USER MANUAL (Original Instruction for Use) PLAN

Valid for CAM SW 5.3 (AMARIS SW 6.1)

SCHWIND Custom Ablation Manager

Valid for Modules:

ORK-CAM and Comparison

PresbyMAX®

PTK-CAM

The SCHWIND CAM manual does not contain the description of the software modules. Refer to Treatment Planning Guideline(s) of the respective SCHWIND CAM module(s).

CE 0483

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

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1 GENERAL INFORMATION

1.1 Product Identification Data

Product name:	**SCHWIND CUSTOM ABLATION MANAGER** Consists of modules: **ORK-CAM, PresbyMAX®, PTK-CAM** (Refer to appropriate Treatment Guideline(s))
Product description:	See chapter 4 Product Description
Medical Device Class:	**IIb (according to MDR Annex VIII)**
Software version:	**5.3.23.2417** (SCHWIND CAM)
EMDN (European Medical Device Nomenklature):	Z12011092 (Laser Surgery Instruments – Medical Device Software)
Basic UDI-DI:	**426015714E071-CAM-SW6W**
Unique Device Identification (UDI-DI):	**(01)04260157140318**
CE labelling:	CE 0483
Approved device compatibilities:	Refer to chapter **3.4**
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 local SCHWIND representative
Current document status:	**Version 5.3 SCHWIND CAM EN / 2024-04-26**

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 SCHWIND CAM User Manual

The purpose of the SCHWIND CAM User Manual is to familiarize the operator(s) of the SCHWIND CAM software with the safety instructions, set-up, handling and operation of the SCHWIND CAM software.

IMPORTANT NOTE

Read the SCHWIND CAM User Manual carefully and consider all safety instructions and warning notes before you start running the SCHWIND CAM with its software modules included.

This User Manual does not contain all information which is necessary for the safe and effective application of the SCHWIND CAM according to its intended use.

Consider the following accompanying documents:

- **Treatment Planning Guideline ORK-CAM**
- **Treatment Planning Guideline PresbyMAX®**
- **Treatment Planning Guideline PTK-CAM**

IMPORTANT NOTE

The English manual is the ORIGINAL INSTRUCTION, which is legally binding. Translations of these must bear the words "Translation of the Original Instructions".

IMPORTANT NOTES

The SCHWIND CAM may be used in combination with supporting diagnostic devices, which are distributed by SCHWIND.

Consider the user documentation of the respective diagnostic device(s) (Corneal Wavefront Analyzer, Ocular Wavefront Analyzer, SCHWIND SIRIUS or SIRIUS+, SCHWIND MS-39, SCHWIND PERAMIS) **as listed in the User Manual of the WORKSTATION, for ensuring compatibility and safe operation of the combination between the devices.**

IMPORTANT NOTES

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

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 8 Manufacturer / Technical Assistance / Application Support.

1.4 Scope of Accompanying Documentation

The scope of documentation of the SCHWIND CAM includes the:

Accompanying Documentation "SCHWIND MEDICAL PRODUCTS", consisting of:

- Medical Apparatus Book "SCHWIND MEDICAL PRODUCTS" (EN) or (DE)
- CD-ROM/DVD with Product Documentation for SCHWIND CAM and 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 SCHWIND CAM and SCHWIND AMARIS manuals / guidelines, current version)	163430x

The Accompanying Documentation will be delivered with the SCHWIND AMARIS laser device.

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.

The SCHWIND CAM software has been developed according to the applicable requirements of the European Medical Device Directive 93/42/EEC (MDD), as amended.

Since replacement of MDD by the Medical Device Regulation (EU) 2017/745 (MDR), the SCHWIND CAM 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 eye-tech-solutions or a distributor which is authorized by SCHWIND eye-tech-solutions;
- All service and maintenance work is performed only by personnel who are authorized by SCHWIND eye-tech-solutions;
- 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 **Declaration of Conformity** for SCHWIND CAM with its modules ORK-CAM, PTK-CAM and PresbyMAX can be found on the CD/DVD-ROM "Product Documentation SCHWIND AMARIS", Ref.no. 163430x.

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.

Due for the following courses of action:

- Lack of reading this SCHWIND CAM user documentation completely and carefully before starting operations with CAM software.
- Using the CAM 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 CAM software or any of its components in a different application other than integrated modules of the SCHWIND CAM software platform.
- Manipulation, alterations or damages to the software 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 Malware: Virus, Worm, Trojan horse, Spy ware, Backdoor, Ad ware, Scare ware, Root kit and so on.
- 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.
- Operating the SCHWIND CAM in any configuration not explicitly allowed in the SCHWIND CAM documentation.
- Acts of nature.

1.7 Warranty

Consider the General Warranty Regulations of SCHWIND eye-tech-solutions GmbH License Agreement.

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

1.8 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 trademark misuse.

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

1.9 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.

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

8 Manufacturer / Technical Assistance / 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.

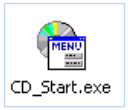
For your information, the CD-ROMs only contains instructions in English. The Instructions in other languages are available in the SCHWIND Portal. For safety-related changes in the instructions you will be informed immediately by the SCHWIND company by email.

Upon request, you will receive the paper format of the IFU by mail within in 7 working days – free of charge (see contact in 8 Manufacturer / Technical Assistance / Application Support).

1.10 Using the Product Documentation CD-ROM with the eIFU

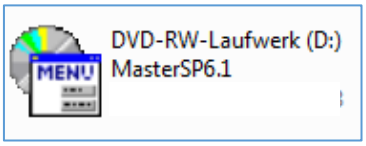
To read the SCHWIND **electronic Instructions for use** contained on the "SCHWIND Product Documentation" CD-ROM, perform the following steps:

- 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 Notes

The instructions given in this chapter are to be considered for proper and safe operation of the SCHWIND CAM software including the modules ORK-CAM, PresbyMAX®, and PTK-CAM. The SCHWIND CAM and its integrated modules are intended for use only within the environment of ophthalmic surgery, i.e. operating room or diagnostic room.

IMPORTANT NOTES

Observe all safety regulations in this SCHWIND CAM User Manual!

Observe any other safety instructions and requirements provided by the user documentation of the respective medical device(s) (for resale) for ensuring compatibility and safe operation of the combination between devices.

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

IMPORTANT NOTE

Prior to export from the diagnostic device (e.g. SCHWIND Corneal Wavefront Analyzer, SCHWIND SIRIUS or SIRIUS+, SCHWIND PERAMIS, SCHWIND MS-39) the user must check the diagnostic data for possible artefacts incurred during the measurement.

In this regard, the user shall comply with the manufacturer's operation instructions.

2.2 Regulations for Medical Devices

IMPORTANT NOTE

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

The most important regulations are:

1. **European Medical Device Regulation (EU) 2017/745**

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

2. **Medical Product Operator Regulation – MPBetreibV**

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

2.3 Restrictions of Use and Safety Precautions

The purpose of safety precautions and preventive measures is to reduce the possibility of injuries to the patient and to avoid other risks.

Please strictly follow the notes listed below:

IMPORTANT NOTE

Medical product use by trained personnel only!

Only authorized and suitably trained personnel should use / operate the SCHWIND CAM software.

Service by authorized personnel only!

Only suitable trained or authorized personnel may perform initial installation, modifications of the SCHWIND CAM software.

IMPORTANT NOTES

Observe further restrictions of use and safety precautions contained in the user manuals of the respective diagnostic devices.

Refer to instructions contained in chapter 5.1 General Installation and Operation Notes.

2.4 Manufacturer's Responsibility

- Manufacturer is only responsible for proper operation, reliability and security of the medical product 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 medical device 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 this user manual.

2.4.1 Training of User's and Operating Personnel

As with any technological highly-developed medical product, the operation of the SCHWIND CAM software requires special training and abilities of the user's personnel.

IMPORTANT NOTE

The SCHWIND CAM software shall only be operated by authorized and suitably trained personnel!

Demand or agree on regular training upgrades whenever you feel that you or your team needs further support.

Likewise, the medical product shall be used by persons specializing in ophthalmology with specific training in the preparation, calibration, and maintenance of the device and accessories, 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 or your authorized local SCHWIND representative.

IMPORTANT NOTE

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

WARNING!

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

SCHWIND eye-tech-solutions or authorized representative will instruct and train the user's personnel according to the User Manual SCHWIND CAM and the Treatment Planning Guidelines of the CAM modules.

The completion of training for the responsible SCHWIND CAM operators and other persons involved in operation of the SCHWIND CAM software 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 by SCHWIND eye-tech-solutions with the medical device.

2.5 Operator's Responsibility

In order to ensure the safety of patients and of the service personnel, the operator / user must undertake certain measures as listed below:

The operator / user is responsible for:

- Compliance with accident prevention regulations and regulations concerning installation, operation and safe usage of medical products. For more information refer to chapter 2.2 Regulations for Medical Devices.
- Proper and secure condition of the medical product.
- Storage of the user manual near the medical device.

2.5.1 Patient Safety

Follow also the instructions and notes given in chapter 2.3 Restrictions of Use.

WARNING!

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

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

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

2.5.2 Data and Virus Protection

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

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

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

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

The user is obliged to make updates of the malware-protection software on his 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 devices.

CAUTION

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.

2.5.3 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.

2.5.4 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 devices 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.
- During storage it is essential that hardware and storage media are completely operational and that the data have not been damaged.
- Keep back-up files and important data at another location other than your diagnostic device.
- Study the process of data retrieval.
- Use diagnostic tools with particular care.
- Do not install any additional software on SCHWIND devices.

IMPORTANT NOTE

The user is obliged to ensure the data storage! It must be ensured that only authorized staff has access to the data carriers.

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.

2.5.5 Protection from Unauthorized Use

The operator (clinic) is advised to protect the medical software and all medical devices from unauthorized use, for security, safety and data privacy reason.

- Prevent physical access to the SCHWIND medical software and devices when not in use. (locked security doors; ...)

2.6 Dangers Resulting from Software Operation

To ensure safe operation of the medical software and device please operate the device according to the instructions given in this manual and in the user manuals of the appropriate medical device. Primarily follow all notes in the following chapters.

2.7 In Case of Emergency

A case of emergency arising from using the SCHWIND CAM is not known.

2.8 Labelling

2.8.1 Identification Label

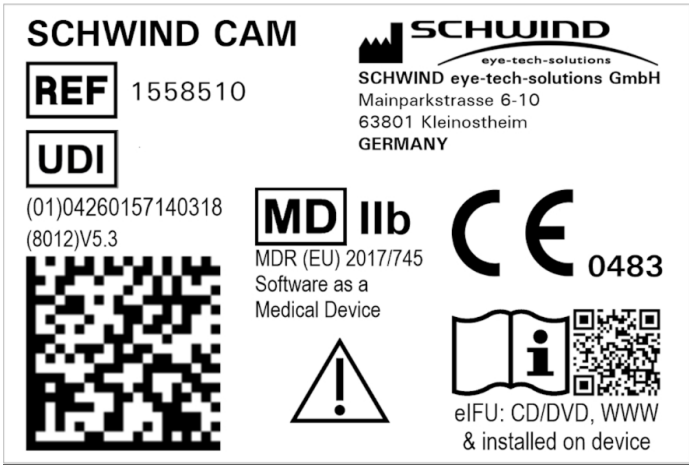


Figure 2-1: Identification label SCHWIND CAM

Location of the Label

The identification label with UDI information and Data Matrix Code included is placed and shown within the SCHWIND CAM software installed: push <Info> and <CE0483> afterwards to view the details (Figure 2-1).

Explanation of Signs and Symbols

The following symbols are used on the identification label:

Symbol	Explanation
SCHWIND eye-tech-solutions	SCHWIND Company Logo
	ISO 15223-1, 5.1.1 Designation / address of the manufacturer *Benennung / Adresse des Herstellers*
REF	ISO 15223-1, 5.1.6 Article number *Artikelnummer*
UDI	ISO 15223-1, 5.7.10 Unique device identifier, acc. MDR (EU) 2017/745 with GS1-Data matrix code. *UDI-Kennung entsprechend MDR (EU) 2017/745 mit GS1-Datamatrix Code.*
MD IIb MDR (EU) 2017/745 Software as a Medical Device	ISO 15223-1, 5.7.7 Medical product, indicating medical device class IIb in accordance with MDR (EU) 2017/745 and that it is medical software. *Medizinprodukt, mit Angabe der medizinischen Geräteklasse IIb entspr. MDR (EU) 2017/745 und dass es sich um eine medizinische Software handelt.*
CE 0483	The device is CE certified. The number 0483 is the ID of the notified body MDC (Medical Device Certification GmbH) through which the certification was carried out. *Das Gerät ist CE zertifiziert. Die Nummer 0483 ist die Kennung der benannten Stelle MDC (Medical Device Certification GmbH) durch die die Zertifizierung erfolgte.*
	ISO 15223-1, 5.4.4 Instructions for use contain important information regarding the safe use of the device. *Die Begleitpapiere (Gebrauchsanweisung) enthalten wichtige Informationen zur sicheren Verwendung des Gerätes.*
 eIFU: CD/DVD, WWW & installed on device	ISO 15223-1, 5.4.3 Read the instructions for use before operating, note on electronic instructions for use. *Vor Verwendung des Gerätes Gebrauchsanweisung lesen, Hinweis auf elektronische Gebrauchsanweisung.*

3 INTRODUCTION

3.1 Intended Use

The SCHWIND CAM software is intended for planning correction volumes for refractive or therapeutic corneal surgery.

3.2 Contraindications

There are no contraindications resulting from the use of the SCHWIND CAM software.
Regarding possible contraindications arising from the treatment planning with diagnostic devices and/or laser treatment, please refer to the documentation of the appropriate diagnostic devices and/or the excimer laser.

3.3 Side Effects

There are no adverse side effects resulting from the use of the SCHWIND CAM software.
Regarding possible side effects arising from the treatment planning with diagnostic devices and/or laser treatment, please refer to the documentation of the appropriate diagnostic devices and/or the excimer laser.

3.4 Device Compatibilities

SCHWIND eye-tech-solutions declares full compatibility of the SCHWIND CAM software with the devices listed in the following sub-sections.

3.4.1 Compatibility with Diagnostic Devices

Use the SCHWIND CAM software and its modules only in combination with the following SCHWIND approved diagnostic devices:

- CSO EyeTop Topographer („Eye-Top“)
- SCHWIND ORK Wavefront Analyzer („COAS“)
- SCHWIND Ocular Wavefront Analyzer („irx3“)
- SCHWIND Corneal Wavefront Analyzer („Keratron Scout / Keratron“)
- SCHWIND SIRIUS or SIRIUS+
- SCHWIND PERAMIS
- SCHWIND MS-39

The information of the current diagnostic device software version and the related compatible SCHWIND devices are available at your authorized local SCHWIND representative or SCHWIND eye-tech-solutions directly.

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).

WARNING

Make sure that your diagnostic devices have received all adequate inspections and calibrations for proper use and measurement.

In case of upgrades and updates of the devices, please contact your authorized local SCHWIND representative or SCHWIND eye-tech-solutions directly for ensuring compatibility and safe operation of the combination between devices.

3.4.2 Compatibility with SCHWIND Laser

The **SCHWIND CAM V5.3** software may only be used in connection with the following treatment devices / SCHWIND lasers:

- SCHWIND AMARIS
- SCHWIND AMARIS 500E
- SCHWIND AMARIS 750S
- SCHWIND AMARIS 1050RS

Make sure that your SCHWIND AMARIS has received all adequate inspections and calibrations for proper use and therapy.

The information of the current compatible AMARIS software is available from your SCHWIND distributor or directly from SCHWIND eye-tech-solutions.

IMPORTANT NOTE

SCHWIND CAM V 5.3.23.2417 [full version] can only be installed on SCHWIND approved diagnostic devices or lasers that run on operating system WINDOWS 10, i.e. new SCHWIND CAM installations on diagnostic device workstation CSO EyeTop Topographer („Eye-Top"), SCHWIND ORK Wavefront Analyzer („COAS"), SCHWIND Ocular Wavefront Analyzer („irx3"), or SCHWIND Corneal Wavefront Analyzer („Keratron Scout / Keratron") cannot be executed.

SCHWIND AMARIS lasers may request a PC upgrade (incl. WINDOWS 10) for the use of AMARIS Application Software with SCHWIND CAM V 5.3.23.2417 included.

4 PRODUCT DESCRIPTION

The **SCHWIND CAM** serves as the software platform for SCHWIND corneal refractive surgery application together with the SCHWIND AMARIS product family. The SCHWIND CAM is in use since SETS offers aspheric ablation profiles in 2004. The SCHWIND CAM software is intended for planning correction volumes for refractive or therapeutic corneal surgery. The SCHWIND CAM software can import, visualize, and analyze diagnostic data of the eye (comprising corneal wavefront, ocular wavefront, or corneal pachymetry data). The SCHWIND CAM software consists of separate modules for different applications: ORK-CAM (Optimized Refractive Keratectomy) and PresbyMAX (for compensation of presbyopia symptoms) belong to the refractive part, PTK-CAM is therapeutic.

The **ORK-CAM and PresbyMAX** modules create defined aspheric ablation profiles with three different treatment types available: Aberration-Free™ (AF), Corneal Wavefront (CW), and Ocular Wavefront (OW). Sphere, cylinder, and axis can be entered in each type. Furthermore, the import of diagnostic data of a patient's cornea or respectively the entire patient's eye obtained by an external diagnostic device is possible.

The **PTK-CAM** module creates ablation profiles for therapeutic applications with intention of refraction-neutrality. The PTK profile is designed by the input of depth and diameter (with several options available). It can be shifted to different positions on the patient's cornea by using ablation and pupil offsets.

Each software module typically transfers and converts either wave aberration data or height data together with additional parameters entered by the user/surgeon (comprising e.g. keratometry, and optical zone) to a (individual) predefined volume of tissue which will be exported to the SCHWIND laser system and removed.

This volume of tissue removal, prepared and exported by any SCHWIND CAM software module can (only) be used with an additional software module (shot file generator) on the SCHWIND laser systems (e.g. AMARIS).

After transferring the volume to the shot file generator, it translates and calculates the laser shot coordinates, so that the SCHWIND laser system is able to apply laser pulses on the patient's cornea to remove the predefined amount of corneal tissue.

5 INSTALLATION

5.1 General Installation and Operation Notes

SCHWIND CAM Demo Version

The installation of Software as a Medical Device 'SCHWIND CAM' with different CAM modules included on personal computers or non-medical notebooks **will be permitted only as DEMO**.

This can be executed by the user himself. However, once the installation is completed, no export of treatment data is allowed. The full version with data file export functionality shall not be used and is restricted to the software installed on the computers officially approved by SCHWIND eye-tech-solutions.

IMPORTANT NOTE

The SCHWIND CAM software supports a DEMO installation on personal computers or non-medical notebooks with operating system Microsoft® Windows 10 and Windows 11 and a minimum screen resolution of 768 pixels vertically.

SCHWIND CAM Full Version

The SCHWIND CAM software has 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.

CAUTION

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

Trained service personnel of SCHWIND eye-tech-solutions or your authorized local SCHWIND representative will perform the initial installation/start-up of the SCHWIND CAM on your medical device.

IMPORTANT NOTE

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

If you have any questions regarding any matters, contact an authorized local SCHWIND representative or SCHWIND's application specialists directly for clarifying any doubts prior or during the use of the SCHWIND CAM and its software modules.

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.

5.2 System Requirements

The SCHWIND CAM software or any of its modules must only be used on computers conforming to the requirements established by the IEC60601-1 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.

IMPORTANT NOTE

External mass-storage devices (e.g. card reader & memory card) 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.

Operating system:	Microsoft® Windows 10, approved by SCHWIND eye-tech-solutions
▪ Storage capacity:	Min. 300 MB available
▪ Storage space per treatment file:	Up to 3 MB per eye with all diagnostic information included (Up to 6 MB for bilateral planning)
▪ Internal memory:	1024 MB (recommended 2048 MB)
▪ Recommended screen resolution:	1280x1024
▪ Recommended graphic card:	With 64 MB graphic memory or higher (with DirectX™ 8.1 support)
▪ Graphic interface:	DirectX™ 8.1 compatible
▪ Color setting:	High colour 16 bit or True colour 32 bit

For Import / Export function:

- Hard drive (e.g. D:\)
- Card reader (SD memory card)

IMPORTANT NOTE

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

5.3 Software Installation

For installation of SCHWIND CAM software the file **setup.exe** with exact version number to be started: Setup_CAM_Amaris_external_5.3.23.2417.

CAUTION

Do not delete installation files manually. If necessary, uninstall and reinstall the software application.

To execute this procedure, the following steps have to be carried out.

➔ Start the Setup.exe, with 'right mouse click' on the setup symbol and click on "Run as Admin" (while a Windows 10 operating system is in use).

1. **Installation Wizard appears with License Agreement**

   Accept the license agreement to continue installation process.

→ Click Next >

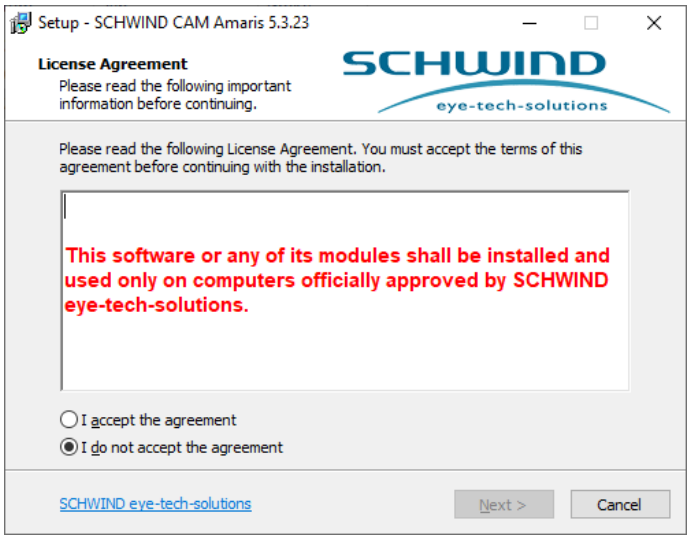


Figure 5-1: License Agreement

2. ReadMe Information

Read the computer specification information carefully before you decide whether to continue or not.

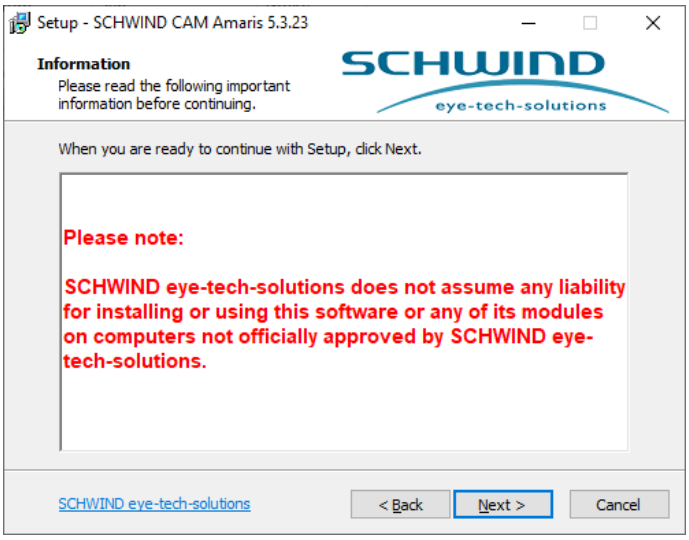
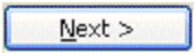


Figure 5-2: ReadMe Information

→ Click 

3. Ready to Install

This display informs that everything is ready for installation.

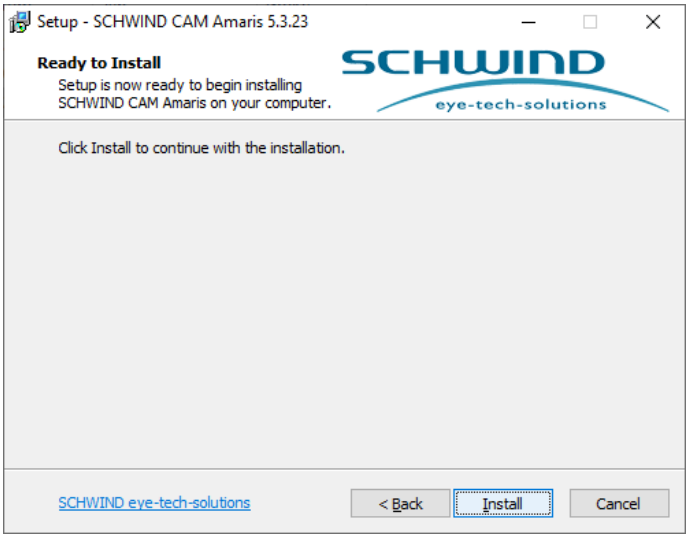


Figure 5-3: Installation process (example)

→ Click 

4. Installing Process

The setup starts automatically installing the SCHWIND CAM program to **"C:\Program Files\Schwind eye-tech-solutions\Schwind CAM 5.3\"**.

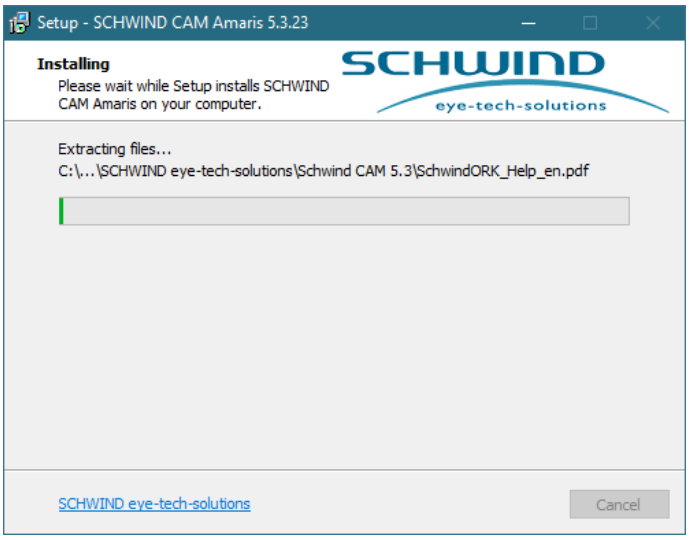


Figure 5-4: Installation process (example)

5. Installation Completed

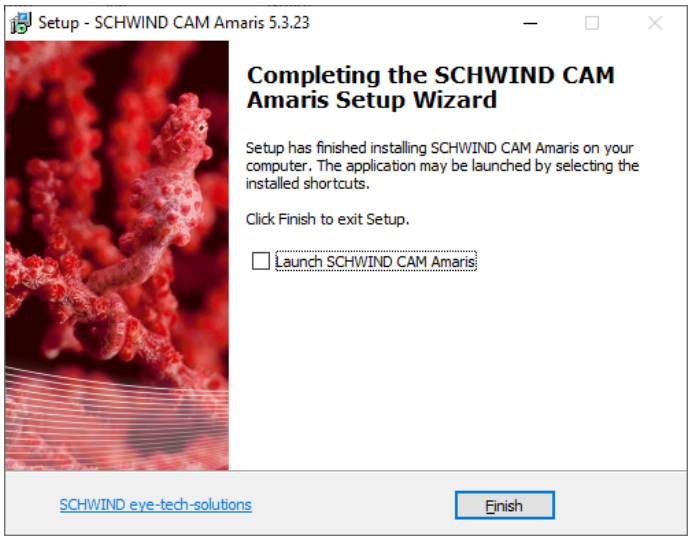


Figure 5-5: Installation Completion

→ **Click** Finish to complete the installation.

6. Desktop icon appears automatically

7. Double-click on the ‚SCHWIND CAM Amaris' desktop icon to start the registration procedure.

IMPORTANT NOTE

Make use of 'right mouse click' on the desktop icon 'SCHWIND CAM Amaris' and click on "Run as Admin" for full software capabilities (while a Windows 10 operating system is in use).

5.4 Registration of Software

When the non-registered (demo mode) SCHWIND CAM software is started, a form will appear (Figure 5-6) indicating a serial number.

This can be sent to SCHWIND eye-tech-solutions via email (codesystem@eye-tech.net) in case activation of SCHWIND CAM full version is necessary.

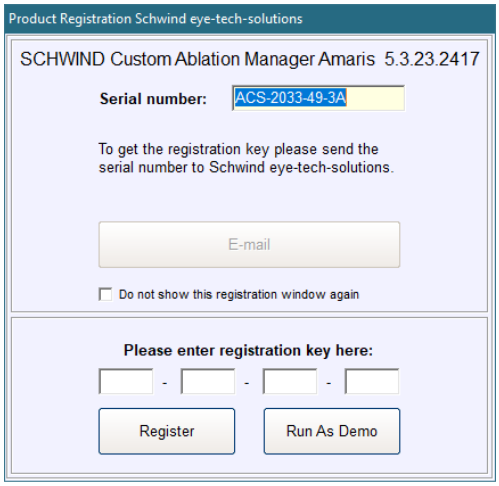


Figure 5-6: Product Registration [Full version]

IMPORTANT NOTE

Panel-PCs officially approved by SCHWIND eye-tech-solutions do not have an email assisting program installed. If no e-mail client is installed, the <E-mail> button is disabled.

If the registration requester for the full version of SCHWIND CAM software was suppressed by clicking the "Do not show this registration window again" option, you can show the registration requester by following these steps:

- Start the CAM software in demo mode via <**Run As Demo**>.
- Click on the Info button in "Welcome Screen".

- After the software info window opens, click on the button <**Activations**>
- Select <CAM registration> for the registration requester.
- Proceed as described below.

Figure 5-7 Software info window

➔ **Enter** the registration key (ACS – xxxx-xxxx-xx) for full setup version (allowed on "Panel-PC's officially approved by SCHWIND eye-tech-solutions") that was ordered at SCHWIND eye-tech-solutions via email.

IMPORTANT NOTE

SCHWIND CAM software does not have to be registered for demo purposes (anymore). The use in Demo Mode offers no save function and thus, export to the SCHWIND laser system is not possible.

The SCHWIND CAM software supports a DEMO installation on personal computers or non-medical notebooks with operating system Microsoft® Windows 10 and Windows 11 and a minimum screen resolution of 768 pixels vertically.

The registration (**ACS – xxxx-xxxx-xx**) is for using the software as full version including save and export functions.

5.4.1 Deliver Serial Number

By pressing the <E-mail> button (applicable only if email assisting program installed), a window appears Figure 5-8) where additional information is requested about person, location, and address for which the software is installed. The serial numbers of SCHWIND products should be entered as well.

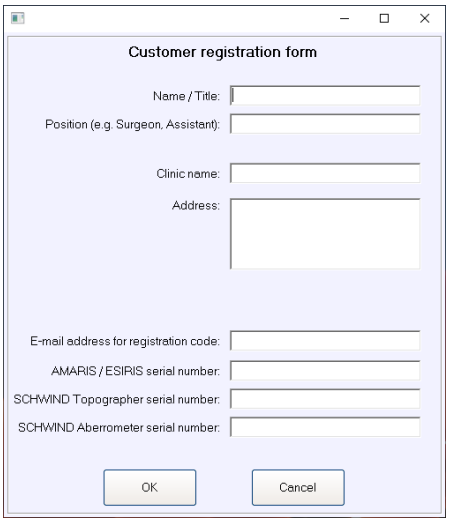


Figure 5-8: Form for Registration Purposes

➔ **Enter** the information requested and **click** OK to continue.

IMPORTANT NOTE

SCHWIND officially approved computers do not have an email client installed, so the registration via email can only be performed on private personal computers or non-medical notebooks for DEMO software access.

In case of E-mail delivery the data of serial number has to be sent to SCHWIND eye-tech-solutions (codesystem@eye-tech.net).

5.4.2 Enter Registration Key

The registration key generated by SCHWIND eye-tech-solutions will be delivered via E-mail to the customer.

The registration key can be entered at the bottom of the product registration window (Figure 5-6: Product Registration [Full version]) either immediately or upon a restart of the software.

A pop-up window indicates whether registration key entry was correct and registration successful.

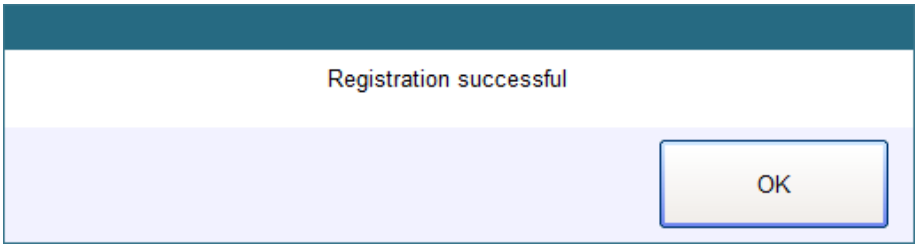


Figure 5-9: Product Registration successful

CAUTION

The full version software can only be started after a successful registration.

A new registration will only be required if SCHWIND eye-tech-solutions offers an update to the software (new registration key), after installing the software on a new operating system, or if the operating system has to be reinstalled due to previous hardware or software errors.

CAUTION

Do not delete installation files manually. If necessary, uninstall and reinstall the software application.

5.4.3 Foresight

After <Activations> button (Figure 5-7) is pushed, the interface to **Foresight** visualisation could be activated separately, and after SCHWIND CAM [full version] registration. Foresight provides an estimation of the post-operative corneal shape of the patient eye with respect to the current SCHWIND CAM individual treatment plan. → visualisation requirement: *.ork, *.pby, *.ptk include content of SCHWIND SIRIUS, SCHWIND SIRIUS+ or SCHWIND MS-39 by CSO Phoenix V4.1.4.7.

This activation is fee-based and limited in time but re-activation is possible.

IMPORTANT NOTE

Please contact SCHWIND eye-tech-solutions or your authorized local SCHWIND representative and ask for an offer if interest in the SCHWIND Foresight application exists.

6 OPERATION – RUNNING SCHWIND CAM

To run the SCHWIND CAM software, double click the **"SCHWIND CAM AMARIS"** link on the windows desktop.

The **SCHWIND CAM** Welcome Screen (Figure 6-1) appears with the ORK-CAM, the PresbyMAX, and the PTK-CAM software modules included. Wave aberration information can be compared via Comparison software module and various general settings can be made which will be subsequently explained in detail.

Figure 6-1: SCHWIND CAM Welcome Screen with modules: ORK-CAM, PresbyMAX, PTK-CAM, and Comparison (setting of display buttons: large)

CAUTION

Choose <Run as Demo> in product registration window to start the SCHWIND CAM. The software will start in DEMO Mode.

The registration window pops up and it is asked for full setup registration (ACS – xxxx-xxxx-xx) as long as "Do not show this registration window again" is not enabled.

6.1 Software Module File Extension

SCHWIND CAM supports the treatment planning of SCHWIND AMARIS lasers. Each software module creates its own project treatment file, respectively with separate file extensions for clear distinction:

Files out of the ORK-CAM software module have the extension: ***.ork**

Files out of the PresbyMAX® software module have the extension: ***.pby**

Files out of the PTK-CAM software module have the extension: ***.ptk**

IMPORTANT NOTE

During the 'open project file'- process, the user can decide in open dialog (via "Files of type") whether all SCHWIND projects or only projects of a specific software module (ORK, Presby, PTK) shall be displayed.

6.2 Diagnostic Device File Extension

SCHWIND CAM supports the import of data files from SCHWIND approved diagnostic devices. Each export file of a SCHWIND diagnostic device is created with its own extension for clear distinction:

Export files out of **CSO EyeTop Topographer** "Eye-Top" with extension: ***.ccw**

Export files out of **ORK Wavefront Analyzer** "COAS" with extension: ***.wow**

Export files out of **Ocular Wavefront Analyzer** "irx3" with extension: ***.iow**

Export files out of **Corneal Wavefront Analyzer** "Scout" with extension: ***.scw**

Export files out of **SCHWIND SIRIUS** or **SIRIUS+** with extension: ***.ccw**

Export files out of **SCHWIND PERAMIS** with extension: ***.csw**, ***.osw**, respectively ***.ocw**

Export files out of **SCHWIND MS-39** with extension: ***.mcw**

IMPORTANT NOTE

The information of the current diagnostic device software version and the related compatible SCHWIND devices are available at your authorized local SCHWIND representative or SCHWIND eye-tech-solutions directly.

WARNING!

Try to obtain diagnostic maps with very good quality. It is better to repeat a measurement rather than compromising the clinical outcome.

Check the proposed ablation profile for plausibility (e.g. wavefront map and ablation map in SCHWIND CAM software modules similar to the diagnostic maps of topography and wavefront).

IMPORTANT NOTE

The SCHWIND Corneal Wavefront Analyzer exports a file ***.scw** for **Corneal Wavefront** and can automatically attach a further (hidden) file with extension ***.ser** for Static Cyclotorsion Control (SCC) functionality available at the AMARIS laser.

The CSO diagnostic devices (SIRIUS or SIRIUS+, PERAMIS, MS-39) with link to SCHWIND lasers automatically attach a further (hidden) file with extension ***.cer** (security certificate) for **SCC** functionality, when exported.

CSO Phoenix software includes a separate export button "**Refractive Export to SCHWIND:** ..." (after activation or use of the SCHWIND plug-in by manufacturer CSO) that creates export files (OW, CW, or both) for treatment planning with SCHWIND CAM modules.

SCC data are directly linked to the wavefront export file in case of Scout, SIRIUS, SIRIUS+, MS-39 or PERAMIS. <**Corneal data**> makes this SCC information also available in all <AF> and <OW> (COAS, irx3) treatment plans.

Only in case the "**SCC Check**" was passed (= green traffic light) within your diagnostic device, the related file (*.ser or *.cer) is attached to the treatment plan as well as SCC option is activated within the AMARIS laser, the SCC functionality can be of success during surgery.

6.3 Software Configuration / General Settings

In order to adapt the program to the requirements of the user, some settings can be made which are also preserved when SCHWIND CAM is restarted. The three related buttons (Figure 6-2) for these configurations are located in the lower right corner of the SCHWIND CAM Welcome Screen.

Figure 6-2: Info and configuration buttons

IMPORTANT NOTE

In number entries the keyboard's dot and comma can be independently used as decimal separator and will work in all cases. The decimal separator (dot or comma) is shown according to the computer operation system settings.

6.3.1 Setting Buttons

Using the icon <**Settings**> on the SCHWIND CAM Welcome Screen, six different tabs can be chosen for either general CAM, files and display options, or module specific pre-setting issues:

Figure 6-3: Tabs within Settings

A virtual keyboard for data entry can be activated and used via button <**Keyboard on**> beside the standard external keyboard (Figure 6-4).

Figure 6-4: Confirm and activation buttons within Settings

Changes within '**Settings**' can be confirmed, cancelled or reset:

<**OK**>: new settings are taken for future planning

<**Cancel**>: close without any change to current settings

<**Reset**>: manufacturers' software default values are taken.

6.3.1.1 CAM Tab

- **Cylinder format**: negative or positive cylinder entry convention
- **K-reading format:** diopter or millimeter entry format
- **Ablation offset format:** polar (radius R and angle) or Cartesian coordinates (X and Y)
- **File name format:** project folder and file name includes patient-ID, last name, and first name with structure selection either Patient ID_Lastname_Firstname or Lastname_Firstname_PatientID
- **Print settings** (for a second page): the choice to print the high order aberrations (=Zernike pyramid) separate for all custom treatments (corneal and ocular wavefront-guided) or in case of filtered (=disabled) aberrations only.
- **Treatment settings:** default vertex distance [0.0 to 24.0 mm] can be defined and possible activation of extended treatment ranges is given.

The refractive zone of 4 mm cannot be changed. This zone is necessary for refractive value calculation of sphere and cylinder.

Extended treatment ranges can be activated by the user with confirmation of information within Figure 6-5.

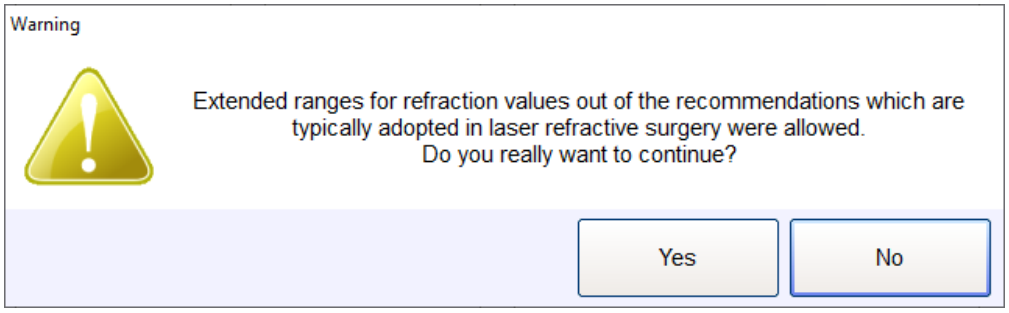


Figure 6-5: Confirm and activation button within settings

⟶ Please refer to Treatment Planning Guideline ORK-CAM, chapter 2.2.2 "Extended Input Refraction Ranges in Diopters" / Treatment Planning PresbyMAX, chapter 2.2.2 "Extended Ranges in Diopters for PresbyMAX Input Refraction" for the limits.

Furthermore, a limit for minimum ablation is mentioned and cannot be changed. If a refractive treatment plan calculates less than 5 µm in maximum ablation depth, an information message appears to be confirmed. Therapeutic treatments below 5 µm in depth cannot be planned.

(De-)activation of the asymmetric offset (= activation of symmetric offset) results in a different ablation strategy whenever a pupil offset is entered unequal to zero. Asymmetric is the default setting with its ablation profile concentric to the pupil area, symmetric shifts the whole ablation towards the `corneal vertex` (= centre of ablation is given by the pupil offset input values).

Epithelium: thickness values can be defined for the center [20 to 75 µm] towards the periphery [20 to 100 µm] for a diameter selected [5.0 to 9.0 mm] which are taken into account for calculation purposes within the RST manager in PRK and LASEK mode, and for epithelium removal with the laser; i.e. in TransPRK procedures and possibly in the PTK methods.

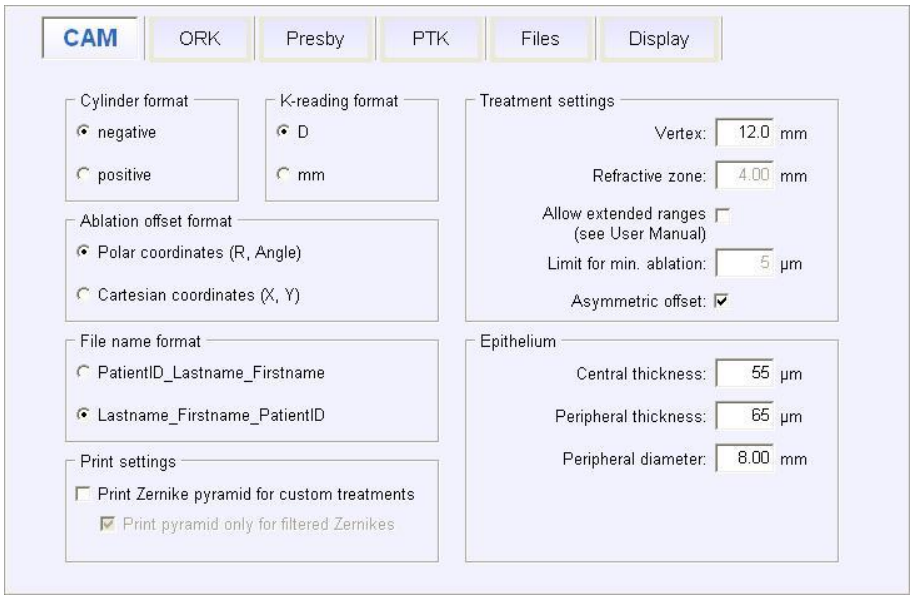


Figure 6-6: General Settings Mask – CAM (default)

IMPORTANT NOTE

Refractive power in dependency of vertex distance

$$P_{VD_{new}} = \frac{P_M}{1+(VD_{new}-VD_{old})*P_M} = \frac{1}{\frac{1}{P_M}-\Delta VD}$$

P_M = refractive power of a meridian [D]

VD = vertex distance [m]; e.g. 0.012 m (= 12mm)

ΔVD = VD_{new} - VD_{old} [m]

6.3.1.2 ORK Tab

- **RST-Configuration:** default central and peripheral flap thicknesses [50 to 250 µm according to the preferred microkeratome or microkeratome head] can be set, as well as minimum Residual Stromal Thickness [250 to 500 µm] for calculation purposes.
- **Optical zones:** an individual default value [6.00 to 7.50] in three different refraction types (Myopia dom., Astigmatism dom., Hyperopia dom.) can be chosen. The refraction type is based on the laser spherical equivalent (SEQ) value and cylinder amount (both @ VD = 0) in reference to the laser-refraction display in each patient's eye.

IMPORTANT NOTE

Myopia dominant, i.e. SEQ negative and sphere numerically larger than cylinder

Hyperopia dominant, i.e. SEQ positive and sphere numerically larger than cylinder

Astigmatism dominant, i.e. SEQ zero or cylinder numerically larger than sphere

The SCHWIND recommendation in terms of ORK-CAM optical zone size selection is equal or bigger than 6.3 mm in myopia, equal or bigger than 6.7 mm in hyperopia, and equal or bigger than 7.0 mm in astigmatism dominance (=ORK-CAM software default settings). Make always sure that optical zone size selection covers minimum the whole pupil area in low mesopic/scotopic light conditions for good vision at all light conditions.

WARNING!

Make sure to select the flap to an adequate thickness corresponding to your experience.

The treatment plan naturally proposes smaller optical zone (OZ) sizes than default when import information/diameter with extended functionality included is still smaller than OZ default setting. Make sure that OZ is always large enough for each individual patient.

Figure 6-7: General Settings Mask – ORK (default)

IMPORTANT NOTE

Further ORK details can be found in the separate Treatment Planning Guideline **"Module: ORK-CAM" of the SCHWIND CAM.** Choose <**Help**> and 'ORK' within SCHWIND CAM for eIFU access.

6.3.1.3 Presby Tab

- **RST-Configuration (from ORK):** default central and peripheral flap thicknesses [50 to 250 μm] as well as minimum Residual Stromal Thickness [250 to 500 μm] have to be set in ORK tab and serve as overview here.
- **Optical zones:** an individual default value [6.00 to 7.50 mm] in three different refraction types (Myopia dom., Astigmatism dom., Hyperopia dom.) can be chosen. The refraction type is based on the laser spherical equivalent (SEQ) value and cylinder amount (both @ VD = 0) in reference to the laser-refraction display in each patient's eye.

IMPORTANT NOTE

Myopia dominant, i.e. SEQ negative and sphere numerically larger than cylinder.

Hyperopia dominant, i.e. SEQ positive and sphere numerically larger than cylinder.

Astigmatism dominant, i.e. SEQ zero or cylinder numerically larger than sphere.

The SCHWIND recommendation in terms of PresbyMAX optical zone size selection is equal or bigger than 6.2 mm in myopia, equal or bigger than 6.5 mm in hyperopia, and equal or bigger than 6.8 mm in astigmatism dominance (= PresbyMAX software default settings). Make always sure that optical zone size selection covers minimum the whole pupil area in low mesopic/scotopic light conditions for good vision at all light conditions.

In case of PresbyMAX® planning, both eyes are taken with equal optical zone (OZ) size, i.e. the bigger OZ of the recommended is chosen as default.

WARNING!

The treatment plan naturally proposes smaller optical zone (OZ) sizes than default when import information/diameter with extended functionality included is still smaller than OZ default setting. Make sure that OZ is always large enough for each individual patient.

The manufacturer's default optical zones (OZ) (refer to Figure 6-8) shall be considered as guideline for OZ as a compromise between tissue removal, biomechanical stability and reasonable contributions of the central and peripheral for near and distance vision, respectively.

- **Presbyopia treatment model:** a Bi-Aspheric multifocal profile binocular centrally near distance corrected and peripherally far distance corrected with two adapted transition zones included. The Bi-Aspheric model proposes the same default addition of +1.75 D for all types [input range +0.75 to +3.00 D]. The selected near (non-dominant) eye behaves equal in all types but distance (dominant) eye differs in terms of the multifocal approach.
  - Type **'*μ*-Monovision'**: the target multifocality is equal in distance eyes (100%) and near eyes (100%).
  - Type **'Hybrid'**: the target multifocality is different in distance eyes (50%) and near eyes (100%).
  - Type **'Monocular'**: the target multifocality is different in distance eyes (0%) and near eyes (100%). I.e. the distance eye follows the typical Aberration-Free (AF) concept.
  - Selection of the amount of **'Anisometropia'**: a difference of the refractive target (post-operative) between distance and near eyes can be adjusted within certain limits [0.00 to 1.50 D]. Default setting is 0.88 D according to SCHWIND preference.

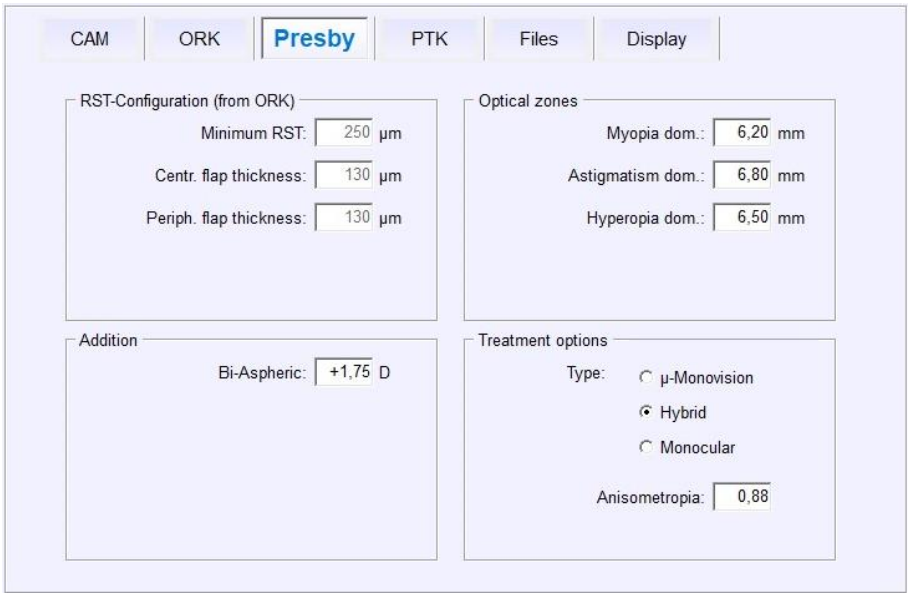


Figure 6-8: General Settings Mask – Presby (default)

IMPORTANT NOTE

Further PresbyMAX details can be found in the separate Treatment Planning Guideline **"Module: PresbyMAX" of the SCHWIND CAM**. Choose <**Help**> and 'PresbyMAX' within SCHWIND CAM for eIFU access.

6.3.1.4 PTK Tab

- **RST-Configuration:** minimum Residual Stromal Thickness [300 to 500 µm] can be adapted.
- **Show ellipse input fields:** enables the input of a long and short diameter value for elliptical shape (instead of circular) as default.
- **"Use transition zone"** is automatically decided with 0.50 mm size and both settings cannot be changed by the user.
- **"TransPTK"** can be (de-) activated.

IMPORTANT NOTE

With TransPTK, the shot profile considers the ablation to be started on top of the cornea, i.e. with epithelium included. But it does not necessarily mean that the complete epithelium is removed due to this function (compared to TransPRK).

As long as the ablation depth planned in PTK is less than the individual epithelium profile depth entered when TransPTK is selected (range 20 to 75 µm in the centre and 20 to 100 µm towards the periphery @ 5 to 9 mm), the patient's stromal tissue is theoretically not touched and the ablation takes place within epithelium tissue only.

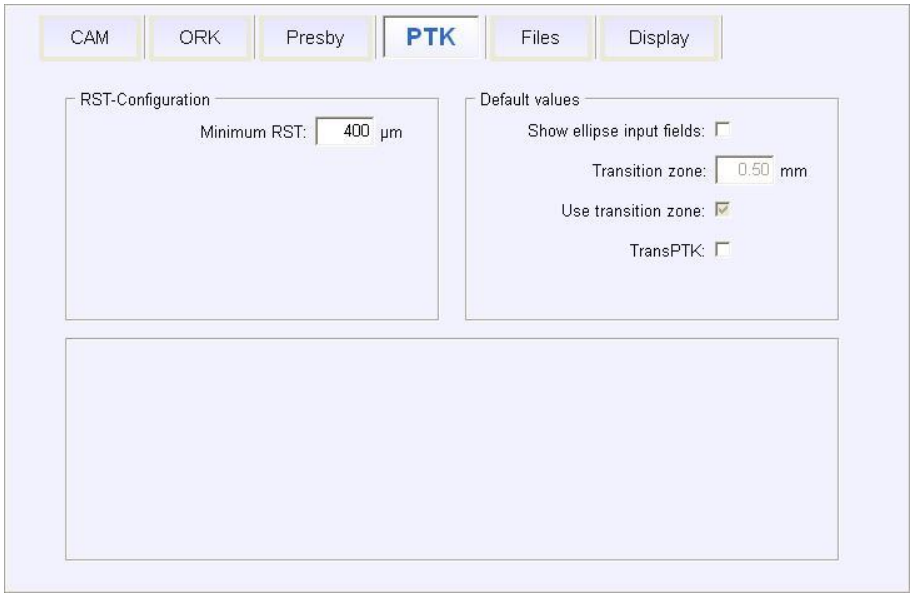


Figure 6-9: General Settings Mask – PTK (default)

IMPORTANT NOTE

Further PTK details are found in the separate Treatment Planning Guideline **"Module: PTK-CAM" of the SCHWIND CAM**. Choose <**Help**> and 'PTK' within SCHWIND CAM for eIFU access.

6.3.1.5 Files Tab

By enabling "Use standard paths" different file paths for import and export activities can be defined for easy and faster access:

- **OW:** create a file path with direct access to***.iow** –,***.wow** –, ***.osw** – respectively ***.ocw** – files (export from Ocular Wavefront device).
- **CW:** create a file path with direct access to ***.scw** –, ***.ccw** –, ***.mcw** –, ***.csw** – respectively***.ocw** – files (export from Corneal Wavefront device).
- **Corneal Pachy:** create a file path with direct access to ***.ccp** – files (export from Pachymetry device).
- **Save:** create a file path with access to the directory for project saving aspects.
- **Export:** create a file path with access to the directory for project export aspects.
- **Open:** project re-load aspects can be achieved with access to the save file path or to the export file path or an individual custom file path is created.

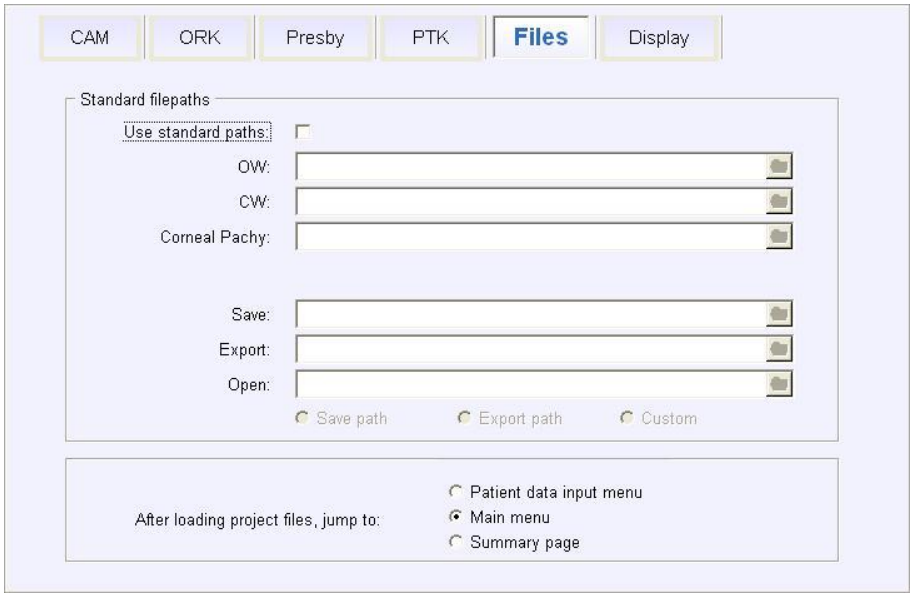


Figure 6-10: General Settings Mask – Files (default)

IMPORTANT NOTE

If "Use standard paths" is not enabled, the directory always remembers the last file path that was used.

CAUTION

If a data carrier cannot be found, e.g. SD card for export files is not in the drive, but related file path was taken as default, the main directory "My documents" opens instead.

Furthermore, a selection in files tab exists whether project file re-loads shall be opened at Patient Data Input Menu, Main Menu, or Summary Page. Access to Summary Page is only given when all data needed were entered.

IMPORTANT NOTE

In treatment planning that has not been accomplished for laser export or requests confirmation of warning messages, direct access to the Summary Page is denied. The Main Menu opens instead.

6.3.1.6 Display Tab

- **View:** the display of maps can be pre-defined as 2-dimensional or 3-dimensional.
- **Surface:** the display of maps can be standard solid or wireframe.
- **OSA conformity**: the ablation and wavefront maps can be shown in OSA standard, normalized scale, or zero-to-max.
- **Axes, Angle, Circles, and Grid:** the display of each feature can be separately (de-) activated.
- **Display buttons:** the buttons on the right and left side (in Main Menu) of SCHWIND CAM window can be decided to be small or large. In small icons information pops up when mouse over is performed.

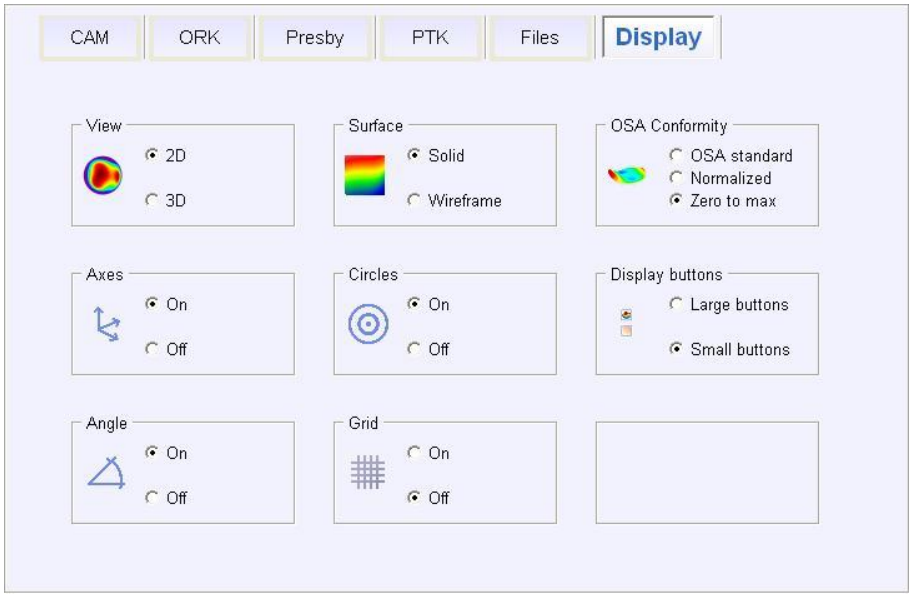


Figure 6-11: General Settings Mask – Display (default)

CAUTION

Using <**Tab**> moves, the (de-) activation procedure in fields with radio buttons is possible via arrow keys (up, down, left, and right).

IMPORTANT NOTE

The data in chapter 6.3.1 Setting Button will be saved in system files, thus being preserved with a restart of the computer and also with SCHWIND CAM software updates. Nonetheless, updates may include new setting options.

The messages in Figure 6-12 and Figure 6-13 indicate that new application and display settings have been added and used according to manufacturer's default. Adaptations are always possible by the user.

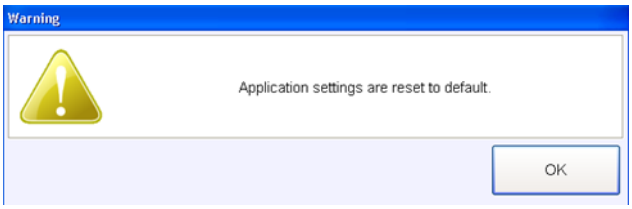


Figure 6-12: Message 1 in SCHWIND CAM after software update and successful registration

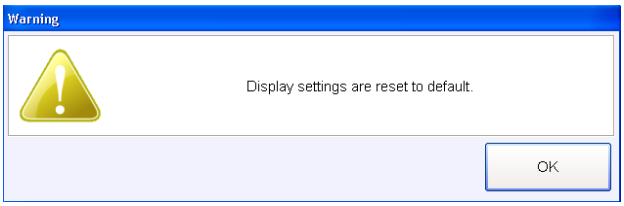


Figure 6-13: Message 2 in SCHWIND CAM after software update and successful registration

IMPORTANT NOTE

Default settings (CAM, ORK, Presby, PTK, Files, and Display) have to be determined before starting any SCHWIND CAM module!

User Manual(s)/IFU(s) or Treatment Planning Guidelines and information screen including software details can be chosen even when a CAM module is running.

CAUTION

If the 'Setting Files' are not readable, all configurations are set back to 'Default Values' in the next step and must be entered again.

6.3.2 Help Button

Access to SCHWIND CAM related treatment planning guideline(s), e.g. ORK-CAM, (Figure 6-14) can be achieved by pressing <**Help**> on the SCHWIND CAM Welcome Screen.

The manual of SCHWIND CAM or its corresponding module will be accessible in PDF format (eIFU). Choose the button <CAM> for general software and setting information or the button of the specific CAM module for details.

<**Close**> has to be used if help window with access to manuals shall disappear.

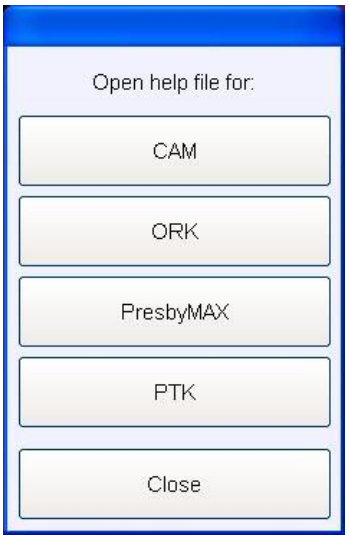


Figure 6-14: Icon(s) for Manual Access

CAUTION

A PDF Reader has to be installed and started once for gaining access to the User Manual/ IFU or Treatment Planning Guideline (PDF document).

6.3.3 Info Button

The software <**Info**> button on the SCHWIND CAM Welcome Screen can be pressed to receive information about CE with details, the SCHWIND CAM serial number, the operating system, and contact to SCHWIND eye-tech-solutions (Figure 6-15). Push <**CE0483**> to receive further identification info with unique device identification (UDI) included of the medical device software 'SCHWIND CAM'.

Figure 6-15: Example of SCHWIND CAM Information

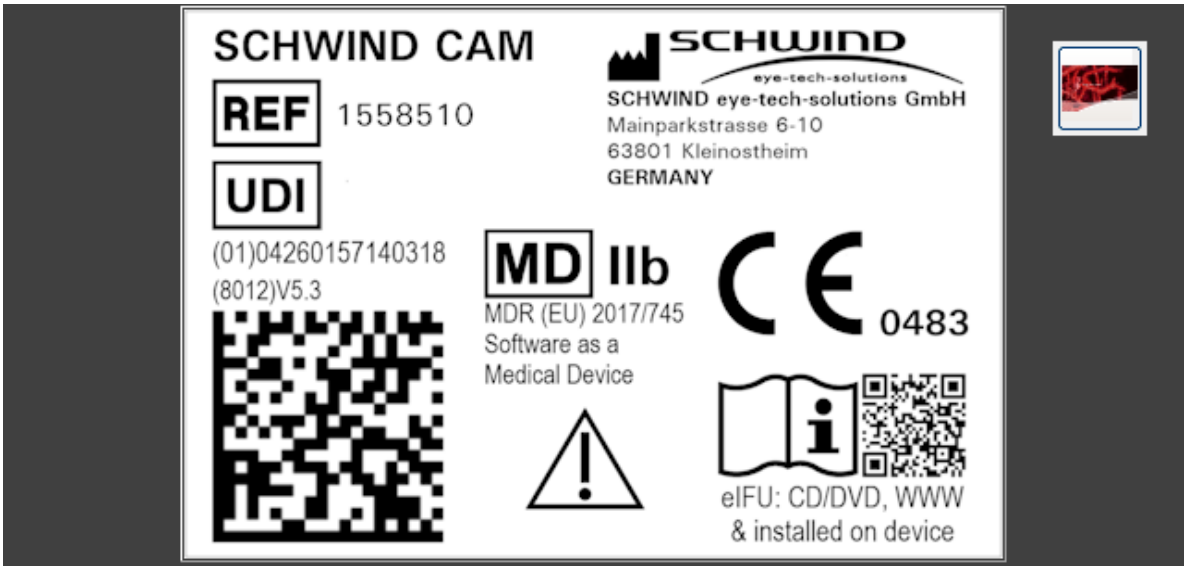


Figure 6-16: Identification Label SCHWIND CAM: "Software as a Medical Device"

Push  to come back to Figure 6-15.

<**OK**> button has to be pressed to close the window screen.

6.3.3.1 System Info Details

More detailed information about the data files used in this setup is shown in <**Details**>.

6.3.3.2 Print Settings

The current treatment settings (general and display settings as well as specific ones for each integrated module) can be printed for user documentation and user information via <**Print Settings**> button.

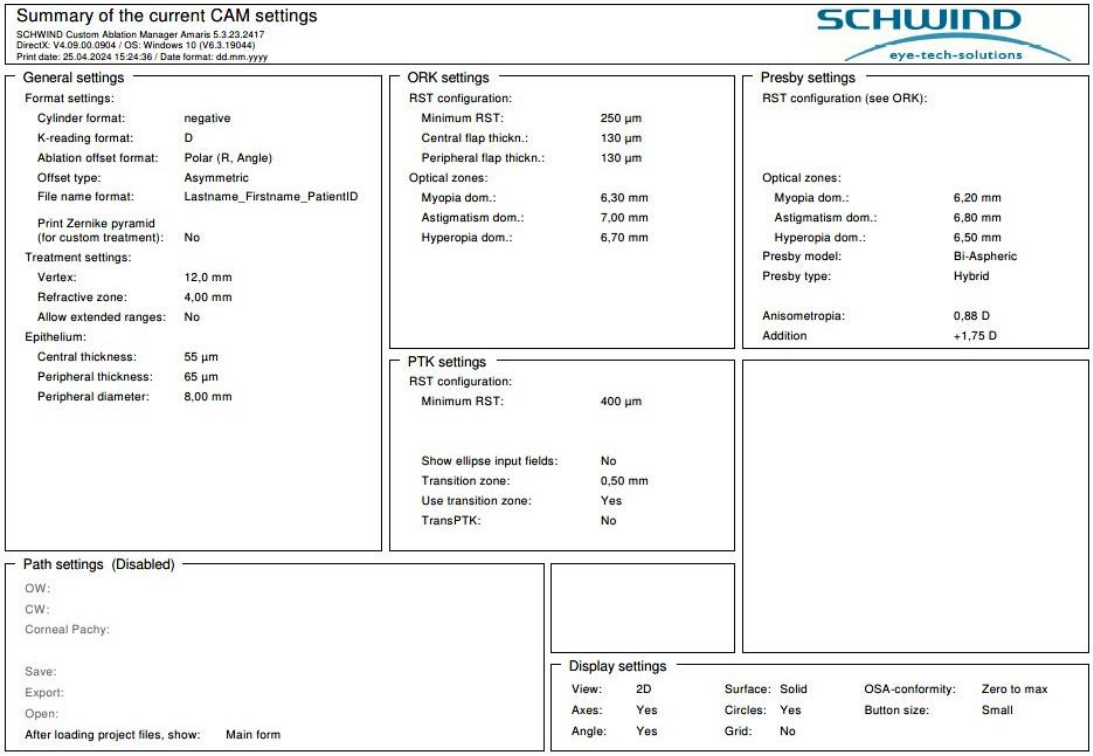


Figure 6-17: Summary of current SCHWIND CAM settings (manufacturer default values)

6.3.3.3 Activations

The activation center for SCHWIND CAM and its modules is accessible via the <**Activations**> button. The window for SCHWIND CAM [full version] key code entry can be shown again via <**CAM registration**> if the message: **"Do not show this registration window again"** in full setup registration window was activated once but full setup registration may be executed later on.

Furthermore, it is possible to activate the interface to **Foresight** (see 5.4.3 Foresight) after SCHWIND CAM [full version] registration. The Foresight activation is fee-based and limited in time. Validity is displayed next to <Foresight> button.

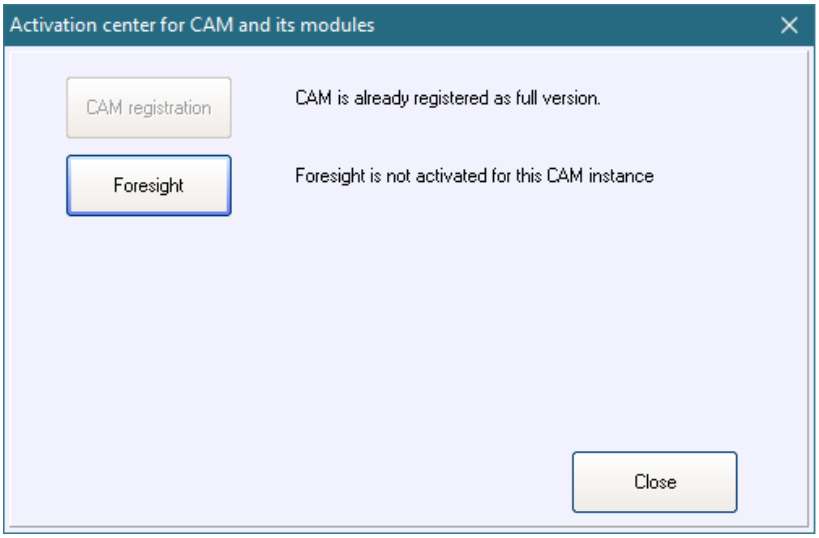


Figure 6-18: Activation center with CAM registration only

IMPORTANT NOTE

Please contact SCHWIND eye-tech-solutions or your authorized local SCHWIND representative and ask for an offer if interest in the SCHWIND Foresight application exists.

7 TROUBLESHOOTING

No.	Troubleshooting	Solutions
1	User-specific settings are missing.	Make sure that 'Settings' of the SCHWIND CAM Welcome Screen are entered correctly. Repeat the entry of user-specific settings and confirm with <OK>.
2	Software cannot be started.	Registration has not been accomplished. Uninstall and re-install the software.
3	Manual cannot be opened	A PDF Reader (for users' manual function within the software) has not been installed on (Panel-) PC.
4	Projects cannot be saved on HDD or external medium	The disk free space and the main memory fall below certain limits.
5	Software cannot be registered	Obtain a new registration code, the code received is incorrect.
6	Software cannot read the settings	Restart of the software or even new installation if restart is not successful.
7	The active window does not show up again after SCHWIND CAM software was minimized.	Maximize the SCHWIND CAM window (get access to SCHWIND CAM) with use of <Alt> and <Tab> combination.
8	The SCHWIND CAM software shuts down while software start	Make sure that the level of acceleration supplied by the graphics hardware is fully activated in C:\Control Panel\Display\Display Properties: Tab "Settings"; button: Advanced; Tab: "Troubleshoot"; Hardware acceleration has to be full.
9	The SCHWIND CAM software shuts down while planning	Regional windows settings or display resolution has been changed by the user.
10	The selected file path is invalid (e.g. F:\)	Check whether the card reader is properly connected to the device. A memory card has to be inserted into the card reader.
11	Treatment cannot be started (within AMARIS laser)	No credit left for this kind of treatment.

8 MANUFACTURER / TECHNICAL ASSISTANCE / 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 Service or Customer Support 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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