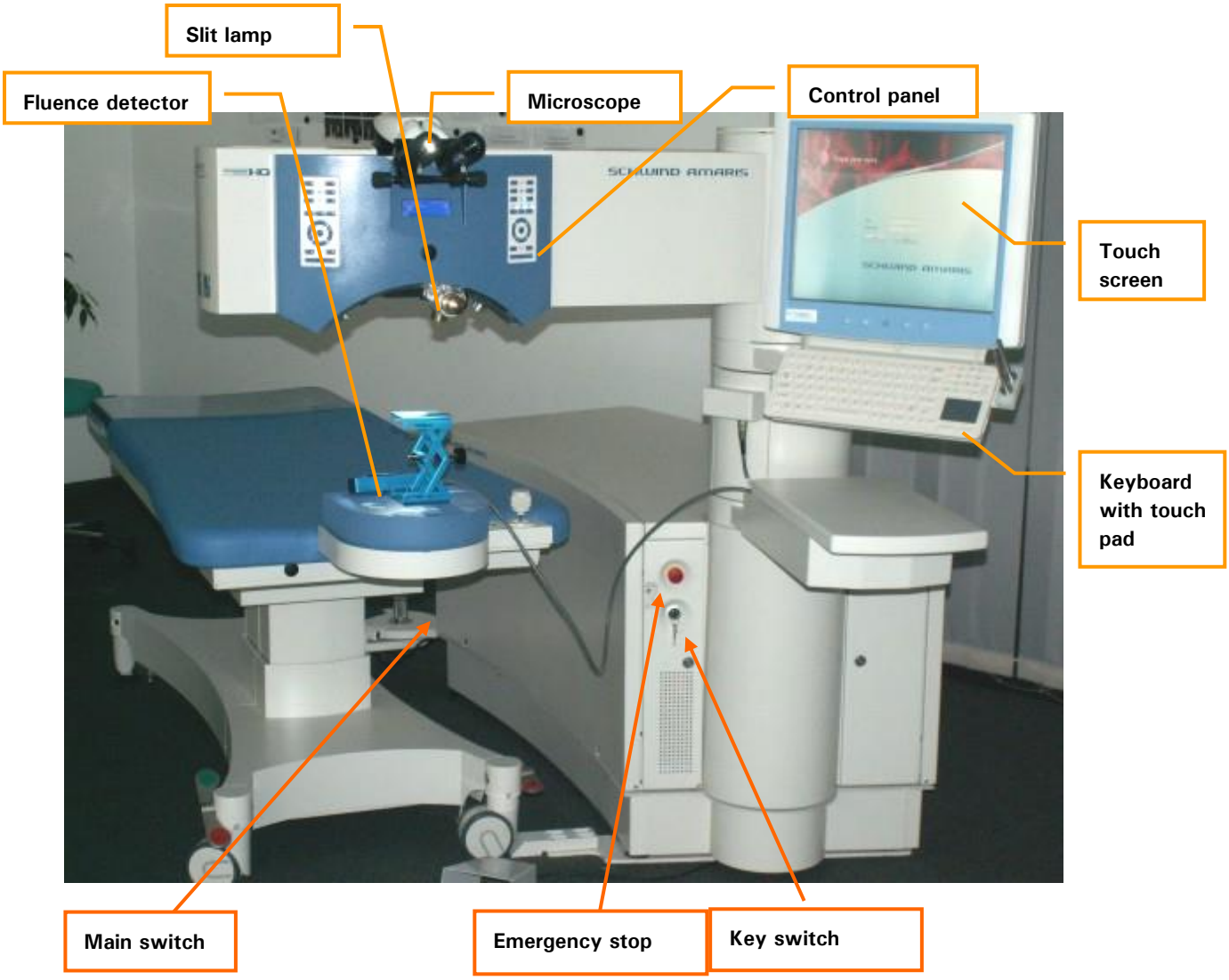


Figure 9-1: Parts, components and units of AMARIS to be manually cleaned

IMPORTANT NOTE

When using disinfection agents while cleaning please pay attention to spray on the tissue used for cleaning and not on the device itself.

9.2.1 Cleaning of Excimer Laser Housing

The excimer laser housing does not come in contact with the patient.

When cleaning and disinfecting the surfaces of the unit, the following cleaning procedure should be observed:

- ➔ Normal dirt and grime of the housing parts may be cleaned using a moist (not wet!) cloth. Non-abrasive and non-aggressive cleaning solutions may be used for more stubborn dirt and grime. Ordinary dry foam may also be used.
- ➔ If necessary, wipe all surfaces with a lint-free cloth dampened with disinfection solution.
- ➔ To wipe off the fluid (for example on patient bed) use a clean, dry and lint-free cloth.

CAUTION

Damage of device!

Do not clean the optics on the lower side of the optic arm cover. This will be done by the service engineer using a special cleaning fluid.

Do not touch any optical surfaces, as this can lead to system malfunctions.

9.2.2 Cleaning of the Patient Bed

- ➔ Normal dirt and grime may be cleaned using a moist (not wet!) cloth.
- ➔ Non-abrasive and non-aggressive cleaning agents may be used for more stubborn dirt and grime. Ordinary dry foam may also be used.
- ➔ Material-preserving care is not necessary.

- ➔ If necessary, wipe all surfaces with a lint-free cloth dampened with disinfection solution.

CAUTION!

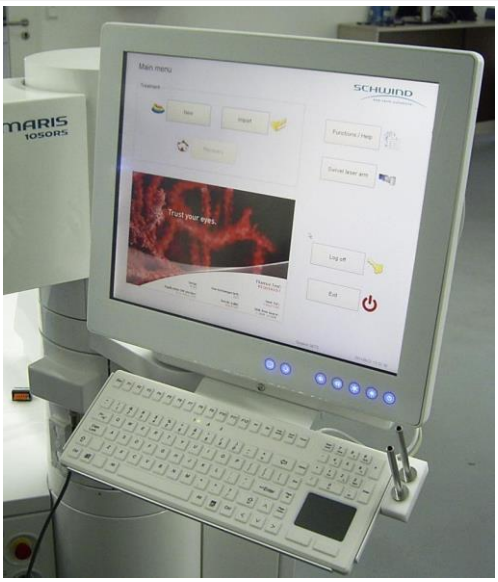
Damage of device!

Disconnect the patient bed from power supply before and during manual cleaning and disinfection!

Consider also the instructions in the user manual of the patient bed.

9.2.3 Cleaning of Touch Screen and Keyboard with Touch Pad, Control Panel, Control Elements

If necessary, wipe all surfaces of the parts as listed below with a lint-free cloth dampened with disinfection solution.

• Touch screen and keyboard with touch pad.	
• Control panel	
• Control elements (key switch, emergency stop switch)	

9.2.4 Cleaning of the Operating Microscope

- ➔ If required, the housing parts can be cleaned with a dry cloth.
- ➔ The lenses of the microscope oculars may be cleaned with a special micro fibre tissue which is located in a transparent plastic box in the drawer fastened to the tower (underneath the monitor).
- ➔ At longer intervals painted surfaces may be cleaned with a damp cloth, as required. Use an aqueous solution of a commercial cleaning agent.

CAUTION!

Damage of device!

Make sure that no water penetrates inside the microscope.

The **caps of the microscope and joystick** are re-sterilisable parts and should be sterilised by special reprocessing method as described in the separate manual **"Reprocessing Instruction for Re-sterilisable SCHWIND Products"**.

9.2.5 Cleaning of the Fluence Detector

- ➔ For cleaning fluence detector use a special micro fibre tissue (refer to chapter 9.2.4) which is located in a transparent plastic box in the drawer fastened to the tower (underneath the monitor).

WARNING!

Risk of incorrect ablation!

To clean the fluence detector window, do not use alcohol or liquids containing ammonia!

Such agents could prevent the successful execution of a fluence test, or result in over-/under corrections during treatment.

IMPORTANT NOTE

Clean the glass window of the fluence detector from ablation remains every time before a new fluence test starts and after a fluence test.

9.2.6 Cleaning of the Laser Beam Aperture Area

Contamination on the 6D eye tracking projection mirror and the area of the laser beam aperture **(LED light sources, slit lamp, position light, microscope lens** etc.) shall be regularly cleaned by the user.

Liquids spraying or splashing e.g. BSS (Balanced Salt Solution) from LASIK canula into the area of the laser beam aperture during the refractive surgery can harm the projector of the 6D eye tracking as well as the LED light sources, the slit lamp and the microscope lens. If any fluid pollutes the projector or LED light sources, functionality of the z-tracking or rolling cannot be guaranteed.

We recommend to check the laser beam aperture area after each patient treatment and to clean it.

For cleaning use a special dry micro fibre tissue (refer to chapter 9.2.4) which is located in a transparent plastic box in the drawer fastened to the tower (underneath the monitor).

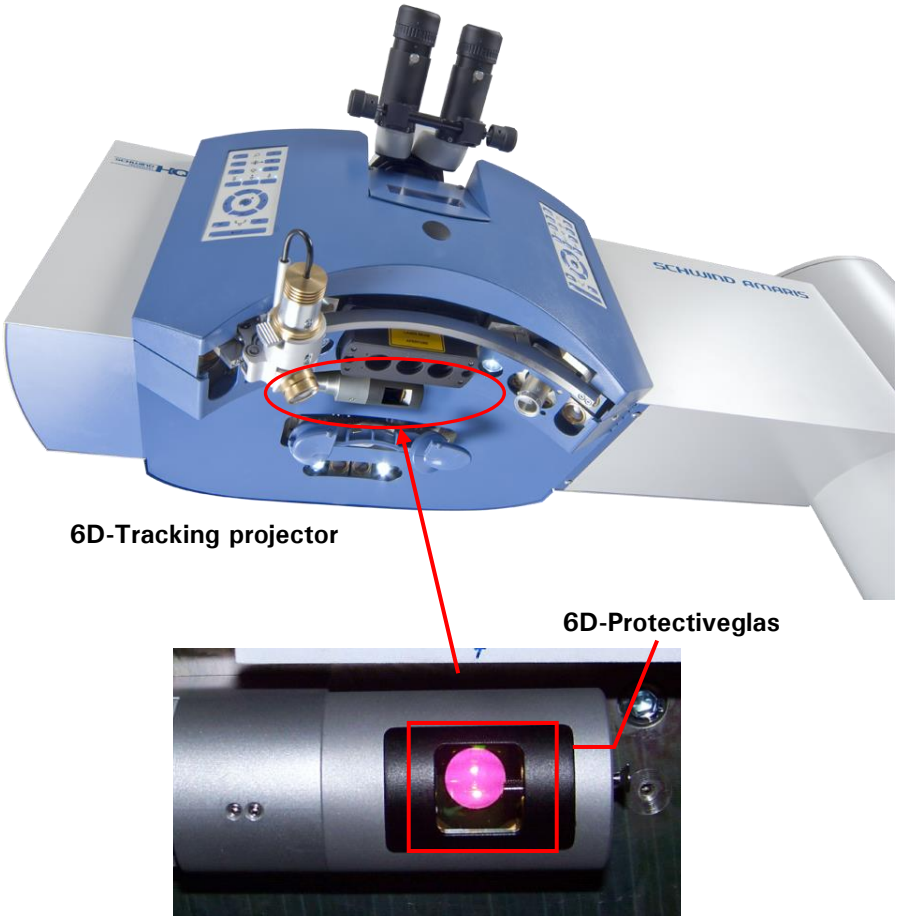


Figure 9-2: 6D tracking projector (exemplary illustration)

CAUTION

To clean the **protective glass, LED lights, slit lamp and microscope lens** do not use alcohol or liquids containing ammonia! Such agents can reduce the laser energy during treatment.

IMPORTANT NOTE

The **protective glass** for the 6D projector is an optional component and can be ordered from SCHWIND eye-tech-solutions.

Refer to chapter 10.7 Components and Consumables

9.2.7 Cleaning of the Nozzles of Particle Aspiration and Plume Evacuation systems

If necessary, clean all surfaces with a lint-free cloth dampened with disinfection solution.

IMPORTANT NOTE

Clean and disinfect the nozzle at least 30 minutes before the OP treatment.

CAUTION

Damage of device!

Do not immerse the nozzle into water or into other cleaning liquids.

9.3 Reprocessing of Re-sterilisable Parts, Components

The **only** parts to be sterilised at all AMARIS models, are the **re-sterilisable pen** for operation the panel PC touch screen under sterile conditions and **caps for microscope and joystick**

Re-sterilisable pen

Caps for microscope and joystick

The special reprocessing method of **re-sterilisable parts and components** is described in the SCHWIND manual **"Reprocessing Instruction for Re-sterilisable SCHWIND Products"**.

10 MAINTENANCE

10.1 General Notes

IMPORTANT NOTE

The user of the system does not need to perform any maintenance tasks except gas changes, exchanging the nozzles of the Partical aspiration system and surface cleaning.

IMPORTANT NOTES

As a result of improperly performed repair and service work, as well as improperly performed technical inspections or services, the user and patient can encounter potentially dangerous system malfunctions.

Only proper service of the device within the prescribed service intervals can guarantee that no undue radiation can escape from the device.

All repair and service works, including regularly performed technical inspections and services, may only be performed by persons authorized by SCHWIND eye-tech-solutions GmbH.

Authorized persons are customer service employees of SCHWIND eye-tech-solutions GmbH as well as customer service technicians who have been authorized for this purpose and who are affiliated with an authorized SCHWIND eye-tech-solutions GmbH distributor which has finalized a valid and existing dealership agreement. If, for any reason, the dealership agreement is terminated, the authorization of the customer service technician is also automatically terminated.

Carrying out of service works as well as technical inspections and service through unauthorized persons leads to forfeiture of any claim of warranty, guarantee or liability against SCHWIND eye-tech-solutions GmbH.

The loss of warranty, guarantee or responsibility claims against SCHWIND eye-tech-solutions GmbH also occurs if a prescribed service/inspection or a due service action is not carried out or carried out within the required time limit.

CAUTION

Damage of device!

Do not make changes to any component of the respective device without the supplier's authorization!

We do not release for use with your specific system any parts and/or optional components that are not supplied with your order.

Do not open the laser housing!

Only authorized personnel may open the device, perform modifications or repair works.

10.2 Troubleshooting and Remedies of Operating Microscope

Failure	Remedy
Blurring when changing magnification	Check the ocular setting and re-adjust. Re-adjust at maximum magnification
Blurring image	Re-focus the microscope

10.3 Maintenance of the Particle Aspiration System

The nozzle with filter of the Particle Aspiration System is a consumable and has to be replaced **after 4 weeks** (28 days) by trained personnel. This is necessary for the Particle Aspiration System to be able to work correctly and to prevent infectious impact to patients, surgeon or personnel.

IMPORTANT NOTE

The change Particle Aspiration System nozzle should be performed by trained personal only.

Change the nozzle with integrated filter of the Particle Aspiration System **every 4 weeks**, even if there have been no or few treatments performed, in order to prevent the development of bacteria cells.

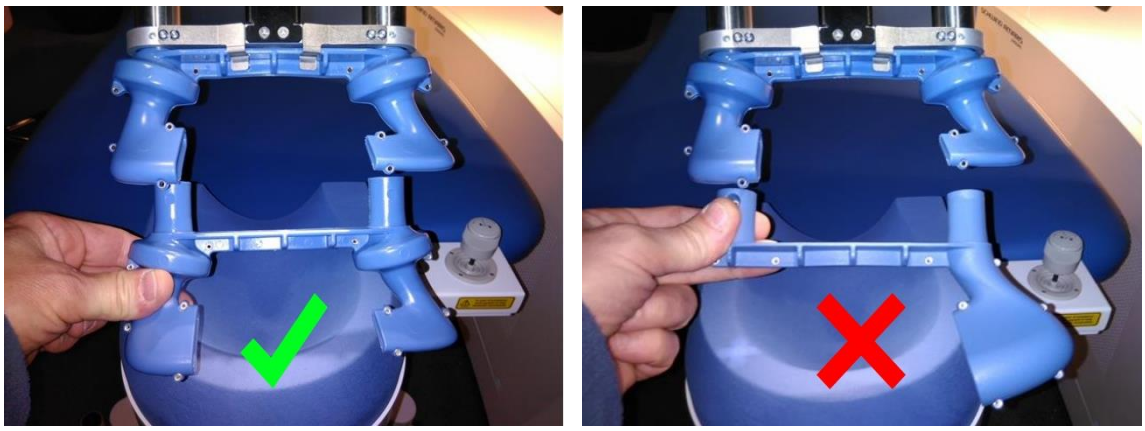


Figure 10-1: Replacing a double-channel nozzle

WARNING!

Do not mismatch the nozzles, risk of under correction!

Do not use the single-channel nozzle of the Plume Evacuation System!

Refer to chapter 4.11 Plume Evacuation System.

Maintenance

The AMARIS Application software has an integrated test which checks if the current particle aspiration filter is older than **28 days**. If this is the case a message will appear at login to remind the user to exchange the particle aspiration nozzle (see Figure 10-2). This is confirmed by entering the serial number of the new particle aspiration filter into the AMARIS Application software.

Change of the Nozzle for Particle Aspiration System

- To exchange the debris removal nozzle enter the LOT number of the new nozzle (see Figure 10-3).
- Then start a fluence test, bring the debris removal in position and exchange the old versus the new nozzle.
- There is a security clamp which has to be released before it is possible to pull the old nozzle out (see Figure 10-4).

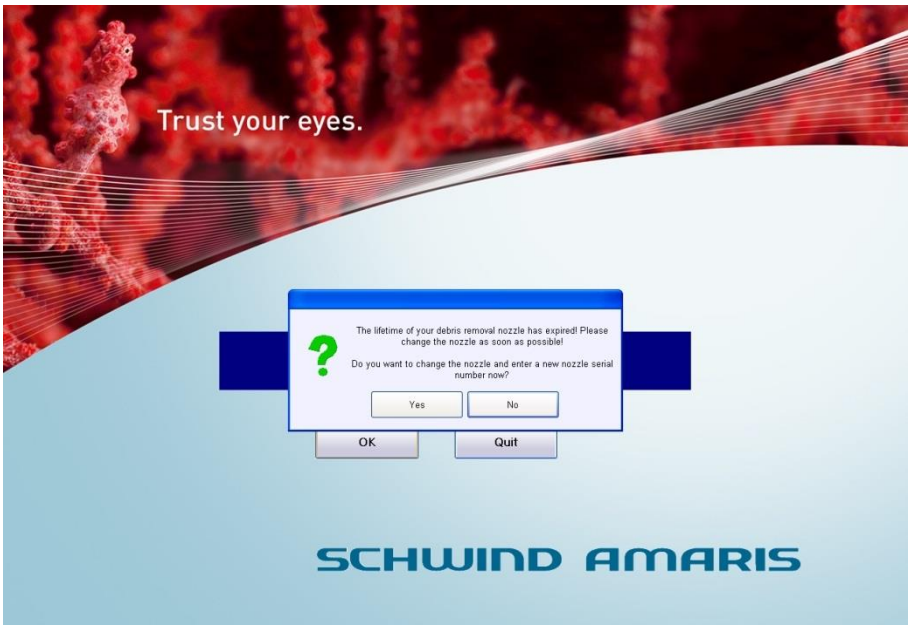


Figure 10-2: Reminder for exchange of nozzle for particle aspiration system

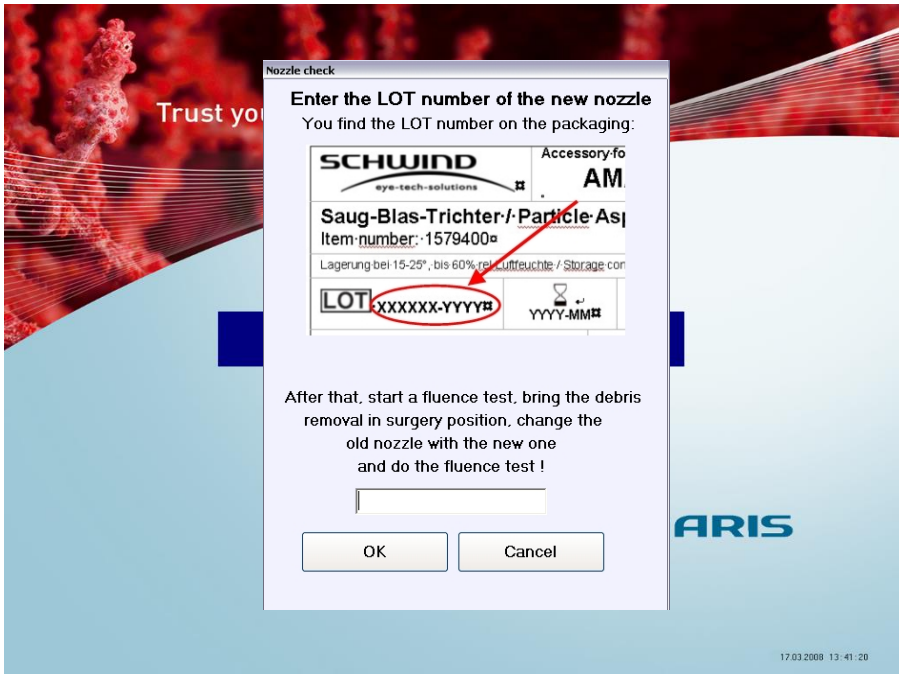


Figure 10-3: Entering the serial number of the new particle aspiration filter

To remove the used nozzle of the Particle Aspiration System, hold the part on both ends release the security clamp and pull it out of the tubes/openings. Insert a new nozzle, also holding with both hands.

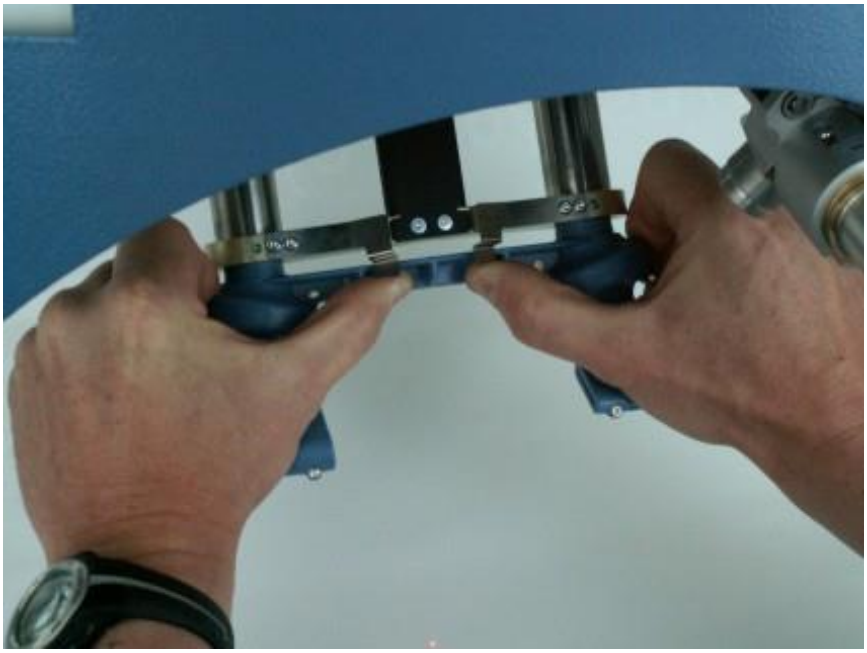


Figure 10-4: Changing the nozzle

WARNING!

Risk of injury!

Do not attempt to change the nozzle if a patient is situated on the patient bed!

IMPORTANT NOTE

The used Particle Aspiration filter has to be disposed in a professional way only (medical special refuse).

10.4 Maintenance of the Plume Evacuation System

The AMARIS can be equipped either with the plume evacuation system or the particle aspiration system. The plume evacuation system can be recognized by a nozzle with one channel on the right side (see the left Figure 10-5).

IMPORTANT NOTE

The change Plume Evacuation System nozzle should be performed **once a year** by a service technician only, tipically, during the annual service visit.

When replacing the nozzle, it must be ensured that the same type of nozzle is available. Check the type of nozzle before unpacking. See the following images for illustration.

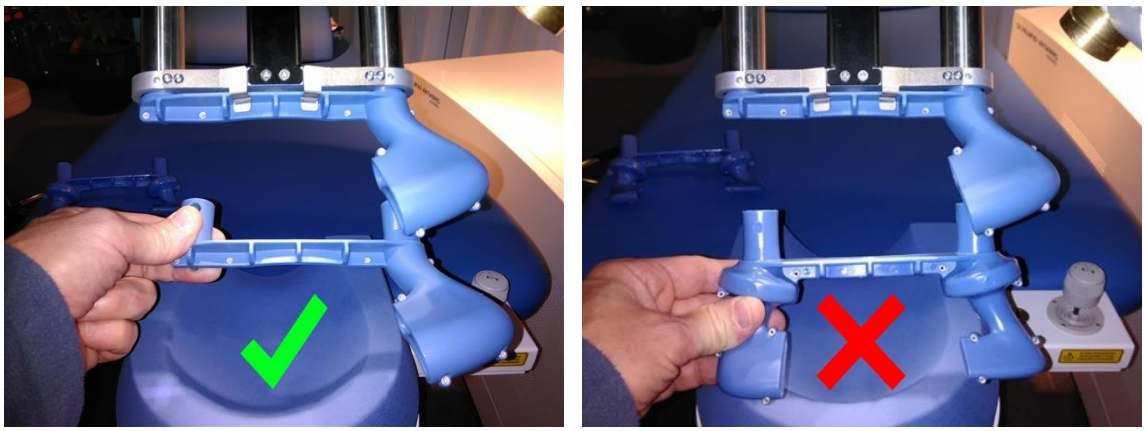


Figure 10-5: Replacing a single-channel nozzle

If the new nozzle you want to install is not of a similar type as the previous one, please contact the SCHWIND hotline or your local distributor.

10.5 Changing of the ArF Premix Gas Bottle or Helium Gas Bottle

Changing of gas bottles is only allowed to be carried out by service technicians authorized by SCHWIND eye-tech-solutions.

After the replacement of every two premix gas bottles, the halogen filter (scrubber) has to be replaced also.

IMPORTANT NOTE

Used halogen filters have to be disposed in a professional way as special refuse.

10.6 Technical Safety Check (TSC)

In order to ensure the error-free functioning of the excimer of laser, please ensure that an annual technical safety check (TSC) is performed.

The Service Representatives of SCHWIND eye-tech-solutions or service technicians specifically authorized by SCHWIND eye-tech-solutions will carry out a technical safety inspections (TSC) in **yearly** intervals and document it in the Medical Device Logbook (Medical Apparatus Book).

When the TSC comes due, it will be indicated by the software. Additionally, the date for the next TSC is displayed on a label applied to the Panel PC.

Please contact SCHWIND eye-tech-solutions in order to coordinate the inspection date.

The safety inspections contain the exchange of components, wearing parts, disposable articles and the device interfaces used in connection with the deployment of the device whenever the safety of system use can be significantly influenced by these secondary components.

IMPORTANT NOTE

If inadequacies are found during the technical inspection, which can affect the safety of patients, users or third parties, the device may not be used until the deficiencies have been eliminated.

The service technicians will complete the test protocol during the corresponding service intervals of the entire system.

10.7 Components and Consumables

Optional Components

The following components and features are **optional** and they are **not included in the scope of delivery** of AMARIS 1050RS / AMARIS 750S / AMARIS 500E / AMARIS. They can be **optionally ordered** at SCHWIND eye-tech-solutions.

Description	Article Number
Video system consisting of observe camera with	15147
Video extender HDMI	1768400
TFT monitor 19"	1303402
Uninterruptible Power Supply 230V (UPS) 3kVA (other voltages on request)	1739100
Advanced Cyclotorsion Control for corneal Wavefront guided treatments (SCC)	15121
Advanced Cyclotorsion Control for ocular Wavefront guided treatments (SCC)	15120
Advanced Cyclotorsion Control Dynamic cyclotorsion control for online correction (DCC)	15122
Slit lamp	15888
6D tracking (AMARIS 750S and 1050RS only)	15172
Latency free tracking (AMARIS 1050RS only)	18610
Cross laser	15448
C-eye Cross-Linking Kit for AMARIS [1],[2] (C-eye (CXL) device AND C-eye Sliding Unit) **C-eye Sliding Unit for AMARIS** (WITHOUT C-eye (CXL) device)	1871000 1870500
Plume evacuator for 1) **AMARIS 500E,** 2) **AMARIS 750S,** 3) **AMARIS 1050RS, AMARIS**	1) 17414 2) 17413 3) 17422
Video extender HDMI for 1) **AMARIS 500E,** 2) **AMARIS 750S,** 3) **AMARIS 1050RS, AMARIS**	1) 17482 2) 17481 3) 17480

[1] *C-eye (Cross-Linking Kit) as an option is available for specific countries only*

[2] *C-eye is a medical device whose manufacturer is ‚Costruzione Strumenti Oftalmici' (CSO) in Firenze/Italy*

CAUTION

Use approved components only!

Use only components together with the AMARIS excimer laser which have been approved by SCHWIND eye-tech-solutions. These parts and items are specially designed for the system. The use of other than original parts does not ensure design and manufacture in accordance with the service and safety requirements of the equipment.

CAUTION

Load of Power outlets for components

For max. load of power outlet sockets for **components** refer to **Potential Free Power Supply Output** in chapter 2.7 Electrical Safety - Connection of Devices to External Plugs.

IMPORTANT NOTE

Not necessarilly all products, components, options, or system combinations mentioned in this documentation may be available in your country. Please ask your local distributor for availability.

Consumables

The following consumable are available to customers:

Description	Article Number
HS foil for fluence test (clear, transparent plastic foil)	1206601
Alignment photo paper (for drift measurement)	15887
Caps for joystick	12038
Caps for microscope	15184
Nozzle for Particle Aspiration System (set of 6 pcs)	1621000-12
Nozzle for Plume Evacuation System (1 pcs)	1996101-12
Gas bottle 10L (a)	1212100-10
Gas bottle 10L (b)	1212200-10
PMMA testplates	1628510
Sterilisable Touch-Pen	1624003

The nozzle for Particle Aspiration System is available as a set of quantity 6 only. The nozzle for Particle Aspiration System and the nozzle for Plume Evacuation System is available in grey.

The purchase order for the **consumables** can be send to salesadmin@eye-tech.net directly.

10.8 Product Life Expectancy and Expected Service Life

The EXPECTED SERVICE LIFE within the device is expected to remain safe is 1 (one) year.

The Treatment Device is intended to be in a regular preventative maintenance program, in order to renew the EXPECTED SERVICE LIFE by a technical safety check and to replace any component that may show signs of wear. The device includes parts subjected to natural wear and tear. The lifetime of those parts is either depending on the frequency of use or the time itself. Those parts can be replaced within service intervals. To ensure correct treatment parameters a test and calibration routine is intended to be performed in a defined interval. The treatment unit will be blocked from treatment if the calibration routine fails.

With the purchase of the SCHWIND AMARIS, SCHWIND eye-tech-solutions guarantees continuing to provide wear parts for 5 years from date of purchase.

The device itself has a product life of 6 years when following the service strategy as described above.

10.9 Disposal

Upon reaching the end of its lifetime, the AMARIS is considered to be metal and electronic scrap and should be appropriately disposed of according to **European Directive 2012/19/EEC** (Waste Electrical and Electronic Equipment – WEEE)

(Regulation valid for EEC countries; Please consider the valid national regulations)

The laser device must be disposed of separately from other household waste.

Please contact your local authority or waste disposal service for the return and recycling of this product.

Prior to disposal, the **laser tube** must be pumped clean and flushed with helium 3 times.

The **premix gas bottles** are to be disposed of at the gas supplier. The helium gas bottles are disposables and can be disposed of as scrap metal.

IMPORTANT NOTE

Consider national regulations for waste disposal!

IMPORTANT NOTE

Used **particle aspiration filters** have to be disposed of in a professional way only (medical special refuse).

Batteries

The internal computers of the system contain **backup batteries.**

The laser system does not contain any **rechargable batteries.**

IMPORTANT NOTE

The batteries must be disposed of separately from other household waste. Consider national regulations for waste disposal!

11 TECHNICAL DATA

In this chapter you will find all technical data of the AMARIS. Detailed technical data of patient bed are contained in a separate SCHWIND Patient Bed User Manual.

Working Laser	**ArF-Excimer Laser**
Type	ArF-Excimer laser
Laser class	4 (according to IEC 60825-1:2014)
Wavelength	193 nm
Mode	pulsed
Pulse energy (beam output)	14 mJ max.
Pulse frequency	500 Hz (AMARIS / AMARIS 500E) 750 Hz (AMARIS 750S) 1050 Hz (AMARIS 1050RS)
Pulse duration	3 – 15 ns
Pulse-to-pulse stability	< 3 %
Beam diameter (output)	6 x 3 mm
Beam divergence	1 x 2 mrad
Treatment Parameter	
Energy	0.67 to 1.0 mJ (nominal)
Treatment area	App. 193 mm under beam output; Reference: lower edge of objective
Beam diameter (treatment area)	0.54 mm FWHM (Full Width Half Maximum)
Aiming Laser	**Diode Laser**
Laser class	1 (according to IEC 60825-1:2014)
Wavelength	650 nm
Power (middle, beam output)	< 0.3mW
Mode	cw (continuous wave)
Laser arm	90° swivelling
Cross Laser (option)	**Diode Laser**
(For AMARIS 750S / 1050RS only)	
Laser class	1 (according to IEC 60825-1:2014)
Wavelength	635 nm
Power	<0.3mW
Mode	cw
OCP Laser (option for all AMARIS types)	
Laser class	1 (according to IEC 60825-1:2014)
Wavelength	1280 to 1360 nm
Energy / Power	<1 mW
Mode	cw

Technical Data

Control System	**Medical Touch Screen Panel-PC**
User PC	Windows based Panel PC pivotable on 2 axes
Monitor	17", TFT flat screen, resistive touch 19" TFT flat screen, resistive touch (from AMARIS 1050RS on) Additional dot-matrix display at the laser arm
Keyboard	washable keyboard with integrated touch pad 2 keypads for peripherial control at the laser arm
Eye-Tracker:	
Frame rate	1050 Hz
Response time	< 3 ms 0 ms with Latency Free (Option for AMARIS 1050RS only)
Cooling:	**Air**
Cooling circulation	Internal fan
Air condition: heat load	1.5 kWh

Input Requirements of laser/ Electrical Data

Power supply:	Single Phase, 100, 110, 120, 127 VAC, max. 20 A 208, 220, 230, 240 VAC, max. 10.5 A
Frequency:	50 / 60 Hz
Fuse (internal circuit breaker):	12 A at 208 - 240 VAC 20 A at 100 -127 VAC
Device connections:	acc. to IEC standard
Protection class:	Class I (according to IEC 60601-1:2005)
IP Protection:	IP20 (according to IEC 60529:1989)
Mode of Operation:	Continuous operation
UPS:	Required 3kVA (refer to chapter 4.14.7 Uninterruptable Power Supply (UPS)
Door interlock:	Potential free contact 24 V DC / 0.1 A
Laser warning lamp:	Potential free contact 24 V DC / 1 A
Power outlet sockets:	Potential free outputs, max. power: (refer to chapter 2.7 Electrical Safety - Connection of Devices to External Plugs)
Plume Evacuator	
Power supply:	12V DC, 2.0A IEC60601-1
Air inlet:	D = 38mm
Gas supply	**20 l /10 l ArF Premix bottle**
Environmental Conditions	**Refer to chapter 5.2.4**

Technical Data

Dimensions and Weight AMARIS / AMARIS 750S / AMARIS 1050RS

Dimensions of device	Width1443 (± 50) mm, Height 1418 mm, Length 2634 mm (incl. patient bed)
Floor space	Refer to chapter 5.2.2 Device and Room Dimensions
Weight excimer laser	485 kg (net weight – AMARIS 750S/AMARIS 1050RS)
Weight gas bottle (10 l Premix gas)	approx. 15 kg
Weight gas bottle (20 l Premix gas)	approx. 27 kg

Dimensions and Weight AMARIS 500E

Dimensions of device	Width 1486 (± 50) mm, Height 1411 mm, Length 2265 mm (incl. patient bed)
Floor Space	Refer to chapter 5.2.2 Device and Room Dimensions
Weight excimer laser	340 kg (net weight – AMARIS 500E)
Weight gas bottle (10 l Premix gas)	approx. 15 kg
Weight gas bottle (20 l Premix gas)	approx. 27 kg

Floor Requirements:

Ground and floor covering:	Standard reinforced concrete floor; Flatness ≤ 7mm / meter; PVC or stable, **vibration free underground** (no carpet!)
Floor loading:	285 kg/m2
Vibration characteristics of the floor/ground:	Max. speed of oscillation: v < = 1.0 mm/s

Patient bed	**swivelling up to 90°**
Weight:	163 kg (patient bed manually traversable) 185 kg (patient bed motorized traversable)
Max. allowed patient weight:	150 kg

For further details refer to Patient Bed User Manual

EU-Labelling	**CE 0483 marking, Medical Device Class IIb** acc. to MDD 93/42/EEC, resp. MDR 2017/745

Standards for AMARIS (all models):

IEC 60601-1:2005 + AMD1:2012 + AMD2:2020
IEC 60601-1-2:2014 + AMD1:2020
IEC 60601-1-6:2010 + AMD1:2013 + AMD2:2020
IEC 60601-2-22:2019
IEC 60825-1:2014
IEC 62304:2006 + AMD1:2015
IEC 62366-1:2015 + AMD1:2020

12 APPENDIXES

12.1 Backup Batteries

Default settings are stored by backup batteries located in Panel PC and embedded PC:

Panel PC:	Advantec	Bios backup battery	type	CR 2032, 3V
Panel PC	ONYX	Bios backup battery	type	CR 2032, 3V
Panel PC	ONYX Zeus	Bios backup battery	type	CR 2032, 3V
EPC up to 1521413:		Bios backup battery	type	CR 2032, 3V
EPC starting from 1521414:		Bios backup battery	type	TL-5242, 3,6V
EPC starting from 1521415		Bios backup battery	type	CR 2032, 3V with solder tags

WARNING!

Keep the batteries away from children!

Do not swallow, open, recharge or expose to water, fire or high temperature: may explode, leak or cause damage.

Please consider the disposal instructions of the backup batteries, refer to chapter 10.9 Disposal.

12.2 Nomogram

What is here introduced as a nomogram file is, in reality, a profile definition. Currently, no classical nomogram is used well. The laser has an aspheric “aberration-free” profile definition, but no compensation based on the dioptric deviations coming from the experience.

The “nomogram” must consider the latest knowledge on Age Factors, Customized Ablations, Aberration-free profiles and it logically considers the differences existing between myopia and hyperopia, and between surface and stromal ablations.

Age Factors

In Age Factors the nomogram considers three implicitly intended contributions:

a) Water content of the cornea

b) Over/Under refraction due to accommodation

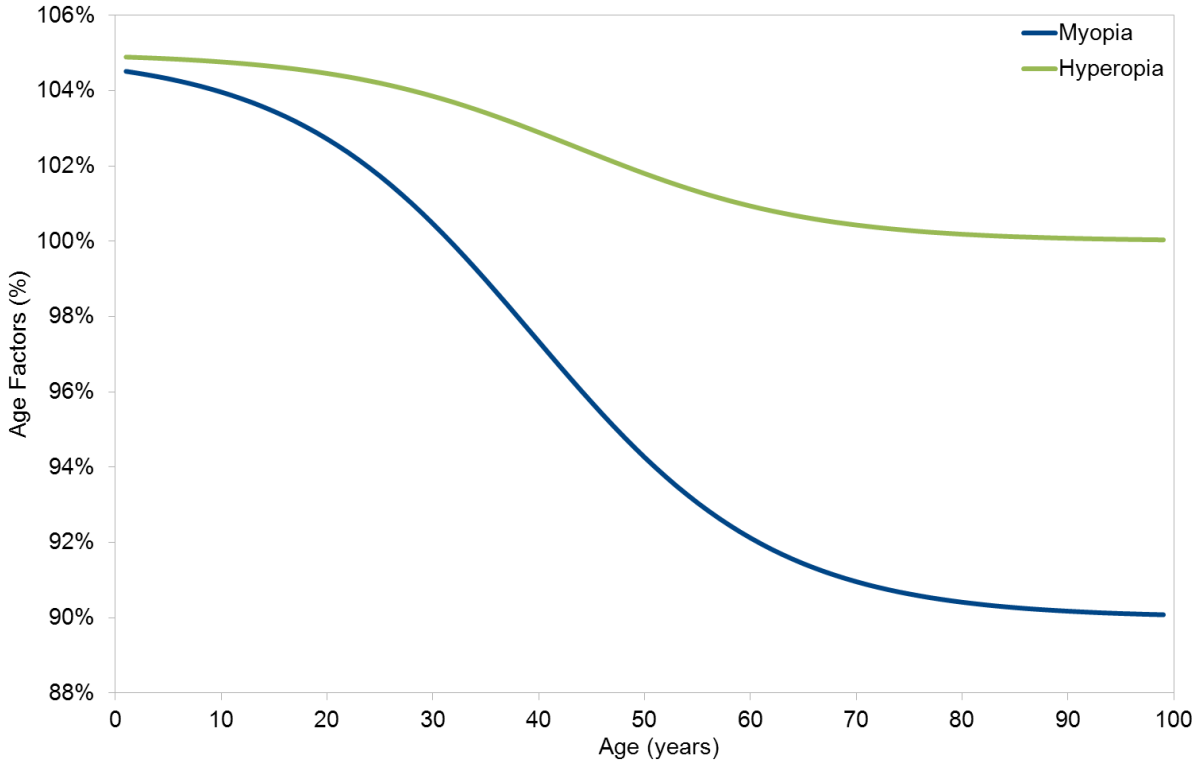
c) Target refraction

The water content of the cornea decreases with age, and it is independent from the refraction or from the type of refraction. The more water the cornea contains the less effective the ablation is.

The ability to accommodatie decreases with Age, and it is independent from the refraction or from the type of refraction. This means that typically the patients are over minused in the refractions when they are myopic, and underplused when they are hyperopic. Young patients often become happier if they are slightly hyperopic as they are able to accommodate greatly. Mature patients are satisfied by being plano while they still can accommodate, and older patients are happier by being

slightly myopic as soon as they can not accommodate any more, or if are constrained in their accommodation.

Considering all above-mentioned factors and adding them together, the profile definition for the AMARIS Excimer laser results in the following attributes:



IMPORTANT NOTE

Please **DO NOT** perform your own nomogram adjustments based on considerations of age factors of the patients since the laser is correcting for it automatically.

The age-based nomogram, or profile definition, that is incorporated in SCHWIND AMARIS laser systems progressively changes between 0 and 100 years of age while maintaining cornerstones from our previous approach using three age-groups only.

In myopic cases, the AMARIS profiles include +5% overplanning for a “zero” year old patient, -3% underplanning for a 40-year old and -10% underplanning for a 100-year old patient compared to the reference value (100%).

In hyperopic cases, AMARIS profiles include +5% overplanning for a “zero” year old patient, +3% overplanning for a 40-year old and neutral planning for a 100-year old patient compared to the reference value (100%).

12.2.1 Customized Ablations

In Zernike Factors, the profile definition considers the differences between the different devices that we are linking to the SCHWIND CAM software, therefore to AMARIS:

a) CSO EyeTop Topographer (“Eye-Top”))
b) SCHWIND Corneal Wavefront Analyzer (“Keraton Scout / Keraton”)
c) SCHWIND Ocular Wavefront Analyzer (“irx3”)
d) SCHWIND ORK Wavefront Analyzer (“COAS”)
e) SCHWIND PERAMIS
f) SCHWIND MS-39
g) SCHWIND SIRIUS or SIRIUS+

IMPORTANT NOTE

Manufacturer of the diagnostic devices SCHWIND SIRIUS or SIRIUS+, SCHWIND MS-39, and SCHWIND PERAMIS: C.S.O. S.R.L., Italy. For some countries, availability may be restricted due to regulatory requirements.

The same holds for the other manufacturers of diagnostic devices (see list of devices above) that SCHWIND distributed in the past (before its discontinuation).

12.2.2 Surface and Stromal Treatments

Based on good experience with the profile definition as used in the previous ESIRIS Excimer laser with SCHWIND CAM software, we have observed that LASIK patients (stromal treatments) needed more adjustment (more number of pulses, considered as deeper ablations) than PRK/TransPRK or LASEK patients (surface treatments). Moreover, we have observed a higher tendency for overcorrections after thin-flap LASIK (anterior stromal treatments) as compared to thick-flap LASIK (deep stromal treatments).

The observed behaviour is to be balanced by the number of pulses and not with deeper ablations with the AMARIS Excimer laser. For that reason, we have included a Shot Depth Factor parameter depending on the applied technique.

12.3 Electrical Safety Parts Inside the SCHWIND AMARIS

Fuse	Location of installation	Type	Nominal value	Trip characteristic
Mainswitch +MS-S1	Main supply unit	MD2-B-24-612-1-A15-B-E MD2-B-24-620-1-A65-B-E	12A for 208-240V supply 20A for 100-127V supply	MEDIUM
+PSP-F1	Standby Power Supply	5x20mm T 500 mA L / 250V	500mA	slow blow
+PSP-F2	Standby Power Supply	5x20mm T 500 mA L / 250V	500mA	slow blow
+TS-F1 Panel PC, EPC, 24V	Terminal Strip	S201-C6	6A	slow, Hi-Inrush
+TS-F2 Laser Source	Terminal Strip	S201-B10	10A	MEDIUM
+TS-F3 SC,ET,OCP	Terminal Strip	S201-B6	6A	MEDIUM
+TS-F4 external Devices	Terminal Strip	E-T-A 1180-01-2A	2A	slow, Hi-Inrush
+PSP-F3 Spare	Power supply unit	E-T-A 104PR	4A	slow, Hi-Inrush
+PSP-F4 LACU,ILCU	Power supply unit	E-T-A 104PR	8A	slow, Hi-Inrush
+PSP-F5 Spare	Power supply unit	E-T-A 104PR	4A	slow, Hi-Inrush
+PSP-F6 Supply PSC	Power supply unit	E-T-A 104PR	5A	slow, Hi-Inrush
+EPC-F1 5V	EPC	5x20mm T 6,3 A L / 250V	6,3A	Slow blow
+EPC-F2 12V	EPC	5x20mm T 2 A L / 250V	2A	Slow blow
+EPC-F3 5Vsb	EPC	5x20mm T 1,6 A L / 250V	1,6A	Slow blow
+PSC-F4 24V supply	PSC	TR5 T 4 A L / 250V	4A	slow
+GS-F5 24V supply	GSCU	TR5 T 4 A L / 250V	4A	slow
+LA-F4 24V supply	LACU	TR5 T 4 A L / 250V	4A	slow
+LA-F5 5V supply	LACU	TR5 T 315 mA L / 250V	315mA	slow
+IL-F4 5V supply	ILCU	TR5 T 315 mA L / 250V	315mA	slow

12.4 EMC Guidance and Manufacturer's Declaration

12.4.1 Electromagnetic Interference

Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC).

The **SCHWIND AMARIS, SCHWIND AMARIS 500E, SCHWIND AMARIS 750S and SCHWIND AMARIS 1050RS** have been tested and found to comply with the limits defined in the IEC 60601-1-2 standard (version 2014) for devices classified as Group 1, Class A according to the CISPR 11 standard.

In this Guidance SCHWIND AMARIS, SCHWIND AMARIS 500E, SCHWIND AMARIS 750S and SCHWIND AMARIS 1050RS are called AMARIS EXCIMER LASER(S).

This equipment needs to be installed and put into service according to the EMC information and instructions provided in the present chapter. The device only shall be installed and operated according to the SCHWIND instructions, otherwise there is no guarantee that no abnormal interference will occur.

WARNING!

Risk of electromagnetic interference!

Portable and mobile RF communications equipment such as cellular phones, non-OEM Bluetooth or wireless LAN devices, wireless surveillance monitors or microwave ovens have the potential to adversely affect medical electrical equipment.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the AMARIS EXCIMER LASER, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

For Information about respective frequency range and the maximum output power ratings of the RF appliances, the recommended separation distance between any part of AMARIS and the RF appliance refer to table 4.

The use of components, transducers and cables other than those specified or supplied by the manufacturer of the AMARIS excimer lasers may result in increased electromagnetic emissions or decreased electromagnetic immunity of the AMARIS excimer lasers. Refer to chapter 12.4.3.

The essential performance of the AMARIS EXCIMER LASER can be lost or degraded due to EM disturbances. Refer to chapter 12.4.2.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. Tested equipment is listed in chapter 4.15 and chapter 10.7.

NOTE: "The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (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."

NOTE: SERVICE RECOMMENDATION:

To prevent affect to the Emissions and Immunity of the equipment throughout the expected service life it is recommended to use the product always with its complete and original enclosure, with original parts from the manufacturer and to use the product according to the EMC instructions in the IFU.

Table 2: ELECTROMAGNETIC EMISSIONS

Guidelines and declaration of conformity – electromagnetic emissions		
The AMARIS excimer lasers are intended to be used in the electromagnetic environment specified below. The customer or the user of the AMARIS excimer laser should assure that it is used in such an environment.		
Electromagnetic emission	**Compatibility**	**Electromagnetic environment - standards**
RF emission CISPR 11	Group 1	The AMARIS excimer lasers use RF energy for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
HF emission CISPR 11	Class A	**NOTE:** The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (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. ***1**).
Harmonic test not applicable, refer to NOTE.	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

***1**) = In combination with an UPS the AMARIS excimer laser can be directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Table 3: ELECTROMAGNETIC IMMUNITY (1)

Guidelines and declaration of conformity – electromagnetic immunity

The AMARIS excimer lasers are intended to be used in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT. The electromagnetic environment is specified below. The customer or the user of the AMARIS excimer laser should assure that it is used in such an environment. The AMARIS excimer lasers are not intended to be used in exclusions, such as hospitals with near active HF SURGICAL EQUIPMENT and RF shielded rooms of an ME System for magnetic resonance imaging or other environments where the intensity of EM DISTURBANCES is high.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	Floor should be according to the guidance "Room Requirements". If floor is 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 ±1kV for input / output lines 100kHz repetition frequency	±2 kV for power supply lines ±1kV for input / output lines 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV line(s) to line(s) ±2 kV line(s) to earth	±1kV line(s) to line(s) ±2 kV 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	100% dip in U_T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 100% dip in U_T for 1 cycle 70% U_T (30% dip in U_T) for 25 cycles 100% dip in U_T for 250 cycles	100% dip in U_T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 100% dip in U_T for 1 cycle 70% U_T (30% dip in U_T) for 25 cycles 100% dip in U_T for 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AMARIS EXCIMER LASER requires continued operation during power mains interruptions, it is recommended that the AMARIS EXCIMER LASER be powered from an uninterruptible power supply (UPS).

Power frequency (50 / 60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Table 4: ELECTROMAGNETIC IMMUNITY (2)

Guidelines and declaration of conformity – electromagnetic immunity (Equipment and systems that are not life-supporting)			
The AMARIS excimer lasers are intended to be used in the electromagnetic environment specified below. The customer or the user of the AMARIS excimer laser should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150kHz to 80MHz 6 Vrms in ISM bands 3 V/m 80MHz to 2,7GHz For special test frequencies refer to **Note 3.**	3 Vrms 150kHz to 80MHz 6 Vrms in ISM bands 3 V/m 80MHz to 2,7GHz	a) Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the AMARIS, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
Note 1: At 80 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 an people.			

Note 3: Additional special test frequencies for Radiated RF:

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

12.4.2 Essential Performance and Basic Safety

According to the intended use the purpose of the AMARIS EXCIMER LASER is to ablate corneal tissue using an excimer laser beam with defined energy and positioning.

Essential Performance	Foreseeable Hazard	Possible Harm	Measure
Control of the laser energy of the excimer laser (working laser) within ±20%. (acc. IEC 60825-1.)	Exposure of too high output energy of the working laser	Incorrect treatment, loss of visus	Protective system with independent energy monitoring and inducing of the safe state.
Positioning of the laser beam	No positioning of the laser beam	Penetration of the cornea	Protective system with monitoring of the scanner positioning and inducing of the safe state.

Table 5: ESSENTIAL PERFORMANCE ACCORDING TO IEC 60601-1-2 (2014) Clause 5.2.1.1 b)

Feature/Function	Foreseeable Hazard	Possible Harm	Measure
Exposure of laser radiation	Unintended activation of the laser beam	Burn, Bodily harm of patient, user or third parties	Protective system: Shutter acc. IEC 60825-1.
Gas supply of the excimer laser	Uncontrolled emersion of toxic gas	Contamination with fluorine, pulmonary edema	Appropriate design layout and protective system with control of pressure
Aiming laser	Exposure of too high laser power of the aiming laser	Harm of the patient's eye, retina	Protective system within the laser diode module to limit the laser power or shutdown of the laser diode. Inherent limitation to Class I laser radiation acc. IEC 60825-1.

Table 6: BASIC SAFETY ACCORDING TO IEC 60601-1 (2014)

12.4.3 List of Replaceable Cables and Components

Cables and components according to the following table are likely to affect compliance of EMC and have to be replaced as specified.

Port	Description	Classification	Cable type	Cable length used	Cable length maximum
+MS-X1	USB cable	signal/control	Shielded	2.0 m	5.0 m
+MS-X4	BNC cable	signal/control	Shielded	2.0 m	---
+MS-X5	HDMI cable	signal/control	Shielded	2.0 m / 4.0 m	---
+FD-X1.1	SCHWIND Fluence Detector Art.No. 15552xx	signal/control	Shielded	1.3 m	1.3 m
+MS-X7	Plume Evacuator cable Art.No. 1734701 E057_W1-EXT-X7	signal/control	unshielded	2.0 m	2.0 m

Table 7: REPLACEABLE CABLES AND COMPONENTS

13 MANUFACTURER / TECHNICAL SUPPORT/ APPLICATION SUPPORT

SCHWIND eye-tech-solutions offers a comprehensive warranty and service support.

Highly qualified representatives from our CUSTOMER SERVICE department are available to support you and to solve any operational questions.

Should you have any questions, please do not hesitate to contact our Customer Service Hotline. The Service Hotline is free of additional charges (only regular telephone charges are incurred).

CAUTION

In the event of a serious incident or health emergency, please promptly inform the local competent authority.

Our customers outside of Germany should use the service hotline provided by our local distributor or authorized Service Representative first.

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