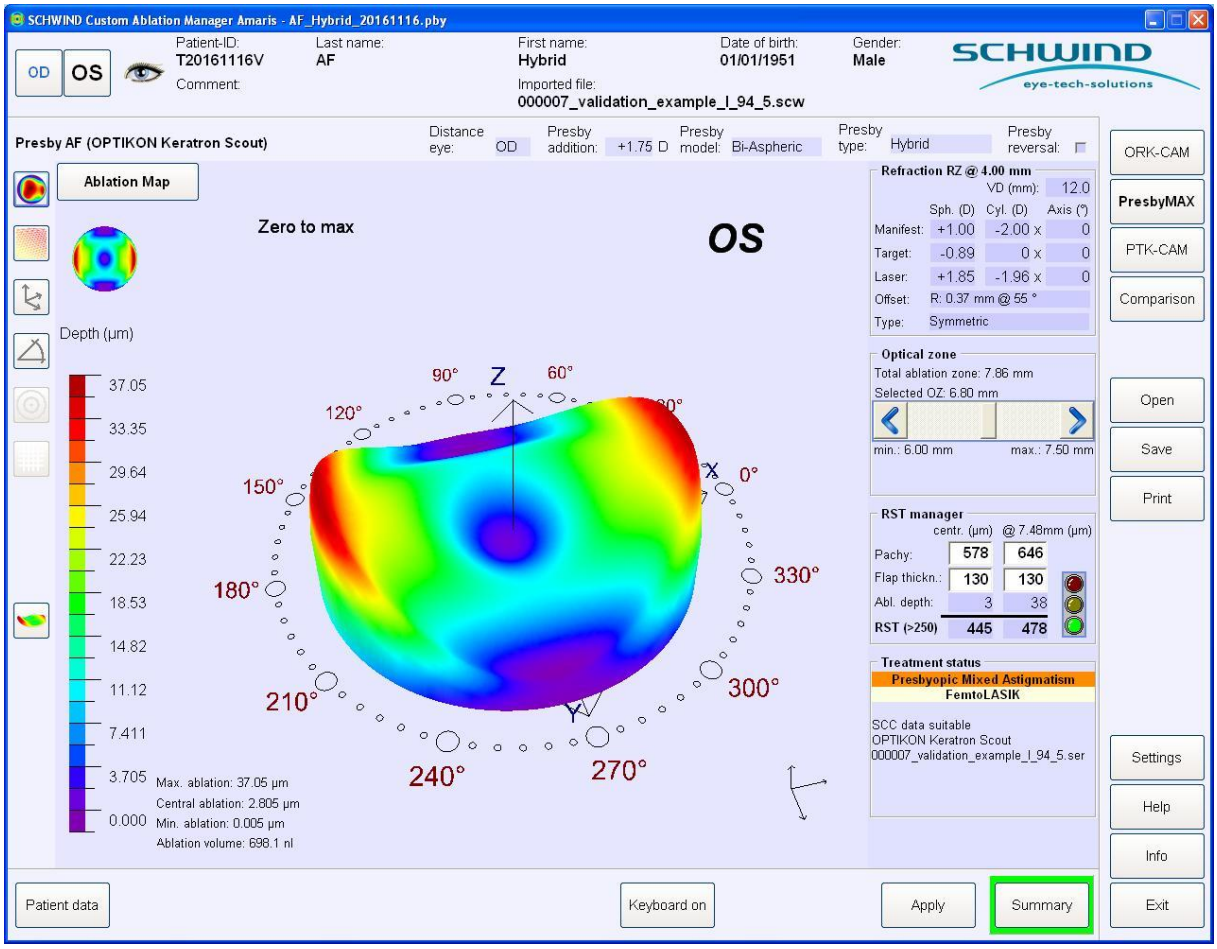
Treatment Planning Guideline (Original Instruction for Use) PLAN

Valid for CAM SW 5.3 (AMARIS SW 6.1)

SCHWIND Custom Ablation Manager

PresbyMAX® Module



The PresbyMAX® Treatment Planning Guideline does not contain the description of the SCHWIND CAM. Refer to the main User Manual of SCHWIND CAM

CE 0483

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1. GENERAL INFORMATION

1.1 Product Identification Data

Product name:	**SCHWIND Custom Ablation Manager** (CAM) **Module: PresbyMAX®**
Product description:	Refer to main User Manual of SCHWIND CAM (Chapter 4 Product Description)
Medical Device Class:	**IIb (according to MDR Annex VIII)**
Software version:	**5.3.23.2417** (SCHWIND CAM)
CE labelling:	CE 0483
Approved device compatibilities:	Refer to main User Manual of SCHWIND CAM, chapter 3.4
System requirements:	Refer to User Manual SCHWIND CAM, chapter 5.2
Manufacturer	**SCHWIND eye-tech-solutions GmbH** Mainparkstraße 6 – 10, D-63801 Kleinostheim
Delivery	**SCHWIND eye-tech-solutions GmbH** or authorized SCHWIND distributor
Current document status:	**Version 5.3 PresbyMAX EN / 2024-04-26**

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 PresbyMAX Manual

The purpose of the **PresbyMAX Treatment Planning Guideline** is to familiarize the operator(s) of the SCHWIND CAM software with the safety instructions, set-up, handling and operation of the SCHWIND PresbyMAX software module.

IMPORTANT NOTE

Read this manual carefully before you start running the PresbyMAX software module.

This Treatment Planning Guideline does not contain all information which is necessary for the safe and effective application of the SCHWIND CAM module PresbyMAX according to its intended use.

Consider the accompanying documents!

- **Main User Manual SCHWIND-CAM**

Observe all safety regulations, warning notes and further instructions contained in **main User Manual of SCHWIND CAM**!

Please keep the PresbyMAX Treatment Planning Guideline and all related documents close to the medical device. Always allow any user access to this User Manual at all times, store it readily available.

IMPORTANT NOTE

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

1.4 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

5 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.

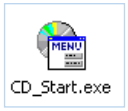
For your information, the CD-ROMs only contains instructions in English. The Instructions in other languages are available in the SCHWIND Portal. For safety-related changes in the instructions you will be informed immediately by the SCHWIND company by email.

Upon request, you will receive the paper format of the IFU by mail within in 7 working days – free of charge (see contact in 5 Manufacturer / Technical Assistance / Application Support).

1.5 Using the Product Documentation CD-ROM with the eIFU

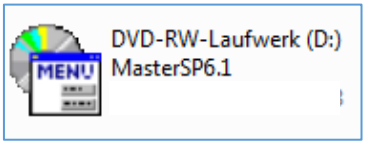
To read the SCHWIND **electronic Instructions for use** contained on the "SCHWIND Product Documentation" CD-ROM, perform the following steps:

- 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. OPERATION – RUNNING PRESBYMAX® MODULE

The <**PresbyMAX**> button on the SCHWIND CAM Welcome Screen activates this module (the button is located in the upper right part of the screen).

WARNING!

Take time to plan each single presbyopia treatment in an optimal manner (several diagnostic measurements, take the „best" one, several plan settings, take the „best" one, etc...)

2.1 Treatment Data Input Mask

The Presbyopia Treatment Data Input Mask (Figure 2-1) comes up after the icon <**PresbyMAX**> is pressed.

CAUTION

Mainly the "TAB" function on keyboard is active to move forward and to confirm entries; the "ENTER" key is applicable on buttons only. Further button activation with space bar is possible.

Backward jumps are possible with the combination of "Shift" + "TAB".

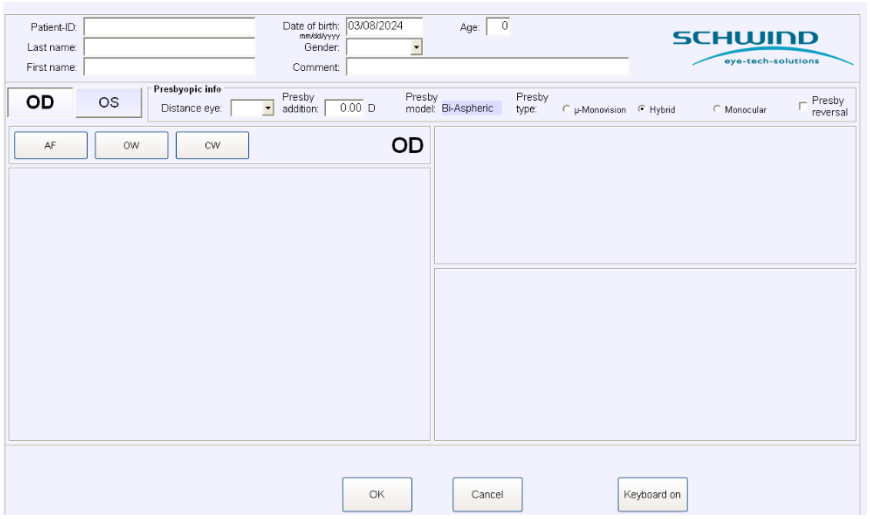


Figure 2-1: Presbyopia Treatment Data Input Mask (default)

IMPORTANT NOTE

This software offers a virtual keyboard for data entry (supports the touch screen functionality) beside the standard external keyboard.

The button <**Keyboard on**> can be used if entries shall be applied via touch screen. Another press switches the <**Keyboard off**> again.

2.1.1 Basic Patient Information Data

Patient-ID

A patient-ID is required for each creation of presbyopia treatment files. Letters and numbers as well as special signs can be used.

Lastname & Firstname

The patient's name has to be entered in these two fields.

IMPORTANT NOTE

First letter of Last name(s) and First name(s) start automatically with capital (no "Shift" necessary).

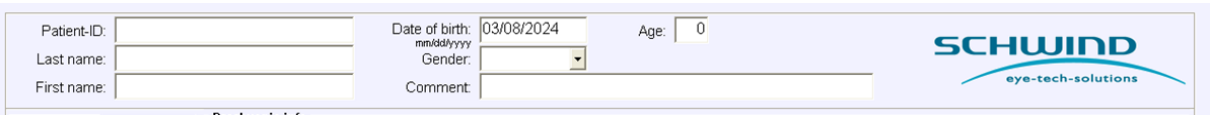


Figure 2-2: Patient Data Input Mask

CAUTION

Special characters are allowed to be used within SCHWIND CAM, but will be replaced by underscore ("_") if they are part of patient's file name (patient-ID, last name, first name) while export to the AMARIS excimer laser is prepared.

Date of Birth & Age

The date of birth must be entered manually, e.g. **mm/dd/yyyy**. The age will be automatically calculated from this. If only age is entered, the date of birth will be set to 01/01/XXXX.

IMPORTANT NOTE

Only numbers have to be entered for the date of birth. The separators between month (m), day (d), and year (y) are provided automatically. The number of digits shall be used according to the proposal in SCHWIND CAM software (e.g. mm/dd/yyyy).The date format is related to Windows regional settings (on Panel PC).

The entry of age is checked for plausibility: the normal range accepted in SCHWIND CAM is 18 to 99 years, entries below or above have to be confirmed explicitly.

WARNING!

Entry of correct patient's age is required considering the correct age-related compensational factors for the ablation process.

Nevertheless, for presbyopia 40 years is the minimum age entry to continue without any warning in this module. The accommodative response of each individual healthy emmetrope ("far distance best corrected") below 40 shall usually allow reading without additives.

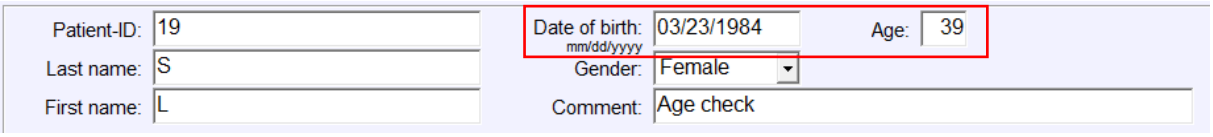


Figure 2-3: Example of treatment for a patient under the age of 40

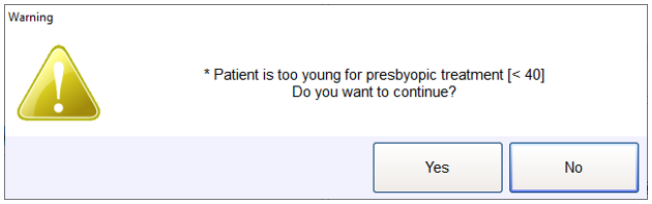


Figure 2-4: Warning for treatment under the age of 40

CAUTION

Patient's addition value proposal belongs to pre-setting (with +1.75D as a so-called 'all-rounder solution') and is not related to patient age entry. Possibility exists to individually change the presby addition within a +0.25 to +3.00 D range in Patient Data Input Mask.

Gender

The gender (female/male/ other/ undisclosed) has to be chosen by using the arrow button next to the related column, by clicking within the column directly or by using the arrow keys from keyboard.

Comment

The comment field enables an optional free text entry (maximum 255 characters).

IMPORTANT NOTE

Entering a comment for the treatment is optional and not necessarily needed for the treatment planning.

Any comment entered will be included on the printout, in PresbyMAX summary page and AMARIS treatment protocol.

2.1.2 Presbyopic Information

Distance eye

A distinction between distance and near eyes is necessary for correct application as PresbyMAX includes a defined (default) anisometropia of 0.88 D at corneal plane in all ablation profiles. Selection of the distance eye includes an emmetropic far distance target refraction (0.00 D @ VD = 0), the corresponding near eye approaches a myopic far distance (default) target of -0.88 D @ VD = 0.

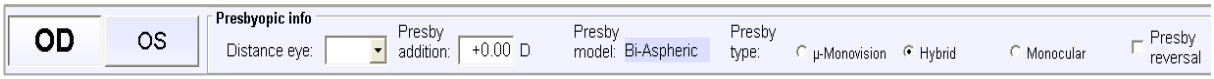


Figure 2-5: Presbyopic Information

Presby addition

The compensation factor for patient's presbyopic symptoms (at 40 cm) in dioptres is automatically proposed: +1.75D as default value after initial installation. Basically, the software allows an addition range of +0.25 D to +3.00 D.

IMPORTANT NOTE

The addition value of +1.75 D can be considered as so-called 'all-rounder solution' (in combination with a myopic far distance target of -0.88D @ VD=0). This value proposal is not related to patient age entry. Changes of the addition value can still be individually considered according to patient needs by the physician or treatment planner.

Presby model

Bi-Aspheric: the Presby model bases on bi-aspheric, multifocal ablation profiles, i.e. each concentric area is aspheric multifocal with a transition between the both providing intermediate vision. For each patient eye, it optimizes the central corneal area for near vision and the pericentral cornea for far vision (Figure 2-7).

The Bi-Aspheric model proposes a default addition of +1.75D. The targets at far distance are 0.00D (distance eye) and -0.88D (near eye) at corneal plane (PresbyMAX defaults after initial installation; changes are possible in presby section of 'CAM Settings'). The amount of target multifocality (to aim for more negative corneal spherical aberration or a hyperprolate cornea) depends on the presbyopic addition value ('Presby addition') as well as the treatment type selection ('Presby type'). The selected near (non-dominant) eye behaves equal in all types but distance (dominant) eye differs in terms of the multifocal approach.

Presby type

'μ-Monovision': the target multifocality is equal in distance (100%) and near eyes (100%).

'Hybrid': the target multifocality is different in distance (50%) and near eyes (100%).

'Monocular': the target multifocality is different in distance (0%) and near eyes (100%). I.e. the distance eye follows the typical aberration-free (AF) concept.

IMPORTANT NOTE

The **near (non-dominant) eye** approach is in all presby types (μ-Monovision, Hybrid, Monocular) the same, the difference exists in **distance (dominant) eyes** only including either 100% (μ-Monovision), 50% (Hybrid), or 0% (Monocular) intended multifocality.

The more multifocality is included the better the reading ability supposed to be and the bigger the binocular overlap (stereo acuity) - particular in intermediate distance range - BUT the bigger the compromise in far distance vision also will be.

CAUTION

Selection of the PresbyMAX type should be taken with care, i.e. a detailed patient exam (refraction, diagnostics), possible vision simulations (contact lens, trial frame), and patient interview with analysis of vision tasks and distances to be done before decision is established.

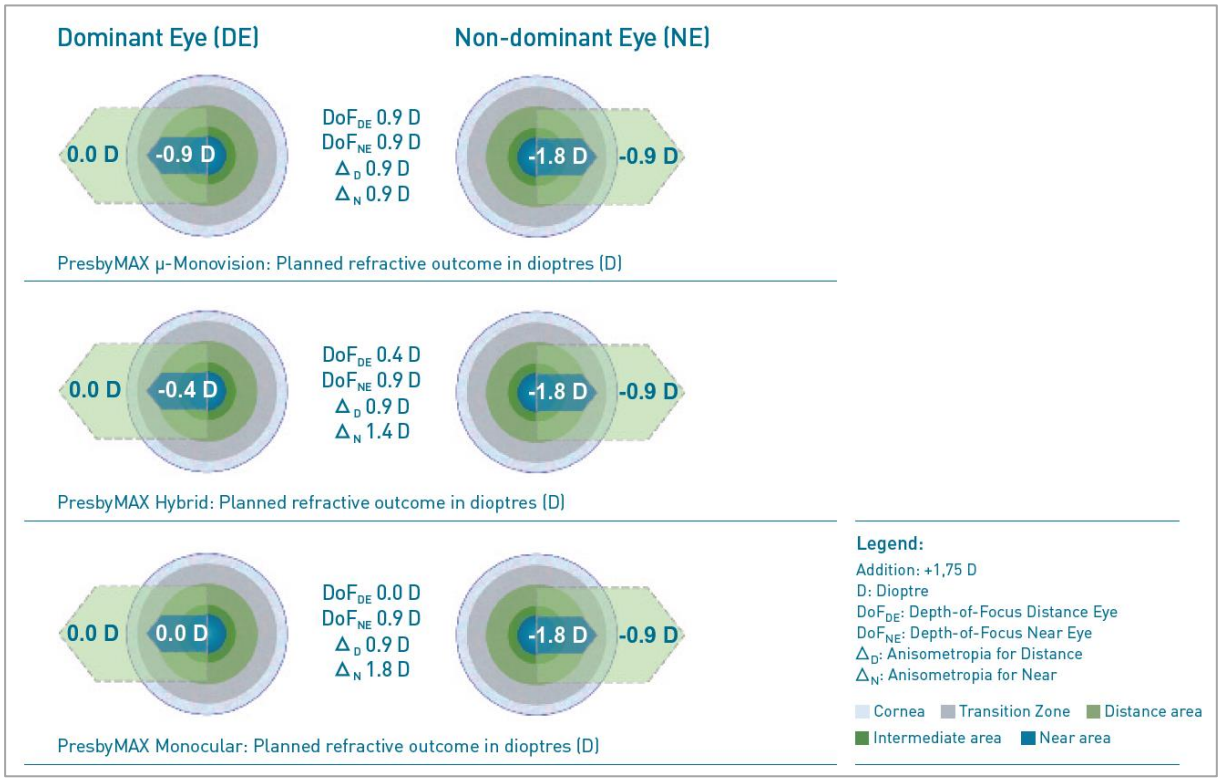


Figure 2-6: Top view of a PresbyMAX® prolate bi-aspheric multifocal cornea with targets for the central and mid-peripheral areas (PresbyMAXμ-Monovision in comparison with PresbyMAX Hybrid and PresbyMAX Monocular, all with an addition selection of +1.75 D and a myopic far distance target of -0.9D in near eyes (NE))

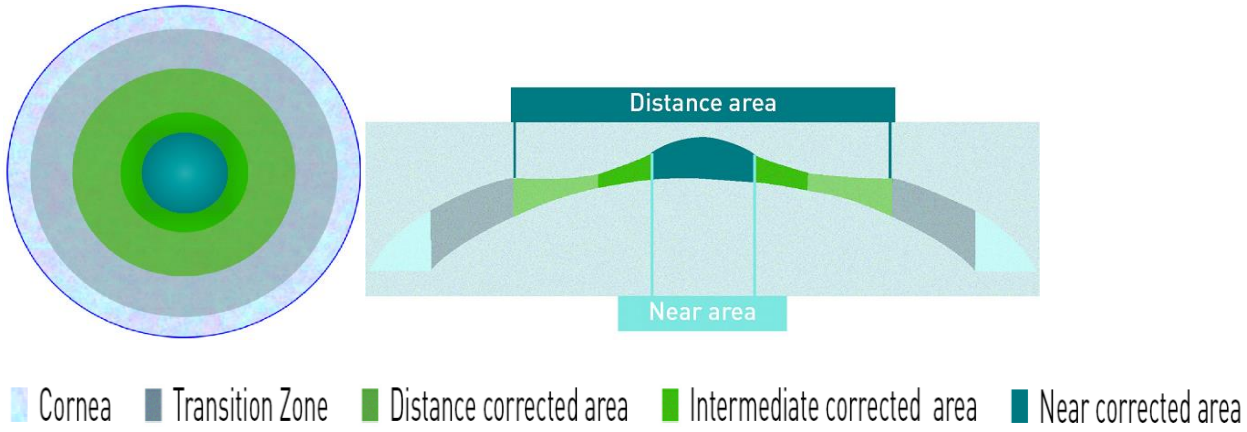


Figure 2-7: Top view and cross section simulation of a PresbyMAX® prolate bi-aspheric multifocal cornea

Presby reversal

Enabling the **Presby reversal** option creates a reversed presbyopic correction, in an attempt to correct residual refraction and to remove induced multifocality in total or part of a previous PresbyMAX treatment. The Presby reversal model bases on bi-aspheric, multifocal ablation profiles, i.e. each concentric area is aspheric multifocal with a transition between the both providing intermediate vision. Presby reversal mode corrects the central corneal area strongly for far vision and the pericentral cornea for far vision with aim of a more monofocal (=less hyper-prolate) cornea. The addition value shows a negative algebraic sign in reversal application. Presby reversal can be combined with all presby types; the type selection and amount of addition value depends on the intended multifocality to be removed.

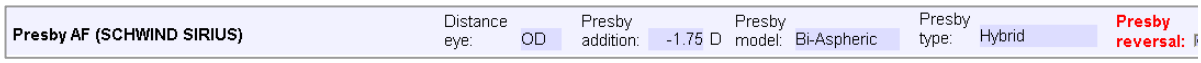


Figure 2-8: Presby reversal information with negative presbyopic addition (excerpt out of Main Menu)

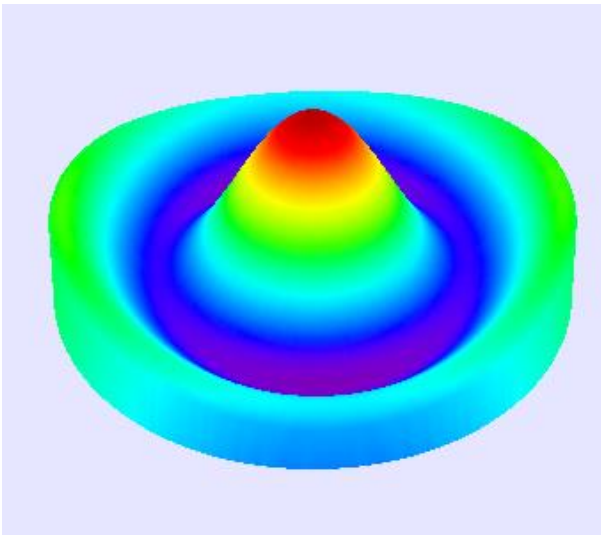


Figure 2-9: Ablation volume and depth for a myopic astigmatism (Laser: -0.37 / -0.25 @ 0°, VD 12 mm) with presbyopic reversal of -1.75D @ 6.5 mm optical zone (in the near eye).

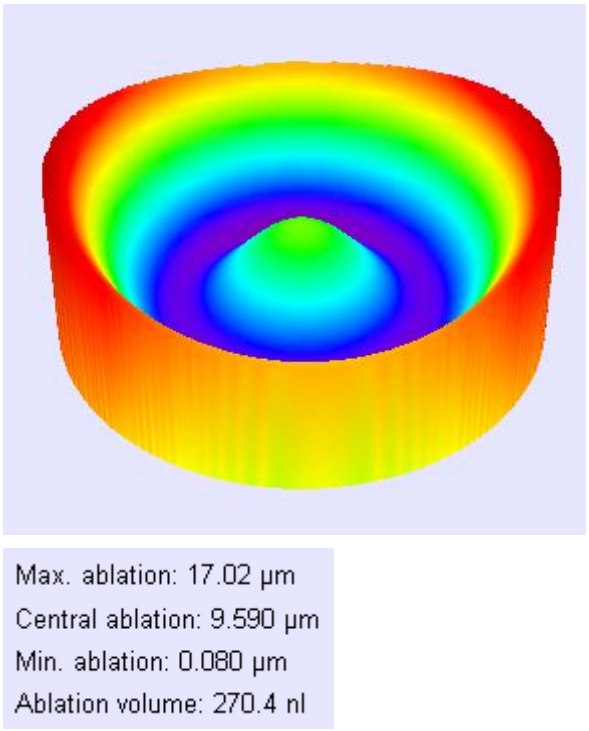


Figure 2-10: Ablation volume and depth for a hyperopic astigmatism (Laser: +0.63 / -0.25 @ 0°, VD 12 mm) with presbyopic reversal of -1.75D @ 6.5mm optical zone (in the near eye).

WARNING!

The Presby reversal option is not foreseen for planning initial PresbyMAX corrections in the form of "peripheral PresbyLASIK".

Ensure that the addition value in Presby reversal is always with NEGATIVE algebraic sign!

CAUTION

The Presby reversal option is not foreseen for planning all retreatments after PresbyMAX. Only plans to correct residual refraction together with the need of induced multifocality removal in total or part of a previous PresbyMAX treatment shall benefit from Presby reversal.

IMPORTANT NOTE

Presby reversal profiles cannot be combined with wavefront customisation (neither corneal nor ocular wavefront-guided), and are only enabled in the aspheric Aberration-Free (AF) mode.

The Presby reversal option can be used in all Presby types: μ-Monovision, Hybrid, and Monocular.

A PresbyMAX reversal treatment consumes less than 6.5 μm per dioptre addition @ a 6.5 mm OZ to remove 100% of the initially induced multifocality.

An already calculated PresbyMAX treatment cannot be switched to Presby reversal (or vice versa).

2.1.2.1 Types of Treatments

Eyes OD / OS

Bilateral treatment planning is required. The presbyopia treatment plan (files) has to be generated for both eyes OD (patient's right eye) and OS (patient's left eye) at the same time.

INFORMATION NOTE

Bilateral presbyopia treatment planning is required: both eyes contribute to providing visual acuity at all distances by actively participating in the visual process for creating binocular visual impressions: the presby types '***μ*-Monovision'** and particularly '**Hybrid**' are the favoured options.

Even if some patients accept classical monovision, and for those PresbyMAX® on only one eye – the presby type: 'Monocular' - might be a choice, the full capabilities of PresbyMAX® are not exploited this way. 'Monocular' has the advantage over classical Monovision that also intermediate vision can be addressed and binocular compromise should be less.

Types of PresbyMAX® Treatments

For each eye three types of PresbyMAX® treatment are possible. The choice is given to create a bi-aspheric multifocal "Aberration-Free" (AF) treatment or bi-aspheric multifocal treatments based on diagnostic devices "Corneal Wavefront" (CW) or "Ocular Wavefront" (OW).

The related button <**AF**>, <**CW**> or <**OW**> has to be chosen for starting an individual presbyopia treatment planning (Figure 2-1). Another press deletes all previous settings and imports (=no treatment selection), and new planning is necessary.

Figure 2-11: Types of Presbyopia Treatment

In Presby Corneal or Presby Ocular Wavefront treatments as much patient and diagnostic information as possible will be supplied from the export files of diagnostic systems.

2.1.3 Corneal Data

<**Corneal data**> button is visible with selection of <**AF**> and allows import of patient eye information (demographics, keratometry, pupil offset, and SCC) either from SCHWIND Corneal Wavefront Analyzer (Keratron Scout), SCHWIND SIRIUS or SIRIUS+, SCHWIND MS-39 or SCHWIND PERAMIS. In <OW> and <CW> treatment planning the <Corneal data> button appears only if SCC status is 'none' or 'data quality low' exists, i.e. a patient eye information update with good quality SCC is still possible. <Corneal data> does not import or overwrite wavefront information (higher-order aberrations) itself.

IMPORTANT NOTE

Make use of patient data import via <**Corneal data**> BEFORE refraction entries or changes in PDIM as target values are reset to zero with data import! Re-enter the planned target (refraction) if necessary. Furthermore, the software looks for ambiguous patient data (demographics) with file import.

<Corneal data> button disappears with import of good quality SCC data, except in the case of *.osw (Ocular Wavefront, PERAMIS) with basic patient eye information missing by nature of the diagnostic file content.

CAUTION

Check correctness of refraction data in Treatment Data Input Mask before continuing.

IMPORTANT NOTE

A corneal wavefront-guided (CW) treatment plan automatically uses the static cyclotorsional compensation (SCC) information that belongs to the diagnostic export file, i.e.

i. Corneal Wavefront "Scout": import of ***.scw**- respectively ***.ser**- file

ii. Corneal Wavefront "SIRIUS" or "SIRIUS+": import of ***.ccw**- respectively ***.cer**- file

iii. Corneal Wavefront "PERAMIS": import of ***.csw**-/***.ocw**- respectively ***.cer**- file

iv. Corneal Wavefront "MS-39": import of ***.mcw**- respectively ***.cer**- file

Aberration-Free (AF) and Ocular Wavefront (OW) treatment plans– that does not automatically include SCC information - can attach and use the SCC information of each device (i.- iv.) via <Corneal data>. As long as an export file of a SCHWIND diagnostic device does not contain good quality SCC data, treatment planning still allows attachment of SCC info by a different data file (i.- iv.).

SCC function is ready and enabled in your SCHWIND Corneal Wavefront Analyzer (Scout), i.e. a button <**ACC**> next to <SCHWIND Export>, respectively in your SCHWIND SIRIUS or SIRIUS+, SCHWIND MS-39 and SCHWIND PERAMIS with a "**SCC Check**" within the export area.

The SCC information will be attached automatically to the export file of your diagnostic system and import to PTK-CAM software module is possible afterwards.

Only in case the "**SCC- Check**" was passed (= green traffic light) within your diagnostic system, 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.

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 that SCHWIND distributed in the past (before its discontinuation).

2.1.3.1 Static Cyclotorsional Control

Static Cyclotorsional Control (SCC) data can be individually attached to an Aberration-Free (AF), Ocular Wavefront (OW) or Corneal Wavefront (CW) treatment using the <**Corneal data**> button, or information is imported together with Corneal Wavefront (CW) or Ocular Wavefront (OW) data in one step; all depending on the diagnostic device to be used.

Either data from SCHWIND Corneal Wavefront Analyzer ("SCOUT"; ***.scw**- respectively ***.ser**- file), SCHWIND SIRIUS or SIRIUS+ (***.ccw**- respectively ***.cer**- file), SCHWIND MS-39 (***.mcw**- respectively ***.cer**- file) or SCHWIND PERAMIS (***.csw**- /***.ocw** respectively ***.cer**- file) can be used for SCHWIND SCC.

After SCC file import the diagnostic device for SCC data acquisition, a status check, a quality evaluation of SCC and the related file name are displayed within Treatment Data Input Mask.

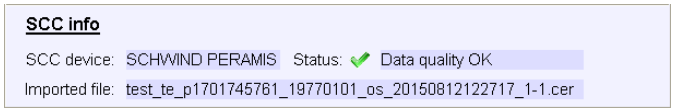


Figure 2-12: SCC info – data quality OK

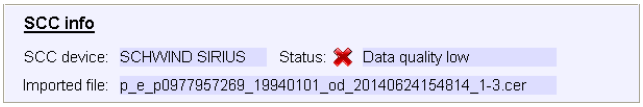


Figure 2-13: SCC info – data quality not suitable

SCC- quality information and SCC -file information are displayed in each screen of PresbyMAX software module.

CAUTION

Check correctness of input and import data in Treatment Data Input Mask before continued. Static cyclotorsion control will not be possible during treatment with wrong SCC file data.

2.1.4 Ambiguous Patient Information Data

In case of ambiguous basic patient information data a window as shown in Figure 2-14 appears. The user can select between two different patient information data, project and imported data, whereas project patient data is always the one that was entered or loaded first. <**Cancel**> removes the basic patient information data together with its details that were supposed to be imported. The project patient data stay with Treatment Data Input Mask when <Cancel> is pressed.

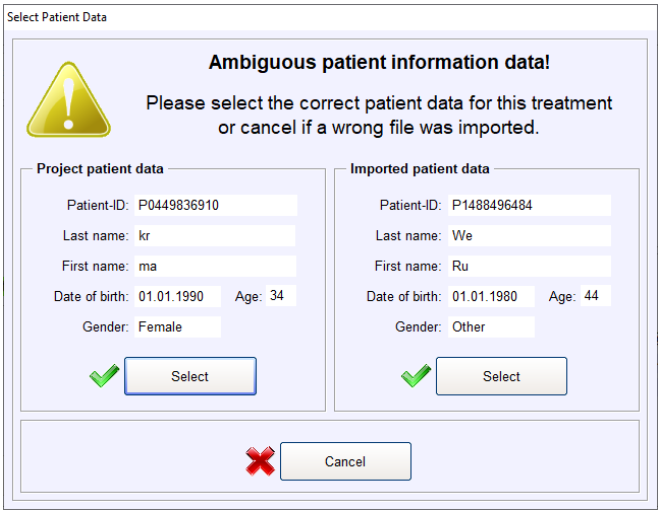


Figure 2-14: Ambiguous Patient Information Data

Please make your decision using <**Select**> or <**Cancel**>.

CAUTION

Be sure that both, project and imported patient data belong to one and the same patient if <**Select**> is used. <Select> takes the basic patient information data chosen for the Treatment Data Input Mask but keeps additionally all import information for both OD and OS. Check whether the imported files fit to basic patient information data on top of Treatment Data Input Mask.

Ensure that <**Cancel**> deletes all diagnostic file data from screen as well as memory. If not, reset the complete treatment plan with AF, OW or CW button and start treatment plan with proper data again.

IMPORTANT NOTE

The information of the eye that was entered respectively loaded first within the Treatment Data Input Mask is always shown on the left with headline "Project patient data", the headline on the right shows "Imported patient data", both independent from OD and OS!

2.1.5 Presby Aberration-Free (AF) Treatment

For a **Presby Aberration-Free** treatment, the <**AF**> button has to be pressed.

Either patient data are entered manually or panels are filled with use of button <**Corneal data**> that allows import of topography information (demographics, keratometry, pupil offset, and SCC).

IMPORTANT NOTE

The basic patient data (demographics) come together with <**Corneal data**> import, independent from whether these are coming from SCHWIND Corneal Wavefront Analyzer (Keratron Scout), SCHWIND SIRIUS or SIRIUS+, SCHWIND MS-39 or SCHWIND PERAMIS.

Make use of patient data import via <**Corneal data**> BEFORE refraction entries or changes in PDIM as target values are reset to zero with data import! Re-enter the planned target (refraction) if necessary.

It is possible to manually enter or import a treatment offset (= ablation centre for sphere and cylinder is different from pupil centre). Make sure to use treatment offsets with care, corresponding to pupil offsets measured by trustable diagnostic measurements. Treatment centring onto corneal vertex (= use of pupil offsets) shall be preferred to reduce induction of unwanted aberrations to a minimum.

Epithelium data import exists with use of SCHWIND MS-39 data files (*.mcw), i.e. automatic filling of the central and peripheral value in respect to the setting of the reference diameter within SCHWIND CAM module. Import values (of the periphery) of SCHWIND MS-39 measurements are adjusted appropriately for the ablation with SCHWIND lasers. Nonetheless, adaptations of epithelium data are still possible by the user after import.

CAUTION

Check plausibility of epithelium data in Treatment Data Input Mask compared to patient's MS-39 diagnostic data or the display of 'Refractive Export to SCHWIND: MS-39', respectively, before continuing.

Furthermore, check the planned ablation profile for plausibility, i.e. the content of the ablation map in PresbyMAX software module in comparison to diagnostic map information.

Figure 2-15: Presbyopic Aberration-Free (AF) Treatment Data Input Screen (example OD)

2.1.5.1 Refraction

Manifest Refraction

The ranges for sphere and cylinder values are related to 'normal' or 'extended' limit activation (refer to chapter 2.2 Boundaries of Input Refraction for Presbyopia), the treatment method (PRK, LASEK, and (Femto-)LASIK), and the type of refraction (Presbyopic myopia, Presbyopic compound myopic astigmatism, Presbyopic hyperopia, Presbyopic simple hyperopic astigmatism…).

The cylinder convention is according to the user settings (refer to User Manual SCHWIND CAM, chapter 6.3.1 Settings Button). The convention selected (negative or positive) is displayed within the refraction panel.

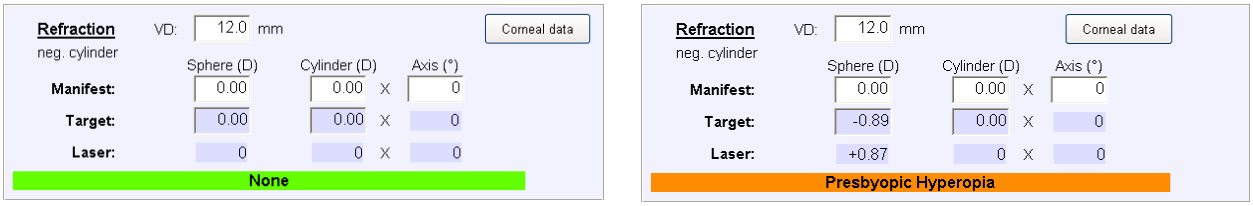


Figure 2-16: Presbyopia Refraction Panels in distance (left) and near (right) eyes

WARNING!

Pay attention to your astigmatism sign and axis convention as well as to the settings of the vertex distance.

For manifest refraction, use the optometric rule: take the measurement with the least negative (most positive) amount of defocus (SEQ), if several of them are equal in terms of SEQ then take the measurement with the least amount of astigmatism (Cyl) if several of them are equal in terms of Cyl then take the measurement with the astigmatism closest to with-the-rule (principle of minimum risk).

The algebraic sign always must be prefixed in case of sphere and cylinder value entries – otherwise no numeric input is possible.

IMPORTANT NOTE

If you are working with an English keyboard ("QWERTY") without separate numeric pad, positive refraction values cannot be entered until the input field is completely empty!

Use <**SHIFT**> and <+> for positive value entries on English keyboard in this case.

Target Refraction

The targets in PresbyMAX are 0.00D of sphere (distance eye) and -0.88D of sphere (near eye) by default at corneal plane. The target refraction indicates the desired postoperative subjective (manifest) far distance refraction. The target refraction cannot be manually adapted in this section of treatment planning module but able to preset within 'Settings' (Presby).

IMPORTANT NOTE

Please refer to 'Settings' (Presby) of SCHWIND CAM if anisometropia shall be different to post-operative target of - 0.88 D (default), and be modified within the range of 0.00 to 1.50 D.

Laser Refraction

The combination of 'Manifest' and 'Target' results in 'Laser'. Both manifest refraction and target refraction values (main meridians) are calculated back to corneal vertex (VD = 0) first, then added, and the result out of it (= laser refraction) is afterwards expressed for defined vertex distance again.

The (extended) presbyopia treatment ranges (at corneal vertex) that the laser refraction maximum accepts can be seen in chapter 2.2 Boundaries of Input Refraction.

IMPORTANT NOTE

The 'Laser' display is always related to the defined vertex distance entered in the Treatment Data Input Mask, not to the corneal vertex as treated with the laser!

Vertex Distance (VD)

For Presby Aberration-Free treatment mode, the vertex distance value is initially taken from user settings (refer to the User Manual SCHWIND CAM, chapter 6.3.1 Settings Button).

In customized Presby Corneal or Presby Ocular Wavefront treatments the refraction values are recalculated from the vertex distance of the import file (according to prior choice within the diagnostic system) to the vertex distance of the user settings. A change of the vertex distance value is possible afterwards.

WARNING!

Pay attention to the settings of the vertex distance.

CAUTION

Refraction data from SCHWIND released diagnostic devices are recalculated from the vertex distance of the import file (according to prior choice within the diagnostic system) to the vertex distance of the user settings within SCHWIND CAM.

View of Refraction Type

The refraction type is displayed automatically based on refraction data input (= laser setting) with "Presbyopic" prefix in front. The type can be seen just beneath the columns for manifest refraction entry (with blue background for myopia, orange background for hyperopia, and green background for zero spherical equivalents).

The word "Presbyopic" immediately advises the user working with the SCHWIND presbyopia software solution.

List of refraction types:

Myopia:	Only myopia without astigmatism.
Compound Myopic Astigmatism:	Both principal meridians are myopic, but with different refractions.
Hyperopia:	Only hyperopia without astigmatism.
Compound Hyperopic Astigmatism:	Both principal meridians are hyperopic, but with different refractions.
Simple Astigmatism:	Only astigmatism; One principal meridian is either myopic or hyperopic, the other principal meridian is emmetropic.
Mixed Astigmatism:	One principal meridian is myopic, the other principal meridian is hyperopic.
Only High-Order-Aberration:	Both principal meridians are emmetropic, but with correction of high-order-aberrations.

IMPORTANT NOTE

"None" [AF] or "Presbyopic Only High-Order-Aberration" [Presby CW/ Presby OW] is displayed whenever laser refraction results in zero sphere and cylinder power.

2.1.5.2 Keratometry

The preoperative K-readings shall be entered separately for both meridians (K1 and K2). These meridians must be arranged perpendicular to each other (regular astigmatism). Thus, the angle of the second meridian (K2) will be calculated automatically and cannot be changed manually.

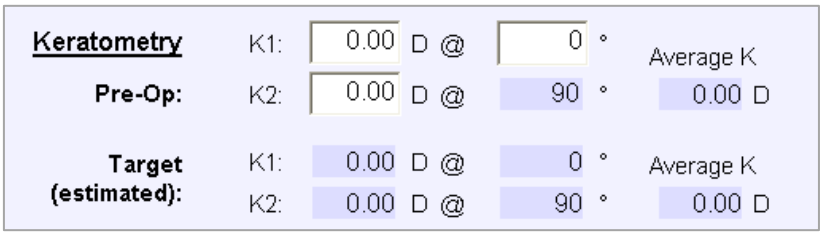


Figure 2-17: Presbyopia Keratometry Panel

The software allows the entry of pre-op k-readings7.50 D ≤ K ≤ 60 D (45 mm ≥ K ≥ 5.63 mm).

Nevertheless, an information message will show up in the confirmation window if pre-op k values exceed the normal range of 35-48 D (9.64 – 7.03 mm).

The estimated postoperative target k-readings are calculated taking the preoperative k-readings and the laser refraction information into account. The calculation considers the refractive index of 1.3375 that is used in SCHWIND diagnostic topography devices.

If the postoperative target k-reading is expected to exceed the normal range of 35-48 D (9.64 – 7.03 D) due to laser treatment, a notice will be available within the input confirmation window. The range for an expected postoperative k-reading value is 7.50 D ≤ K ≤ 60 D (45 mm ≥ K ≥ 5.63 mm) to perform a laser treatment.

WARNING!

The calculation for compensation of energy loss of ablation efficiency at non-normal incidence due to different local corneal curvature is based on pre-op k-reading(s) and refraction and depth and, therefore, they are necessary to enter correctly. The entry of both K1 and K2 is more precise for the ablation process with the laser than entry of avg. K only, especially in patients with higher corneal astigmatism.

Further, the profile considers the effect that with tissue removal (in myopic-like ablation) a shift closer to the retina exists. The slight ablation differences existing also base on pre-op k-reading(s) with less tissue/depths removal in steeper corneas (“shorter eye length”) compared to flatter corneas (“longer eye length”).

2.1.5.3 Treatment Method

Use either the <**TransPRK**>, <**PRK**>, <**LASEK**>, <**LASIK**>, <**FemtoLASIK**>, <**Re-Lift**> icon to select the desired presbyopia treatment method. The active button will be surrounded in blue colour.

Figure 2-18: Presbyopia Treatment Methods

Treatment method **Re-Lift** is specially designed for (Femto-)LASIK re-treatments lifting an existing flap. The Re-Lift method includes the compensation factors as in surface ablation techniques (PRK, LASEK) but transition zone sizes stay optimized to (Femto-)LASIK procedures to fit into the stromal bed under the flap again.

WARNING!

Performing (Femto-) **LASIK** treatments that were planned as PRK or LASEK would result in postoperative undercorrection, whereas performing surface treatments planned as (Femto-) LASIK would result in postoperative overcorrection. Thus, be sure that the correct treatment method is chosen.

TransPRK stands for Transepithelial PRK and considers the epithelium to be removed with the excimer laser. In TransPRK mode, the calculated ablation volume takes an epithelium into account that can be adjusted individually (range: 20 to 75 µm in the centre and 20 to 100 µm towards the periphery @ 5 to 9 mm); default settings are 55 µm in the center and cumulative 65 µm @ 8 mm diameter extra compared to "normal" PRK treatment plans where the epithelium is manually removed. If changes from software epithelium default values are considered by the user, SCHWIND recommends to change central epithelium value (avg.) in the CAM only and let the CAM software propose the peripheral epi value (central epithelium +10 µm @ 8 mm) for treatment.

Be careful in PresbyMAX and TransPRK because the intended multifocality might be (partly) covered and smoothed out by the re-epithelialisation processes – PRK or LASEK method is preferred in presbyopia treatments using surface ablation.

Refer to section 2.1.5.4 Epithelium Thickness and possibly to 'Theoretical analyses of the refractive implications of transepithelial PRK ablations; Arba Mosquera S, Awwad ST; Br J Ophthalmo;2013;97:905-911' for additional information and possible risks with TransPRK.

Performing **LASEK** or **PRK** treatments planned as **TransPRK** would result in unnecessary tissue removal. Thus, be sure that the correct treatment method is chosen.

If **PRK** mode is set but unintentionally used transepithelial, i.e. the epithelium is not (manually) removed before the laser treatment, a **TransPTK** treatment can immediately follow to finally bring the whole PRK profile (refractive correction and optical zone as intended) into the stroma: make use of the **PTK-CAM treatment module**, start treatment planning with (epithelium) depth selection equal to the previously intended plan (e.g. 55µm for central epithelium removal AND activate 'TransPTK' for peripheral depth adjustment and refraction-neutrality) and an optical zone (= diameter in PTK) equal or larger than the total ablation zone (TAZ) of the PRK profile from before.

IMPORTANT NOTE

TransPRK may also be known as "one-touch PRK" or even "no-touch PRK" technology. The brand SmartSurf^{ACE} advertises the combination of 'one-step' TransPRK and Smart Pulse Technology (SPT) in particular.

Be sure that you have selected the correct treatment method for surgery procedure that is performed on each individual patient!

E.g. in (Femto-) LASIK procedures, additional compensation for flap-induced aberrations is considered whereas in Re-Lift method this compensation does not exist.

2.1.5.4 Epithelium Thickness

The epithelium thickness panel appears while selecting treatment method TransPRK, PRK or LASEK. The thickness profile of epithelium can be imported (via SCHWIND MS-39 data file: *.mcw) and/or individually adjusted for these treatment methods with modification/entry of central value and peripheral value with a reference diameter.

This actively influence the TransPRK ablation profile (in depth and volume) and in addition, the RST calculation in PRK and LASEK. The import or input range is 20 to 75 µm in the centre and 20 to 100 µm towards the periphery @ 5 to 9 mm. The default epithelium thickness values - out of 'CAM Settings' - are shown at start of a new treatment plan (as long as no import of a *.mcw-file exists).

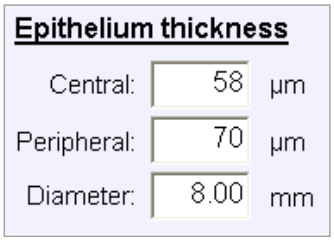


Figure 2-19: Epithelium thickness panel with values different from installation default.

IMPORTANT NOTE

The epithelium thickness import and adjustment option can be in particular advantageous in combination with Optical Coherence Tomography (OCT) devices detecting a patient's epithelial thickness map very much different from software default setting (55 µm and 65 µm @ 8 mm). Nonetheless, SCHWIND recommends to always start with CAM default TransPRK setting (55 µm / 65 µm @ 8 mm) if no experience with AMARIS SmartSurf^{ACE} exists.

SCHWIND CAM uses 55 µm as central epithelium default value for corneal stroma break-through. In addition, refractive-neutral transepithelial ablation considers a default of 65 µm @ 8 mm.

If you gained experience and you like to make use of individual OCT epithelium map readings, you either use SCHWIND MS-39 data files (*.mcw), i.e. automatic filling of the central and peripheral value in respect to the setting of the reference diameter within 'CAM Settings', or you change central epithelium value (e.g. avg. of 3 mm diameter like in SCHWIND MS-39) in the CAM only and let the CAM software propose the peripheral epithelium value (central epithelium +10 µm @ 8 mm) for treatment. Import values (of the periphery) of SCHWIND MS-39 measurements are adjusted appropriately for the ablation with SCHWIND lasers.

Ensure that the resolution of your OCT device – if different to SCHWIND MS-39 - is good enough for clinical evaluation. Always check and ensure that OCT measurements are properly evaluated, and possible changes in the CAM epithelium profile enables a break-through of the ablation profile into the corneal stroma for treatment efficacy and a sufficient (functional) optical zone size.

WARNING!

Change epithelium thickness values with care! Make sure to use (central) thickness values measured by trustable diagnostic measurements.

Do not take the peripheral readings of any OCT device different from SCHWIND MS-39 data import into PresbyMAX for treatment because of "compensation" effects that are necessary to consider and include for treatment and precise outcomes.

Significant deviations from software default setting and changes in the centre-to-periphery ratio could cause a waste of tissue and unexpected results (over- or undercorrection) if epithelium profile is not measured and evaluated properly before surgery.

Furthermore, be careful in PresbyMAX and TransPRK because the intended multifocality might be (partly) covered and smoothed out by the re-epithelialisation processes – PRK or LASEK method is preferred in presbyopia treatments using surface ablation.

2.1.5.5 Pupil Offset

The pupil offset can be entered numerically either in Cartesian (x, y) or polar (R, angle) coordinates according to the user settings. Both formats are visible after entering offset values. These offset values shall include a reference pupil diameter for which they hold.

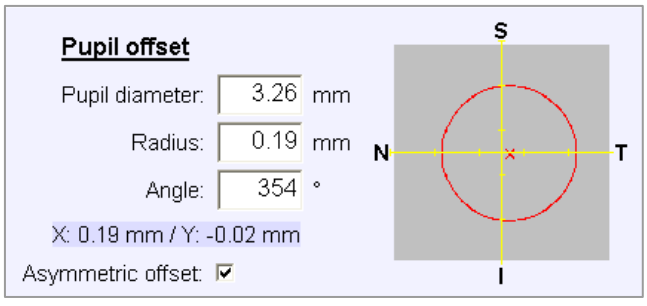


Figure 2-20: Presbyopia Pupil Offset Panel

The software allows the entry of pupil diameters (PD) 2mm ≤ PD ≤ 8mm. Nevertheless an information message will pop up to be confirmed if pupil diameter value exceeds the normal range of 2.5 – 4.5mm.

The software allows the entry of pupil offset values corresponding to a distance ≤ 0.75mm. Nevertheless an information message will pop up to be confirmed if offset values exceed the normal range of -0.1 inferior to 0.4mm temporal side or -0.1mm inferior to 0.2mm superior.

WARNING!

The calculation for compensation of energy loss of ablation efficiency at non-normal incidence due to different local corneal curvature is based on pre-op k-reading(s), pupil offset, refraction, and depth. Therefore, they are necessary to be entered correctly.

IMPORTANT NOTE

Treatment centring onto corneal vertex (= use of pupil offsets) shall be preferred to reduce induction of unwanted aberrations to a minimum.

IMPORTANT NOTE

The pupil diameter entered into the SCHWIND CAM software also has an influence on the Eye Tracking of the AMARIS excimer laser since the Automatic Pupil Size Control of the laser will modify the surgery illumination in order to have approximately the same pupil size like it was entered into the SCHWIND CAM software.

2.1.5.6 Ablation Strategy: Asymmetric vs. Symmetric

A selection between two different ablation strategies, **ASYMMETRIC or SYMMETRIC,** is possible for all treatment types (AF, OW, CW). The ablation profile becomes different in asymmetric vs. symmetric mode whenever a pupil offset unequal to zero is used.

Asymmetric offset- strategy is the software default setting with the edges of the optical zone being concentric to the pupil center and with the optical axis of the ablation profile coincident with the corneal vertex (Figure 2-21).

Symmetric offset- strategy displace the whole ablation pattern according to offset entry (Figure 2-22), assuming the ablation profile to be ablated on the corneal vertex and to be concentric to the corneal vertex, with the need of an “extended” optical zone to cover both edges of the “scotopic” pupil.

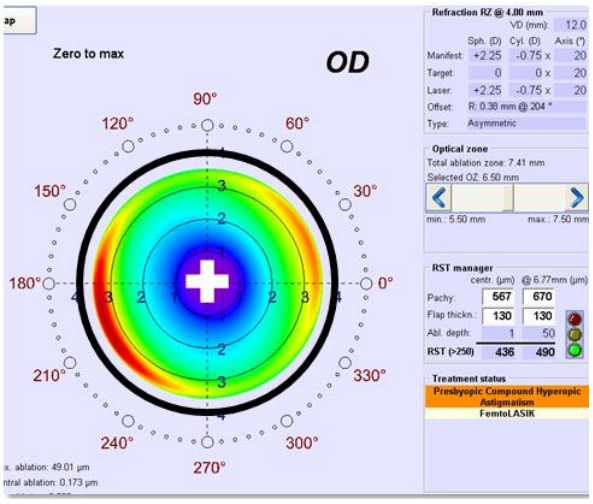


Figure 2-21: Ablation map with asymmetric offset selection (example). The reference centre is concentric to the pupil.

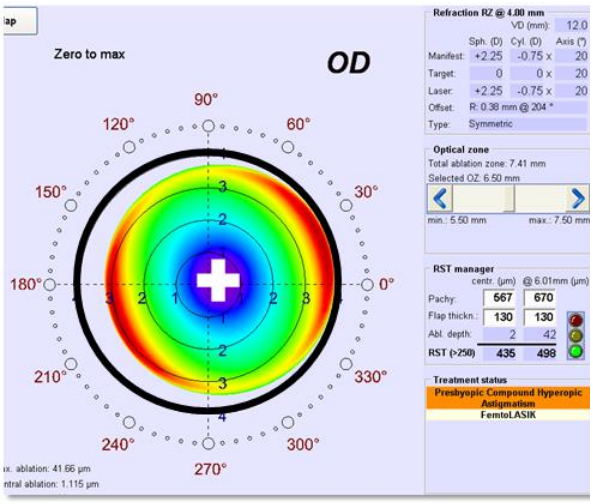


Figure 2-22: Ablation map with symmetric offset selection (example). The reference centre is concentric to the corneal vertex.

IMPORTANT NOTE

Symmetric ablation strategy needs bigger optical zone sizes, and thus more ablation depth and volume, compared to asymmetric ablation strategy to cover the whole pupil area.

2.1.5.7 Wavefront Info

Basic diagnostic information of the patient eye that is imported via <**Corneal data**> is displayed in the 'Wavefront info' panel. In <AF> treatment planning this section can show diagnostic data file content in terms of:

'Total Zernike' display whenever both anterior and posterior cornea data are available and of good quality (based on SCHWIND evaluation of the diagnostic data import).

'Epithelium thickness' display with respect to data import by SCHWIND MS-39 diagnostic device or SCHWIND CAM default settings.

'Pupil offset' display with respect to data import by SCHWIND approved diagnostic device.

'Imported file' displays the name of the file(s) from diagnostic device that were imported and used.

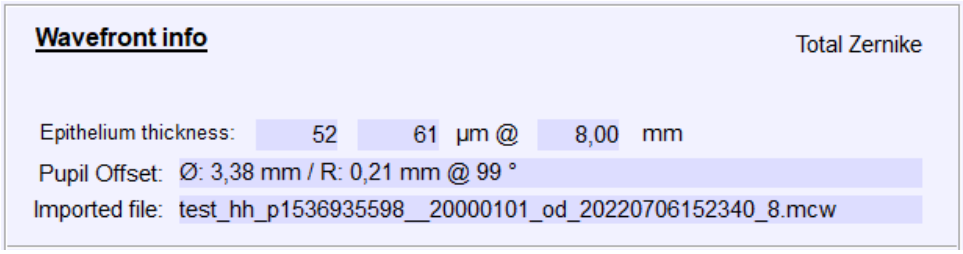


Figure 213: Wavefront Info (AF) panel

2.1.6 Static Cyclotorsional Control (SCC)

The information necessary for Static Cyclotorsional Control [SCC] detection on the AMARIS laser is either imported to PresbyMAX® software module (together with wave aberration data) from SCHWIND Corneal Wavefront Analyzer (Keratron Scout), SCHWIND SIRIUS or SIRIUS+, SCHWIND MS-39 or SCHWIND PERAMIS, or the <**Corneal data**> button gives the opportunity to attach SCC data to the presbyopia treatment plan.

Afterwards the diagnostic device for SCC data acquisition, a status check, a quality evaluation of SCC and the related file name are displayed within Treatment Data Input Mask (below 'Wavefront info'; refer to (Figure 2-29).

SCC- quality information and SCC -file information are displayed in each screen of PresbyMAX® software module.

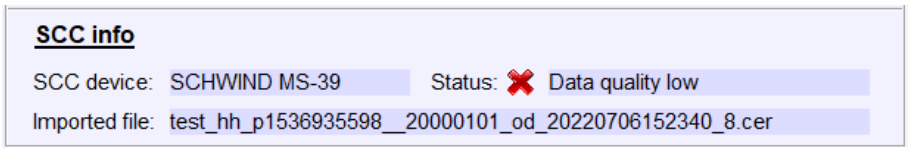


Figure 2-23: SCC Info (AF) panel

IMPORTANT NOTE

Diagnostic data file imports that include **SCC of low quality** can make use of <Corneal data> to overwrite and update patient eye information with good quality SCC from a different file (of the same patient).

IMPORTANT NOTE

SCC function is ready and enabled in your SCHWIND Corneal Wavefront Analyzer (Keratron Scout), i.e. a button <**ACC**> next to <SCHWIND Export>, respectively in your SCHWIND SIRIUS or SIRIUS+, SCHWIND MS-39 and SCHWIND PERAMIS with a "**SCC Check**" within the export area.

The SCC information will be attached automatically to the export file of your diagnostic system and import to ORK-CAM software module is possible afterwards.

SCC data are directly linked to the wavefront export file in case of Scout, SIRIUS, or SIRIUS+, MS-39 or PERAMIS. <**Corneal data**> makes these 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 system, 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.

2.1.7 Presby Ocular (OW) and Presby Corneal (CW) Wavefront Treatments

For **Presby Ocular** or **Presby Corneal** wavefront-guided treatments the <**OW**> or the <**CW**>button has to be pressed.

Ocular Wavefront accepts the import of ***.iow**,***.wow**, ***.osw**, and ***.ocw** files, *Corneal Wavefront* accepts the import of ***.scw**,***.ccw**, ***.mcw**, ***.csw**, and ***.ocw** files.

WARNING!

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

Furthermore, check the planned ablation profile for plausibility, i.e. the content of the ablation map in PresbyMAX software module in comparison to diagnostic map information.

For maximizing measurement area, during Ocular Wavefront acquisition try to get a centred pupil.
Take at least 3 maps per eye, compare them for repeatability, and check that the difference between any two does not locally exceed plausible values at any point (discard those maps), with the repeatable maps take the map with smallest wave aberration value (RMS HO) to minimize the risk of overcorrection.

For manifest refraction, use the optometric rule: take the measurement with the least negative (most positive) amount of defocus (SEQ), if several of them are equal in terms of SEQ then take the measurement with the least amount of astigmatism (Cyl) , if several of them are equal in terms of Cyl then take the measurement with the astigmatism closest to with-the-rule, and if you still did not make a decision take the one with less Higher-Order-Aberration-RMS (RMS HO) (principle of minimum risk).

Pay attention to your astigmatism sign and axis convention as well as to the settings of the vertex distance.

IMPORTANT NOTE

The basic patient data (demographics) come together with import of the diagnostic file, independent from the SCHWIND diagnostic device to be used for wavefront-guided ablation.

Make use of patient data import via <**Corneal data**> BEFORE refraction entries or changes in PDIM are reset to zero with data import! It is possible to manually enter or import a treatment offset (= ablation centre for sphere and cylinder is different from pupil centre). Make sure to use treatment offsets with care, corresponding to pupil offsets measured by trustable diagnostic measurements.

A WINDOWS dialog appears as shown in Figure 2-24 (Ocular Wavefront) and Figure 2-25 (Corneal Wavefront) select the desired file and press open.

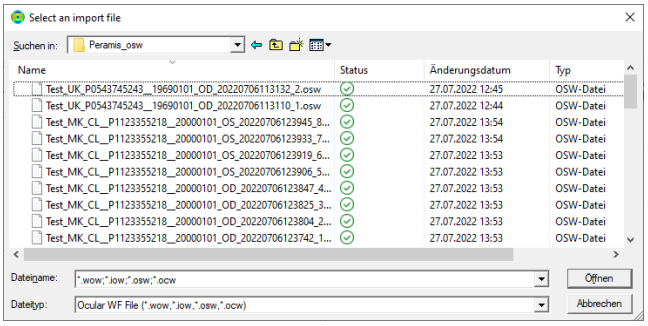


Figure 2-24: OW Data Import – Windows dialog window

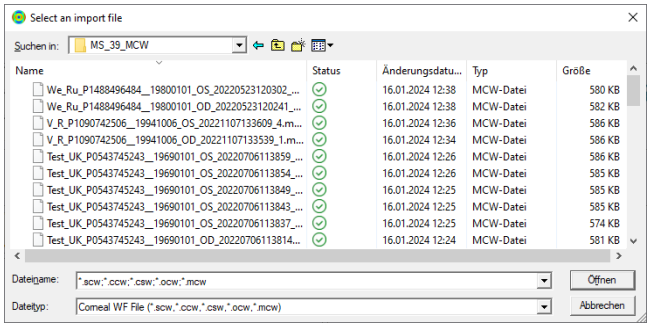


Figure 2-25: CW Data Import – Windows dialog window

Basic patient data, wavefront refraction, keratometry, and pupil offset data are taken as much as possible from the selected Ocular or Corneal Wavefront import file (Figure 2-29).

While import, the refraction data from SCHWIND released diagnostic devices are automatically recalculated to the vertex distance of the user settings within SCHWIND CAM.

The SCHWIND CAM cylinder convention being preset (negative or positive cylinder) is used.

IMPORTANT NOTE

A re-calculation of the sphero-cylindrical-combination (manifest and wavefront refraction display in Treatment Data Input Mark) takes always place if vertex distance in imported file differs from the vertex distance in CAM user settings.

E.g. Sph -10.00DCyl -6.00D @ 15° in 13.8mm vertex distance (diagnostic system) is equal to Sph -9.82DCyl -5.73 @ 15° (PresbyMAX® software module display with 12mm vertex distance).

A re-calculation of the sphero-cylindrical-combination always place if SCHWIND CAM cylinder convention or entry in diagnostic system is in the opposite way.

E.g. Sph -4.00DCyl +3.00D @ 110° (diagnostic system with plus cylinder convention) is equal to Sph -1.00DCyl -3.00D @ 20° (PresbyMAX® software module display with negative cylinder convention).

CAUTION

Refraction data from Ocular Wavefront Analyzers are (slightly) different compared to the display in SCHWIND CAM (Ext. Zernike Refraction @ 4 mm) because of different calculation approaches. The extended Zernike refraction includes the effect of all higher-order spherical and astigmatic components onto sphere and cylinder values. The display of Zernike refraction values fits to the vertex distance of the user settings within SCHWIND CAM.

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]

2.1.7.1 Keratometry Import Values

The acceptance of K-readings outside 7.50 D ≤ K ≤ 60 D (45 mm ≥ K ≥ 5.63 mm) can be overpassed after file import (Figure 2-26), but the treatment plan takes the limit value [K-reading(s)] for calculation.

In case of <**Yes**> the maximum possible value is taken (either 7.50 D or 60 D) for the treatment planning.

If <**No**> is chosen, the real K values are displayed in Treatment Data Input Mask but further planning will be blocked due to exceeded K(s). Keratometry values could still be manually changed within accepted range to continue.

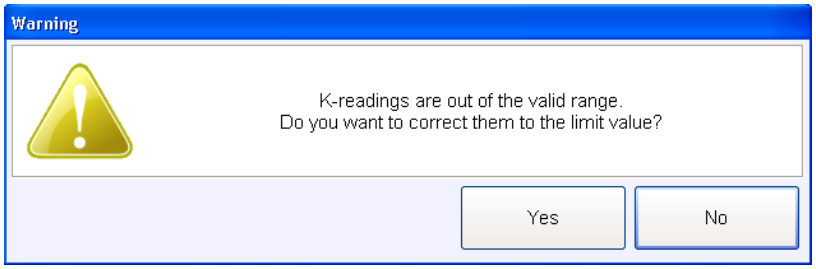


Figure 2-26: K-readings are out of the valid range

Example:

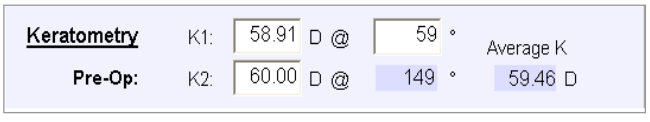


Figure 2-27: Display of K-readings if correction was accepted (<Yes>)

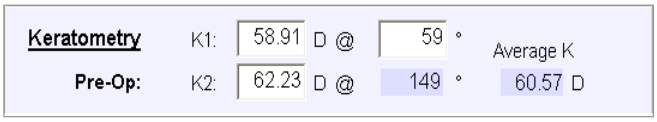


Figure 2-28: Display of K-readings if no correction was accepted (<No>)

Remark: Original K2 value (62.23D) is changed to maximum possible K of 60.00D. K1 is within normal range and stays like original. The average K is calculated out of new K1 and K2.

Remark: Original K-readings K1 and K2 are taken but further planning is not possible because K2 = 62.23D > 60.00D.

Refer to chapter 2.1.5.2 Keratometry for further K-reading range information.

WARNING!

The calculation for compensation of energy loss of ablation efficiency at non-normal incidence due to different local corneal curvature is based on preoperative k-reading(s), pupil offset, refraction, and depth. Therefore, they are necessary to be entered correctly.

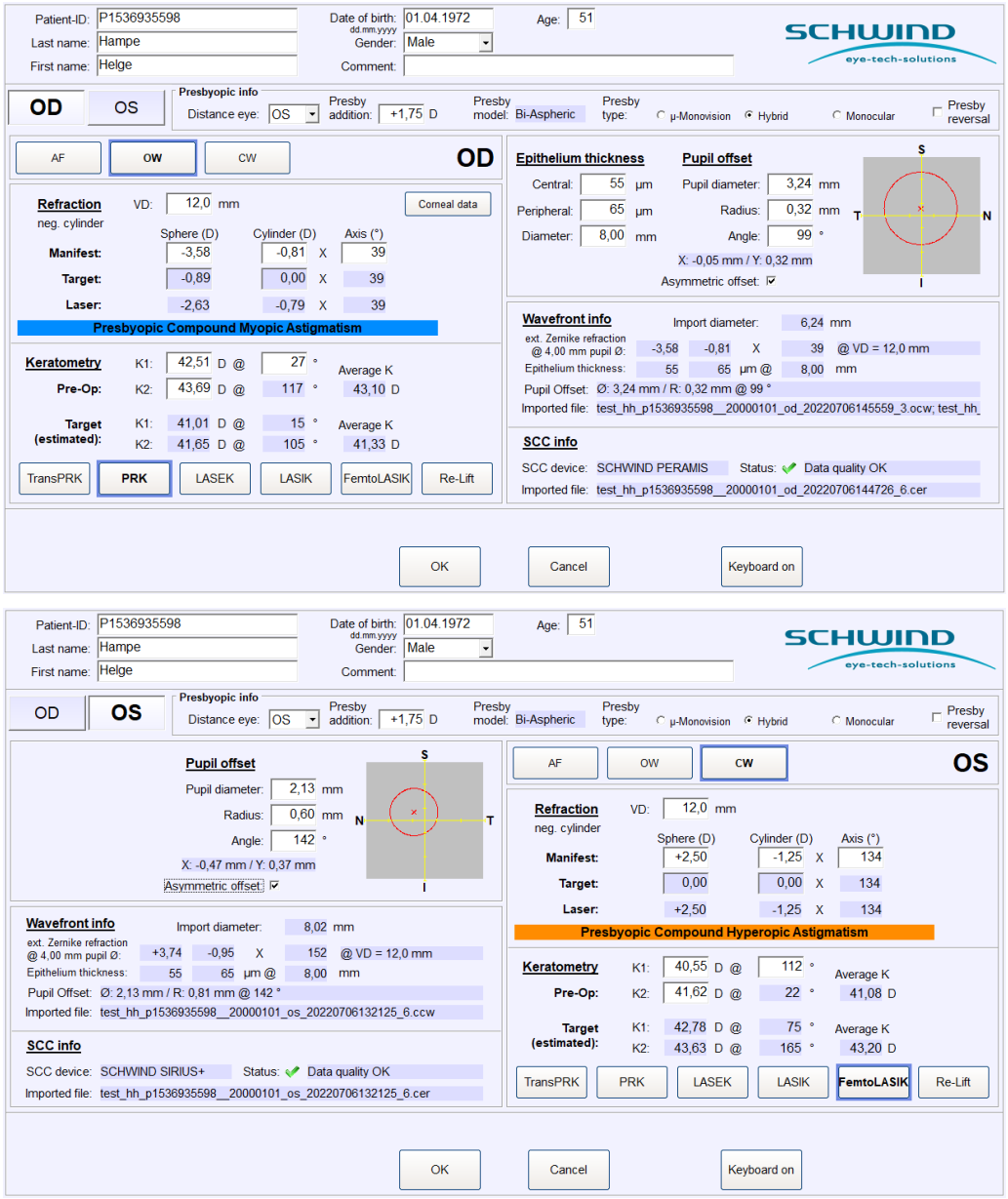


Figure 2-29: Presby Ocular-and Presby Corneal-Wavefront Treatment Plan (examples)

Basic **'Wavefront Information'** is displayed in the lower part of the eye that was selected for a presbyopia wavefront-guided treatment. In <OW> or <CW> treatment planning this section can show diagnostic data file content in terms of:

'Import diameter' with reference to the maximum delivery of cornea data / wave aberrations

'Total Zernike' display whenever both anterior and posterior cornea data are available and of good quality (based on SCHWIND evaluation of the diagnostic data import).

'Extended Zernike refraction @ 4 mm pupil diameter' for defined corneal vertex distance (VD) delivers refraction information extracted from the measurement of wave aberrations

'Epithelium thickness' display with respect to data import by SCHWIND MS-39 diagnostic device or SCHWIND CAM default settings.

'Pupil offset' display with respect to data import by SCHWIND approved diagnostic device.

'Imported file' displays the name of the file(s) from diagnostic device that were imported and used.

Furthermore, information about the diagnostic device for Static Cyclotorsional Control (SCC) data acquisition, a status check, a quality evaluation of SCC and the related file name are displayed if imported.

IMPORTANT NOTE

Diagnostic data file imports that include **SCC of low quality** can make use of <Corneal data> to overwrite and update patient eye information with good quality SCC from a different file (of the same patient).

CAUTION

The epithelium thickness panel appears only with treatment method selection TransPRK, PRK or LASEK. The panel disappears with selection of LASIK, FemtoLASIK or Re-Lift.

2.1.8 Confirmation of Data

If all necessary patient data are entered, the Treatment Data Input Mask has to be confirmed by pressing <**OK**>.

Messages will appear just above the <**OK**> and <**Cancel**> buttons if information is still missing, incorrectly entered or even out of entry limits. The cursor then automatically jumps to the field(s) with insufficient or wrong data.

CAUTON

Check correctness of refraction data in Treatment Data Input Mask before continued.

'Confirm Input' is an additional pop-up window which summarizes the data entered and checks them on normality. An example is shown in

Figure 2-30: Input Confirmation (example) below.

Hints and warning signs about values which are out of normality can be found. The information must be reconfirmed by pressing <**OK**>.

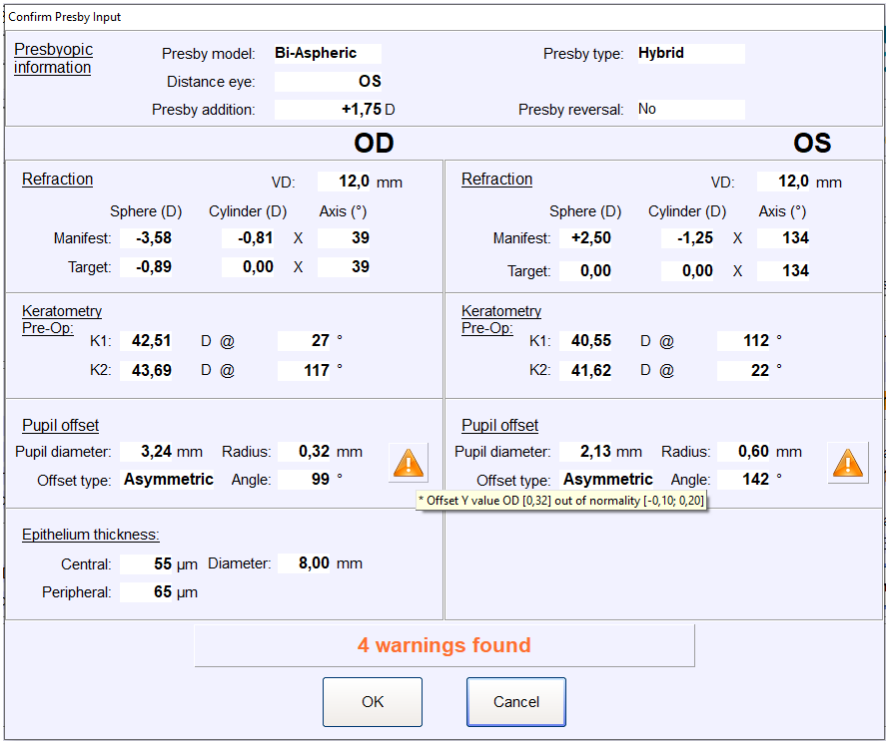


Figure 2-30: Input Confirmation (example)

IMPORTANT NOTE

An epithelium thickness panel appears only with treatment method selection TransPRK, PRK or LASEK for an eye in Treatment Data Input Mask before. This panel is empty with selection of LASIK, Femto LASIK or Re-Lift.

Mouse over warning signs displays information for each specific panel that are out of normality (refer to keratometry pre-op pop up information within

Figure 2-30: Input Confirmation (example)).

Pressing the <**Warnings found**> button enables a separate window with summary of all "warnings" subdivided for OD and OS <**OK**> closes the summary window (Figure 2-31).

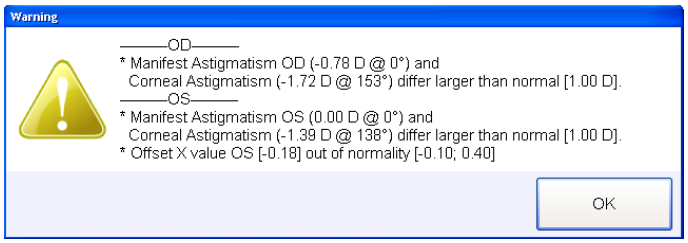


Figure 2-31: Summary of Warning Messages (example)

If the Confirm Input window is considered to be <**OK**>, the Main Menu of the PresbyMAX software module opens. Otherwise, <**Cancel**> has to be used to go back to the Treatment Data Input Mask.

2.2 Boundaries of Input Refraction for Presbyopia

2.2.1 Normal Ranges in Diopters for PresbyMAX® Input Refraction

The following table describes the allowed **normal** presbyopia input values for the manifest refraction (with presbyopic addition influence included) independent from the preset cylinder notation within the PresbyMAX® software module.

Allowed Presby Range	Conditions	Sphere (D)	Cylinder (D)	SEQ (D)	Addition (D)
Corneal Manifest Refraction		-8.00 to +6.00	-6.00 to +6.00	-8.00 to +6.00	+0.25 to +3.00
Corneal Target Refraction		automatic	---	---	---
Corneal Laser Settings SCA	(Femto)LASIK or Re-Lift	-8.00 to +6.00	-6.00 to +6.00	-8.00 to +6.00	---
	(Trans)PRK or LASEK	-8.00 to +6.00	-5.00 to +5.00	-8.00 to +6.00	---

2.2.2 Extended Ranges in Diopters for PresbyMAX® Input Refraction

The following table describes the **extended** presbyopia input ranges for the manifest refraction (with presbyopic addition influence included) independent from the preset cylinder notation within the PresbyMAX® software module.

Allowed Presby Range	Conditions	Sphere (D)	Cylinder (D)	SEQ (D)	Addition (D)
Corneal Manifest Refraction		-12.00 to +8.00	-7.00 to +7.00	-12.00 to +8.00	+0.25 to +3.00
Corneal Target Refraction		automatic	---	---	---
Corneal Laser Settings SCA	(Femto)LASIK or Re-Lift	-12.00 to +8.00	-7.00 to +7.00	-12.00 to +8.00	---
	(Trans)PRK or LASEK	-10.00 to +8.00	-7.00 to +7.00	-10.00 to +8.00	---

IMPORTANT NOTE

All values mentioned within the tables are according to corneal vertex distance (VD = 0 mm)!

SCA: abbreviation for Sphere (S), Cylinder (C), and Axis (A)

The PresbyMAX Target Refraction is automatically and equally set for all types (μ-Monovision, Hybrid, Monocular): 0.00 D in the distance (dominant) eye and -0.88 D (by default) in the near (non-dominant) eye @ VD = 0 mm. The post-operative target setting can be modified within the range of 0.00 to 1.50 D.

Extended Ranges have to be activated within 'Settings' [treatment settings panel of CAM tab] if needed.

2.3 Main Menu

The Main Menu of the PresbyMAX® software module appears (Figure 2-32) after successfully importing diagnostic information data and after manual entry of necessary information, e.g. sphere, cylinder, axis, addition, eye dominance, k-reading(s), and confirming the correctness of all information.

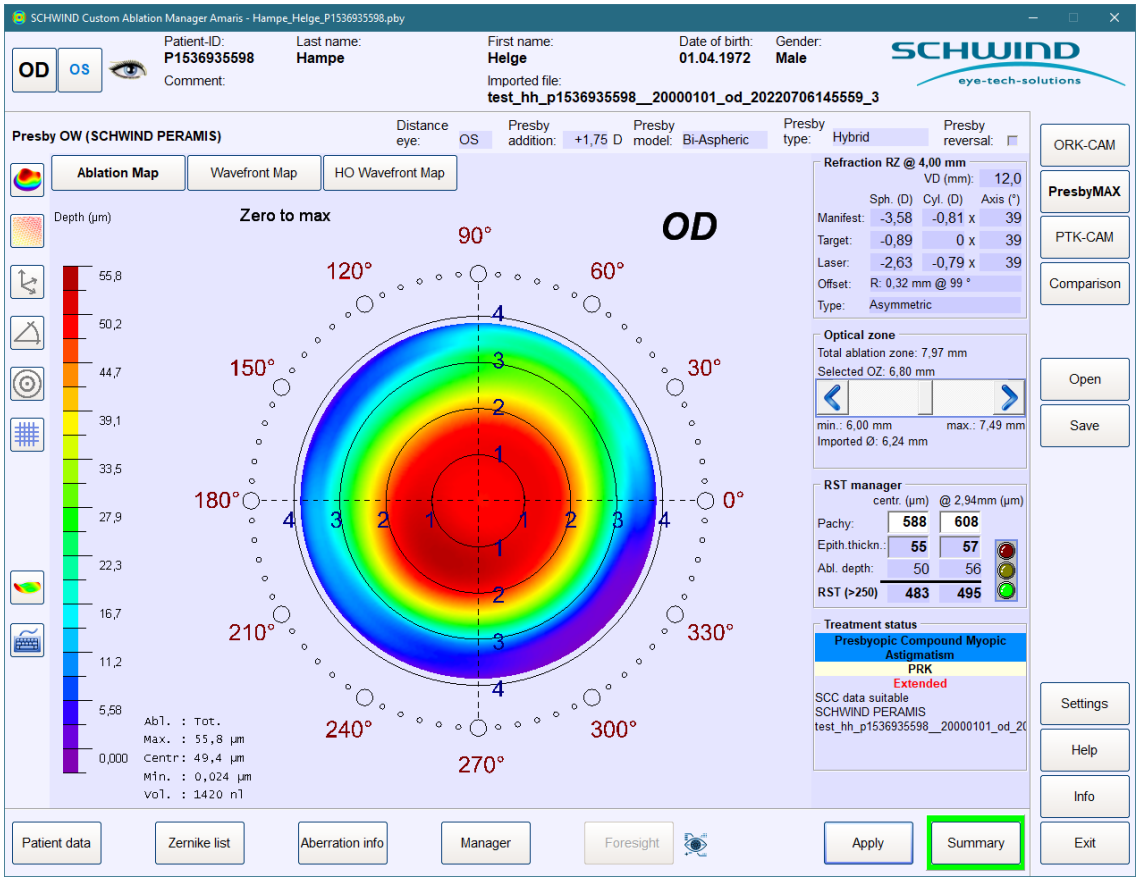


Figure 2-32: Main Menu Display (Presby Ocular Wavefront Treatment in OD – near eye example)

2.3.1 Basic Patient Information Data

Patient demographics (ID, Lastname, Firstname, Date of Birth, and Gender), a possible comment, and the import file name from the diagnostic device if used, is mentioned in the header of the Main Menu.

The eyes are indicated by <**OD**> and <**OS**> in the upper left corner. The information on the screen is always related to the eye (OD or OS) that is marked bold face. The distance (dominant) eye is shown in blue colour, the near (non-dominant) eye is written in black.

2.3.2 Type of Treatment

The treatment type ('Presby AF', 'Presby CW' or 'Presby OW') is mentioned just below the header of basic patient information. If any diagnostic device information are imported at start of treatment planning, e.g. in a wavefront-guided treatment, the name of the device used is displayed in

brackets. Furthermore, the word 'Total' (e.g. CW (SCHWIND MS-39) - Total) indicates that a treatment plan includes both anterior and posterior wave aberration data.

IMPORTANT NOTE

SCHWIND- approved diagnostic devices SCHWIND SIRIUS or SIRIUS + and SCHWIND MS-39 can provide sufficient data for a TOTAL corneal wavefront treatment, i.e. wave aberrations of the anterior AND posterior cornea are used.

2.3.3 Presbyopia Information

The presbyopia information and selections from Treatment Data Input Menu are displayed below the header with patient demographics: distance eye, presbyopic addition, presbyopic model, presbyopic type, and presbyopic reversal. The selection of 'Presby reversal'is assigned with a check mark and turns to red font colour to be more highlighted.

IMPORTANT NOTE

The functions available in the Main Menu depend on the treatment type chosen, i.e. a wavefront-guided ablation selection offers more tools for individual adjustment parameters than the aberration-free mode.

2.3.4 Graphical Display and Functionality of Maps

Display Options

The buttons and its related icons (Figure 2-33) show always the opposite state of DirectX panel, i.e. the status written and displayed at the border will be present for the map if button is pressed.

The first two buttons change view (2-dimensional [2D] vs. 3-dimensional [3D]) and surface (solid vs. wireframe) state, the next two (de-) activate axes and angle, and the last two (de-)activate circles and grid whereas these two work in 2D only. Furthermore, a button exists to switch between views Zero-to-max, OSA standard, and Normalized.

Zero-to-max and Normalized display more details with bigger scale compared to OSA standard. Zero-to-max is the most popular display. Views in OSA standard let distinguish easily between refractive powers. Normalized is especially preferred for ablation maps in TransPRK mode to better detect the refractive correction part.

The colour scale uses standardized 21 colours whereas the centre or mid value is green changing to warmer colours (e.g. yellow, orange, red) with bigger depth or more positive values, and to colder colours (e.g. light blue, dark blue, purple) with less depth or more negative values.

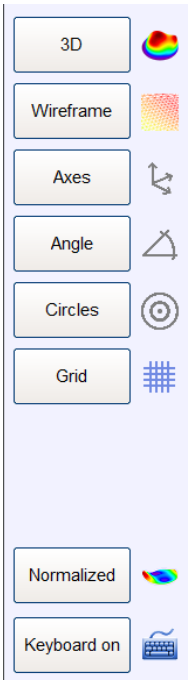


Figure 2-33: Display Options

IMPORTANT NOTE

This software offers a virtual keyboard for data entry (supports the touch screen functionality) beside the standard external keyboard.

The button **<Keyboard on>** can be used if entries shall be applied via touch screen. Another press switches the **<Keyboard off>** again.

Ablation Map

The Ablation Map displays the individual treatment volume (in "3D" mode) that is going to be treated with the laser. This map shows in relation to the displayed colour scale the planned ablation depth in micrometer. Additional information about the central and maximum ablation is displayed below the coloured map. Volume information in nanolitre is furthermore shown.

In TransPRK mode, the refractive (= stroma) and epithelial parts are separated and displayed in brackets (Figure 2-34) The Ablation Map and its depth and volume are based on the selected optical zone size.

```
Abl. : Tot. (Strom / Epith)
Max. : 167 (112 / 65,0) µm
Centr: 166 (111 / 55,0) µm
Min. : 65,0 (0,001 / 55,0) µm
Vol. : 5452 (2445 / 3006) nl
```

Figure 2-34: Ablation Depth display in TransPRK mode (example)

Abl. = Ablation; Tot. = Total; Strom = Stroma; Epith = Epithelium

Max. = Maximum; Centr = Central; Min. = Minimum; Vol. = Volume

IMPORTANT NOTE

The sum of refractive (= stroma) and epithelial ablation depths displays within brackets (TransPRK mode) does not necessarily result in maximum or minimum ablation value. The location of ablation maximum or ablation minimum for refractive part as well as epithelium can be different. Ablation and volume values, i.e. the info before the brackets, consider the whole TransPRK treatment depth/volume at once.

IMPORTANT NOTE

The reference centre of the ablation map is always the pupil centre of the patient which is equal to the centre of the cross-hair. In principle, with use of pupil offsets for corneal vertex centring the aspheric manifest refraction correction is shifted within the ablation map of 10 mm maximum.

Different compensation values for coma, trefoil, and spherical aberration components are existing, depending on the ablation strategy used (asymmetric offset vs. symmetric offset). Both strategies create aspheric ablation profiles that

follow the 'aberration –free' concept but having different axially symmetric centres:

Asymmetric offset ablation with the edges of the optical zone being concentric to the pupil center and with the optical axis of the ablation profile coincident with the corneal vertex. These ablation profiles seem asymmetric from both pupil and vertex references.

Symmetric offset ablation displaces the whole ablation pattern onto the corneal vertex, being concentric to the corneal vertex, with the need of an "extended" optical zone to cover both edges of the "scotopic" pupil. These ablation profiles seem symmetric from both pupil and vertex references.

SCHWIND's Centration Strategies can be used for any treatment type, be it presbyopic Aberration-Free (AF), presbyopic Corneal Wavefront (CW), or presbyopic Ocular Wavefront (OW).

By clicking a mouse button (only in "2D" mode) while the cursor is within the range of ablation or wave aberration image in DirectX panel, ablation depth respectively wave aberration (WAb) of the selected point will be displayed in a yellow-coloured box (Figure 2-35). Cartesian and polar coordinates, as well as ablation depth or wave aberration, are mentioned according to the point chosen.

Figure 2-35: Display of Coordinates and Depth Value

By clicking the left mouse button and moving the cursor (only in "3D" mode), the ablation or wavefront image in DirectX panel can be tilted and turned.

Wavefront Map

In the Wavefront Map, the central, maximal, and minimal wave aberrations (WAb) are displayed in micrometer. The 2nd to 8th orders are included in all wave aberration calculation. The diameter and values shown for the wave aberration are based on the selected optical zone size, or on the maximum imported diameter from diagnostic system.

HO Wavefront Map

In the HO Wavefront Map, exclusively the higher-order wave aberrations (WAb) are displayed in micrometer. The 3rd to 8th orders are included in all wave aberration calculation. The diameter and values shown for the wave aberration are based on the selected optical zone size, or on the maximum imported diameter from diagnostic system.

2.3.5 Patient Data

The <**Patient data**> button can be used to return to the Treatment Data Input Mask. All presbyopia treatment data that are listed in Confirm Input screen can still be modified, except the option of 'Presby reversability'.

IMPORTANT NOTE

A need in treatment type and reversibility change ('Presby Reversal') requires the start of a new PresbyMAX treatment planning.

2.3.6 Zernike List

The weight coefficients of the Zernike polynomials (Figure 2-36) are displayed in micrometer according to the selected optical zone size (in OSA standard according to standards ANSI Z80.28-2004 Methods for Reporting Optical Aberrations of the human eye, ISO 24157:2008 Ophthalmic optics and instruments -- Reporting aberrations of the human eye).

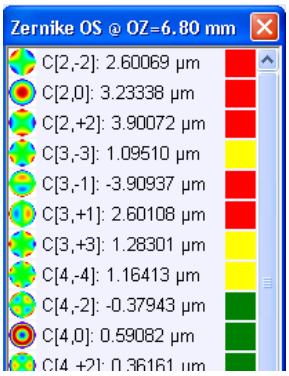


Figure 2-36: Excerpt of Zernike List

If the coefficient is coloured green (Optical Blur ≤ 0.25 D), there is no influence of the related coefficient expected for the patient eye; yellow colour might affect (0.25 D < Optical Blur ≤ 0.50 D); and red colour will affect (Optical Blur > 0.50 D). The values and colours will be adjusted automatically while switching between maps or changing the optical zone size.

Left mouse click on any coefficient results in highlighted blue colour (Figure 2-37) and gives additional reference about the acronym, the (de-)activation status out of the Manager (refer to chapter 2.3.8 Manager) the terminology, the micrometer (µm) and the dioptre (D) value of the wave aberration.

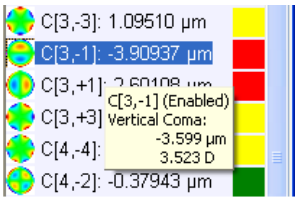


Figure 2-37: Coefficient Info in Zernike list

2.3.7 Aberration Info

The Aberration info (Figure 2-38) shows an overview of major aberration components: Coma, Trefoil, SphAb, P-V, RMS HO, and RMS total values are displayed in micrometer and in dioptres (Optical Blur) according to the selected optical zone respectively the maximum import diameter.

The values will be adjusted automatically when the optical zone size is changed and confirmed via <**Apply**>.

P-V: Peak-to-Valley (distance between minimum and maximum wave aberrations [WAb])

RMS HO: Root-Mean-Square calculation of higher-order aberrations only

RMS total: Root-Mean-Square calculation of higher-order aberrations and lower-order aberrations

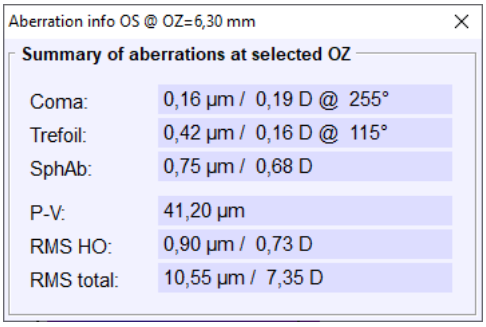


Figure 2-38: Aberrations Info Display

IMPORTANT NOTE

If windows of Zernike list or Aberration info are moved, the software remembers the last position even with restart of the SCHWIND CAM software.

2.3.8 Manager

The manager function in Figure 2-32 gives the opportunity to individualize Presby Corneal and Presby Ocular Wavefront treatments. Two functions <**Refraction**> and <**Pyramid**> for adaptation and optimisation are included.

CAUTION

The <**Manager**> function has to be used after the final adjustment of optical zone was made. If other values e.g. manifest refraction (MR), target refraction (TR) or optical zones (OZ) are changed after confirmation of manager calculations or settings, it cannot be guaranteed that the previous manager output is still optimum for the changes made in treatment plan. Repeat your steps within <Manager> for recalculation and finding the new optimum.

Refraction

Figure 2-39: Refraction in Manager (example)

The patient's laser settings that was decided or entered before <**Manager**> entry can be optimized or minimized with buttons <Depth> and <Volume>; e.g. in cases of thin corneas where

improvement of visual quality is more important over refractive outcome or in cases where ablation depth with manifest refraction and wave aberrations differ significantly from those in Aberration-Free (AF) mode, <Refraction> option can be of help.

'Current' displays the sphero-cylindrical combination (Sphere, Cylinder, Axis) at defined vertex distance (VD) currently taken for treatment plan.

'Preview' displays the sphero-cylindrical combination that is manually entered or automatically proposed - in consideration of the "Constraints" selection - due to calculation processes started via <**Depth**> or <**Volume**> in minimize section.

'Residual' is the sum of 'Current' refraction and 'Preview' calculation and expresses somehow the possibly residual refractive error if preview values are applied in treatment plan.

But 'Residual' does not include possible difficulties in determining patient's manifest refraction and possible refractive effects of the higher-order aberrations. Patient's manifest refractive power of the eye is influenced by the amount of higher-order aberrations and the refractive compensation factors due to the magnitude of the higher-order aberrations with impact on tissue removal.

The more significant the higher-order aberrations are, in particular r:-1, r:0, and r:+1, the less predictable the 'Residual' should be taken.

Constraints can be (de-) activated and manually adapted to the wish of the user before minimize button <**Depth**> or <**Volume**> is pressed. If the checkbox in front of an individual constraint is ticked activation is given otherwise not (exception: tolerance uses 0.18D range if inactive).

Ranges can be individually changed for tolerance, sphere, cylinder, and axis values. The wider the constraints are set the bigger the deviation (="Residual") from current laser setting (treatment plan) can be. The PresbyMAX default setting accepts a residual refractive error of SEQ ~1D as a kind of safety aspect. But theoretically, the whole refractive treatment range could be used by the operator (refer to chapter 2.2 'Boundaries of Input Refraction for Presbyopia') – if all constraints are inactive (=no tick is set) maximum savings are possible with least focus on residual refractive outcome.

CAUTION

The presbyopia wavefront-guided ablation should be considered with special care. The predictability of refractive correction is reduced in eyes that combine both removal of disturbing higher-order aberrations (for improved visual performance and image quality) and induction of symmetric higher-order aberrations achieving a multifocal cornea at the same time.

Thus, re-treatment rate is expected to be bigger and satisfaction level supposed to be lower in 'Presby OW' and 'Presby CW' compared to 'Presby AF'.

Precision in refractive correction (= intended target refractions) is more important in patients of presbyopic age (together with multifocal concepts) than in younger ones. A presbyopic patient typically reacts more sensitive to possibly unintended deviations.

With press of <**Depth**> or <**Volume**> the refraction optimisation process starts according to previous settings. This process consists of 5 levels with dioptric ranges continuously becoming narrower if calculation is not stopped in-between with <**Stop**> (Figure 2-40).

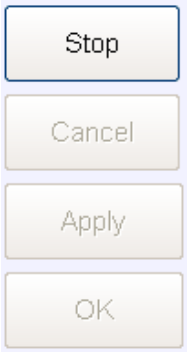


Figure 2-40: Stop button

Each level (pass 1 of 5, pass 2 of 5, etc.) is displayed with time period as well as total running time is included.

Once stopped, "Preview" suggests the refraction that is considered to be the best optimisation at that time.

<**Update preview**> visualizes the newest maps according to setting changes.

<**Cancel**> goes back to Main Menu without any change applied.

<**Apply**> activates the changes (for the treatment plan) and switch between 'Refraction' and 'Pyramid' is possible.

<**OK**> confirms changes (calculations) with return to Main Menu.

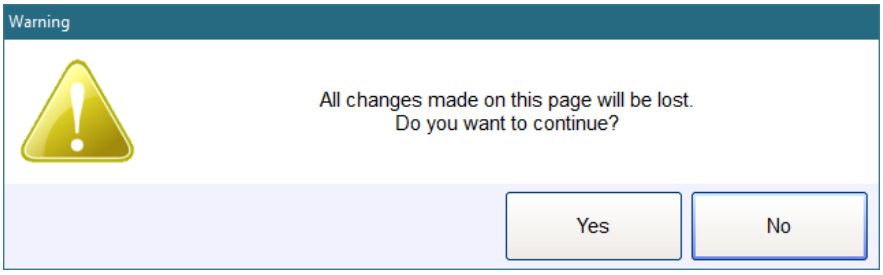


Figure 2-41: Switch between <Refraction> and <Pyramid> tried but changes in current screen have not been confirmed yet via <Apply>

Pyramid

Higher-order aberrations can be (de-)activated in the pyramid (Figure 2-42) obtaining patient optimized treatment profiles and possible tissue saving effects.

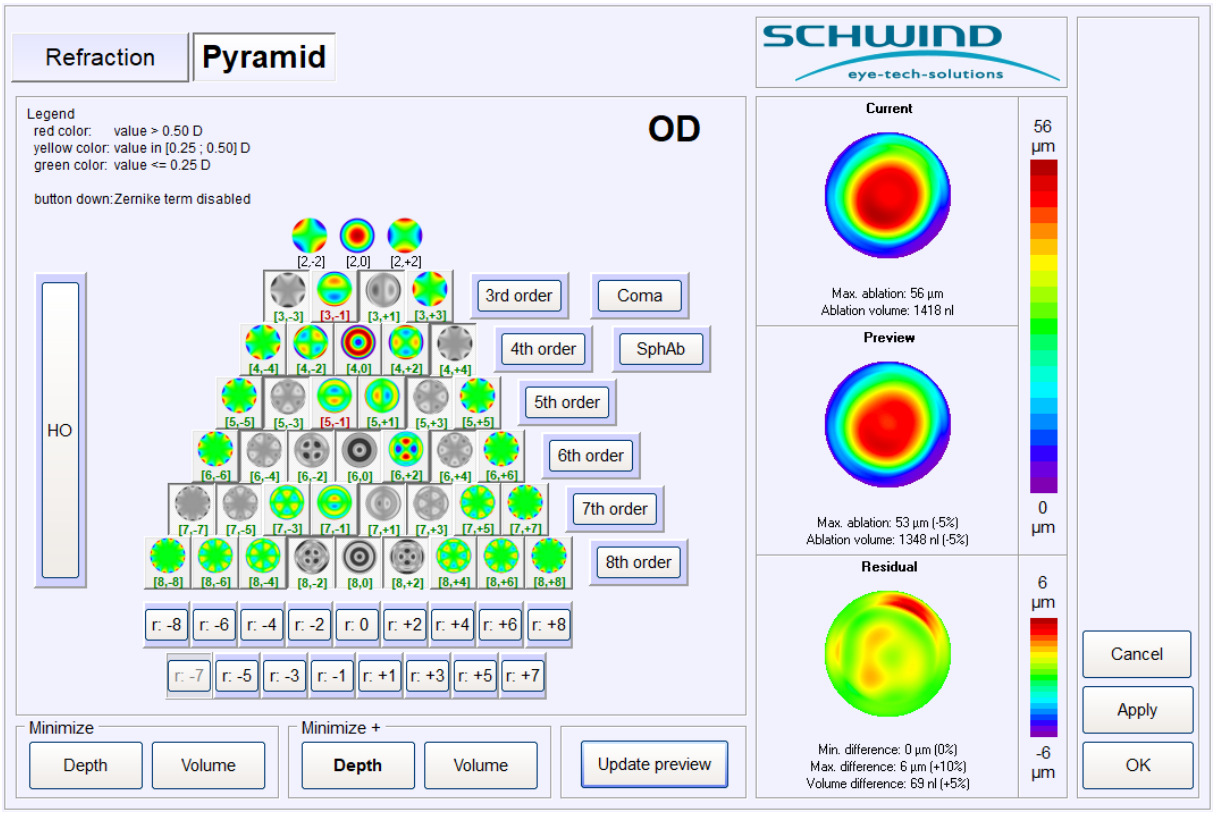


Figure 2-42: Pyramid in Manager (example)

As default, all aberrations in pyramid are active (= in colour) and, therefore, would be considered for surgery. The lower-order aberrations are fixed and related to the manifest refraction respectively have been modified in <**Refraction**>panel first.

Moving the mouse pointer within the pyramid, the acronym, the terminology, the micrometer (µm) and dioptre (D) value of each wave aberration is displayed (Figure 2-43).

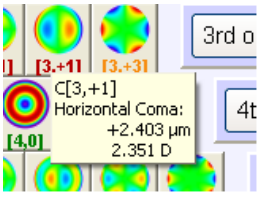


Figure 2-43: Aberration coefficient info in Pyramid

'Current', **'Preview',** and **'Residual'** give a visual impression of the ablation profile (change) according to the choices within the pyramid.

<**Update preview**> enables the changes made within pyramid, updating the maps 'Preview' and 'Residual'.

CAUTION

The <**Manager**> function has to be used after the final adjustment of optical zone was made. If other values e.g. manifest refraction (MR), addition/target refraction (TR) or optical zones (OZ) are changed after confirmation of manager calculations or settings, it cannot be guaranteed that the previous manager output is still optimum for the changes made in treatment plan.

Repeat your steps within <Manager> for recalculation and finding the new optimum.

The characteristic of each Zernike coefficient (wave aberration) is displayed either in green, yellow or red. The significance of each colour is shown and described in the '**Legend'** section and in the <**Zernike List**> (refer to chapter 2.3.6 Zernike List).

Zernike Coefficients

All wave aberration panels shown coloured within the pyramid will be considered for the treatment. Zernike coefficients planned not to be treated have to be pressed and a change to grey coloured panels (=deactivated) appears. The (de-) activation can be performed either by clicking the buttons within the pyramid or by clicking those outside the pyramid (e.g. <Coma>, <SphAb>, <HO>). Complete radial orders (3rdorder, 4thorder,...) or angular frequencies (...,r:-7, r:-6,...r:0...,r:+6, r:+7,...) can be chosen, as well.

The manager window includes a legend with colour code and (de-)activation status explanation.

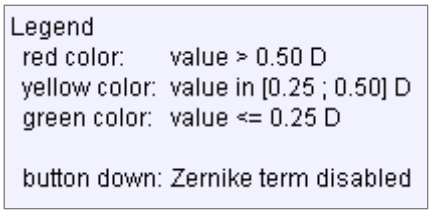


Figure 2-44: Legend in Manager

Optimized Depth and Optimized Volume (Tissue Saving)

The Minimize and Minimize + function either in <**Depth**> or in <**Volume**> can be used for an optimized treatment volume. The reason can be tissue saving, i.e. safety aspects.

<**Stop**> Figure 2-40 can interrupt the calculation at any time of the calculation process. The best approach at time stopping is displayed on the screen then.

Minimize Depth' or '**Minimize Volume'** searches for those higher-order aberrations out of the pyramid consuming less total depth or volume (the amount of lower-order aberrations has an impact on this calculation process, too).

All coefficients marked yellow or red are mandatory to include for the treatment. Green coefficients will be taken only if they contribute to minimized tissue ablation.

The addition '+' considers only the "red" coefficients as mandatory. Yellow- and green-marked coefficients that contribute to an even smaller depth or volume are considered for the treatment.

CAUTION

Make sure to use Manager HOA terms selection reasonably, i.e. use minimize functions (= automatic optimization calculations) at your disposal, but use manual selections of HOA (= Higher-Order Aberrations) terms with care. Observe always, with the help of the preview, whether your selection – compared to a full HOA correction profile – still matches with patient's topography and wavefront.

Changes in <**Refraction**> have to be performed before minimize functions in <**Pyramid**> are used! If not, it cannot be guaranteed that the combination of refraction values and higher-order aberrations selected are optimum and the most tissue saving for the patient.

<**Cancel**> goes back to Main Menu without any change applied.

<**Apply**> activates the changes (for the treatment plan) and switch between 'Refraction' and 'Pyramid' is possible.

<**OK**> confirms changes (calculations) with return to Main Menu.

IMPORTANT NOTE

<**OK**> in the 'Manager' confirms all the changes within the 'Pyramid' and 'Refraction' panel and takes these settings into account for the (new) ablation profile, i.e. treatment plan.

<**CANCE**L>discards all changes within 'Manager' panels and keeps the ablation profile/ treatment plan before entering <Manager>.

Furthermore, selected optical zone size and import file name are shown as basic information in the header of the manager screen.

Preview and Difference Function

The '**Current**' status includes all components (high-order-aberrations as well as low-order-aberrations) for a selected optical zone that were considered for the treatment plan before the manager function was entered.

The (de-) activation of any high-order-aberration component within the pyramid results in changes of ablation depth and volume.

<**Update preview**> has to be pressed if newest settings shall be visualized in '**Preview**' and '**Residual**' panel. Furthermore, the user is informed about minimum, maximum, and volume differences between current and preview situation.

Beside micrometer (μm) and nanolitre (nl) information the change in percentage (%) is displayed. A normalized colour scale completes the information.

Changes for the presbyopia treatment plan will be activated when <**OK**>or <**Apply**>is pressed and the procedure can be aborted using <**Cancel**>.

As soon as minimum one higher-order aberration component is not considered for treatment, the index **"Filtered"** will be displayed in the Main Menu, Summary Page, and print afterwards.

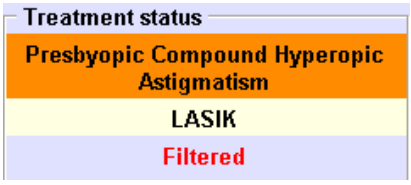


Figure 2-46: "Filtered" in Main Menu

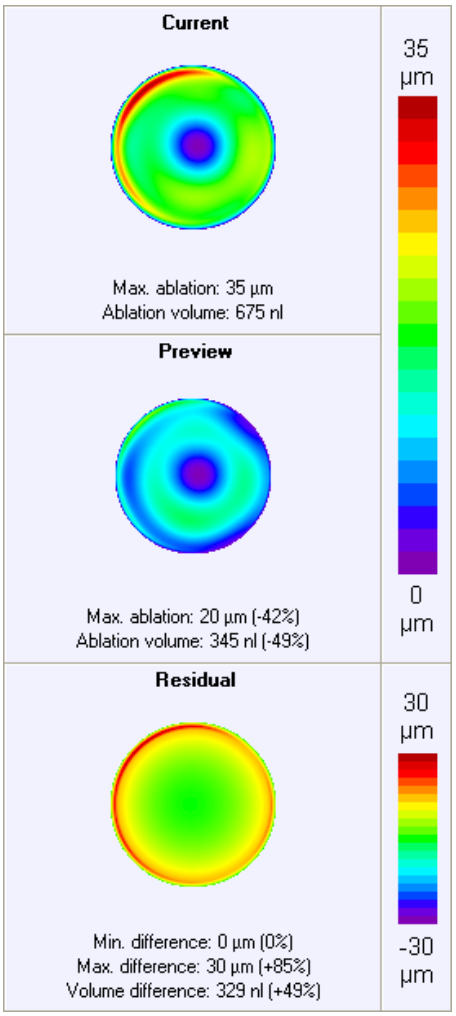


Figure 2-45: Current, Preview, and Residual in "Manager"

All components that were decided to be treated will be displayed within the Zernike list (refer to chapter 2.3.6 Zernike List) of Ablation Map.

The coefficients that are considered to be treated will be displayed in micron (μm) values, the ones that are deactivated will be shown zero (unless affected by the offset input) .

The colour code of aberration significance (green, yellow, red) is independent from (de-) activation procedure and thus, stays unchanged in the Ablation Map. The ablation profile for the laser is based on the Ablation Map information (low and high order aberrations expressed in Zernike).

CAUTION

All coloured icons within the pyramid will be considered for ablation volume calculation. Grey coloured icons will not be considered.

An overview of the Zernike coefficient choices for the presbyopia treatment will be given in the <**Manager**> function and in the <**Zernike list**> of Ablation Map.

Furthermore, a print of the pyramid can be selected in CAM settings (as second page of the PresbyMAX treatment plan). The options in chapters 2.3.6 through 2.3.8 are available in the Main Menu only if Corneal or Ocular Wavefront data are used.

2.3.9 Foresight

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: *.pby- planning file includes content of SCHWIND SIRIUS, SCHWIND SIRIUS+ or SCHWIND MS-39 by CSO Phoenix V4.1.4.7. Details to be found within the additional Foresight documentation by SCHWIND. Access to <Foresight> is possible only with separate activation (refer to current Instruction for Use (IFU) of SCHWIND CAM). Foresight activation is fee-based and limited in time.

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.

2.3.10 Refraction and Laser Setting Values

The refraction values that have been entered in Treatment Data Input Mask (VD, Manifest, Target, Laser, and Offset) are summarized in the panel 'Refractive Zone' (RZ) @ 4 mm (Figure 2-47).

Manifest Refraction

The manifest refraction and vertex distance displayed in the Main Menu are based on the input in the patient data form. These values cannot be changed in the Main Menu. Please refer to / press <**Patient data**> if the patients' refraction or vertex distance has to be changed.

Target Refraction

The target refraction value is automatically calculated and displayed within the Treatment Data Input Mask.

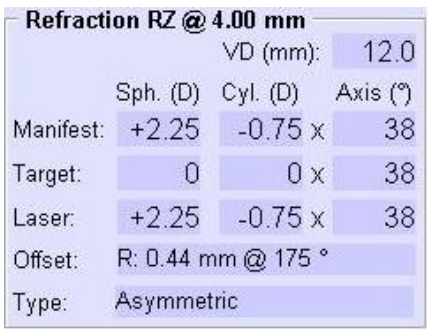


Figure 2-47: Display of Refraction and Laser Setting Values

The targets in PresbyMAX are 0.00 D of sphere (distance eye) and -0.88 D of sphere (near eye) by default at corneal plane.

IMPORTANT NOTE

Please refer to 'Settings' (Presby) of SCHWIND CAM if anisometropia shall be different to post-operative target of - 0.88 D (default), and be modified within the range of 0.00 to 1.50 D.

The target refraction indicates the desired postoperative subjective (manifest) far distance refraction. The target refraction cannot be manually adapted in this section of treatment planning module.

Laser Settings

The combination of 'Manifest' and 'Target' results in 'Laser'. Both manifest refraction and target refraction values (main meridians) are calculated back to corneal vertex (VD = 0) first, then added, and the result out of it (= laser settings) is afterwards expressed for defined vertex distance again.

IMPORTANT NOTE

The 'Laser' display is always related to the vertex distance that is displayed in the 'Refraction RZ @ 4 mm' panel and which has been entered in the Treatment Data Input Mask, **not** to the corneal plane as treated with the laser!

Applied changes in the 'Refraction' panel within <**Manager**> (for tissue saving aspects) will automatically be addressed and shown in Refraction panel of Main Menu respectively Treatment Data Input Mask afterwards.

Offset

The pupil offset is shown according to the entries at the Treatment Data Input Mask and the settings convention decided for in 'CAM settings', either in polar or Cartesian coordinates.

Type

The offset type is shown according to the selection at the Treatment Data Input Mask. '**Asymmetric**' is the default proposal in 'CAM settings' after initial installation, the other option is the use of the '**Symmetric**' ablation offset approach (refer to 2.1.5.6 Ablation Strategy: Asymmetric vs. Symmetric).

2.3.11 Ablation Zone Ranges

Total Ablation Zone

The maximum possible ablation zone diameter is 10 mm.

Total ablation zone (TAZ) minus optical zone (OZ) results in transition zone (TZ) size (diameter value not radius).

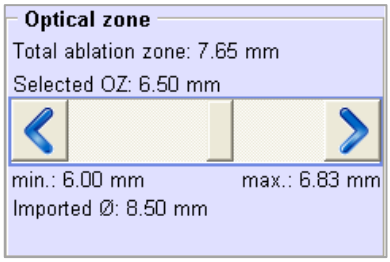


Figure 2-48: Ablation Zone Panel

WARNING!

Pay attention to the total ablation zone (TAZ) settings to avoid ablating the flap, flap edges or the outside of the PRK/LASEK disk.

Selected Optical Zone

The selected optical zone (OZ) is shown based on default setting first. The default setting has three groups with type of refraction as separator: myopia dominant, hyperopia dominant, and astigmatism dominant (refer to User Manual of SCHWIND CAM, chapter 6.3.1.3 Presby-Tab).

The maximum selectable OZ is 7.50 mm for presbyopia. The zone size can be changed either in 0.1 mm or 0.01 mm steps. 0.1 mm-steps are obtained by using clicks within the slider bar or by using the right/left arrow keys on the keyboard. Fine tuning in 0.01 mm-steps can be achieved by using the arrow icons beside the slider bar or by using the up/down arrow keys on the console.

WARNING!

The manufacturer's default optical zones (OZ) (refer to User Manual SCHWIND CAM, Figure 6-6 "General Settings Mask – Presby) shall be considered as guideline for OZ as a compromise between tissue removal, biomechanical stability and reasonable contributions of the central and peripheral area for near and distance vision, respectively. It is recommended to increase optical zone sizes when patient's scotopic pupils are larger than the proposed optical zone size.

In addition, it is recommended to select individual OZ sizes whenever treatment method <**TransPRK**> is chosen and an individual epithelium thickness info/map does not exist.

Depending on the refractive correction plan and the software default epithelial profile of 55 µm in the center gradually increasing to 65 µm @ 8 mm diameter following table for recommended optical zone (OZ) sizes exists:

MYOPIA (most negative meridian)		HYPEROPIA (lowest positive meridian)	
Below -1.00 D:	No TransPRK	Below +1.50 D:	No TransPRK
-1.00 to -2.00 D:	Scotopic pupil + 1.0mm (Minimum 7.30 mm)	+1.50 to +3.00 D:	Scotopic pupil + 0.5mm (Minimum 7.20 mm)
-2.00 to -3.00 D:	Scotopic pupil + 0.5mm (Minimum 6.80 mm)	Above +3.00 D:	Scotopic pupil (Minimum 6.70 mm)
Above -3.00 D:	Scotopic pupil (Minimum 6.30 mm)	**Remark:** Consider haze prophylaxis	

Further options are an optical zone (OZ) enlargement for 6 μm or more of ablation depth - compared to the originally planned OZ - to result in 'achieved OZ ≥ planned OZ', or the use/import of epithelium data by high-resolution OCT devices (e.g. SCHWIND MS-39). Always check and ensure that OCT measurements are properly evaluated, and possible changes in the CAM epi profile enables a break-through of the ablation profile into the corneal stroma for treatment efficacy and a sufficient (functional) optical zone size.

If ***epithelium is thinner*** than the TransPRK epithelial profile used:

- In Myopia: only some extra tissue will be removed. "Full correction" achieved.
- In Hyperopia: only some extra tissue will be removed. "Full correction" achieved.

If ***epithelium is thicker*** than the TransPRK epithelial profile used, i.e. part of the stromal (refractive) ablation is invested in removing the epithelium:

- In Myopia: smaller optical zone size (typically no over- or undercorrection).
- In Hyperopia: wrong curvature correction, i.e. no "full correction" achieved.

If ***epithelium thickness ratio*** (from centre to periphery @ 8 mm) differs from the TransPRK epithelial profile (default ratio: 10μm):

- (minor) refractive differences can be observed.

Refer to chapter 2.1.5.4 Epithelium Thickness and possibly to 'Theoretical analyses of the refractive implications of transepithelial PRK ablations; Arba Mosquera S, Awwad ST; Br J Ophthalmo;2013;97:905-911' for additional information and possible risks with TransPRK.

Transition Zone

The transition zone (TZ) size is dynamic, automatically given, and depends on different circumstances and relationships (optical zone, type of refraction, amount of refraction (sphere cylinder, and addition), type of treatment and treatment method).

The TZ size is in general displayed in diameter not in radius. A TZ size of 0.50 mm is minimum applied, 2.00 mm (SCHWIND CAM default) is taken as maximum. The different TZ sizes are applied to receive maximum selected optical zone sizes with least regression in each presbyopia treatment.

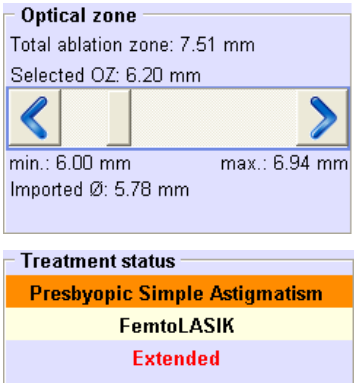


Figure 2-49: Example "Extended"

IMPORTANT NOTE

The transition zone (TZ) concept is equal for aberration-free and wavefront-guided ablations but different between surface ablations (TransPRK, PRK, LASEK) and sub-Bowman ablations (LASIK, FemtoLASIK, Re-Lift), with slightly bigger transition zones in myopic surface ablations compared to flap techniques. Transition zones in hyperopic ablations are bigger in general but also limited to a maximum.

Individual TZ and total ablation zone (TAZ) sizes are seen in 'Optical Zone' panel. The TAZ maximum is 10 mm in all cases.

Extended Optical Zone

When Corneal or Ocular Wavefront data are imported for a presbyopia treatment, the maximum exported diameter of the diagnostic system is displayed

Dependent on imported zone size, an ablation up to 10 mm in total can be performed. There might be a limitation (< 10 mm) because the extrapolation maximum – in reference to an aspheric (AF) profile – is 20 % of the imported zone size.

If the maximum imported diameter from diagnosis is smaller than the optical zone chosen, **"Extended"** is displayed in 'Treatment status' of the Main Menu (Figure 2-32).

The lack of corneal or ocular data will be balanced by an aspheric (AF) profile to the periphery.

Example:

The import diameter from the diagnostic system is 5.78 mm. An optical zone of 6.20 mm is selected for the presbyopia treatment. Thus, the treatment will be 0.42 mm enlarged with an aspheric (AF) profile fit following the size of the imported data. In enlarged cases the information "Extended" is shown.

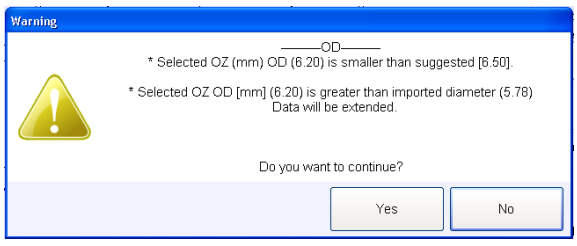


Figure 2-50: Message 'Selected optical zone (OZ) > measured pupil' in "Extended" cases.

In these cases a message pops up before export asking whether extended range shall be taken.

WARNING!

Make sure to use extrapolation reasonably, i.e. the "Extended" feature available for presby wavefront treatments shall NOT be used for all presbyopia treatments. Use extended ranges at your disposal, but use it with care.

If wave aberration data are considered to be taken for laser surgery, receiving as much wave aberration data from diagnostic device as possible must be mandatory in each examination procedure.

The analysis diameter should be at least as large as the optical zone, if possible.

Make sure the ablation map is large enough for the scotopic pupil size.

In general, make sure that no exports are done for selected OZ smaller than 6.00 mm in presbyopic myopia or smaller than 6.20 mm in presbyopic hyperopia. In presbyopic astigmatism dominance no exports smaller than 6.50 mm are recommended.

2.3.12 Treatment Status

Information about the type of refraction (e.g. Presbyopic Compound Myopic Astigmatism, Presbyopic Only High-Order-Aberration…) and treatment method (e.g. LASIK, TransPRK…) are shown according to input and selections within Treatment Data Input Mask and Main Menu.

Figure 2-51: Treatment Status Panel

Information such as "Extended" or "Filtered" will also be displayed in this panel beside SCC- quality check and -file information if comprised in presbyopia treatment planning (Figure 2-51).

IMPORTANT NOTE

A **blue** background stands for myopia, **orange** background for hyperopia, and **green** background for zero spherical equivalent (SEq).

2.3.13 RST Manager

The RST (Residual Stromal Thickness) manager (Figure 2-52) serves as planning support to supervise whether the residual stromal thickness will fall below the critical value of 250 micrometer, particularly with LASIK treatments.

The software allows 250 µm for the lowest barrier, but RST value is adjustable (up to 500 µm) in case higher safety aspects are desired (refer to chapter User Manual SCHWIND CAM, chapter 6.3.1 "Settings Button").

The defined value is shown behind the abbreviation 'RST' in the Main Menu and the Summary Page.

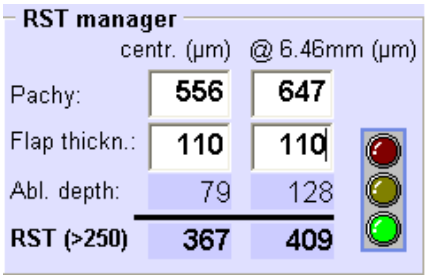


Figure 2-52: RST Manager

It is always necessary to include the pachymetry for the centre of the cornea as well as the pachymetry at the area of maximum ablation; i.e. in myopic ablations center and maximum are typically equal, in hyperopic or wavefront-guided ablations both may significantly differ.

IMPORTANT NOTE

Import data of SCHWIND SIRIUS, SIRIUS + or MS-39 diagnostic device include the central pachymetry value, i.e. the panel 'Pachy – centr. (µm)' in Main Menu is filled out of file. It is still possible to change this value manually, e.g. to the minimum thickness value of patient's cornea.

If "peripheral" pachymetry, i.e. pachy at ablation maximum, is not entered and the summary button is pressed (surrounded in orange colour), a message appears whether estimated "peripheral" pachy values (out of literature research) shall be used to continue (Figure 2-53).

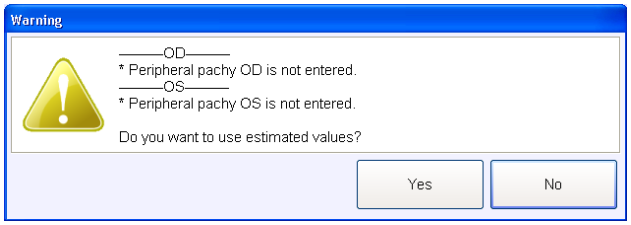


Figure 2-53: Maximum Pachy Value Message

Ablation maximum is typically (close to) the center in myopic cases and more peripheral in hyperopic cases.

Selecting a (Femto-)LASIK or Re-Lift treatment, the flap thickness is automatically taken according to the user settings made by the user (refer to chapter User Manual SCHWIND CAM, chapter 6.3.1 "Settings Button").

The flap thickness value (input range: 50 µm to 250 µm) can be changed directly within the RST manager panel, if necessary. The corresponding value must be entered in micrometer. The flap thickness defined in 'CAM Settings', however, will be taken for the following presbyopia treatment plans again.

In PRK and LASEK treatments, the software takes epithelium thickness data (central thickness, peripheral thickness, and peripheral diameter) – either default values out of 'CAM Settings', imported values by SCHWIND MS-39 device or manually adapted values within Treatment Data Input Mask- for the centre and the maximum epithelium value calculation by a parabolic fit according to the area where maximum ablation takes place.

WARNING!

When exporting the presbyopia treatment plan, it must be noted that real flap thickness can vary from theoretical calculation.

Make sure to select the flap to an adequate thickness corresponding to your experience (an automatic recommendation is provided by the SCHWIND CAM software [Settings: ORK Tab], but it can be changed at your convenience). This has to be considered during evaluation of the RST, i.e. of the residual stromal thickness.

The central and maximum ablation depth of the individual presbyopia treatment plan is taken according to the ablation profile displayed and automatically transferred to the RST manager for the calculation process. The traffic light system in Main Menu provides the user with a simple and clear safety function supervising the residual stromal thickness (RST).

WARNING!

Check always whether the pachymetry value entered equals the thinnest measurement(s) that were determined on the patient's cornea (especially in presbyopia re-treatment cases). Otherwise the traffic light system may give a wrong impression due to false pachymetry input.

If the residual stromal thickness (RST) of a patient's cornea falls below defined limits (absolute minimum is 250 μm) as a result of patient's corneal anatomy and presbyopia treatment plan decision (with sub-Bowman techniques subtracting the intended incision thickness of cornea lamella, and surface techniques subtracting epithelial thickness), the traffic light will be **red** and, thus, an export of the ablation volume will not be possible.

Within a border zone of 10 μm above the defined limit, the traffic light blinks in **yellow**. The yellow light shall give attention to the user but export is still possible. If the RST value calculation results bigger than 10 μm of defined limit, the traffic light appears **green** and the planned ablation volume can be exported.

2.3.14 Apply

If the <**Apply**> button is pressed, a (re-)calculation of the presbyopia treatment data takes place that is currently on the Main Menu screen. Any change in optical zone size requires a recalculation.

The <Apply> button surrounded in orange indicates that changes were applied but recalculation is still pending. As soon as <Apply> is pressed, the Main Menu screen is updated according to actual entries and settings.

IMPORTANT NOTE

A recalculation automatically appears when coming from Treatment Data Input Mask (with changes in the plan and via <OK>) respectively when going to Summary Page. The Main Menu entries and settings that are currently on the screen are taken when <**Summary**> is pressed (even with possibly no <**Apply**> activation in advance).

2.3.15 Warning messages

Warning messages shown in Main Menu before or while pushing <**Summary**> whenever the treatment plan deviates from the recommended (software) input/default ranges or special attention is requested (e.g. Presby reversal).

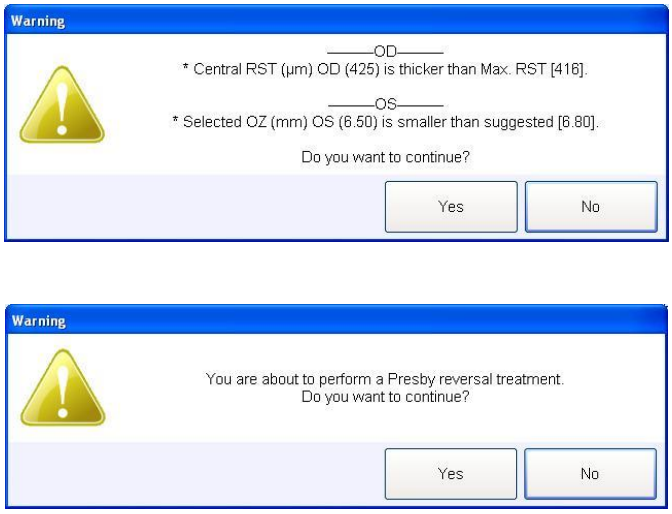


Figure 2-54: Warning Messages

If the treatment plan is considered ok and confirmed via <**Yes**>, the Summary Page of the PresbyMAX software module opens. Otherwise, <**No**> has to be used to still apply changes or abort current treatment plan.

2.3.16 Open Function

The reload of project files can be accomplished via <**Open**> button on the SCHWIND CAM Welcome Screen or within the SCHWIND CAM Main Menu.

Entering previously-memorized project files enables the user to further process the presbyopia treatment planning of individual patient files.

Within the AMARIS laser PresbyMAX® project files (*.pby) can be reloaded using the <**Import**> button on the Welcome Screen of AMARIS Application Software.

The user can select within 'Files' tab of 'CAM Settings' whether the reloaded file shall open up at Treatment Data Input Mask, Main Menu or Summary Page. A file starts at Summary Page only when all necessary entries have been done before, otherwise the Main Menu appears.

IMPORTANT NOTE

Project files created with same main version (e.g.**5.**2.23.2214) cannot be read with the new version **5.3**.23.2417 anymore.

Project files created with the same main version and subversion (e.g. **5.2**.23.1904) can be read in the version (e.g. **5.2**.23.2214) but a confirmation

message before import appears that recalculation of the "old" project for further use is necessary.

Projects generated with newer versions cannot and shall not be loaded on older versions.

2.3.17 Save Function

The <**Save**> button in the Main Menu provides the opportunity to store project files in a directory. The project file is created with memorization of all decisions and entries made for a patient until now. The planning files of PresbyMAX® software module have the extension ***.pby.**

The ***.pby**- file is located in a separate patient folder that is automatically created using <**Save**>.

Furthermore, this patient folder may contain subfolders for eyes OD (oculus dexter) and OS (oculus sinister) where all necessary export information from diagnostic devices (corneal and ocular data) is stored.

WARNING!

Do not rename files after exporting; if needed (and if possible) use the filename entries before exporting. Otherwise, necessary information, like SCC from diagnostic device, may not be available during the presbyopia treatment anymore.

IMPORTANT NOTE

<**Save**> stores equal information than <**Export**> does, but in case of <Save> it is not (yet) required to have all entries ready that are necessary for a presbyopia treatment.

Copy the complete patient folder with subfolders included if necessary. With project file only additional information from diagnostic system(s) may be lost.

Project files (*.pby) can be read, updated, and stored in AMARIS laser, as well. Projects within AMARIS will be saved automatically in D:\Export_SCHWIND_CAM

Saving of files is possible only with sufficient disk space.

2.3.18 Print Function

The <**Print**> button is enabled for printing of actual patient information according to the user's input within PresbyMAX® software module. The printout includes device and version information of SCHWIND CAM Amaris beside information about the computer operating system, the print date and print time. In case of presbyopic wavefront-guided treatment plans, a second page with Zernike pyramid and display of (de-) activated high order aberrations exists when previously selected in 'CAM Settings'.

IMPORTANT NOTE

If software is used in DEMO, "Demo Mode" is watermarked on the print of the Summary Page.

If a document reader is used for printing, a file name proposal is automatically given.

The file name proposal starts with "CAM_treatment_summary_page" and contains patient-ID, last name, first name, eye, date and time.

2.3.19 Summary

The <**Summary**> button is enabled and all entries needed are performed if button is surrounded in green colour. If the button is surrounded in yellow colour, continuation is also possible when the use of estimated "peripheral" pachymetry values (out of literature) is confirmed.

As long as <Summary> is surrounded in red colour some unavoidable entry data (possibly of the second eye) are still missing within Main Menu.

IMPORTANT NOTE

A Summary Page including all relevant presbyopia treatment plan data and settings appears when <**Summary**> is passed in the Main Menu.

Access to the Summary Page and <**Export**> functionality will only be possible if all necessary data are entered (for both eyes).

2.3.20 Exit

The <**Exit**> button (or the white cross in the upper right corner) of the SCHWIND CAM software can be pressed if the software shall be closed. The PresbyMAX® software module asks for saving procedure if a project file is still loaded and the user tries to close the SCHWIND CAM.

The user chooses either '**Yes'**, '**No**' or '**Cancel'** to continue.

2.4 Summary Page

Confirmation and Export of the Presbyopia Treatment Plan

The Summary Page (Figure 2-56: Summary Page (example OD (Presby OW-guided PRK) / OS (Presby CW-guided FemtoLASIK)) pops up after leaving the Main Menu. An overview of all relevant presbyopia treatment data and presbyopia treatment settings of the patient's eye is offered.

The presbyopia treatment plan is completed and <**Export**> of the ablation data for the SCHWIND AMARIS laser can be realized.

The <**OD**> and <**OS**> buttons are available on the Summary Page! The data shown on the screen are related to the eye where the button is surrounded in blue colour.

Figure 2-56: Summary Page (example OD (Presby OW-guided PRK) / OS (Presby CW-guided FemtoLASIK))

IMPORTANT NOTE

Data for both eyes must be checked before the export function is enabled!

The spherical aberration (SphAb [Z(4,0)]) display at defined optical zone / max. import diameter is distinguished in two parts within the Summary Page, i.e. the 'SphAb' of the complete ablation profile and 'Presby' is extracted as part of the

'SphAb' of the individual profile. The magnitude of the 'Presby' component of each eye depends on the selection of eye dominance, addition, and presby type!

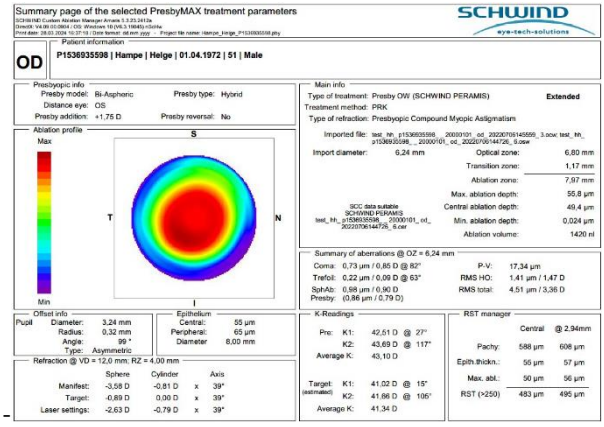
2.4.1 Cancel

You abort the Summary Page view and return to the Main Menu of the PresbyMAX® software module by clicking <**Cancel**>.

2.4.2 Print of Summary Page

The <**Print**> button prints the Summary Page for OD and OS to overview the presbyopia treatment plan according to the user's input within PresbyMAX® software module.

The printout includes device and version information of SCHWIND CAM AMARIS beside information about the computer operating system, the print date and print time. In case of presbyopic "Customized" treatment plans (Presby OW and Presby CW), a second page with Zernike pyramid and display of (de-) activated higher-order aberrations exists when previously selected or activated in 'CAM Settings'.



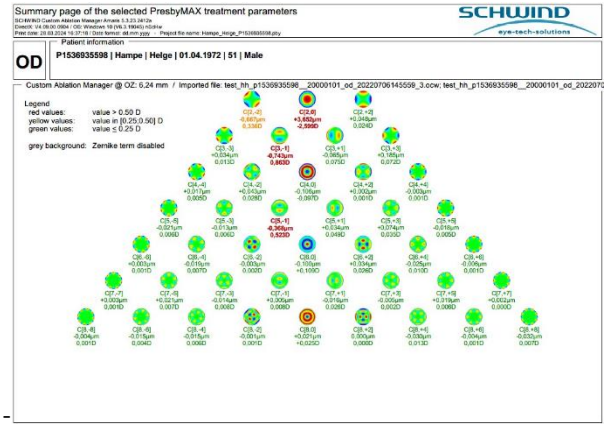
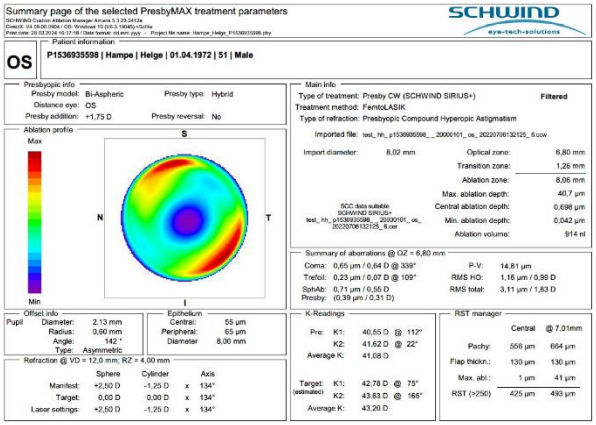


Figure 2-57: Treatment Plan Print - page 1 (examples)



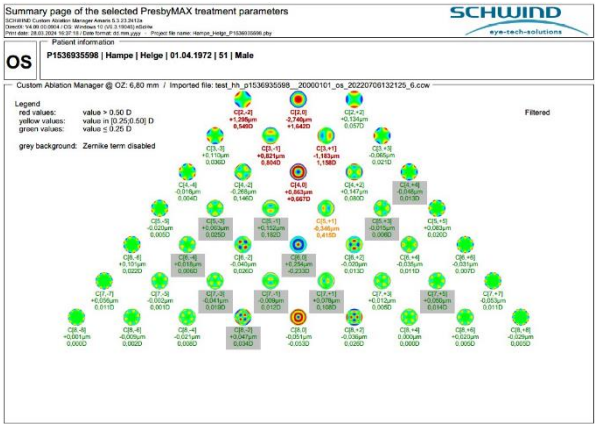


Figure 2-58: Treatment Plan Print - page 2 [optional]

IMPORTANT NOTE

If software is used in DEMO, “Demo Mode” is watermarked on the print of the Summary Page.

If a document reader is used for printing, a file name proposal is automatically given.

The file name proposal starts with "CAM_treatment_summary_page" and contains patient-ID, last name, first name, eye, date and time.

A **Summary Page** print can still be executed within SCHWIND AMARIS laser.

2.4.3 Export

The user confirms that all information was correctly entered by clicking the <**Export**> button.

A patient folder and file name with patient-ID, last name, and first name included is automatically suggested but it can be modified at your disposal.

The presbyopia treatment file **(*.pby)** is stored within the patient folder that is equally named. Further information that is possibly required for the presbyopia treatment procedure (e.g. information out of Corneal and Ocular diagnostic devices) is automatically stored within subfolders OD/OS.

After <**Export**> is successfully performed, direct return to the Main Menu is given.

WARNING!

Do not rename files after exporting; if needed (and if possible) use the filename entries before exporting. Otherwise, necessary information, like SCC from diagnostic device, may not be available during the presbyopia treatment anymore.

Make sure the ablation map is large enough for the scotopic pupil size.

In general, make sure that no exports are done for selected OZ smaller than 6.00 mm in myopia or smaller than 6.20 mm in hyperopia. In astigmatism dominance no exports smaller than 6.50 mm are recommended.

It is recommended to increase optical zone sizes when patient’s scotopic pupils are larger than the proposed optical zone size.

In addition, it is recommended to select individual OZ sizes whenever treatment method <**TransPRK**> is chosen and an individual epithelium thickness info/map does not exist.

Depending on the refractive correction plan and the software default epithelial profile of 55 µm in the center gradually increasing to 65 µm @ 8 mm diameter following table for recommended optical zone (OZ) sizes exists:

MYOPIA (most negative meridian)		HYPEROPIA (lowest positive meridian)	
Below -1.00 D:	No TransPRK	Below +1.50 D:	No TransPRK
-1.00 to -2.00 D:	Scotopic pupil + 1.0mm (Minimum 7.30 mm)	+1.50 to +3.00 D:	Scotopic pupil + 0.5mm (Minimum 7.20 mm)
-2.00 to -3.00 D:	Scotopic pupil + 0.5mm (Minimum 6.80 mm)	Above +3.00 D:	Scotopic pupil (Minimum 6.70 mm)
Above -3.00 D:	Scotopic pupil (Minimum 6.30 mm)	**Remark:** Consider haze prophylaxis	

Further options are an optical zone (OZ) enlargement for 6 μm or more of ablation depth - compared to the originally planned OZ - to result in 'achieved OZ ≥ planned OZ', or the use/import of epithelium data by high-resolution OCT devices (e.g. SCHWIND MS-39). Always check and ensure that OCT measurements are properly evaluated, and possible changes in the CAM epi profile enables a break-through of the ablation profile into the corneal stroma for treatment efficacy and a sufficient (functional) optical zone size.

If ***epithelium is thinner*** than the TransPRK epithelial profile used:

- In Myopia: only some extra tissue will be removed. "Full correction" achieved.
- In Hyperopia: only some extra tissue will be removed. "Full correction" achieved.

If ***epithelium is thicker*** than the TransPRK epithelial profile used, i.e. part of the stromal (refractive) ablation is invested in removing the epithelium:

- In Myopia: smaller optical zone size (typically no over- or undercorrection).
- In Hyperopia: wrong curvature correction, i.e. no "full correction" achieved.

If ***epithelium thickness ratio*** (from centre to periphery @ 8 mm) differs from the TransPRK epithelial profile (default ratio: 10μm):

(minor) refractive differences can be observed.

Be careful in PresbyMAX and TransPRK because the intended multifocality might be (partly) covered and smoothed out by the re-epithelialisation processes–PRK or LASEK method is preferred in presbyopia treatments with surface ablation.

Refer to chapter 2.1.5.4 Epithelium Thickness and possibly to 'Theoretical analyses of the refractive implications of transepithelial PRK ablations; Arba Mosquera S, Awwad ST; Br J Ophthalmo;2013;97:905-911' for additional information and possible risks with TransPRK.

CAUTION

Copy the complete patient folder with subfolders included if necessary. With project file only additional information from diagnostic system(s) may be lost.

IMPORTANT NOTE

Project files **(*.pby**) can be read, updated, and stored in AMARIS laser, as well. Projects within AMARIS will be saved automatically in D:\Export_SCHWIND_CAM.

Saving of files is possible only with sufficient disk space.

A treatment offset (based on diagnostic device information) for presbyopic Aberration-Free AND presbyopic“ Customized” ablations can be entered or modified within the PresbyMAX® software module, NOT in the AMARIS treatment mode.

The user must ensure that the correct patient and the correct eye(s) have been selected for the presbyopia treatment!

Ensure that only authorized staff has access to the processors / the server

PresbyMAX® treatment planning is possible from both external device (workstation) and internally within the AMARIS laser. The presbyopia export files respectively presbyopia treatment patient data folder need to be saved on an external hard drive (SD memory card) if no SCHWIND MedNet (medical network) exists or the PresbyMAX® treatment planning was not internally done in AMARIS.

Both presbyopia treatment file ("export") and presbyopia project file ("save") have the same file extension ***.pby**. Only one treatment or project file is created including information of both eyes OD and OS. The file planned can still be modified within the AMARIS laser until the presbyopia treatment procedure is confirmed with <**Start treatment**>.

3. CLINICAL USE OF PRESBYMAX® MODULE

3.1 Introduction

PresbyMAX® is based on bi-aspheric, multifocal ablation profiles, i.e. each concentric area is multifocal with a transition between both providing intermediate vision. For each patient eye, it optimizes the central corneal area for near vision and the pericentral cornea for far vision.
PresbyMAX® allows the treatment of emmetropic patients as well as patients with refractive deficits whose accommodative response is limited. The SCHWIND AMARIS excimer laser with PresbyMAX® software included combines the treatment of myopia, hyperopia and astigmatism with presbyopia corrections bilaterally. Three types of presbyopia correction are available: PresbyMAX μ-Monovision, PresbyMAX Hybrid, and PresbyMAX Monocular. Correction of visual defects can be performed as "Aberration-Free" (Presby AF) or "Customized" treatments (Presby OW, Presby CW) in methods TransPRK, PRK, LASEK, LASIK, FemtoLASIK, and Re-Lift.

IMPORTANT NOTE

Almost all PresbyMAX® study outcomes are based on LASIK respectively FemtoLASIK method! Experience in PresbyMAX® surface ablation is limited.

Be careful in PresbyMAX and TransPRK because the intended multifocality might be (partly) covered and smoothed out by the re-epithelialisation processes – PRK or LASEK method is preferred in presbyopia treatments with surface ablation.

The sophisticated presbyopia software solution PresbyMAX® was developed by SCHWIND in cooperation with VISSUM Corporation, Alicante, under the direction of Professor Jorge Alió, and the OCIVIS group from the University of Alicante.

- PresbyMAX® can be prescribed to prevent latent presbyopic symptoms.
- PresbyMAX® delays reading-spectacles demands while presbyopia progresses.
- PresbyMAX® can be repeated if reading-spectacles demands renew.
- PresbyMAX® offers external minimally-invasive refractive surgery.

IMPORTANT NOTE

Due to the licence situation the usage of this module is arranged by "credit-codes". Please contact your authorized SCHWIND local representative or SCHWIND eye-tech-solutions directly for your AMARIS PresbyMAX® credits order. An AMARIS PresbyMAX® treatment is not possible without valid credits.

CAUTION

Users can start with PresbyMAX® treatments when experience with the ORK-CAM module is already given and a PresbyMAX application training has been carried out by your authorized SCHWIND local representative or SCHWIND eye-tech-solutions directly.

3.2 Background Information

Near Visual Acuity Scales				**Distance** Visual Acuity Scales			
logRAD (40cm)	**Revised Jaeger** (35 cm)	**Nieden** (40cm)	**Parinaud** (40cm)	**logMAR**	**Feet** 20/	**Meter** 6/	**Decimal**
-0.3	-	-	-	-0.3	10	3	2.00
-0.2	-	-	P1	-0.2	12.5	3.8	1.60
-0.1	-	N1	P1.25	-0.1	16	4.8	1.25
0.0	J1	N2	P1.6	0.0	20	6	1.00
0.1	J2	N3	P2	0.1	25	7.5	0.80
0.2	J4	N4	P2.5	0.2	32	9.6	0.63
0.3	J5	N5	P3.2	0.3	40	12	0.50
0.4	J6	N6	P4	0.4	50	15	0.40
0.5	J8	N7	P5	0.5	63	18.9	0.32
0.6	J9	N8	P6.3	0.6	80	24	0.25
0.7	J10	N9	P8	0.7	100	30	0.20
0.8	J12	N10	P10	0.8	125	37.5	0.16
0.9	J13	N11	P12.5	0.9	160	48	0.13
1.0	J14	N12	P16	1.0	200	60	0.10
				1.1	250	75	0.08
				1.2	320	100	0.06
				1.3	400	120	0.05
				1.4	500	150	0.04
				1.5	600	200	0.03
				1.6	800	340	0.025

3.3 Examination Topics

- Patient interview
- Aberrometry/Autorefractometer
- Pupillometry
- Topography and Corneal Wavefront
- Uncorrected visual acuities (monocular and binocular for distance and near)
- Subjective refraction
- Best-corrected visual acuities (monocular and binocular for distance and near)
- Eye dominance test
- Addition
- Best-corrected visual acuity (monocular and binocular for near)
- Monovision test
- Cycloplegic refraction
- Vision simulation, e.g. multifocal contact lens trial

3.4 Patient Inclusion

- Patients without ocular pathologies who desire near, intermediate, and distance vision with increased spectacle independence.
- Highly motivated patients accepting that reduced distance vision postoperatively (CDVA pre-op vs. UDVA post-op) may occur.
- Clinical decision to enroll patients shall be made in an ethical way (e.g. professional drivers may suffer from reduced distance vision; professions with demands on focused close work may suffer from reduced near vision).
- Check whether profession, hobbies, and expectations of the patient seem to be adequate accepting the PresbyMAX principle.
- Patients who still accept wearing additives in case of really high demands either in distance or near visual performance:
- The potential risk/benefit ratio prior to PresbyMAX should be weighed by the physician:

3.5 Patient Exclusion Criteria / Contraindications

- Patients with ectopic pupils (more than 0.7 mm off-centered).
- Corneal topography with signs of keratoconus.
- Dry eye syndrome.
- Patients with negative spherical aberration terms already preoperative
- Further exclusion criteria for regular corneal refractive surgery.
- Patients with over expectations (e.g. in postoperative image quality and visual acuity).

3.6 Key Factors for Success

- Take time to decide whether a patient is a PresbyMAX® candidate: profession, hobbies, expectations, etc.
- Decision can be based on the catalogue that is successfully used in multifocal IOLs (in your clinic).
- Trial with multifocal contact lenses (centre for near, periphery for distance) could be done prior to surgery. We are of the opinion that the AIR OPTIX® Aqua Multifocal (for extended wear) provides enough similarity on the profile to mimic PresbyMAX. Note that NO Aqua Multifocal TORIC contact lens is available yet; i.e. it will be impossible to mimic PresbyMAX in patients with astigmatism exceed 1D.You may combine multifocal contact lens and trial frame in case of high astigmatism.
    - **PresbyMAX *μ*-Monovision:** Target of -1,00D residual myopia in the non-dominant (near) eye, and target 0.00 in the dominant (distance) eye; medium add power in both distance and near eyes.
    - **PresbyMAX Hybrid:** Target of -1,00D residual myopia in the non-dominant (near) eye, and target 0.00 in the dominant (distance) eye; low add power in the distance eye and medium add power in the near eye.

- **PresbyMAX Monocular:** Target of -1,00D residual myopia in the non-dominant (near) eye, and target 0.00 in the dominant (distance) eye; no add power (=monofocal lens) in the distance eye and medium add power in the near eye

- Or easier, even if no influence/effect in multifocality (SphAb) can be demonstrated, simulate a vision of 1 to 2 lines less than CDVA monocular (distance eye) as well as CNVA monocular (near eye) by targeting for far at -0.25D in the dominant (distance) eye and at -1.00D in the non-dominant (near) eye and by providing ~0.50 D less addition than required for near, and ask for the acceptance.
- Postoperatively, the pupil size can play a critical role: for that reason it is important to have an adjustable illumination condition in the refraction unit in order to teach the patient how to get the best possible results under changing light conditions.
- Pupil sizes vs. distance ranges:

  A pupil size of … 5.00 mm seems optimal for far distance ∞,
  4.25 mm seems optimal for 1.50 m,
  3.50 mm optimal for 70 cm, and
  3.00 mm for near distance 40 cm.

  A pupil size of … 5.00 mm seems to cover the distances from infinity to 80 cm (1.25 D DoF),
  4.00 mm seems to cover 2 m to 50 cm (1.50 D DoF), and
  3.00 mm for 70 cm to 30 cm (1.75 D DoF).

- A variability in pupil size is definitely necessary in this pupil-dependent profile:
  - The pupil size in photopic light conditions shall be 3.00 mm maximum in 'μ-Monovision', respectively 3.50 mm maximum when 'Hybrid' is enabled.
  - The pupil size in scotopic/mesopic low light condition shall be minimum 4.50 mm in 'μ-Monovision' and 'Hybrid'.

PresbyMAX Monocular is less pupil dependent but vision tasks benefit from a variability in pupil size, as well.

- Fast pupil adaptation between bright and dimmed light conditions ("pupil dynamics") is a good and positive indicator for postoperative success.
- High photopic conditions postoperatively are optimal for reading.
- Use of sunglasses in photopic conditions postoperatively helps for distance vision.
- Treatments should be centred on the corneal vertex, whenever the pupil-to-vertex distance exceeds 200 μm, to reduce induction of coma aberrations disturbing vision at all distances.
- Reading Charts with letter sizes up to 0.1 logRAD only could be preferred avoiding over expectations in patient's reading performance

INFORMATION NOTE

Bilateral presbyopia treatment planning is required: both eyes contribute to providing visual acuity at all distances by actively participating in the visual process for creating binocular visual impressions: the presby types 'μ-Monovision' and particularly 'Hybrid' are the favoured options.

Even if some patients accept classical Monovision, and for those PresbyMAX® on only one eye – the presby type: 'Monocular' - might be a choice, the full capabilities of PresbyMAX® are not exploited this way. 'Monocular' has the advantage over classical Monovision that also intermediate vision can be addressed and binocular compromise should be less.

IMPORTANT NOTE

For manifest refraction, use the old optometric rule: take the measurement with the least negative (most positive) amount of defocus (SEQ), if several of them are equal in terms of SEQ then take the measurement with the least amount of astigmatism (Cyl) , if several of them are equal in terms of Cyl then take the measurement with the astigmatism closest to with-the-rule, and if you still did not make a decision take the one with less High-Order-Aberration-RMS (principle of minimum risk).

The manufacturer's default optical zones (OZ) (refer to User Manual SCHWIND CAM, figure 6-6 "General Settings Mans – Presby") 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.

Make sure the ablation map is large enough for the scotopic pupil size.

In general, make sure that no exports are done for selected OZ smaller than 6.00 mm in presbyopic myopia or smaller than 6.20 mm in presbyopic hyperopia. In presbyopic astigmatism dominance no exports smaller than 6.50 mm are recommended.

3.7 Protocol and Standardisation

- The patient's age shall be typically older than 40 years, without specific upper limit on the age whenever all other ocular conditions are met.
- Aberration-Free method preferred (i.e. the patient preoperatively does not complain about visual quality) as wavefront-guided treatments are overall more sensitive.
- Preoperative monocular CDVA 0.1 logMAR (20/25) or better
- Preoperative monocular CNVA 0.1 logRAD (J2) or better

- Preoperative binocular CNVA of 0.2 logRAD (J4) or better with addition of +1.50 D
- Evaluation of eye dominance
- Monovision tolerance test with ≥1.00 D of anisometropia between distance and near eyes
- In contact lens wearers, corneal stability should be established without contact lenses prior to determining manifest refraction
- Corneal curvature (K1, K2) preoperatively between 40 and 48 D.
- Corneal curvature (K1, K2) postoperative estimated target between 35 and 48 D.
- Corneal topography with no signs of keratoconus or irregular astigmatism.
- Corneal spherical aberration [C(4,0)] @ 6 mm should be positive, respectively ocular spherical aberration [C(4,0)] @ 6 mm (if available) should be more positive than -0.2 μm.
- Treatments in presbyopic patients with spherical equivalent (SEQ) from +5.00 D to -8.00 D, astigmatism up to 4.00 D, and addition from 1.25 to 2.50 D:

  (highest satisfaction (= easiest) in hyperopic patients, then high astigmatics, then high myopes, then emmetropes, then low myopes)
- Static Cyclotorsion Compensation (SCC) should be used in cases with astigmatism more than 1.25 D.
- The distance refraction entered to the PresbyMAX® software shall be:
  - Based on the full cycloplegic refraction for hyperopes and emmetropes.

    (But check whether the patient accepts the full cycloplegic amount under photopic light conditions (~4 mm), otherwise look into SCHWIND News 2007-01 "Fundamentals of successful hyperopia treatment" for a test procedure recommended).
  - Based on the subjective refraction for myopes.
- Addition of +1.75 D as all-rounder solution
  - Decrease the addition by 0.10 D per each diopter of hyperopia (Seq)
  - Increase the addition by 0.05 D per each diopter of myopia (Seq)
  - Increase the addition by 0.25 D in case of surface treatment
  - Increase the addition by 0.25 D in case of pseudo-phakic eyes

  e.g. a LASIK treatment of -3 / -2 @177 with addition of +1.75 D will result in a modified addition of +1.75 + (4*0.05) = +1.95 D, a surface treatment of -3 / -2 @177 with addition of +1.75 D will result in a modified addition of +1.75 + (4*0.05) +0.25 = +2.15 D
- Ensure the addition remains within +1.25 D to +2.50 D range
- The corneal vertex should be the center of the treatment to reduce induction of coma aberrations disturbing vision at all distances. Therefore the offset from corneal vertex to pupil center should be used (SCHWIND Corneal Wavefront Analyzer (Optikon Keratron Scout), SCHWIND SIRIUS or SIRIUS+, SCHWIND MS-39 or SCHWIND PERAMIS)

- The treatment is typically performed on both eyes (OD and OS) the same day
- It is advised to treat both eyes simultaneously with equal OZ size – as software planning automatically does - to achieve full PresbyMAX concept capabilities. If not, binocular vision will be compromised from the multifocality on only one eye, but …
    - in cases of emmetropia – with less than 10 μm ablation for multifocality only – the effect on the distance eye may be insignificant
    - the compromise in distance vision may be too much for certain individuals.

  …so that (bilateral) PresbyMAX is not preferred.
- Optical Zone (OZ) decision shall be:

Refraction Type	Optical Zone Ø	Optical Zone minimum	Optical Zone maximum
Presbyopic myopia	6.2 mm	6.0 mm	6.5 mm
Presbyopic hyperopia	6.5 mm	6.2 mm	6.7 mm
Presbyopic emmetropia	6.8 mm	6.5 mm	7.0 mm
Presbyopic simple and compound astigmatism (larger than 2.0 D)	6.8 mm	6.5 mm	7.0 mm

CAUTION

The optical zone (OZ) size proposals do not include TransPRK treatment plannings, i.e. in PresbyMAX treatments and TransPRK selection it is advised to follow the regular recommendation of TransPRK OZ sizes (within this document). Otherwise, corneal regression or epithelium remodelling, respectively, is expected with too small optical zone selection.

- Pupil size conditions under different illumination:
    - Photopic pupil diameter has to be within 2.5 to 3.5 mm
    - Scotopic/ low mesopic pupil size shall be minimum 4.5 mm
    - OZ needs to be larger than the pupil size in scotopic/mesopic low condition

  PresbyMAX 'Monocular' is less pupil dependent due to multifocality on the near eye only but vision tasks also benefit from a variability in pupil size
- Radner Reading chart is preferred to be used to determine the near visual acuity and performance.

- For standardized pupillometry the Corneal Wavefront Analyzer (Scout), the SCHWIND SIRIUS or SIRIUS+, SCHWIND MS-39 or SCHWIND PERAMIS device, or a pupillometer from PROCYON Instruments (e.g. the P3000) should be used.
- The SCHWIND SIRIUS or SIRIUS+, SCHWIND MS-39 or SCHWIND PERAMIS offers:
  - 0.04 lux to measure the scotopic pupil size.
  - 4 lux to measure the mesopic (high) pupil size.
  - 40 lux to measure the photopic pupil size.

IMPORTANT NOTE

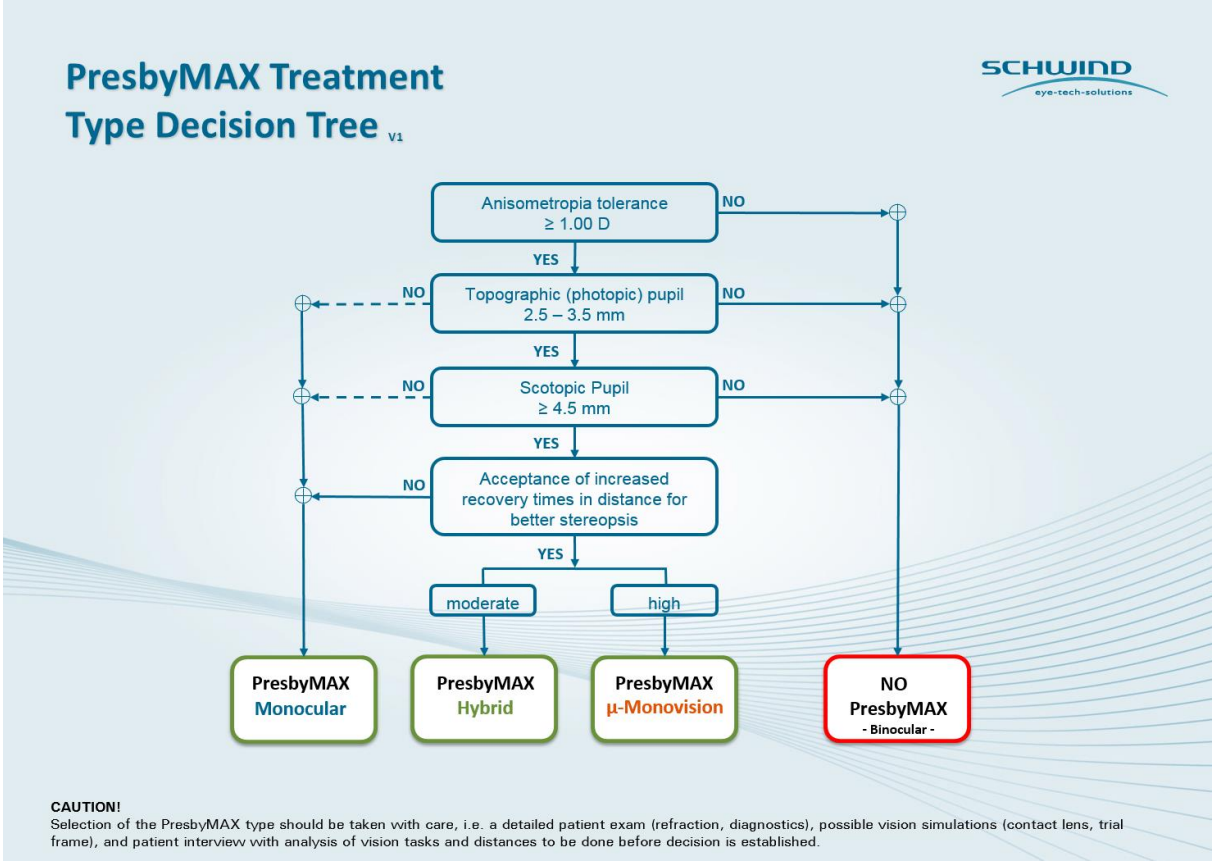
For evaluation of photopic pupil sizes use the topographic pupil (from Optikon Keratron Scout, SCHWIND SIRIUS or SIRIUS+, SCHWIND MS-39 or SCHWIND PERAMIS), and for mesopic and scotopic the pupillometry (from SCHWIND SIRIUS or SIRIUS+, SCHWIND MS-39 or SCHWIND PERAMIS) shall be taken.

- SCHWIND PresbyMAX® patient questionnaire could be used determining subjective visual performance and satisfaction.

3.8 Acronyms

- UDVA: Uncorrected Distance Visual Acuity
- CDVA: Corrected Distance Visual Acuity
- UNVA: Uncorrected Near Visual Acuity
- DCNVA: Distance Corrected Near Visual Acuity
- CNVA: Corrected Near Visual Acuity
- logMAR: logarithm of the Minimum Angle of Resolution
- 20/n: Distance visual acuity in 20 feet scale
- logRAD: logarithm of the Reading Acuity Determination
- Jn: Near visual acuity in Jaeger scale
- SphAb: Spherical Aberration

3.9 PresbyMAX® Treatment Type Decision Tree v1



INFORMATION NOTE

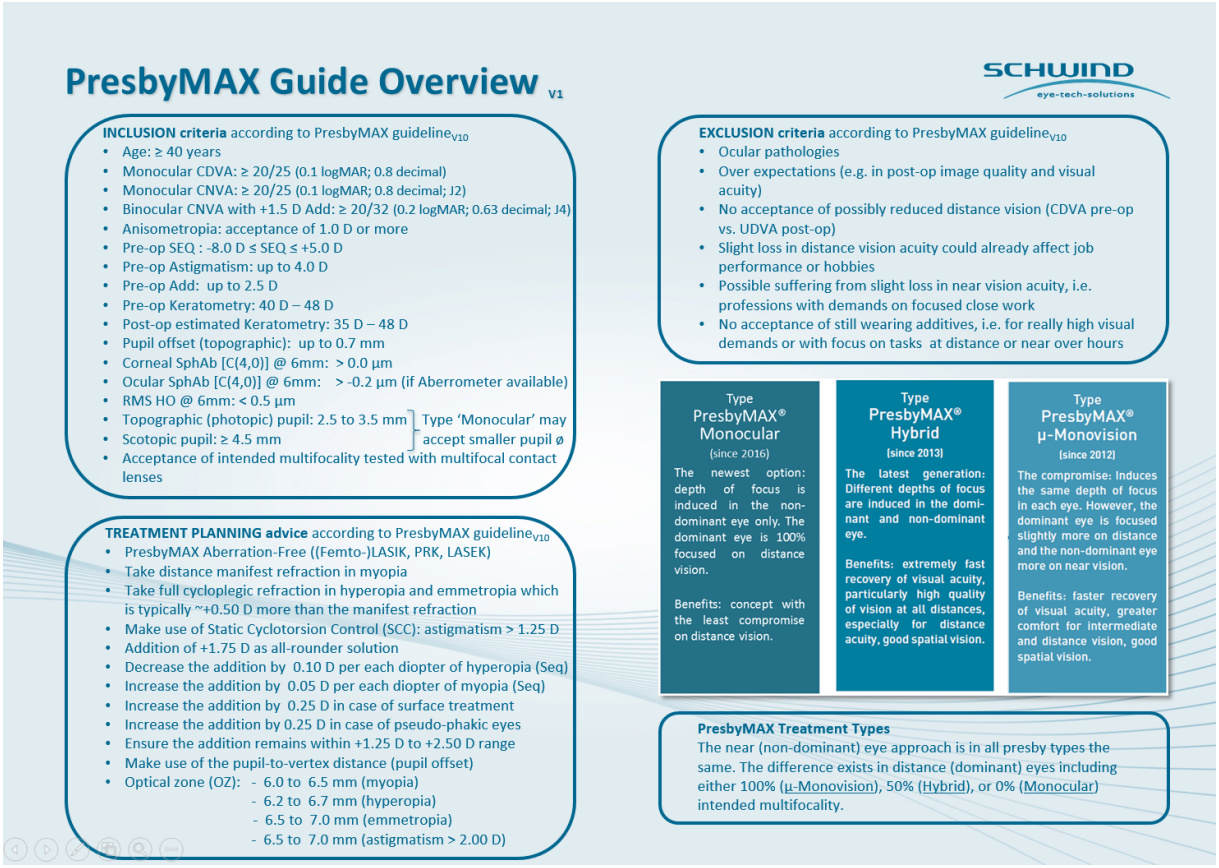
- PresbyMAX **µ-Monovision** is well accepted in hyperopic patients with normal prescription (below +4.00 D)
- PresbyMAX **Hybrid** is favored in (myopic) patients accepting some possibly loss in distance vision
- PresbyMAX **Monocular** is favored for:

  True emmetropic patients with excellent distance vision

  High hyperopes (from ~ +4D)

  Less dependency on pupil sizes, i.e. larger OZs are possible

3.10 PresbyMAX® Guide Overview V1



3.11 Postoperative Performance

Patients may need additives (sunglasses, reading glasses,...) in certain environmental conditions:

- Outdoors in sunny days sunglasses are needed for distance but indoors glasses for distance are not required:
- Indoors for near stronger lightings are requested:
- For working shorter distance than 40 cm or for longer periods of time extra addition (reading glasses) is needed:
- For long distances driving spectacles for far distance could be more convenient – compensating the residual myopic refraction (-0.50 to -1.50 D) of the patient that supports reading performance:

Presbyopic approach	n	Follow-Up	UDVA	UNVA	DCNVA	CDVA	CNVA	Refr.Outc.	Retreat.	Reversal
PresbyMAX µ-Monovision	478	6M	20/23 79%>20/25	J1 90%>J2	J3 83%>+2lns	3% < -2lns	2% < -2lns	87%±0.5DS 93%±0.5DC	15%	1%
PresbyMAX Hybrid	372	6M	20/21 94%>20/25	J1 95%>J2	J3 92%>+2lns	1% < -2lns	1% < -2lns	89%±0.5DS 88%±0.5DC	10%	1%
PresbyMAX Monocular	72	1Y	20/22 87%>20/25	J2 83%>J2	J5	0% < -2lns	---	88%±0.5DS	14%	0%

PresbyMAX treatment outcomes based on SCHWIND data pool for (Femto)LASIK

A near vision dominance is seen in all PresbyMAX types immediately after surgery with distance vision increasing steadily after that.

With PresbyMAX Symmetric distance vision recovery was typically reached around 3-month follow-up, in PresbyMAX µ-Monovision between 1-month and 3-month follow-up, and in PresbyMAX Hybrid and Monocular recovery takes usually up to 1-month after surgery.

The results in PresbyMAX with surface ablation techniques PRK/LASEK behave different in terms of distance vision recovery: myopes typically show good distance visual acuity (~20/25) 3-month after surgery, in hyperopes it takes 6-month and more. With increasing distance vision, near visual acuity becomes typically worse with ~ J4 (0.2 logRAD).

IMPORTANT NOTE

With PresbyMAX µ-Monovision, PresbyMAX Hybrid, and PresbyMAX Monocular the visual recovery time for distance is becoming faster but focus on stereopsis is less compared to PresbyMAX Symmetric.

CAUTION

Be careful in PresbyMAX and TransPRK because the intended multifocality might be (partly) covered and smoothed out by the re-epithelialisation processes.

Some visual effects associated with PresbyMAX may be expected because of the superposition of focused and unfocused images:

- This may include a perception of halos/glare around lights under nighttime conditions.
- It is expected that, in a small percentage of patients, the observation of such phenomena will be disturbing and may be perceived as a hindrance, especially in low illumination conditions.
- On rare occasions these visual effects may be significant enough that patients will request removal of the PresbyMAX profile.

⇨ Refer to chapter 3.13 Re-treatment Options

3.12 PresbyMAX® Literature (peer-reviewed publications)

- M. H. A. Luger, T. Ewering, S. Arba-Mosquera: 3-Month experience in presbyopic correction with bi-aspheric multifocal central presbyLASIK treatments for hyperopia and myopia with or without astigmatism, *J Optom. 2012; 05; 9-23*
- Y. Iribarne, E. Juarez, S. Arba-Mosquera, et al.: Bi-aspheric ablation profile for presbyopic hyperopic corneal treatments using AMARIS with PresbyMAX module: Multicentric Study in Spain, *J Emmetropia. 2012; 3: 5-16*
- D. Uthoff, M. Pölzl, D. Hepper, D. Holland: A new method of cornea modulation with excimer laser for simultaneous correction of presbyopia and ametropia, *Graefes Arch ClinExpOphthalmol. 2012 Nov;250(11):1649-61*
- Luger MHA, Ewering T, Arba Mosquera S. One-year experience in presbyopia correction with bi-aspheric multifocal central presbyLASIK.*Cornea.2013 May;32(5):644-52*
- Baudu P, Penin F, Arba Mosquera S. Uncorrected binocular performance after bi-aspheric ablation profile for presbyopic corneal treatment using AMARIS with PresbyMAX module. *Am J Ophthalmol. 2013 Apr;155(4):636-647*
- M. H. A. Luger, T. Ewering, S. Arba-Mosquera: Nonwavefront-Guided Presby Reversal Treatment Targeting a Monofocal Cornea After Bi-aspheric Ablation Profile in a Patient Intolerant to Multifocality. *J Refract Surg. 2014 Mar;30(3):214-6.*
- Arba-Mosquera S, Alió JL.: Presbyopic correction on the cornea. *Eye and Vision 2014 1:5*
- Luger MHA, McAlinden C, Buckhurst PJ, Wolffsohn JS, Verma S, Arba Mosquera S.: Presbyopic LASIK Using Hybrid Bi-Aspheric Micro-Monovision Ablation Profile for Presbyopic Corneal Treatments. *Am J Ophthalmol. 2015 Sep;160(3):493-505*
- Chan TC, Kwok PS, Jhanji V, Woo VC, Ng AL: Presbyopic Correction Using Monocular Bi-aspheric Ablation Profile (PresbyMAX) in Hyperopic Eyes: 1-Year Outcomes. *J Refract Surg. 2017 Jan 1;33(1):37-43.*
- Asier Villanueva, Veronica Vargas, David Mas, Magda Torky, Jorge L Alió. Long-term corneal multifocal stability following a presbyLASIK technique analysed by a light propagation algorithm. *Clin Exp Optom, 2019 Sep;102(5):496-500.*
- Michiel H A Luger, Colm McAlinden, Phillip J Buckhurst, James S Wolffsohn, Shwetabh Verma, Samuel Arba-Mosquera. Long-term Outcomes After LASIK Using a Hybrid Bi-aspheric Micro-monovision Ablation Profile for Presbyopia Correction. *J Refract Surg, 2020 Feb 1;36(2):89-96.*
- Fang Liu, Ting Zhang, Quan Liu. One year results of presbyLASIK using hybrid bi-aspheric micro-monovision ablation profile in correction of presbyopia and myopic astigmatism. *Int J Ophthalmol, 2020 Feb 18;13(2):271-277.*
- T. Kohnen, M. Böhm, M. Herzog, E. Hemkeppler, K. Petermann, C. Lwowski. Near visual acuity and patient-reported outcomes in presbyopic patients after bilateral multifocal

aspheric laser in situ keratomileusis excimer laser surgery. *J Cataract Refract Surg, 2020 Jul;46(7):944-952.*

- Dan Fu, Jing Zhao, Xing-Tao Zhou. Objective optical quality and visual outcomes after the PresbyMAX monocular ablation profile. *Int J Ophthalmol. 2020 Jul 18;13(7):1060-1065.*
- Dan Fu, Jing Zhao, Li Zeng, Xingtao Zhou. One Year Outcome and Satisfaction of Presbyopia Correction Using the PresbyMAX® Monocular Ablation Profile. *Front Med (Lausanne), 2020 Nov 27;7:589275.*
- Soyoung Ryu, Ikhyun Jun, David S Y Kang, Samuel Arba-Mosquera, Harin Kim, Seung K Jean, Kyoung Y Seo, Eung K Kim, Tae-Im Kim. Presbyopia correction using the monocular bi-aspheric ablation profile in myopic eyes. *J Cataract Refract Surg. 2023 Jan 1;49(1):69-75.*

3.13 Re-treatment Options

- PresbyMAX® can be repeated if reading-spectacles demands renew.
- PresbyMAX® can be repeated if reading quality (multifocality) is not sufficient but distance vision is satisfying.
- Aberration-Free treatment (with equal optical zone size and centring to previous PresbyMAX procedure) with target refraction between -0.50 D and 0 D can be performed on top for improved distance correction if reading quality (multifocality) is satisfying.
- PresbyMAX® Reversal option with distance best corrected refraction included can be performed if the patient does not accept the PresbyMAX® concept at all (too much compromise for the individual). Nonetheless, case-to-case analysis is advised before PresbyMAX® Reversal.

CAUTION

Due to healing process and neuronal adaptation, a re-treatment procedure shall not be performed prior 6 months after surgery.

The gain and loss (e.g. reading glasses are again required after a PresbyMAX reversal) should be demonstrated to the patient always before re-treatment action is decided.

IMPORTANT NOTE

Each specific re-treatment case requires analysis time. It is very important to understand the demands and expectations of the patients (and yours as physician) in order to provide the best suitable solution for that.

Feel free to use presbymax@eye-tech.net , especially in questions of re-treatments. SCHWIND eye-tech-solutions will be able to provide more information about individual re-treatment strategies if necessary.

3.14 PresbyMAX® after Previous Refractive Surgery

- **Previous Corneal Refractive Surgery** (with the aim of emmetropic distance vision)
  Decision shall be equal to patients with virgin corneas: the SCHWIND decision tree for Aberration-Free, Corneal and Ocular Wavefront treatments might be considered.

- **Previous cataract surgery** (natural lens exchange)
  Multifocal enhancement can be performed on the patient's cornea. Decision shall be equal to patients with virgin corneas: the SCHWIND decision tree for Aberration-Free, Corneal and Ocular Wavefront treatments might be considered.

3.15 Intraocular Surgery after PresbyMAX®

- **Aspheric IntraOcular Lenses:**
  Properly calculated aspheric lenses (in the sense of aberration-neutral) after PresbyMAX provide the best quality of vision without compromising the already achieved pseudo-accommodation. (No decentration and tilting of the IOL and correct IOL power assumed)

- **Spheric IntraOcular Lenses:**
  Spheric lenses induce positive spherical aberration and thus would remove in part or in total the already achieved pseudo-accommodation.

- **Multifocal IntraOcular Lenses:**
  Multifocal (refractive, diffractive, or accommodative) lenses induce negative spherical aberration and multiple foci and thus would enhance the already achieved pseudo-accommodation.
  But centration issues of the lenses become critical and may induce large amounts of coma from the misalignment between the PresbyMAX® multifocal cornea and the multifocal IOL.

IMPORTANT NOTE

SCHWIND SIRIUS or SIRIUS+, and SCHWIND MS-39 offers an IOL power calculation method by optical ray-tracing based on the Snell law that can be advantageous in particular in patients post corneal refractive surgery and with irregular cornea. This method is supposed to be independent to the main problems that IOL power calculations – post refractive surgery - typically include[1]:

- The keratometric index problem
- The radius problem or instrument error
- The formula error

Furthermore, historical patient data (i.e. pre surgery) is no requirement and corneal aberrations are considered in the IOL power calculation via ray-tracing.

[1]*Intraocular lens power calculation by ray-tracing after myopic excimer laser surgery. Savini G, Bedei A, Barboni P, Ducoli P, Hoffer KJ. Am J Ophthalmol. 2014 Jan; 157(1):150-153.*

4. DATA TRANSFER TO LASER

4.1 Data Carriers for the PresbyMAX® Treatment Files

In case of external workstation planning and no SCHWIND MedNet (medical network) existence, the patient data folder with presbyopia treatment data files included need to be memorized on a data carrier (SD memory card) in order to provide the AMARIS laser with the presbyopia treatment planning information necessary for the ablation.

The presbyopia treatment planning files (***.pby**) can be reloaded using <Import> button on the Welcome Screen of AMARIS Application Software.

The user has to make sure that the data carriers used are virus-free and that enough storage capacity is available (a minimum of approx. 6 MB is needed for the bilateral data set [presbyopia treatment plan includes OD and OS]).

CAUTION

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.

Make sure that the data carrier is virus-free!

4.2 PresbyMAX® Treatment with AMARIS Excimer Laser

Please refer to the **Main User Manual** for the AMARIS Excimer Laser.

WARNING!

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

Inform your patients on alternative practices, risks and benefits of the presbyopia treatments, as well as secondary effects and postoperative care.

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.

Adapt the AMARIS Treatment Assistant Manager (TAM) steps to your needs for convenient use.

Make sure that surgery is performed according to plan if the presbyopia treatment is decided.

Make sure to use ablation offsets with care, corresponding to pupil offsets measured by trustable measurements.

5. 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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