Scansys TA517

User Manual

Anterior Segment Analyzer

Shanghai MediWorks Precision Instruments Co., Ltd.

Contents

1. Scope of Supplies and Optional Accessories

Serial No	Name of supplies and accessories	Qty	Remark
1	Scansys TA517	1	
2	Computer (HP All-in-One)	1	optional
3	Scansys Software (UD)	1	
4	Instrument table	1	optional

2. Overview

2.1 Preface

Thank you for choosing the Scansys TA517 Anterior Segment Analyzer made by Shanghai MediWorks Precision Instruments Co., Ltd.

- This User Manual is an integral part of the Scansys TA517. Product-related operation instructions and technical instructions are given in this manual. The address for the user inquiry is recorded on the last page of the manual.
- This User Manual contains operation instruction and technical instruction. The equipment classification of the Scansys TA517 according to the requirements of IEC60601-1-1 is also given in this manual.
- The System is used for the observation of corneal thickness, topography of corneal curvature, depth and volume of Anterior chamber, front chamber angle, pupil diameter, the turbidity of lens for the Anterior Segment by medical institution.

2.1.1 Intended use

- Intended Purpose

The device is intended for use in the viewing and imaging of anterior segment ocular structures.

- Indications for Use

The Scansys TA517 is a non-contact, high resolution tomographic and biomicroscopic device indicated for the in vivo imaging and measurement of ocular structures in the anterior segment.

- Intended Users

The device is intended to be used by eye specialists and technicians (trained staff, etc.).

- Intended Population

No restrictions on age, weight, health and condition: Patient is awake and able to understand and to look into a fixation target.

- Contraindications

There are no known contraindications.

2.2 The system operation environment

Temperature	-5℃～+40℃
Relative humidity	≤80%
Pressure	800hPa～1060hPa

2.3 Computer configuration

Core(TM)i5-8500T ,Windows* 10,8GB RAM,VGA graphic card 1920*1080 true color, Gigabit Ethernet, USB interface
Software configuration: Windows 10

2.4 The System storage environment

Temperature	－40℃～＋55℃
Relative humidity	≤90%
Pressure	700hPa～1060hPa

2.5 The System transportation environment

Temperature	－40℃～＋55℃
Relative humidity	≤90%
Pressure	700hPa～1060hPa

2.6 Safety marks, icons and warning symbols stuck on products

Table 1

No.	Mark	Description
1		Date of manufacture.
2		Manufacturer information
3		Consult instructions for use.
4	CE 0197	CE mark
5	REF	Part Number
6	SN	Serial Number
7	EC REP	Authorized Representative in the European Community.
8	Rx only (for US)	USA Federal law restricts this device to sale by or on the order of a physician.
9		**WEEE mark** Please deal with the waste disposal produced by the machine following relevant laws and regulations.
10		TYPE B
11	Power Input	Input：～100-220V, 50/60Hz, 300VA
12	Rate	295VA
13	Fuse	F1AL250V
14	Output	DCV24V,5A

2.7 Device internal tag

Scansys TA517 uses the following tags on the power box.

Table 2

Serial No	Content	Description
1		Protect ground terminal

2.8 Color of indicators

The power switch is a switch with indicator light. When it shows green color, it indicates that the power is on and the device is running.

2.9 Attentions

Dear customers, we provide warranty service — you can check the warranty information on the "Product Warranty Card". The warranty card is attached with this manual. Please fill in the "Product Warranty Card" attached to this manual in time and return it to the MediWorks according to the address on the cover of this manual, so that we can provide you with better follow-up services.

⚠ **Important security precautions**

Dear customers, please read the User Manual carefully before using our products to avoid accidental mechanical hazards and improper use of the user, resulting in unclear images and diagnostic errors. In particular, carefully read the following safety precautions to prevent the product is damaged, personal injury, and other hazards and accidents that may occur.

- Do not disassemble or attempt to perform operations that are not described in this User Manual. If the operation is not performed properly, excessive mechanical force may cause damage to the machine or personal injury. If the instrument fails, please read the troubleshooting guide carefully; follow the troubleshooting methods and steps to troubleshoot the problem; if the problem remain unsolved, please contact our manufacturer and service Department, and our company will arrange professional maintenance personnel to help you troubleshoot.

- Do not store and use in a flammable, explosive, high temperature, high humidity and dusty environment; use it in a clean room, keeping the product clean and dry.
- Other medical instruments and equipment that installed at the same site must comply with the same electromagnetic compatibility principles. Equipment that cannot comply with or is known to have poor electromagnetic compatibility must be installed at least 3 meters away from the equipment and must be powered by a different power cord.
- Please pay attention to the rating of all electrical connection ports.
- The power supply box is specifically provided and used only for power supply of this Analyzer. Any outside components cannot be connected to the power supply box. If the Analyzer is not conneted to the power supply box, it may be insufficiently powered and cannot be used. The power supply box should not be placed on the ground. Meanwhile, it cannot be connected with the other additional sockets and extension cords, and cannot be allowed to connect to the other devices.
- When connecting the device, the user needs to unplug the power cord to avoid the risk of electric shock.
- The maximum capacity of the power supply box is 300VA. It cannot exceed the maximum allowable load of the power supply.
- Before using the instrument, please check all the wires are correctly connected and ensure that the instrument is in good grounding condition; if the wires are inappropriately connected it may cause the instrument to be short-circuited, which may cause the product is damaged and personal injury.
- When replacing fuses and other electrical components, turn off the main power switch. Replace the fuse that meets the specifications specified in this manual. If there is a need to replace power cord, please use the power cord specified in this manual.
- When the System is not operating, the power should be turned off, and cover the instrument with dust cover.
- Please dispose waste generated by equipment and components at the end of its life in accordance with relevant laws and regulations.

- Please read the safety signs and other illustrations used on this instrument carefully to use the device safely.
- Please use this product strictly in accordance with the requirements and precautions of the Scansys TA517 User Manual.
- Classification of Scansys TA517: Class I Type B
- Scansys TA517 should not be positioned at the place where are difficult to operate the disconnection device.
- The fuse type is F1AL250V.

2.10 EMC (Electromagnetic Compatibility)

The Scansys TA517 complies with the International Electrotechnical Commission standards (IEC 60601-1-2: 2014) for electromagnetic compatibility as listed in the tables below. Follow the guidance in the tables for use of the Scansys TA517 in an electromagnetic environment.

<table>
<tr><td colspan="3">Guidance and manufacturer’s declaration of electromagnetic emissions</td></tr>
<tr><td colspan="3">The Scansys TA517 is intended for use in the electromagnetic environment specified below. The customer or the user of the Scansys TA517 should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions test</td><td>Compliance level</td><td>Electromagnetic environment-guidance</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The Scansys TA517 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class A</td><td rowspan="2">The Scansys TA517 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions IEC 61000-3-2</td><td>N/A</td></tr>
</table>

Voltage fluctuations/ Flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration of electromagnetic immunity			
The Scansys TA517 is intended for use in the electromagnetic environment specified below. The customer or the user of the Scansys TA517 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage, dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Scansys TA517 requires continued operation during power mains interruptions, it is recommended that the Scansys TA517 be powered from an uninterruptible power supply or a battery.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration of electromagnetic immunity			
The Scansys TA517 is intended for use in the electromagnetic environment specified below. The customer or the user of the Scansys TA517 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms (V1=3)	Portable and mobile RF communications equipment should be used no closer to any part of the Scansys TA517, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m (E1=3)	$d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and human.
A. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Scansys TA517 is used exceeds the applicable RF compliance level above, the Scansys TA517 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Scansys TA517. B. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

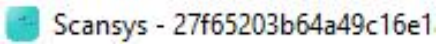
Recommended separation distances between portable and mobile RF communications equipment and the Scansys TA517.			
The Scansys TA517 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Scansys TA517 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Scansys TA517 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

2.11 Scansys TA517 on

Firstly turn on the device power (if just view the case instead of checking, this step is not necessary), then double-click the Scansys software icon on the desktop to open the application, the system will automatically connect to the device, if the connection is successful, the top of the program interface will display corresponding device number.



2.12 Scansys TA517 off

Please turn off the Scansys software firstly, and then turn off the Scansys TA517 device.

2.13 Sketch map of machine components

1. Base Panel

2. Moving Base

   Smoothly move the whole machine in a small range by operating the handle

3. Joystick

   Incline joystick to move the instrument slightly on the horizontal surface and rotate it to adjust the elevation of the microscope. Press shutter to activate scanning.

4. Interface

   Connect with the power and also transport data.

5. Protective Cover

6. Flank Camera

   Capture flank images with the rotation of turntable

7. Front Camera

8. Turntable

9. Forehead Belt

To fix the patient's head on an appropriate position

10. The Fixation Knob of Chin-rest Paper

It is used to fix the chin-rest paper

11. Chin-rest Bracket

To support the chin of the patient

12. Chin-rest Elevation Adjustment Knob

Rotate the knob to adjust the elevation of the chin-rest

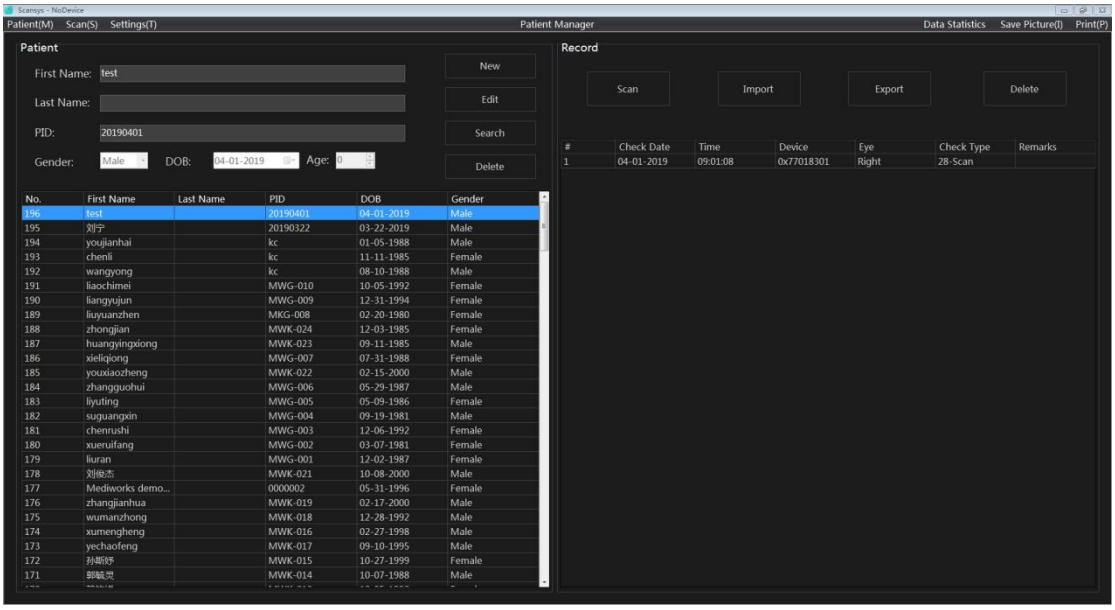
13. Locking Knob

Lock the rotational movement of the microscopes arm.

14. Rail Cover

Protect the rail surface

3. Patient Data and Medical Record (case) Management



The home page is the patient management interface, the left column is the patient data, and the right column is the case data of the corresponding patient.

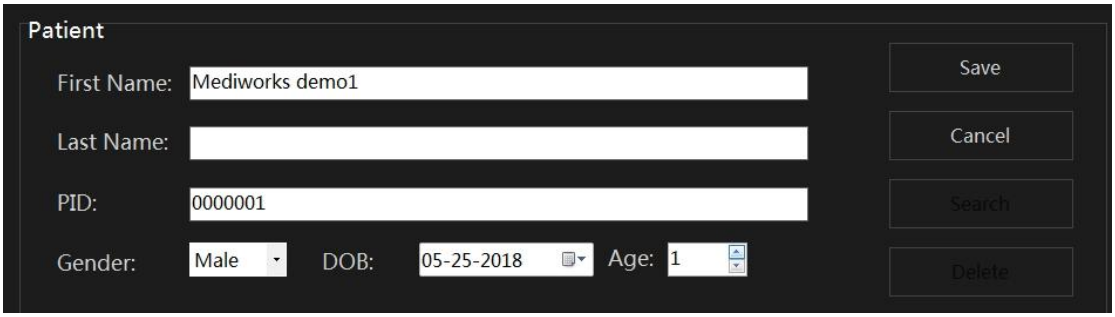
3.1 Adding patients

Click [New] to create a new patient data in the patient data management.

Enter the patient's name, gender, date of birth, and case number on the window page, wherein age is corresponding to DOB. Click the [Save] button to save the currently entered patient data. The new patient data just entered will be displayed in the patient data list.

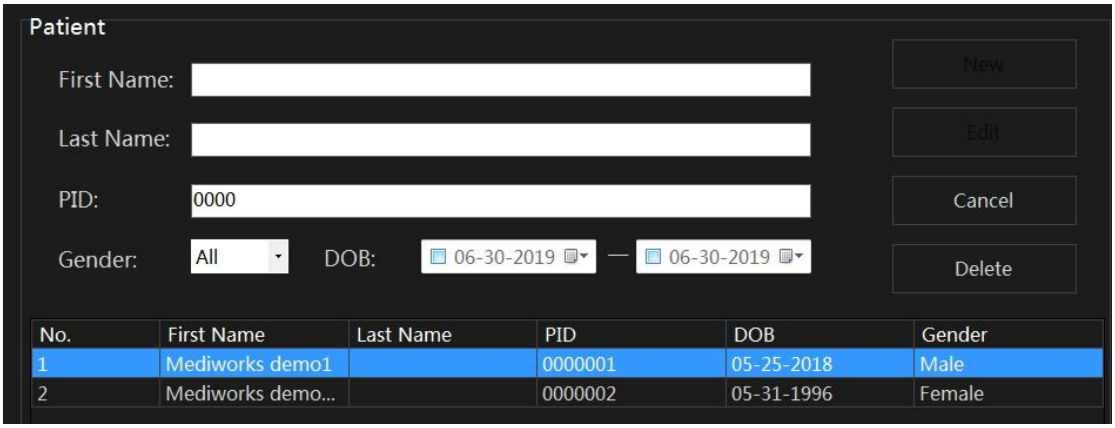
3.2 Editing patients data

Select an existing patient from the patient data list, click [Edit] to re-correct the patient related information, and click the [Save] button to save the current change.



3.3 Searching for patients data

Click [Search] to quickly search the list of patients for the desired data, and the system supports the first word fuzzy search.

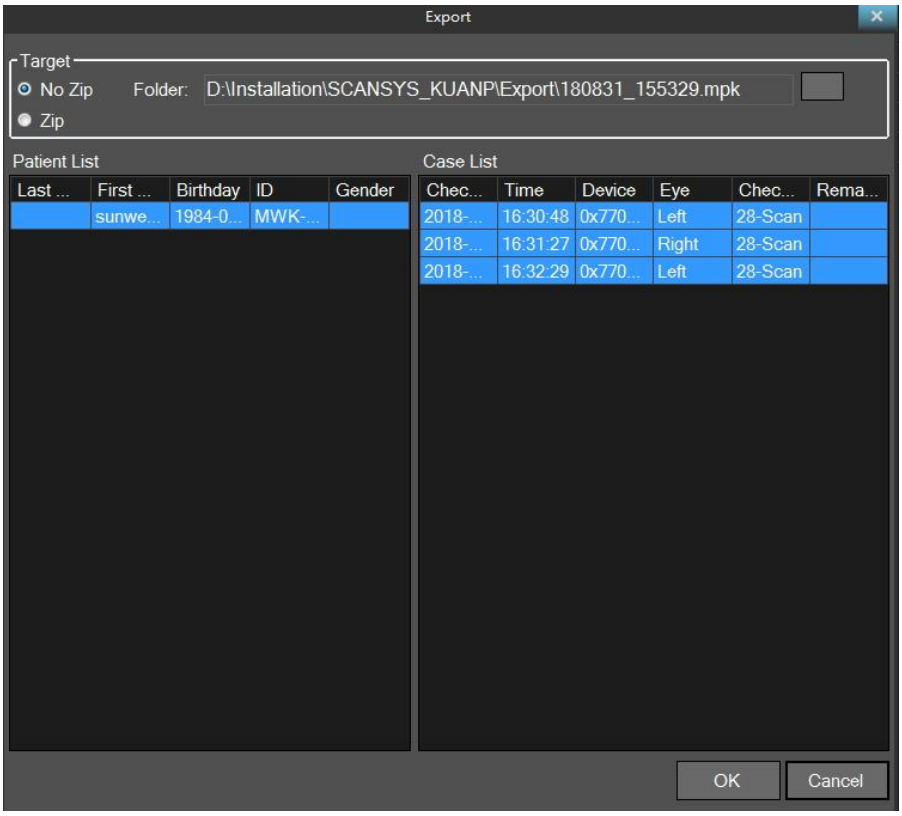


3.4 Deleting patients data

Select the patient to be deleted from the patient data list, and click the [Delete] button to delete current patient's case and all his/her information.

3.5 Import and export of cases

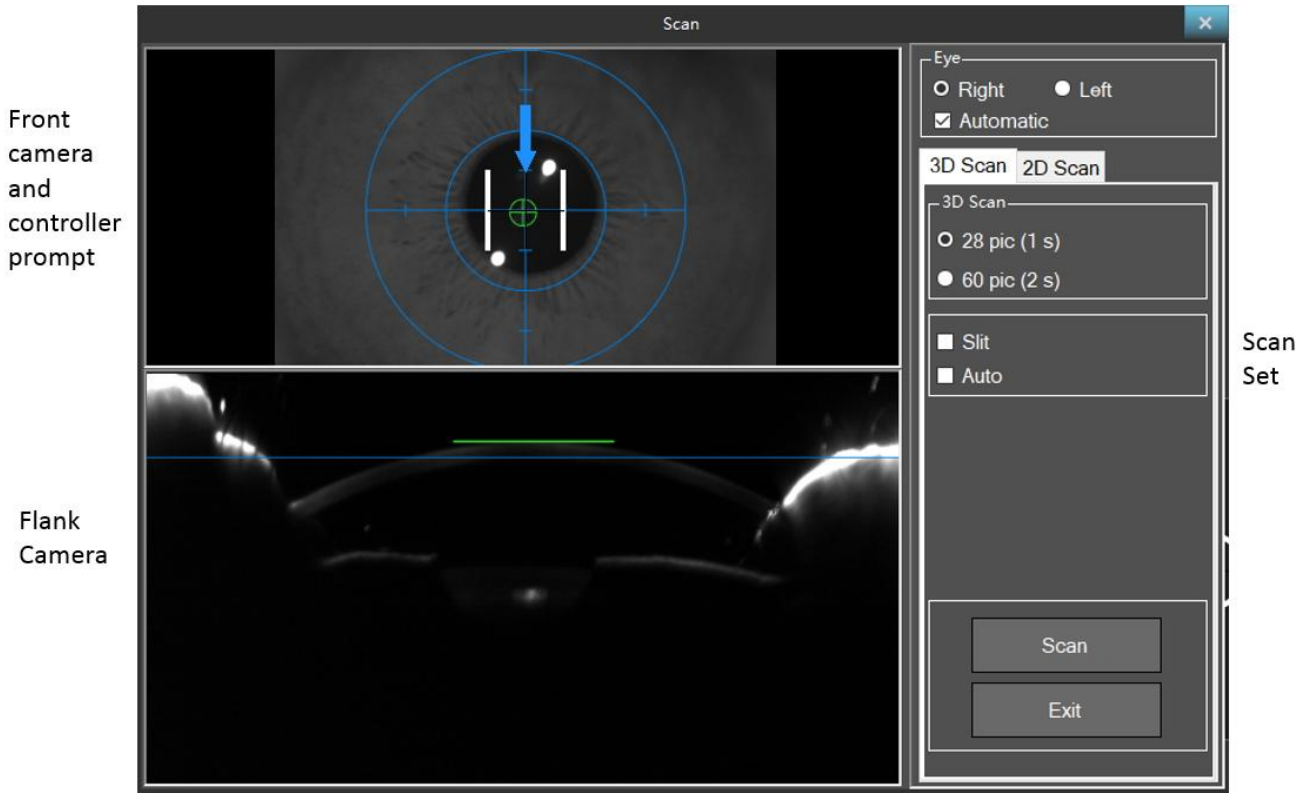
Select one or more case data under a certain patient (the selected patient or case will turn blue), Click the [Export] button in the case box to pop up the following dialog box, select the appropriate path and click the OK button to export the mpk file. If only the patient is selected and the case is not selected, the case data under the current patient is all exported by default. When exporting, it is also possible to select multiple patients to export all case data of the corresponding patient at one time.



Click the [Import] button, the path dialog box will pop up. After selecting the mpk file to be imported, the user can import one or more patient case data under the file according to the needs.

4. Scansys TA517 Examination (scan) Program

After selecting one patient, click the [Scan] (or keyboard F5) button, the program will automatically enter the scan interface and start the Scansys TA517 scan program.



The examination program interface window is divided into three parts, namely the flank camera window, the front camera and controller prompt window and the scan options window.

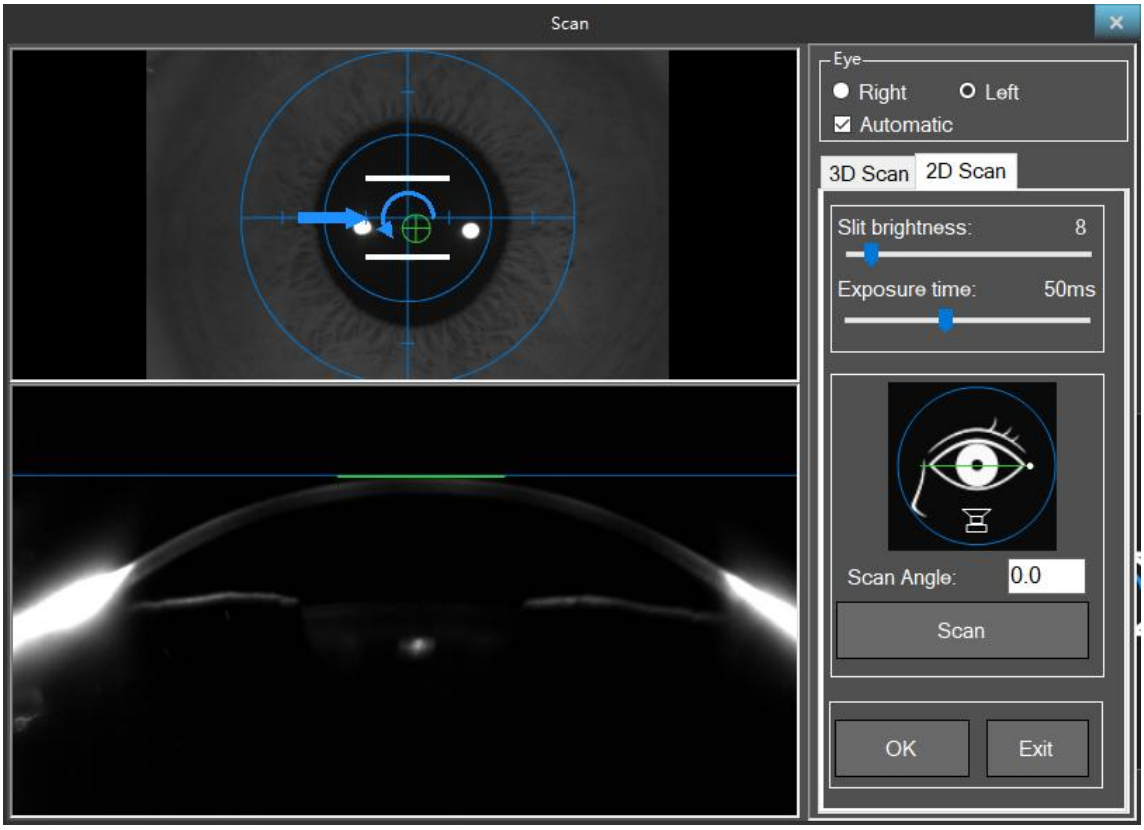
4.1 Scan options setting

4.1.1 Left and right eye selection

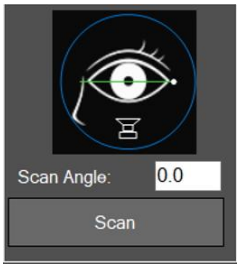
The user can manually select the left and right eyes, or the user can check the automatic options, the program automatically recognizes the left and right eyes.

4.1.2 2D-Scan mode

The program provides 2D-Scan mode. The user can take one or many images of the anterior segment at any angle according to the needs. In this scan mode, the user can manually adjust the brightness of the slit light and time of exposure. By default, the brightness of the slit is the same as that of the 3D scan.



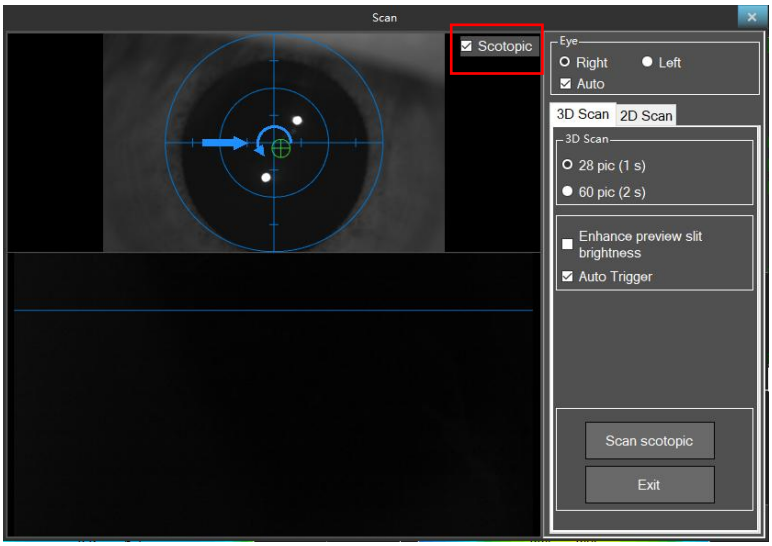
User can click any position in sketch eye icon or input accurate data in Scan Angle to position target location. Once click or press Scan button, the program acquire current flank image and sketch eye icon record corresponding position with white dot. Meanwhile, the scan button also shows the image currently taken.



4.1.3 3D-Scan mode

In 3D-Scan mode, there will be a choice of whether to open ‘Scotopic’ mode (depending on whether the user needs pupil diameter data under dark vision), as shown in the figure below. If the "Scotopic " option is selected, the user first needs to take a frontal image of the eye in a simulated dark vision environment. In this mode, the slit light is not turned on and the scan will not be triggered automatically. The user needs to adjust the image to the center, and manually click the "Scan scotopic" button at the clearest position of the iris or press the middle button of the joystick to scan. After one scan, it automatically enters the subsequent acquisition process. If the "Scotopic " option is

not selected, the above process will not happen, and you will directly enter the 3D-Scan mode process.



The 3D-Scan mode is divided into 28 mode and 60 mode. Whether the blue light is checked does not affect the shooting effect. If the blue light is not checked, the blue light is weak when previewing. When the side image cannot find the vertex, the blue light can be checked to increase the brightness of the slit, therefore find the corneal apex easily. When the auto scan option is selected, and the side camera's corneal apex crosshair is near the blue marker line and the front camera's green crosshair coincides with the blue view crosshair, auto scan is activated automatically. If the program cannot trigger automatic scan due to a case or the automatic scan option is not checked or other unknown reason, the user need to manually click the scan button or press the controller middle button to trigger the scan program.

4.2 Scan steps

Please shoot with the following steps:

1. Settle down patients

- Have the patient put his head on the chin support bracket and hold it against the forehead strap. If the patient is an elderly person or the eyelids are obstructing the eyes, use a cotton swab to gently lift the eyelids. Cover the patient and the Scansys TA517 device with a black shade cloth.

2. Start Scansys TA517 scan

- Adjust the height of the lifting table, move the controller back and forth, left and right until the cornea image appears on the side camera in the scan interface, and the front image appears clear

to the patient's eye image position. At this point the blue slit should just shines on the patient's cornea. Let the patient open his eyes and look at the circular fixation point in the blue slit lamp.

- Move the controller back and forth until the green crosshairs on the cornea attached with the blue line.
- Move the controller inward or outward, left and right, and center the green pupil center with the midpoint of the image.
- Move the controller to the prompted direction and make the necessary adjustments.
- When the eye position is correct, the adjustment window will display a green cross in the center of the circle and four green border lines around it. If the auto-scan option is selected, the Scansys TA517 scan program will be triggered automatically, or by tapping the scan button or pressing the controller scan button. The scan will last for about one second, during which time the patient should be kept possibly motionless.

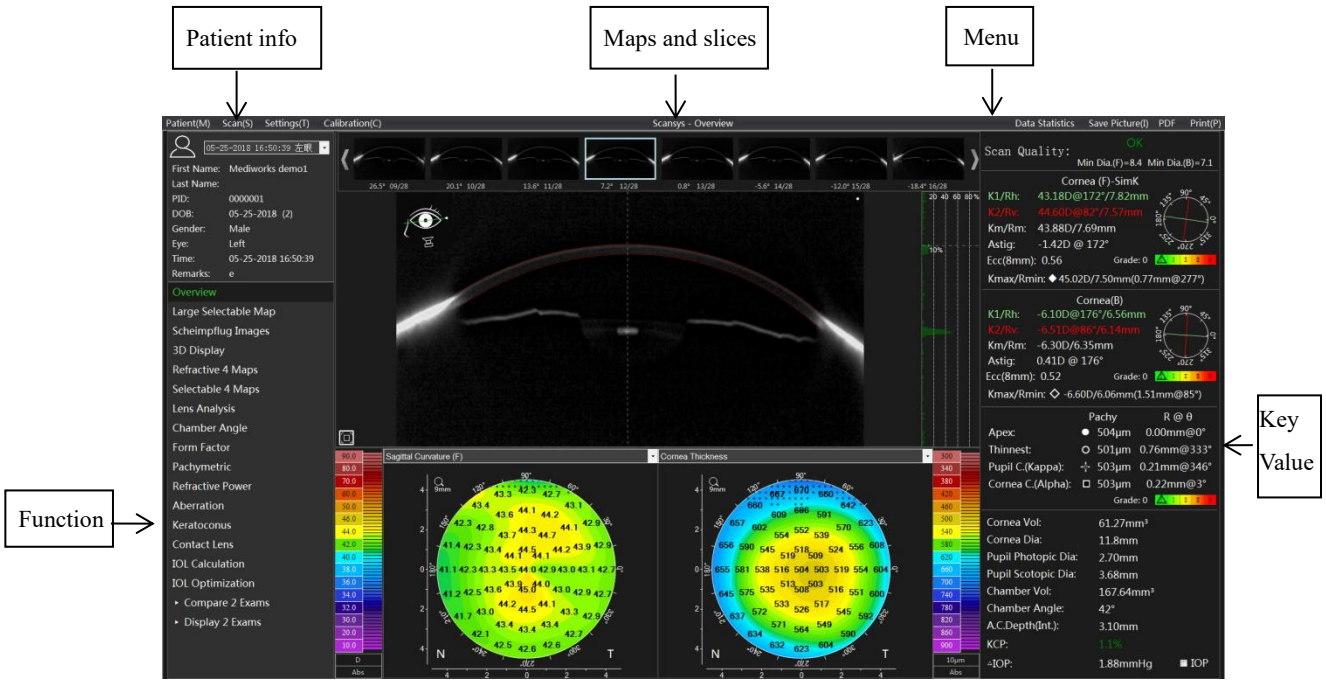
3. View scan quality

- After the scan is completed, the program will jump to the overview interface to check whether the scan quality has passed in the upper right corner.
- If the green color is displayed, it means that the scan is reliable and can be used. If a yellow warning message is displayed, the scan quality is normal, but it can still be used as a reference.
- If the red fail message is displayed, the user will need to shoot again. When scan quality is poor, you can view higher quality scan by clicking on the scan quality option area to view detailed scan quality specifications to get higher quality scan.

5. Scansys TA517 Software Overview and Settings

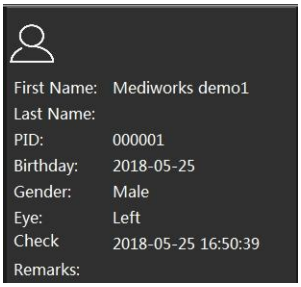
5.1 Overview

If the scan is successful, the program automatically enters the main interface of the overview, or double-clicks the saved case in the patient record interface to enter the program overview interface.



The main interface consists of five parts, Setting Bar, Patient Information, Function Overview, Maps and Slices image display and feature data.

5.1.1 Patient information

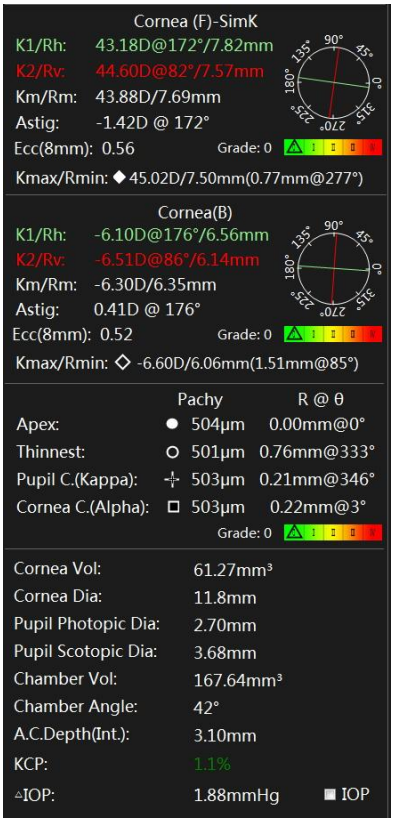


The upper left corner of the main interface is the patient information column, which provides basic information such as the patient's name, medical record number, gender, date of birth, left and right eyes, and date of scan. Click on the blank space of the Remarks to pop up the remarks floating window. The user can add remark information according to their needs, and the information will be displayed in the corresponding case on the patient management interface.

5.1.2 Function overview

This column shows all the functions and detailed inspection results provided by the software. The user can freely view the data under the corresponding functions according to their requirements. See Chapter 6 for details.

5.1.3 Feature data explanation



The feature data is divided into four parts, anterior corneal data, posterior corneal data, pachymetric data, and other anterior segment data.

Among them

Rh / K1 represents the flat k-curvature radius and refractive power within a diameter range of 3mm, @ describes the direction.

Rv / K2 represents steep k-curvature radius and refractive value within a diameter range of 3mm, @ describes the direction.

Rm / Km represents the average radius of curvature and refractive power in the range of 3mm.

Astig represents astigmatism.

Ecc (E、Q、P） represents the corneal morphological factor value of a diameter ring with the apex of the cornea as the center of the circle.

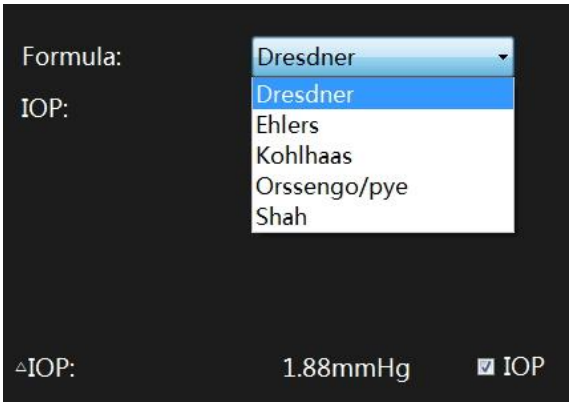
Rmin / Kmax represents the minimum corneal radius of curvature and maximum refractive power, @ describes the position of the point.

Corneal posterior surface parameters are explained with reference to anterior surface parameters.

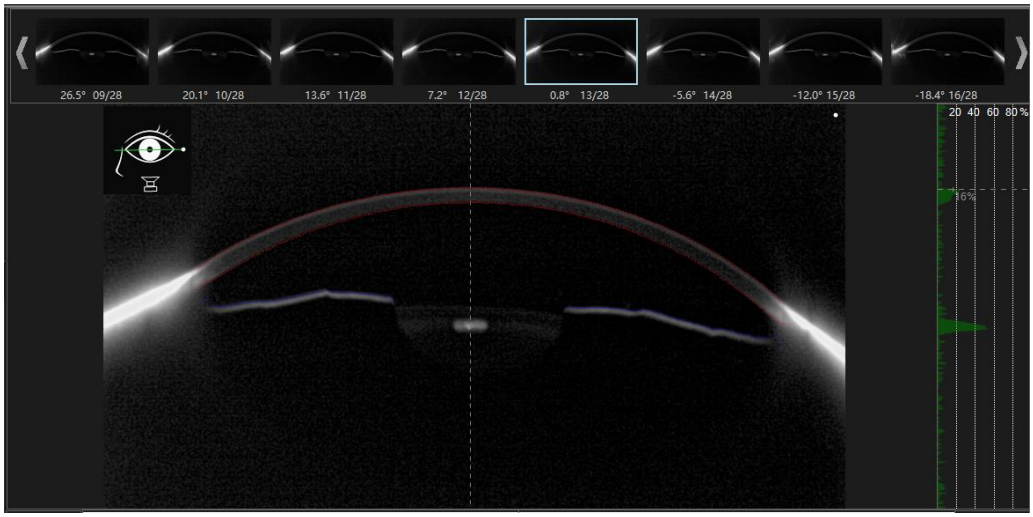
Corneal apex, thinnest point, pupil center, cornea center positions and their corresponding pachymetric data are shown in the pachy area. The pupil center and cornea center correspond to the concepts of kappa angle and Alpha angle, respectively.

In the cornea (F), cornea (B) and pachy area, a five-level grading of 0-4 is carried out according to the extreme of the front and back surface of the cornea curvature and the thinnest point of the pachy, and the color bars are displayed.

Other anterior segment parameters include Corneal Volume, Corneal Diameter (white to white), Pupil Photopic Diameter, Pupil Scotopic Diameter (only scotopic picture was captured), Anterior Chamber Volume, Anterior Chamber Angle (0 degree direction), Anterior Chamber Depth (at the apex of the cornea). KCP (Keratoconus Possibility) indicates the possibility of keratoconus in this case. Its value is distributed in the range of 0-100%. The larger the value, the greater the probability of disease. The values in different areas will be warned in green, yellow and red. △IOP represents the correction value of intraocular pressure, and you can switch between different mainstream formulas by clicking the [IOP] button.

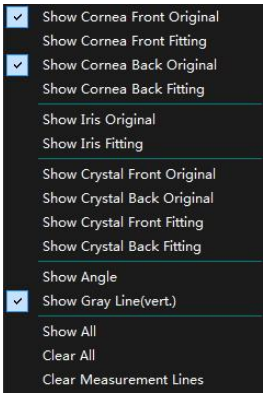


5.1.4 Section view explanation



This section shows all the original images of the anterior segment captured by the flank camera. The user can switch to any one by using the keyboard navigation keys. The user can also click a direction in the upper left corner of the area to display the image of the anterior segment captured in that direction. Usually used to check the image quality after scan is completed.

When right-clicking anywhere in the current image, the image feature curve display options will pop up, including corneal anterior and posterior surface data, iris data, lens anterior surface data, chamber angle data, etc.. Corresponding image data can be displayed or not displayed according to requirements.

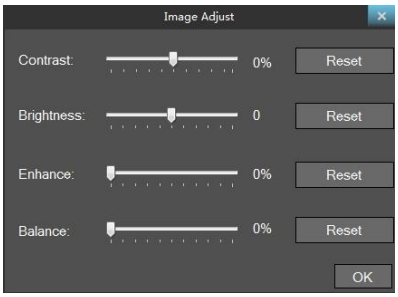


5.1.5 Selectable map

Below the middle bar are two optional topometric maps. See section 6.3 for details.

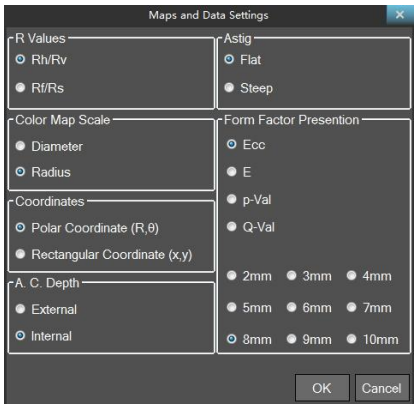
5.2 Settings

5.2.1 Image display setting



Click Settings -> Brightness / Contrast in the menu bar to adjust the Scheimpflug image contrast, brightness, enhance, Balance and other parameters by dragging the corresponding slider, and in the "Overview" section, "Scheimpflug" section, "Lens" section will display the adjusted current parameter image. This option parameter setting window can also be called up when right-clicking in the image switching bar displayed in the “Scheimpflug” image section.

5.2.2 Maps and data settings



Click Settings -> Map and Data Settings in the menu bar.

The two options for the R value (Rh/Rv and Rf/Rs) are two different description methods, flat K and steep K, and a selection is displayed in the feature value window.

The map scale toggles the diameter or radius display in the color map scale option.

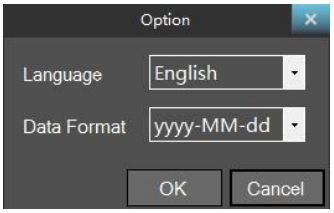
The topographic map coordinates have Polar Coordinate and Rectangular Coordinate two options.

Flat and Steep in Astig respectively indicate whether the astigmatism axis in the key data shows a flat axis or a steep axis.

By switching the internal and external surfaces, a different definition of the A.C. Depth is selected. The different scales of the ring diameter option indicate the range of corneal diameters selected when calculating the form factors and a selection will be displayed in the feature data column.

The program provides four form factors for display, namely Q, P, E, and Ecc. The specific meaning and relationship are referred to Section 6.7. A selection will be displayed in the feature data column and the form factor table of the Topometric Map section.

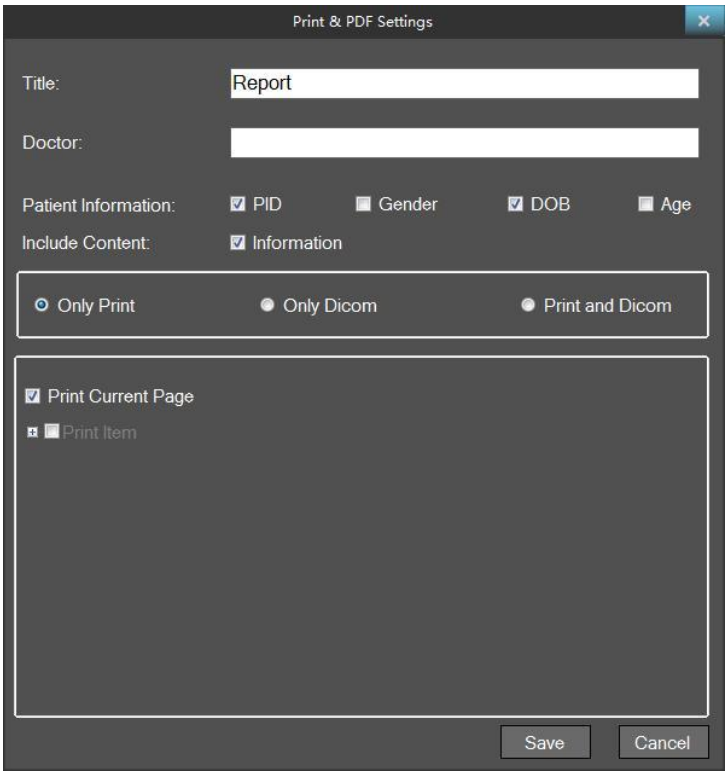
5.2.3 Language and date Format settings



Click Settings -> Language & Date options in the menu bar to switch between software language and date display format.

5.2.4 Print and PDF settings

Click Setting-> Print and PDF settings in the menu bar, user can personalized select printing (pdf export) item as needed according to option box.



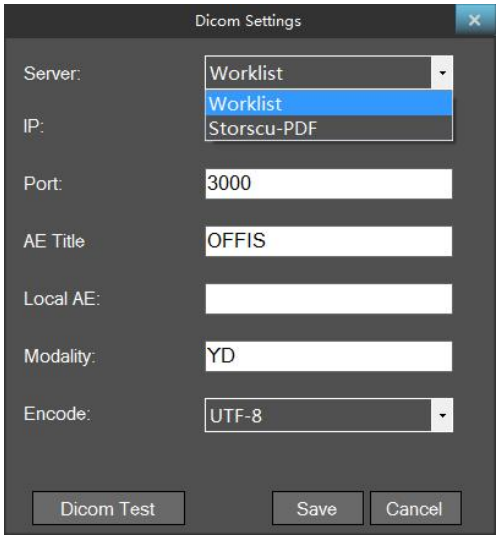
In this setting box, the user can edit the title of the print report, the information of the doctor, and set the Patient information, content and "Dicom" options printed. Among them, when "Only Dicom" is selected, only the report generated pdf file is uploaded to Dicom server.

“Print Current Page” means exporting or printing only the current page when exporting a PDF or clicking the print button. When “Print Current Page” is not activated, all selected items in the print item are exported and printed.

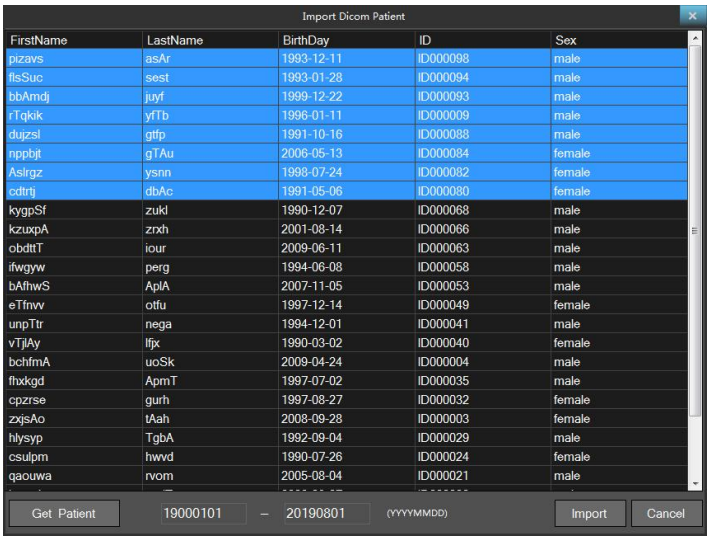
5.2.5 DICOM setting

Detailed settings for DICOM can be set in "Settings" - > "DICOM Settings" in the menu bar.

The servers are divided into worklist and PDF servers, in which the Worklist server is used to pull patient information from the DICOM server, and the PDF service uploads the generated PDF files to the DICOM server.



Pull the patient information interface (Patient -> Import DICOM patient) as shown below.

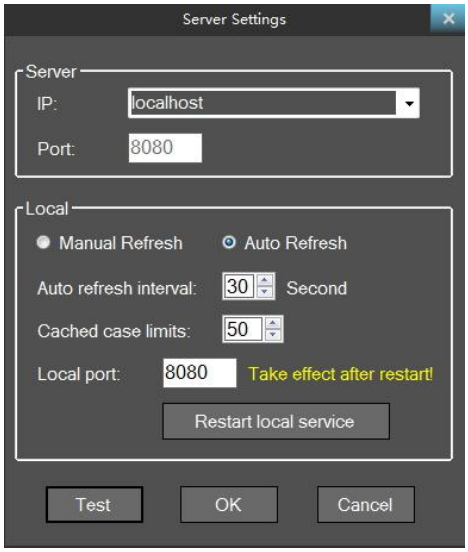


Click the "Get Patient" button, get the patient from the DICOM server, select the patients in the patient list that need to be imported into the local patient, and then click "Import" button.

5.2.6 Server setting

Scansys provides the function of saving the database locally or on other corresponding hardware servers in the local area network. At the same time, you can also view the data on the local or other related servers while browsing the cases.

The detailed settings can be set in the menu bar "Settings" -> "Server Settings".

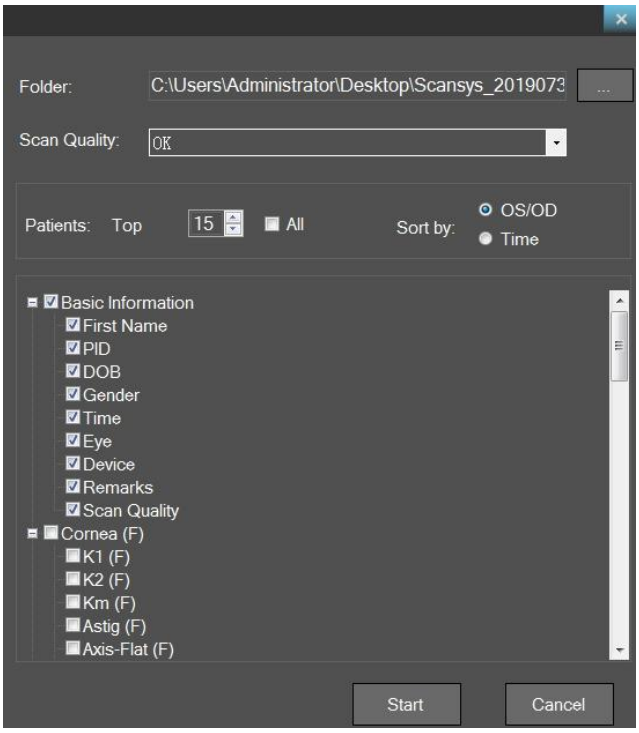


The IP option defaults to localhost. If you need to set the server to another address, you need to type the IP address of the other LAN address by hand. The other options are the default options.

5.3 Data statistics and report

5.3.1 Data statistics

Click the Data Statistics button on the right side of the menu bar, user can select any key parameters of any cases or patients as need in the optional window below. Then export csv format data for analysis or comparing.



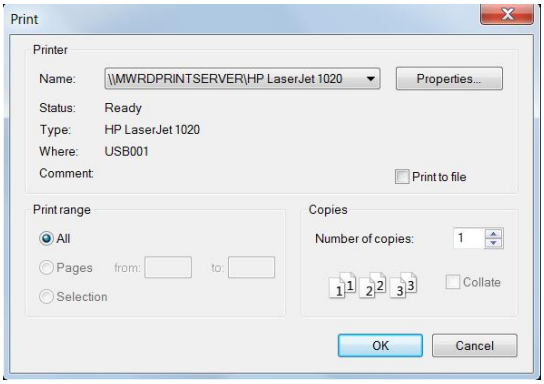
5.3.2 Save picture

Click Save Picture button on the right side of the menu bar to save current window view picture with jpg format.

5.3.3 Export & print report

User can export report or print report directly by clicking “PDF” or “Print” button on the right side of the menu bar. The report items setting refer to 5.2.4 Print and PDF settings in detail.

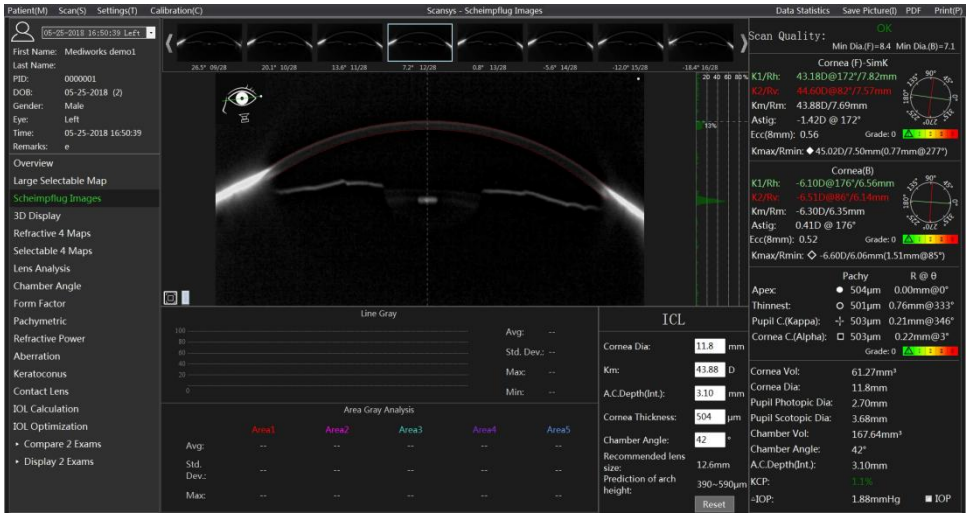
Once take print action, the printer must be configured in advance and the printer properties was show below.



6. Function Modules

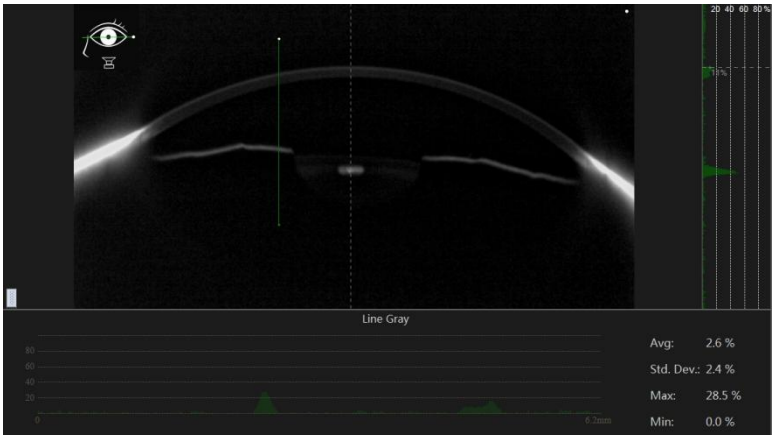
6.1 Scheimpflug images

Click on "Scheimpflug Images" in the section to enter the following interface.

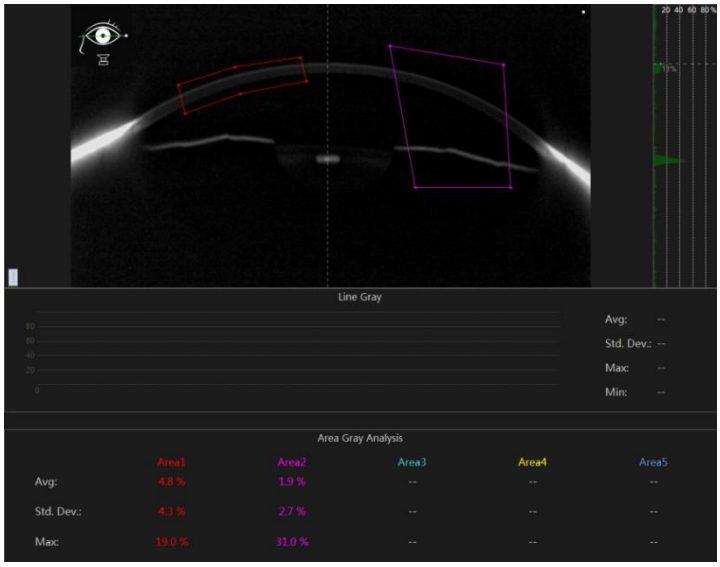


This section is mainly used for density (grayscale) analysis of a Scheimpflug image.Click on the function button in the lower left corner of the image  . The system provides two types of density analysis, namely density analysis along the line, and area density analysis.

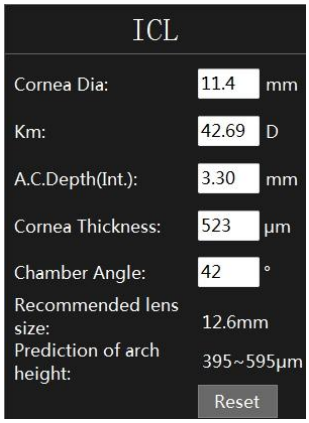
Select the button  and click on the starting point of the tangent part to be analyzed in the image. The analysis result is automatically displayed below the image, includes the entire density profile along the line and the mean value, standard deviation, and maximum.



Select the button  to plot the demand analysis area on the image. The analysis result is automatically displayed directly below the center of the interface, including the density maximum, standard deviation, and maximum value in the analysis area. The system provides results display for up to five analysis areas and is distinguished by different colors.

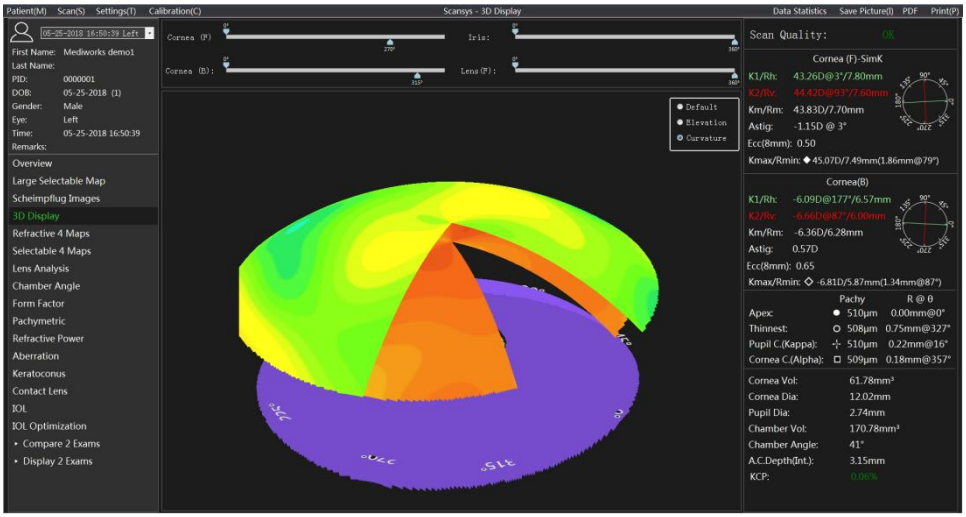


The ICL module displays the cornea diameter, anterior chamber depth and other parameters in the current case, and uses this as a judgment to give the current case's ICL lens size recommendation and postoperative prediction arch height.



6.2 3D Display

Select the “3D Display” option in the section to enter the following interface.

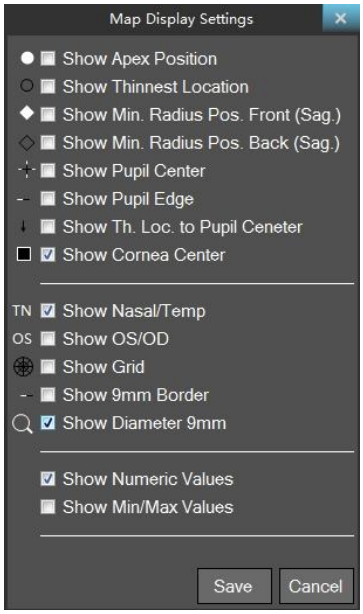


The 3D Display constructed the anterior surface of the cornea (blue), the posterior surface of the cornea (green), the iris (purple), and the anterior surface of the lens (yellow) based on real data. This model is used by doctors to instruct patients or students. The upper right corner is the display options for each structure, including surface display and grid display. The top is the Cutout angle setting (0, 360) for a clearer view of the longitudinal section of the anterior segment. Use the left mouse button to hold down and drag on the form to observe the elevation data and the topological relationship of each structure in the anterior segment from any angle of view.

6.3 Large selectable map

Click on "Large Selectable Map" in the section to enter the large image display mode, and display the various topographic map data under the current case.

6.3.1 Map display settings

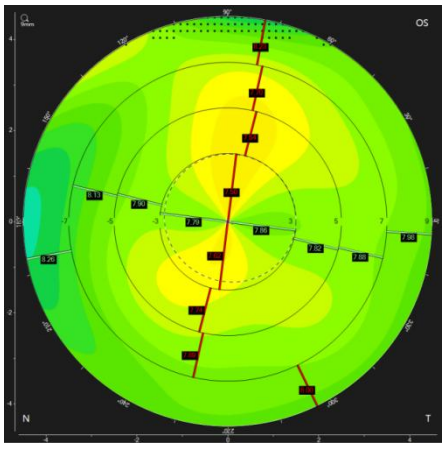


Whether displaying a large image display mode or a 4 Maps mode or other sections, as long as there is an interface displaying the topographic map, right-clicking on the topographic map can bring up the topographic map display setting window. The function of displaying or not displaying the corresponding feature on the topographic map is achieved by checking the feature box.

Among them

- Show Apex Position: solid white point represents apex position;
- Show Thinnest Location: the black border hollow point represents the thinnest point of the corneal thickness;
- Show Min. Rad. Pos. Front (Sag.): white solid diamond represents the maximum curvature point of the anterior surface of the cornea;
- Show Min. Rad. Pos. Back (Sag.): black border hollow diamond represents the maximum curvature point of the posterior surface of the cornea;
- Show Pupil Center: the white and black crosses indicate the center position of the pupil;
- Show Pupil Edge: the black and white dotted line represents the edge of the pupil;
- Show Th. Loc. to Pupil Center: the small black arrow indicates the vector distance from the center of the pupil to the thinnest point;
- Show Corneal Center: white border, black solid square dots indicate the center of corneal edge;
- Show Nasal/Temp: the letters “T”,“N” on the left and right sides of the topographic map: the temporal side and the nasal side, respectively, to facilitate differentiation and positioning;

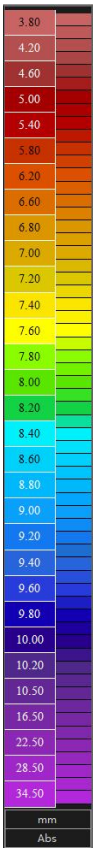
- Show OS/OD: the mark "OS" at the top of the topographic map indicates the left eye, and the "OD" indicates the right eye for easy differentiation and positioning;
- Show Grid: The grid identifier is used to display radial and axial cross grids in the topographic map;
- Show 9mm Border: white and black short dashed lines are used to represent rings from a vertex radius of 4.5mm;
- Show Diameter 9mm: only the topographic map of the corneal diameter of 9mm is drawn;
- Show Numeric value: Display the digital topographic map with a numerical value of 1mm in the radial direction;
- Show Numeric Values: The topographic map is described by the value of 5 points, which are the corresponding topographic map values at the corneal apex, 0°, 90 °, 180 °, 270 ° at the radius of 3 mm. And this setting only applies to corneal thickness and anterior chamber depth map.
- Show Min/Max Values: Display the maximum and minimum values of the corresponding topographic map and the orientation of each of the 3, 5, 7, 9, and 11 mm corneal diameters. And the setting item is only applicable to the anterior and posterior corneal axial curvature and tangential curvature topographic map, the true net refractive topographic map, and the corneal refractive power deviation topographic map.



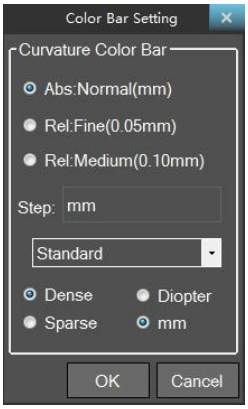
6.3.2 Topography color bar setting

The basic of the topographic map is to represent the overall distribution of the data in different colors. The size of the data represented by the various colors is determined by the topographic map color bar.

Each topographic map in the program will have a corresponding color bar to match. Not only the color scale is marked on the color strip, but also the unit of the corresponding value of the current topographic map and the color strip mode are displayed below. As shown below

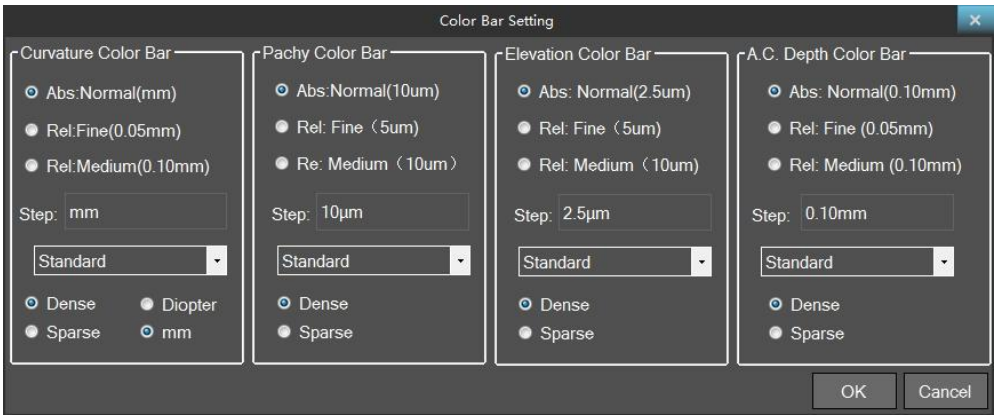


The current topographic map color bar setting dialog box pops up when the color bar is clicked. According to the user preference or better response to the current topographic map change, they can change the color gradation interval (relative, absolute) color bar pattern and density of the color bar, unit conversion (applicable only to curvature-related topographic maps), etc.

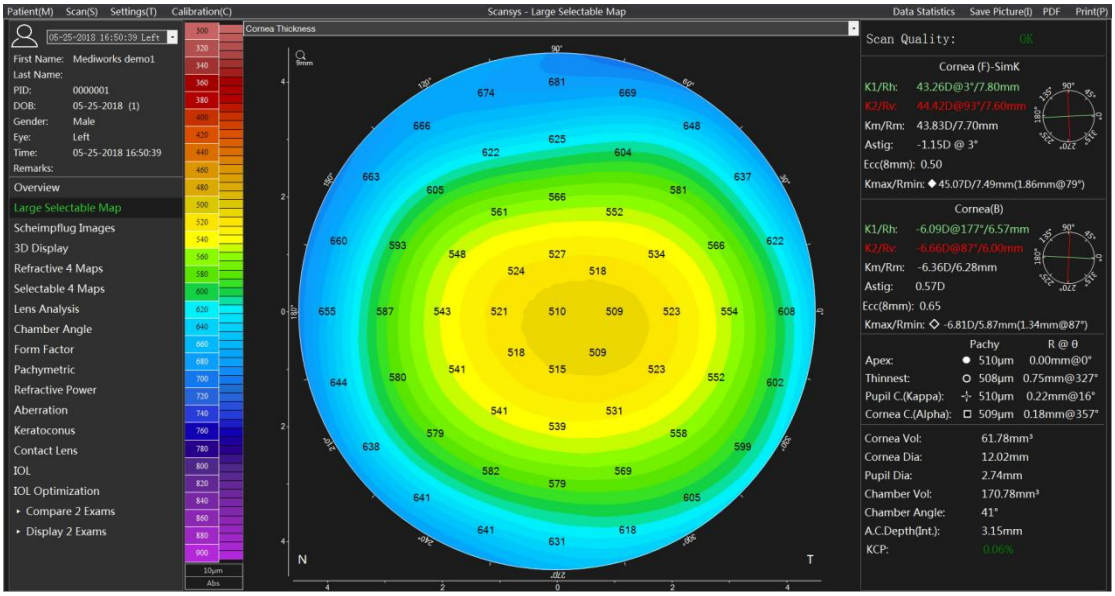


When the color bar is right-clicked, the color bar setting option of the main type topographic map pops up, and color gradation interval (relative, absolute) color bar pattern and density of the color bar,

unit conversion (applicable only to curvature-related topographic maps), etc. under a certain type of topographic map can also be changed, unit conversion (only for curvature-related topographic maps). Under a certain type of topographic map can also be changed.



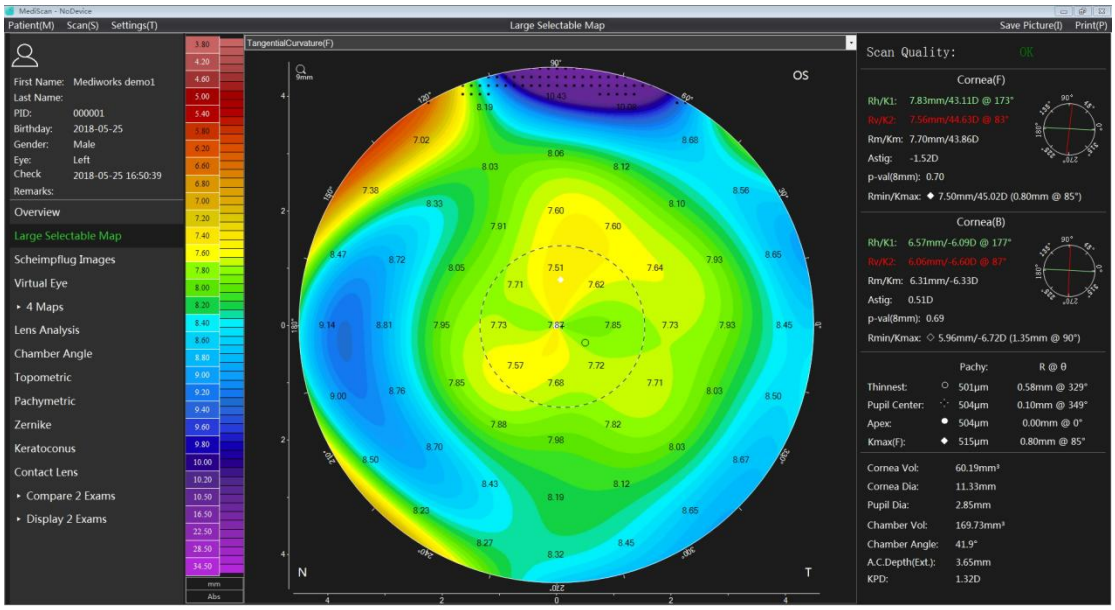
6.3.3 Corneal thickness



The color map depicts the true thickness between the anterior and posterior surfaces of the cornea. The thickness of any point on the cornea is calculated by calculating the distance between the intersection of the anterior and posterior corneas at the normal direction of the point. You can click on any position ($r \in [0,6mm], \theta \in [0,2\pi]$) of the thickness map with the left mouse button and check its value.

The color bars on the left side of the topographic map are the color and color levels. Click on the color bar to change the color accuracy level and style, and refer to the topographic map color bar settings in detail.

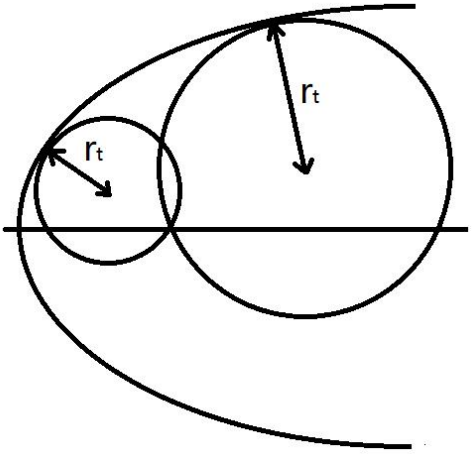
6.3.4 Tangential curvature (front)



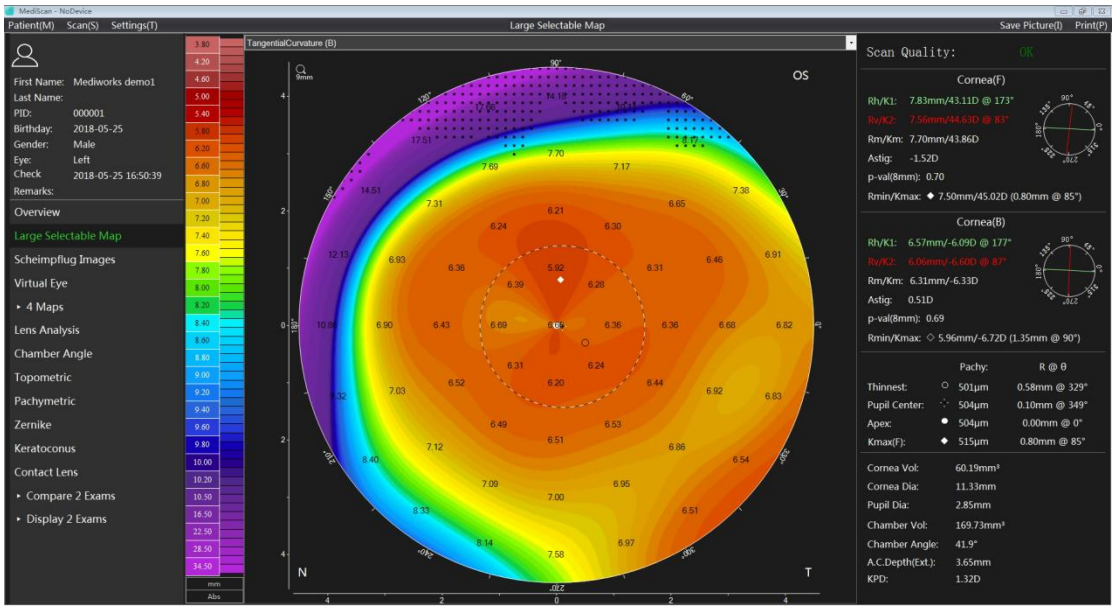
The topographic map depicts the tangential radius of curvature at various points on the anterior surface of the cornea. The user can also click on the color bar to display it in diopter units.

The definition of the tangential radius of curvature at a point: find the radial arc passing through the point and the apex of the cornea and calculate as follows

The geometric irregularities of the cornea are more pronounced in this mode.

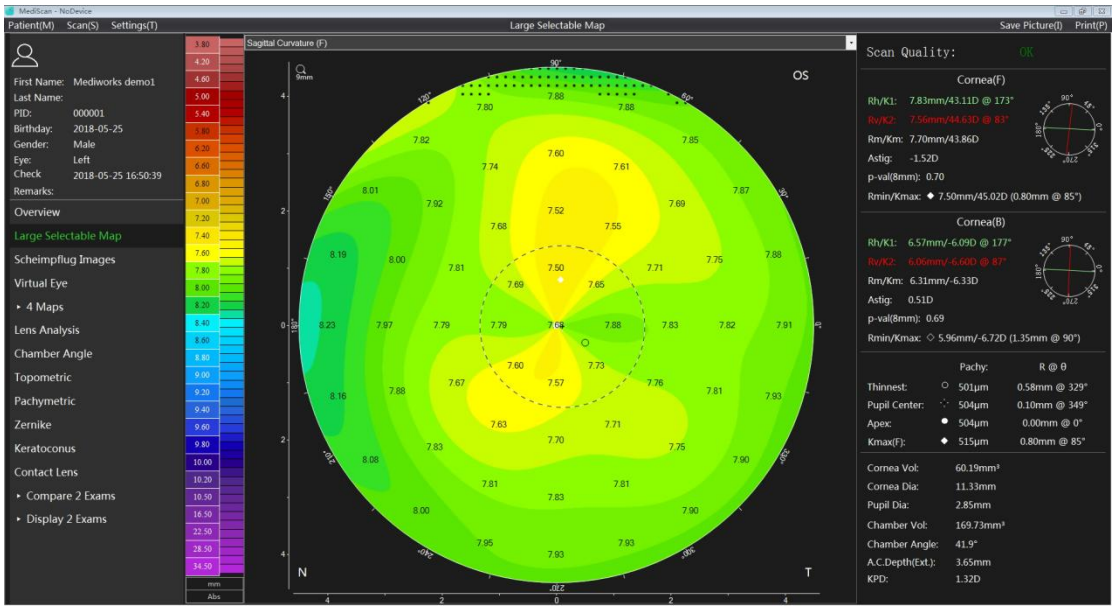


6.3.5 Tangential curvature (back)



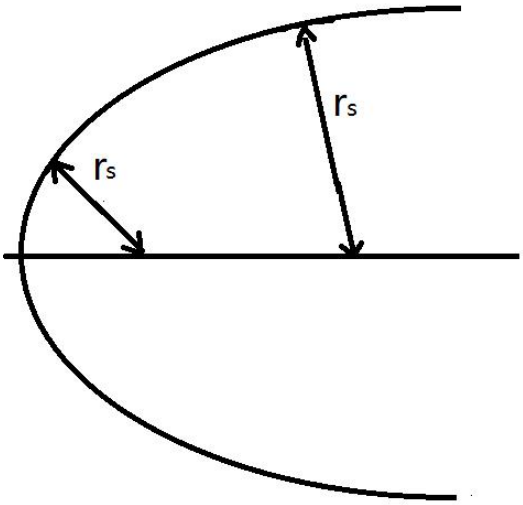
The topographic map depicts the tangential radius of curvature at various points on the posterior surface of the cornea. The user can also click on the color bar to display it in diopter units. Its definition refers to the previous section.

6.3.6 Sagittal curvature (front)



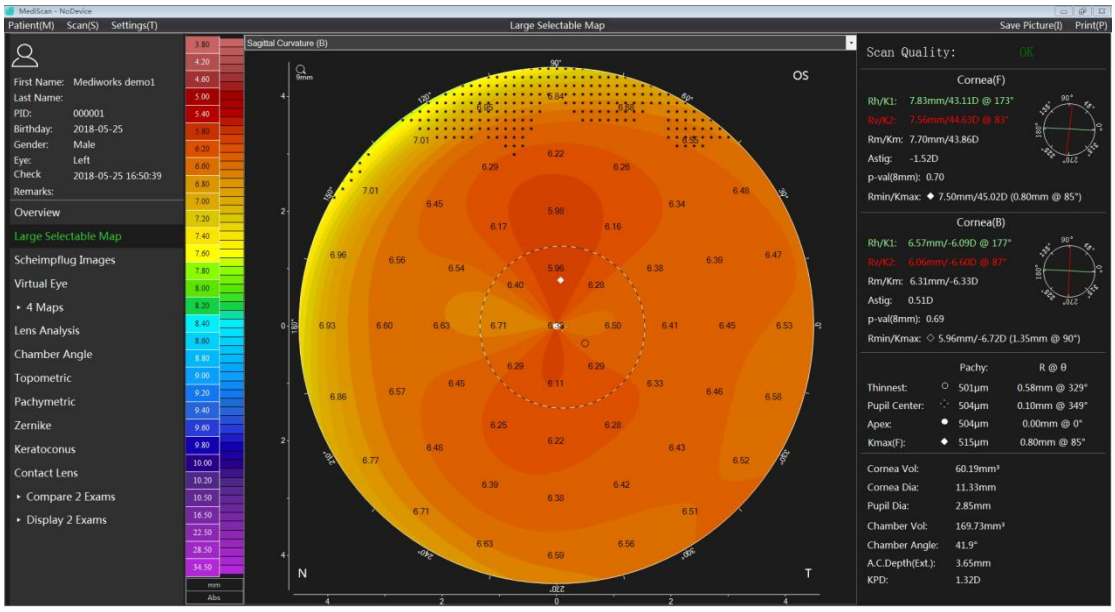
The topographic map depicts the extent of the axial radius of curvature at various points on the anterior surface of the cornea. The user can also click on the color bar to display it in diopter units.

Definition of the sagittal radius of curvature at a certain point: Find the radial arc passing through the point and the apex of the cornea and calculate as follows,



The radial (or sagittal) curvature is equivalent to the distance between the perpendicular to the tangent of the measurement point and the tangent of the measurement point and the axis. In the radial representation mode, the curvature value depends on the slope of the measurement point. And the position of the optical axis should also be considered. The sagittal display mode better represents the effect of the cornea on the patient's visual acuity.

6.3.7 Sagittal curvature (back)



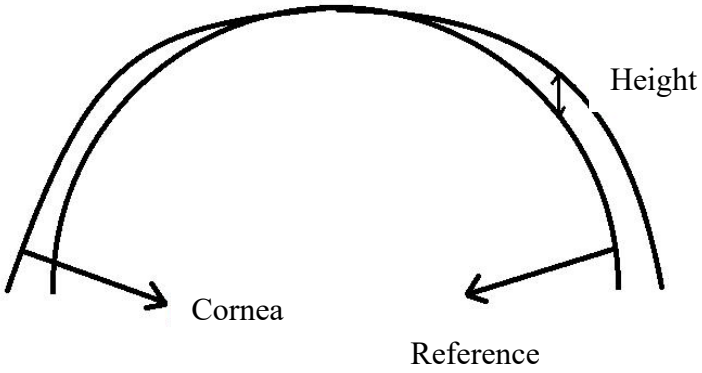
The topographic map depicts the extent of the axial radius of curvature at various points on the posterior surface of the cornea. The user can also click on the color bar to display it in diopter units. Its definition refers to the previous section.

6.3.8 Elevation

6.3.8.1 Elevation map explanation

1. In terms of design principle, the Scansys TA517 system collects height data and internally calculates the three-dimensional mathematical model of the anterior segment by computer software. All functional calculations and other detailed information are derived from the model data. Elevation data is therefore the basis for all calculations, which have the following advantages: Accurate representation of the true corneal (or other anterior segment structure) surface shape;
2. The uniqueness of the elevation data determines the uniqueness of the curvature, which is not feasible while in contrast, which is also the superiority of the Scansys TA517 system compare to the traditional Placido system.
3. The elevation data can be used to define standards and is independent of the type of machine being used;
4. The elevation data is less affected by dummy data, improving data accuracy;
5. The elevation data is the starting point for the data of the anterior and posterior corneal spherical aberration analysis.

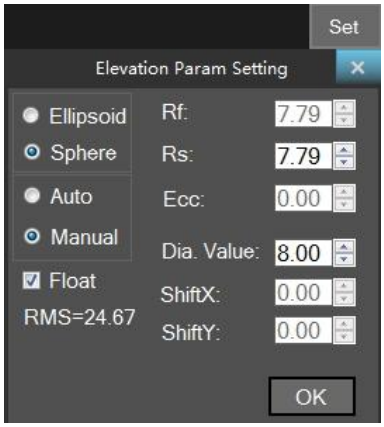
Speaking of elevation, there must be a reference, that is, a relative concept, which can be a plane or an arbitrary surface. The elevation topographic map is described by the difference in elevation between the cornea and the reference.



Its value can be positive (the cornea is higher than the reference body) or negative (the cornea is lower than the reference body).

6.3.8.2 Reference body

Any shape of the reference body can be used as a standard to describe height data, and Scansys TA517 provides two different reference bodies to describe the corneal height. The user can change the options in the upper right corner of the height map by clicking the Settings menu that pops up in the “Set” button.



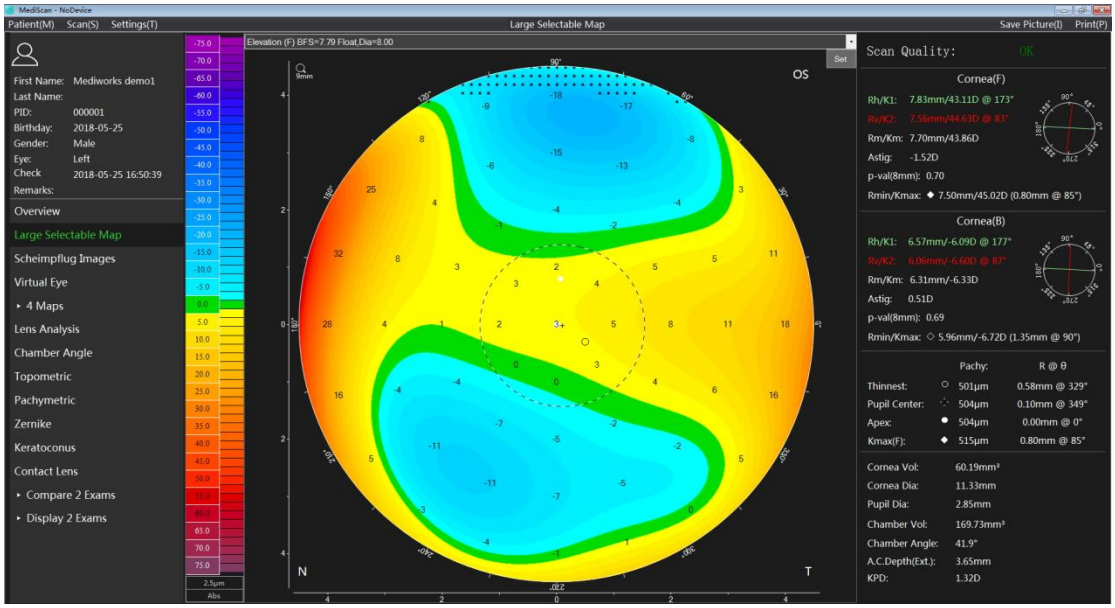
Ellipsoid reference body: Calculated using the elliptical rotation obtained from the average central radius of the cornea and the eccentricity.

Sphere Reference Body: Calculates the true shape that is essentially as accurate as possible to approximate the sphere to the cornea.

After the manual mode is activated, the parameters and position offset of the reference body can be arbitrarily changed. These reference bodies can be located at the center of the apex of the cornea or “floating diagram”. When the floating graph option is selected, the reference body has no fixed center, but is arbitrary, which can reduce the influence caused by the inclination of the cornea itself,

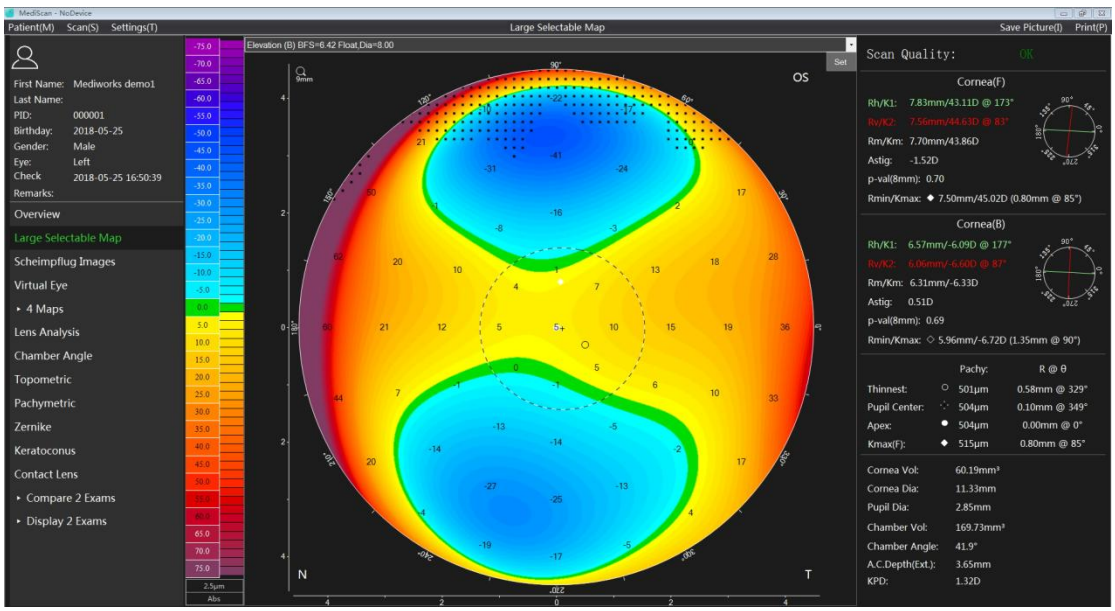
to clearly shows irregularities in the corneal surface. A non-floating display forces the apex of the cornea to be the reference 0 point.

6.3.8.3 Elevation (front)



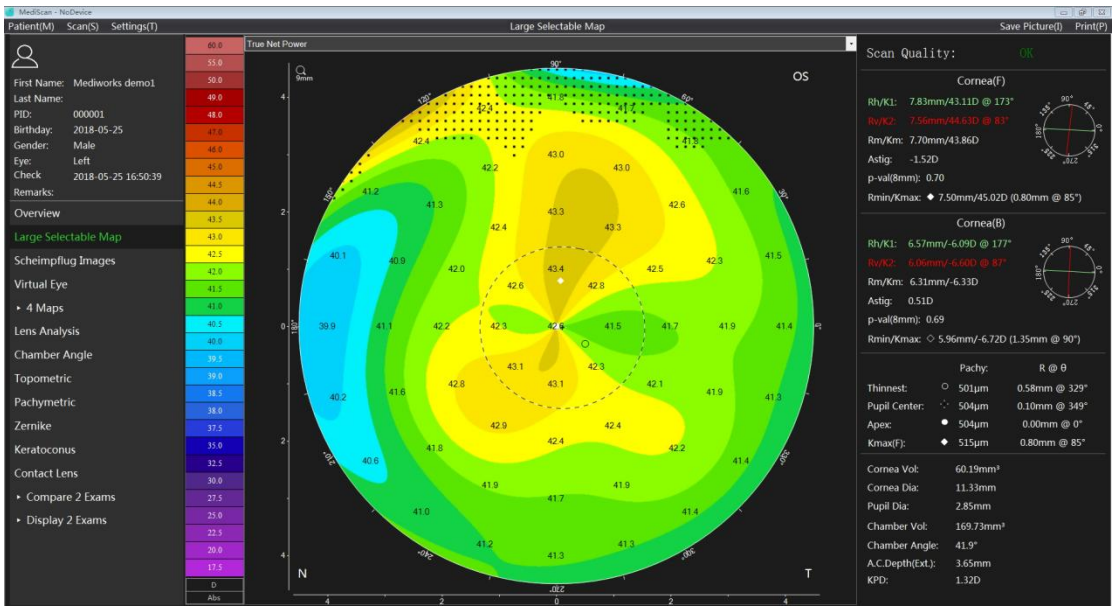
The topographic map depicts elevation data for the anterior surface of the cornea. The elevation here is a relative height concept; the specific meaning refers to the explanation of the elevation data and reference body in the previous two sections. BFS in the topographic map heading indicates the best fit spherical radius of the anterior surface of the corneal data, and Dia indicates the minimum sampling diameter sampled into the cornea.

6.3.8.4 Elevation (back)



This topographic map depicts the elevation data for the posterior surface of the cornea. The specific meaning refers to the previous section.

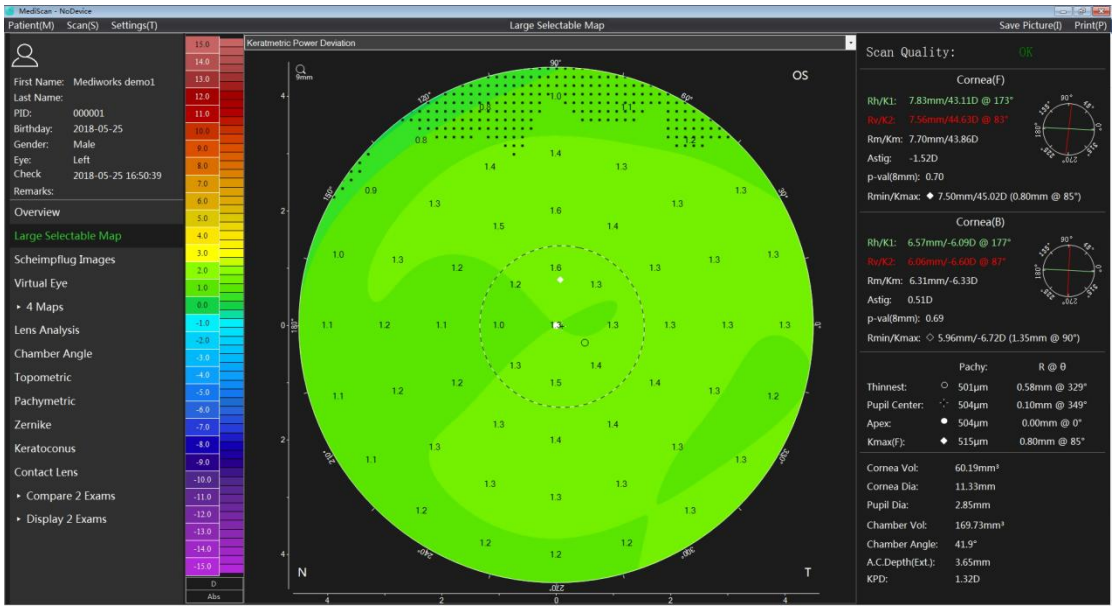
6.3.9 True net power



The true net power topographic map considers the true optical conditions of the entire cornea. For intact corneas, the Placido system typically uses a refractive index of 1.3375 to calculate corneal refractive power. However, only the approximation values are provided because the posterior surface is not considered. This makes the calculation of the irregularly shaped cornea less stringent.

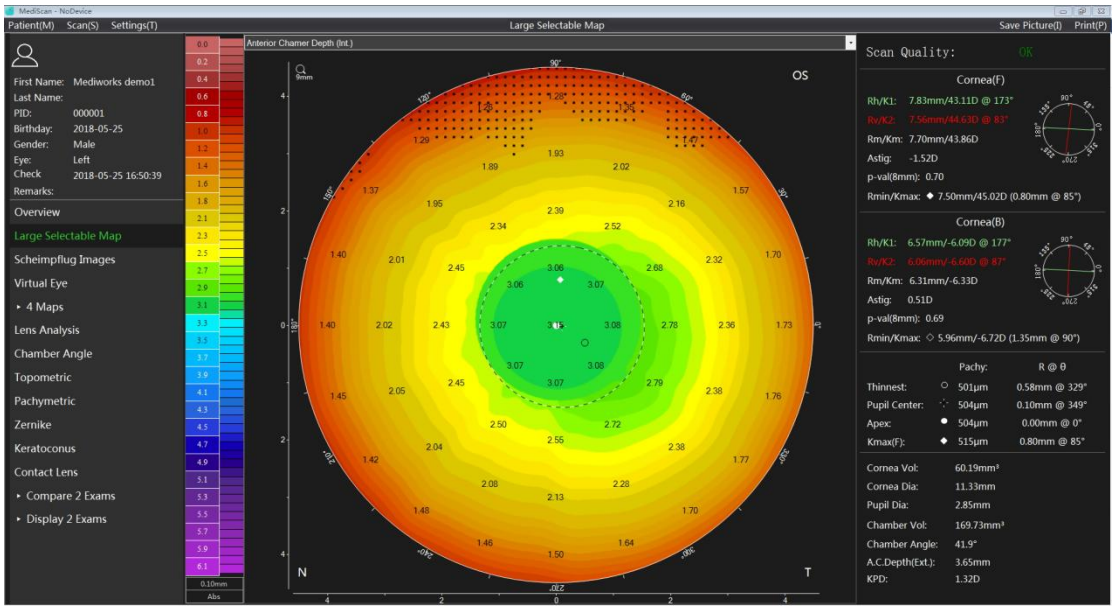
The topographic map calculates the true net power map by calculating the two corneal curvature maps anterior and posterior. First, the corneal anterior surface diopter was calculated using the difference between the refractive index n = 1 in air and n = 1.376 in the corneal tissue. The posterior corneal surface diopter was calculated using the difference between the refractive index n = 1.376 in the corneal tissue and the n = 1.336 in the chamber water. That is, the true net diopter at a certain point$= \frac{1.376-1}{r_a} * 1000 + \frac{1.336-1.376}{r_p} * 1000$ this way, the anterior and posterior surfaces of the cornea are simultaneously considered to obtain a more accurate true keratometry diopter and a true net power figure is generated.

6.3.10 Keratometric power deviation



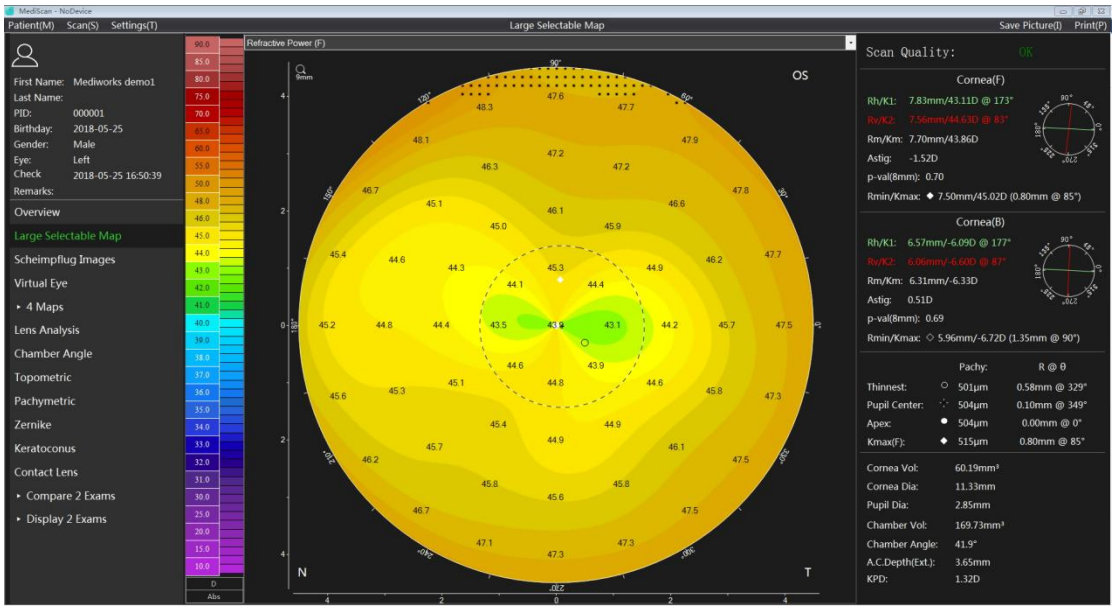
This topographic map reflects the deviation of the axial diopter of the anterior surface of the cornea from the true net power. The erroneous value of the diopter is calculated clearly from the anterior surface curvature value.

6.3.11Anterior chamber depth (Ext)

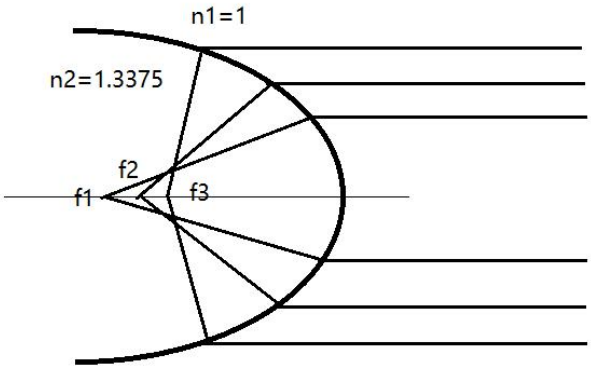


The topographic map is the distance between the posterior surface of the cornea and the iris and lens, defined as the depth of the anterior chamber, expressed in mm. The structural topological relationship of the anterior chamber in the anterior segments is clearly given. The users can right-click the topographic map to show pupil boundaries and centers for easy positioning.

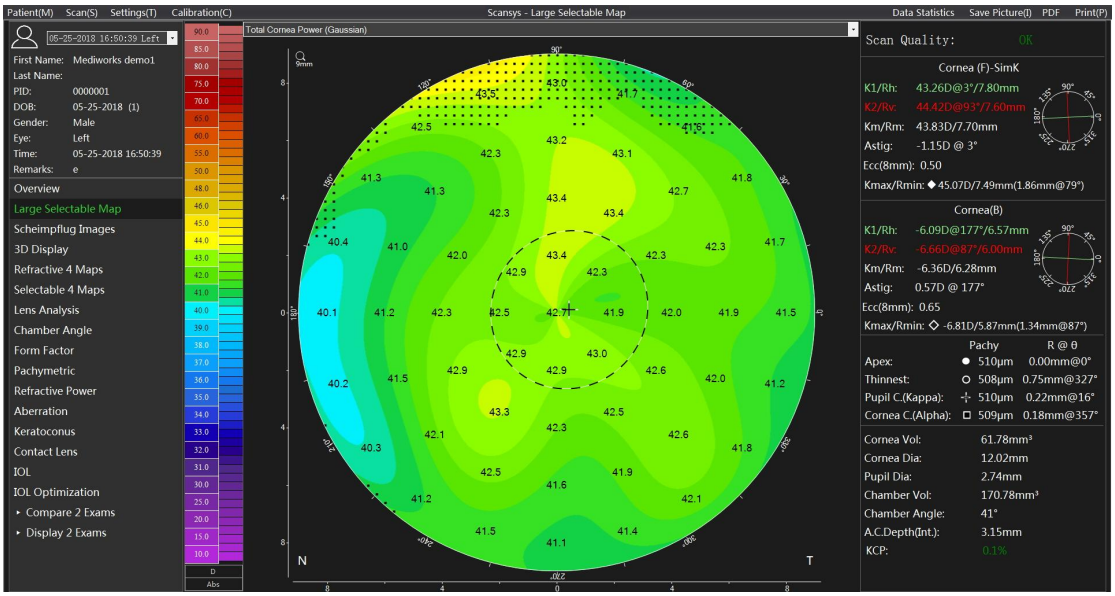
6.3.12 Refractive power (anterior)



The topographic map uses the focal length rather than the curvature value to calculate the power to estimate the optical effect of the anterior surface of the cornea. The focal length is calculated according to Snell's law (ray tracing method) to estimate the difference of spheres. Assuming a standard sphere, the difference in refractive power under this definition is very significant compared to the traditional curvature topographic map. The curvature map shows only one diopter because the curvature of each point of the sphere is the same. Considering the spherical aberration effect, the (f3) diopter around the diopter diagram under this definition will be too large, and the middle (f1) will be small.



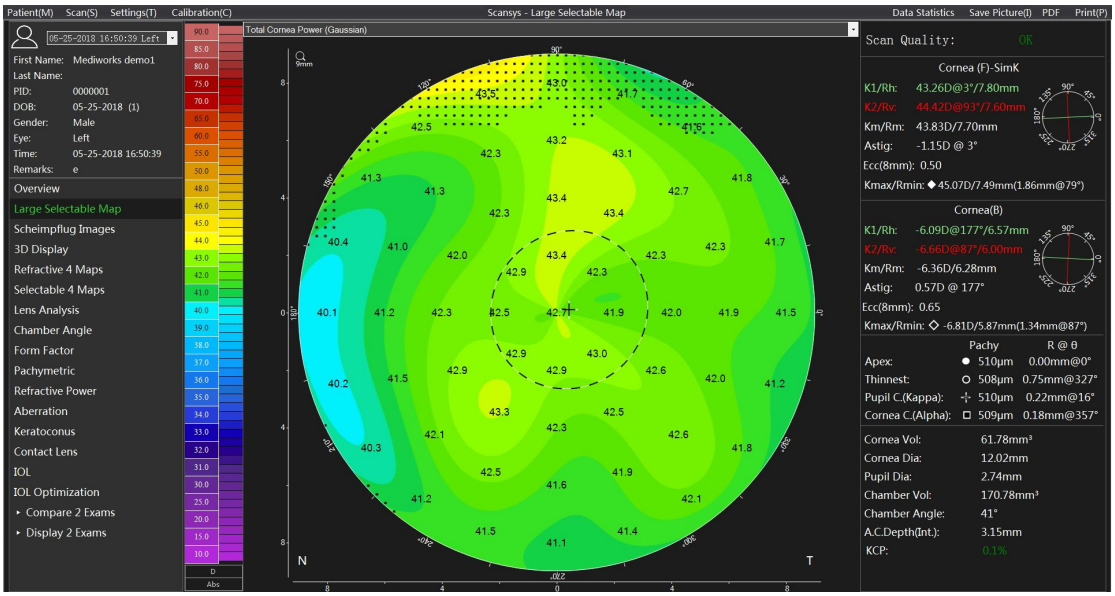
6.3.13 Total cornea power (Gaussian)



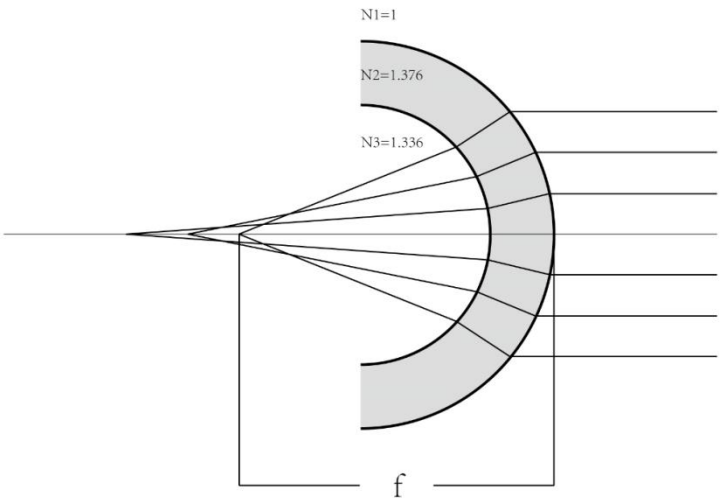
The total cornea power topographic map (Gaussian) considers the true optical conditions of the entire cornea and cornea thickness. For intact corneas, the Placido system typically uses a refractive index of 1.3375 to calculate corneal refractive power. However, only the approximation values are provided because the posterior surface is not considered. This makes the calculation of the irregularly shaped cornea less stringent.

The topographic map calculates the total cornea power map by calculating the two corneal curvature maps anterior and posterior and the central cornea thickness with Gaussian equivalent method. First, the corneal anterior surface diopter was calculated using the difference between the refractive index n0 = 1 in air and n1 = 1.376 in the corneal tissue. The posterior corneal surface diopter was calculated using the difference between the refractive index n1 = 1.376 in the corneal tissue and the n2 = 1.336 in the chamber water. That is, the total cornea power at a certain point$= \frac{1}{r_a} * (\mathrm{n1} - \mathrm{n0}) + \frac{1}{r_p}(n2 - n1) - \frac{d}{n1} * \left(\frac{1}{r_a} * (\mathrm{n1} - \mathrm{n0})\right) * (\frac{1}{r_p}(n2 - n1))$, this way, the anterior and posterior surfaces of the cornea and also cornea central thickness are simultaneously considered to obtain a more accurate total cornea diopter and a corresponding figure is generated.

6.3.14 Total cornea power (Ray Tracing)



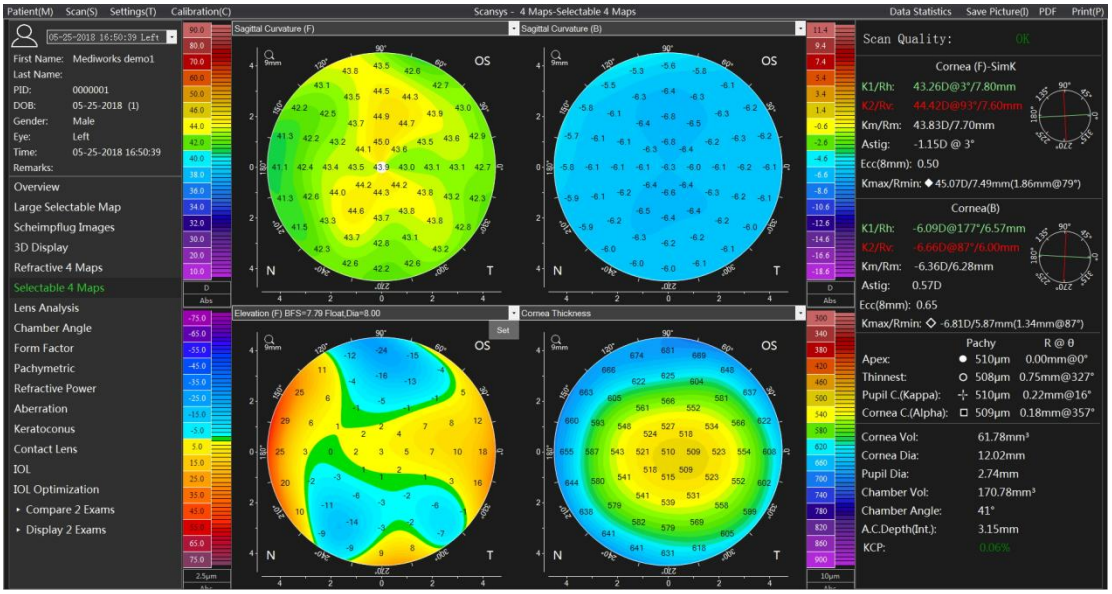
The topographic map of the total corneal power is different from the Gaussian and is calculated by the ray tracing method. According to snell's law, incident parallel light rays refract correspondingly when passing through the anterior and posterior surfaces of the cornea. The slope of the both anterior and posterior surfaces and cornea thickness are taken into consideration, which lead to the result much more realistic. Total cornea power(Ray tracing) is determined by n/f, based on the actual calculated focal length(f), and n is the index of refraction of the aqueous(1.336).



6.4 4 Maps display

6.4.1 Selectable 4 maps

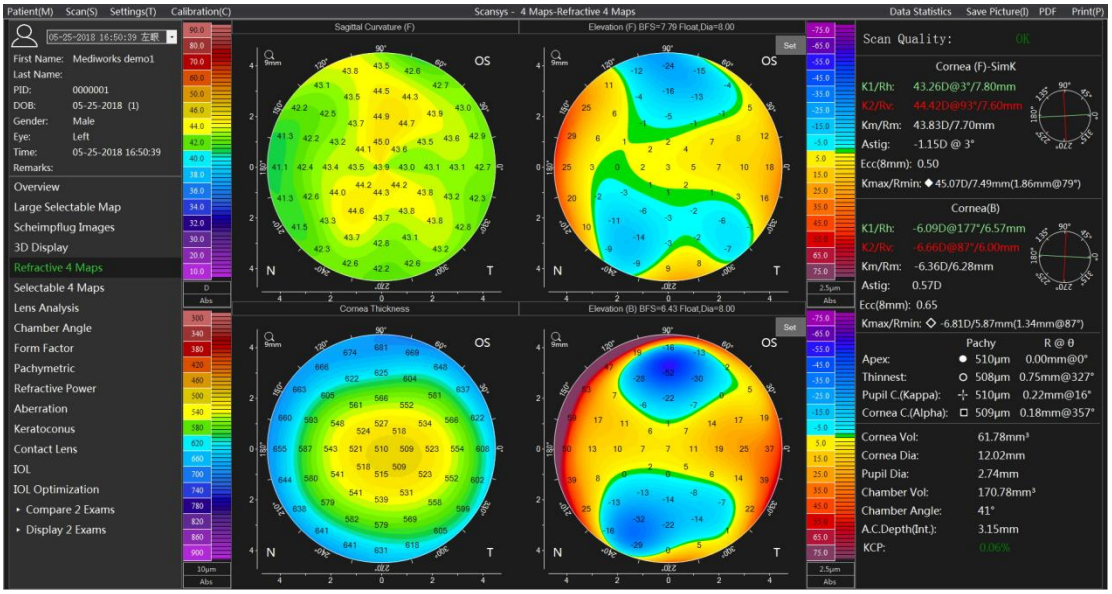
Click on the “Selectable 4 Maps” in the left section to open a window contains 4 optional color maps. Corneal thickness and elevation, etc. can be loaded into one of any 4 fields. As follows



With this option, the user can view and print out important topographic maps needed for daily work in one interface.

6.4.2 Refractive maps

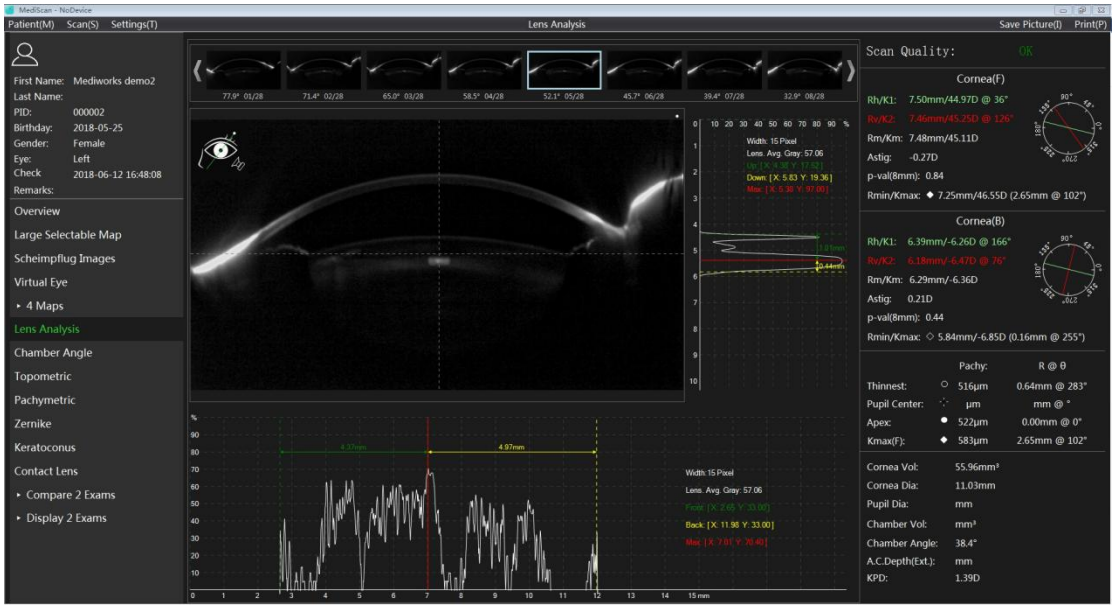
Click on the “Refractive 4 Maps” in the left section to open a window with the anterior and posterior surface Elevation map, Cornea Thickness map, and Sagittal Curvature (front) map. As follows



These types of topographic displayed are fixed. They can support the diagnosis of corneal refractive disease such as keratoconus by ophthalmologists.

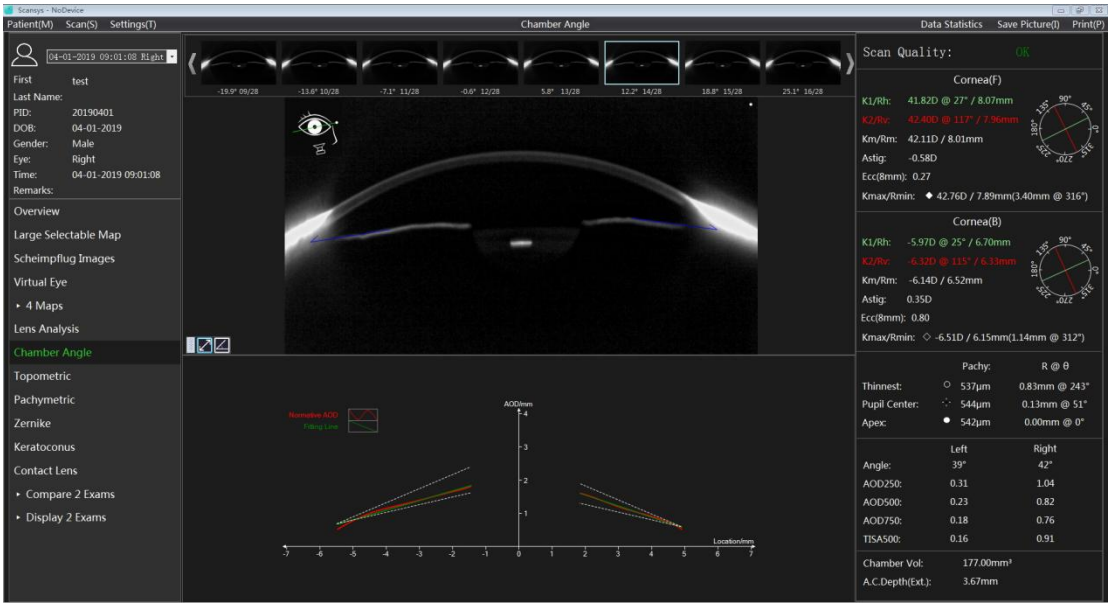
6.5 Lens analysis

Click the “Lens Analysis” button in the left section to enter the lens analysis section. This section is mainly used for lens density analysis and cataract classification. At the top of the interface, The user can view a large view of the section by switching the image. The longitudinal section density value distribution is shown on the right side of the image and the horizontal section density distribution is shown under the image. The solid red line marks the location of the maximum density, and the green dashed line and the yellow dashed line represent the analysis boundary. The lens density varies from 0% to 100%, and a larger value indicates a more turbid lens.



6.6 Chamber angle analysis

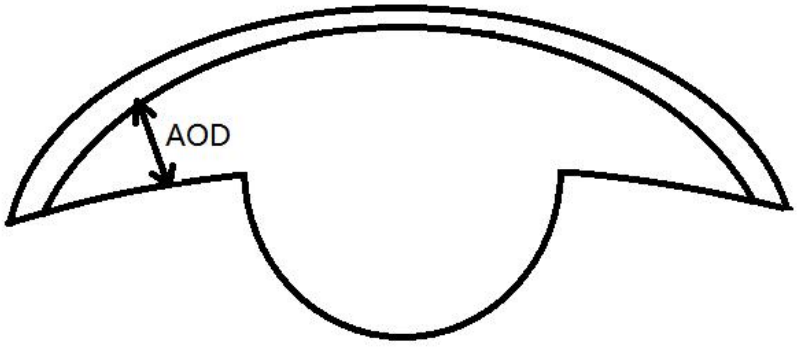
Click on the "Chamber Angle" option in the left section to enter the chamber angle analysis section. This functional section is mainly used for the screening of patients with narrow chamber angles or glaucoma.



The user can also view the cut view by switching the angle position interface. At the bottom of the interface, the original AOD distribution trend and the straight line fitting distribution trend on both sides of the vertices of the current image are given, and the dotted lines denote the normal limits. Click on any two positions on the trend graph to calculate the angle change value automatically.

Parameter definition:

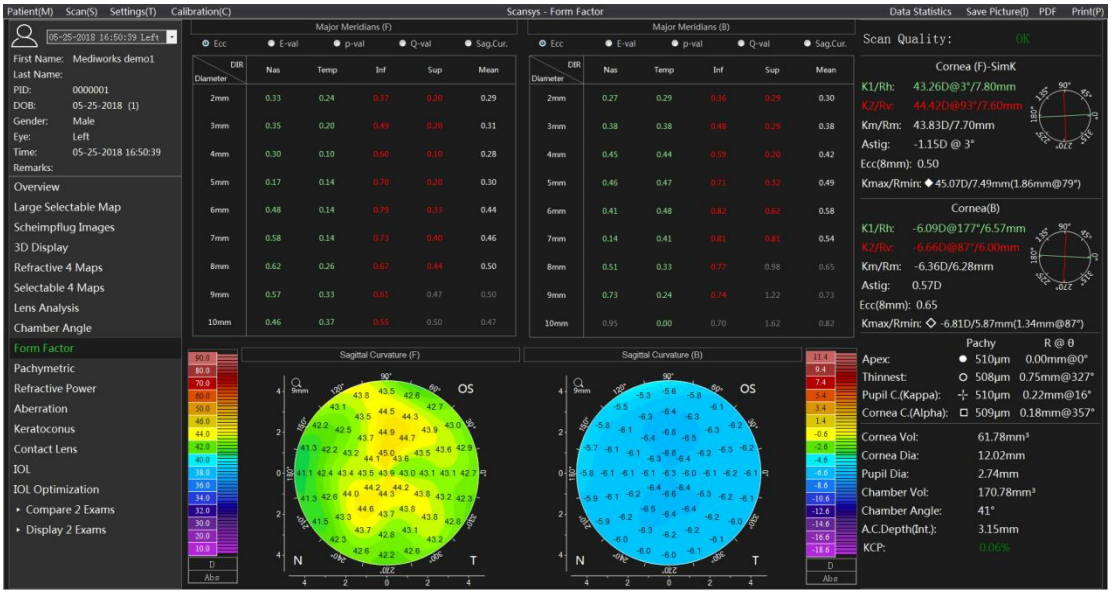
AOD (Angle Opening Distance AOD500 & AOD750): The first point is the point starting from 500um or 500um from the sclera. Second point is the intersect point of two lines: the plane of the iris, and the perpendicular line of first point to the sclera. AOD is the linear distance between the two points.



TISA (Trabecular-iris Space Area TISA500 & TISA750), the boundary of this triangular area is defined as: corner crypt (vertex), AOD500|AOD750 (side of triangle), iris surface and inner surface of the sclera (The side of the triangle). It eats a non-functional area with no aqueous drainage within the sclera, including TISA.

6.7 Form factor

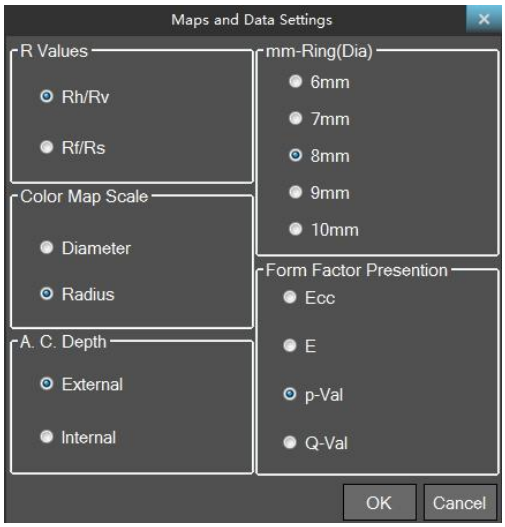
Click on the “Form Factor” option in the left section to enter the Form Factor section.



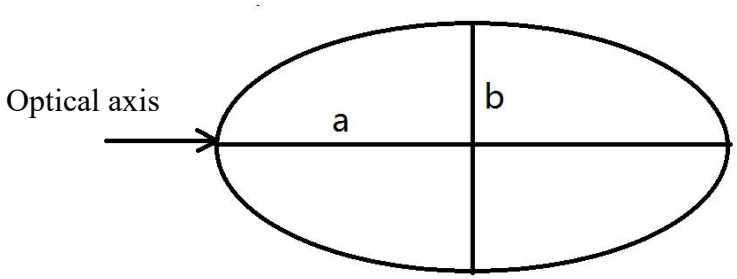
This section shows a topographical view of the Sagittal curvature of the anterior and posterior surface of the cornea. The user can use the color bar settings to select the appropriate topographic map display according to the actual needs.

The chart upper depicts the corneal form factor and the curvature of the anterior and posterior surface of the cornea at the intersection of the radial axis and the four radial directions.

Corneal shape factors include Ecc, E, Q, and P, which can be changed in the “Map and Data Settings” -> “Form Factor Presentation” in the menu bar “Settings” options.



The corneal cross-section is not an ellipse in the strict sense, so it is necessary to find the best-fit ellipse in a certain direction in the calculation. The definition of each form factor is described below based on the ellipse definition.



6.7.1 Form factor

Ecc

It is a standard mathematical definition of elliptical eccentricity, calculated as

$$e = \sqrt{1 - \frac{\min(a,b)^2}{\max(a,b)^2}}$$

It should be noted that the eccentricity *e* cannot distinguish whether it is a flat ellipse.

P

The purpose of this form factor is to address the limitations of the Ecc value. It is defined as $p = \frac{b^2}{a^2}$

Using this form factor, the circle can be described as p=1, the p-value of the prolate ellipse is less than 1, and the p-value of the oblate ellipse is greater than 1.

Q

This form factor can be used to indicate the degree of deviation of a particular curve from the spherical surface, which is defined as$Q = P - 1$

The spherical Q value is 0, the prolate ellipse Q value is negative, and the oblate ellipse Q value is positive.

E

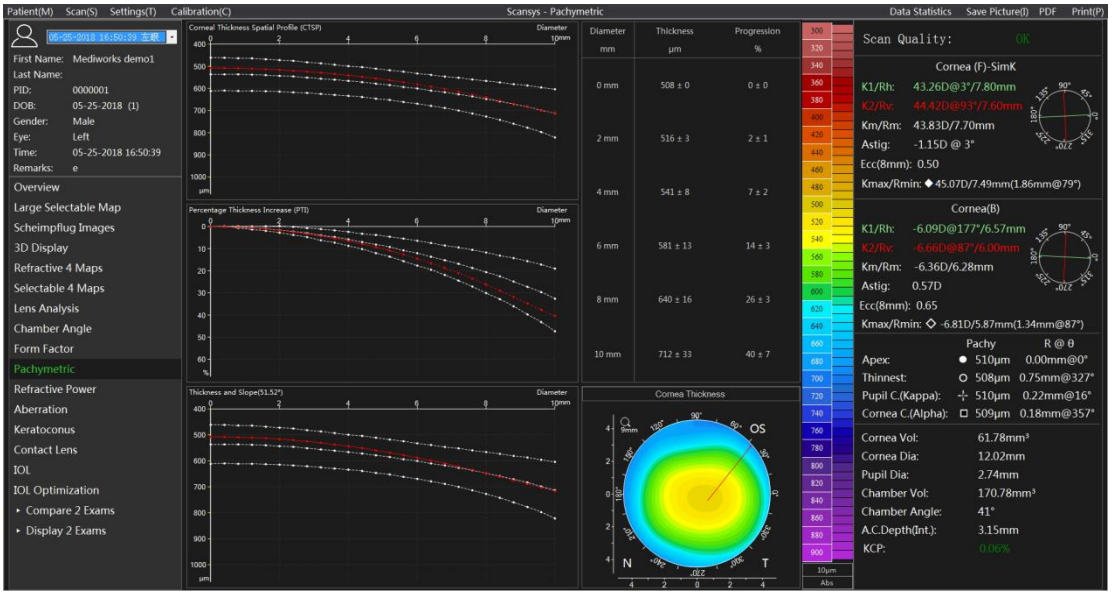
This form factor is similar to the Q value, but the difference is that the prolate ellipse has a positive value and the oblate ellipse has a negative value. It is defined as $E = 1 - \frac{b^2}{a^2}$

The form factors help to partially quantify eye shape characteristics. These factors are all derived from an ellipse approximating the specific cross-section of the eye (usually a steep or flat axis). The applicability of these attributes is described in detail in the article "Cornea shape e, p and Q values" published by Swarbrick in the Journal of Ophthalmologist Refractive Eye Care (December 2014).

The average corneal form factor at the corneal astigmatism position is displayed at the bottom.

6.8 Pachymetric

Click the “Pachymetric” option in the left section to enter the pachymetric section.



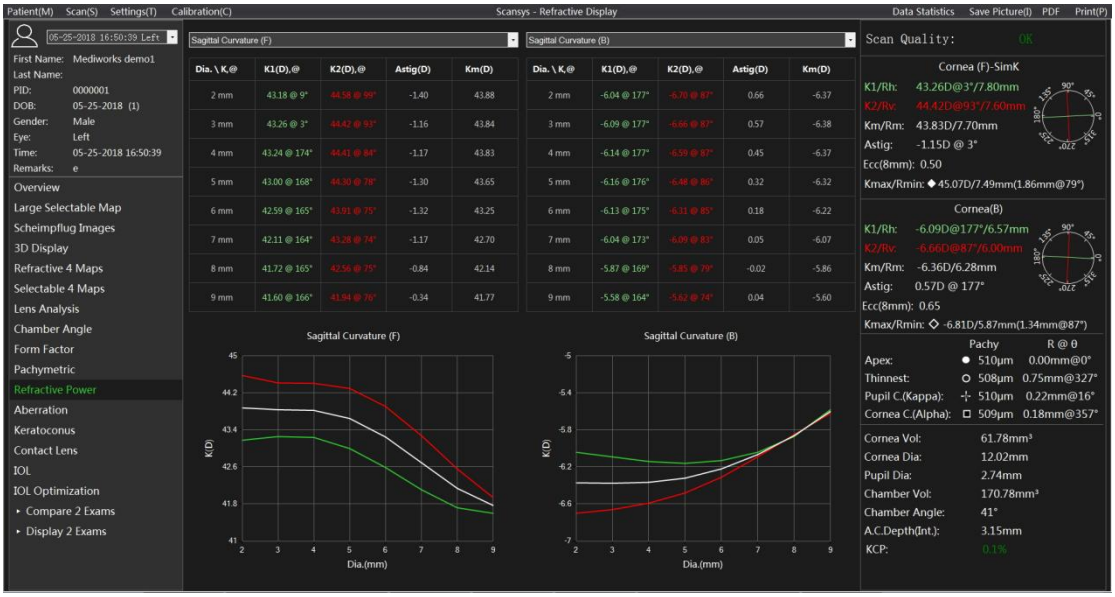
This section describes the distribution of changes in corneal thickness, where the CTSP corneal thickness distribution is based on the average corneal thickness distribution around the concentric ring of the thinnest point of the cornea. Another indicator PTI – the increasing thickness percentage is a dimensionless form describing the percentage distribution of corneal thickness variation based on the concentric ring around the thinnest point of the cornea. The simple formula is $PTI_x = （\mathrm{CTSP}_x - \mathrm{CTSP}_{min}）/\mathrm{CTSP}_{min}$.

The third image – Thickness and Slope (0.00°) shows the trend of thickness values in a certain direction based on the thinnest point of the cornea. It should be noted that the white dotted line is the standard thickness distribution and the red line is the current case data distribution.

The average corneal thickness and deviation of the 2mm, 4mm, 6mm, 8mm, and 10mm rings and the mean and deviation of the percentage increase of the corneal thickness are shown in the upper right. The bottom right is the topographic map of the Corneal Thickness distribution. The red line can be changed by the mouse clicking, indicating a direction along the thinnest point of the cornea, and the thickness distribution in the single left direction changes accordingly.

6.9 Refractive power

Click the "Refractive Power" option in the function module on the left to enter the refractive distribution analysis function module.



In the key parameter column on the right, we give K1, K2, Km, Astig. These values are obtained in the range of 3mm in diameter of the membrane. In order to describe in more detail the difference of these values in each diameter range, We give K1, K2, Km, Astig of the axial curvature of the anterior and posterior corneal, anterior surface refractive power, true net refractive power, full corneal refractive power topographic map, the distribution table of various areas from 2mm to 9mm in diameter, and the distribution curve .The changes of these values in different topographic maps and different diameter ranges are described more intuitively and in detail.

6.10 Aberration

6.10.1 Overview

Zernike polynomials are commonly used to describe wavefront, each beam containing a sinusoidal oscillation, and points in the entire sinusoidal oscillation array having the same phase direction form a refractive surface that is perpendicular to the plane wavefront of the propagation direction. In the ideal case, the incident wavefront juxtaposed to each other are deformed to form a spherical wave that accurately satisfies the focal length F. But this ideal situation will not occur because the true wavefront display is different from the perfect refractive spherical wave.

When the deviation or aberration is smaller, the quality of the refractive system is higher. The Dutch physicist and Nobel laureate Frits Zenike (1888-1966, the inventor of the aberration microscope) successfully gave a mathematical representation of the true wavefront and ideal deviation by polynomial fitting. Each polynomial is named according to the image defect represented (eg. coma, spherical aberration). Zernike polynomials are also known as ring polynomials because they refer to circles with a radius of 1, expressed in polar coordinates. From a mathematical point of view, each Zernike polynomial is represented by a product of multiple powers of radius r and multiple powers of angle variable θ.

A Zernike polynomial has the following definition:

Z0, 0 height constant, average surface height

Z1, ±1 tilt (x direction +1, y direction -1)

Z2, 0 conical part shape focal length or surface

Z2, ±2 astigmatism

Z3, ±1 coma

Z3, ±3 trilobal

Z4, 0 spherical aberration

Z4, ±2 high order (4) astigmatism

Z4, ±4 four-leaf defect

Z5, ±1 high order (5) coma

Z5, ±3 high order (5) trilobal

Z5, ±5 five-leaf defect

Z6, 0 high order (6) spherical aberration

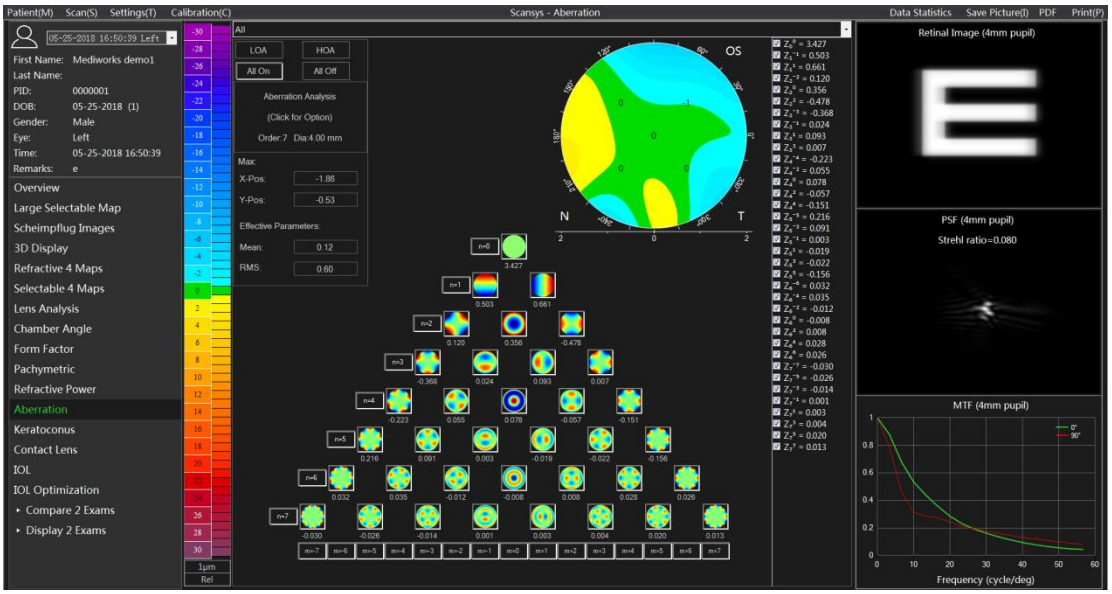
Z6, ±2 high order (6) astigmatism

Z6, ±4 high-order (6) four-leaf defect

Z6, ±6 six-leaf defect

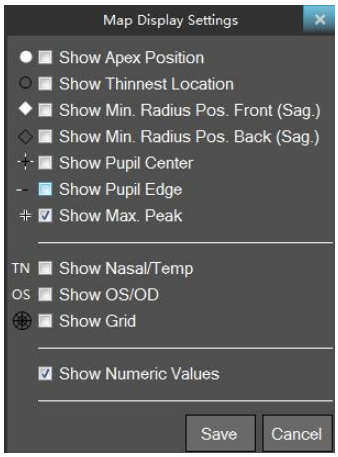
6.10.2 Aberration analysis

Click on the left section to start the Scansys TA517 “Aberration” analysis function. As follows,



This view is based on the measured corneal anterior and posterior surface height data and calculates the true wave front according to the principle of Ray Tracing. It is assumed that the refractive index in the air = 1.0, the refractive index of the cornea = 1.176, and the refractive index of the aqueous humor = 1.336. Then, the difference between the front of the real wave and the front of the ideal wave is used for wavefront aberration analysis. It calculates a coefficient for each Zernike polynomial term, which describes the contribution of this polynomial to the wavefront aberration data.

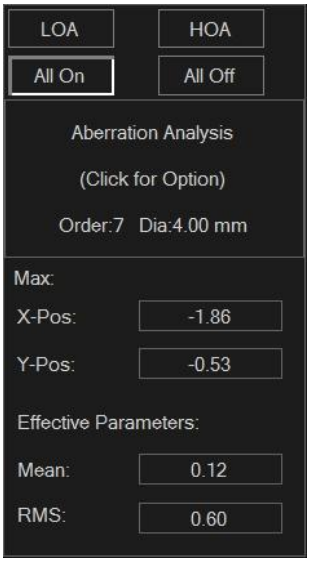
The 2D topographic map on the right upper represents the height data of the fit and can be left clicked to see the height at any location of the cornea. The software automatically finds the highest point, indicated by a white cross on the way. The position of this point is displayed by the option box (x-Pos; and y-Pos) in the upper right corner. Right click on the fitted height map to pop up the topographic Map Display Settings.



Among them

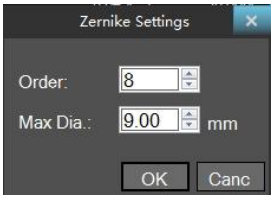
- Show Apex Position: solid white point represents apex position;
- Show Thinnest Location: the black border hollow point represents the thinnest point of the corneal thickness;
- Show Min. Rad. Pos. Front (Sag.): white solid diamond represents the maximum curvature point of the anterior surface of the cornea;
- Show Min. Rad. Pos. Back (Sag.): black border hollow diamond represents the maximum curvature point of the posterior surface of the cornea;
- Show Pupil Center: the white and black crosses indicate the center position of the pupil;
- Show Pupil Edge: the black and white dotted line represents the edge of the pupil;
- Show Max. Peak: White four-right intersection line indicates the position of the largest point on the topographic map;
- Show Nasal/Temp: the letters “TN” on the left and right sides of the topographic map: the temporal side and the nasal side, respectively, to facilitate differentiation and positioning;
- Show OS/OD: the mark "OS" at the top of the topographic map indicates the left eye, and the "OD" indicates the right eye for easy differentiation and positioning;
- Show Grid: The grid identifier is used to display radial and axial cross grids in the topographic map;
- Show Numeric values: Display the digital topographic map with a numerical value of 1mm in the radial direction.

The right upper corner is setting box:



1. By selecting the top drop-down box, select the anterior, posterior, full corneal switching of the corneal anterior and posterior corneal aberration analysis.

2. Click on the upper part of the settings box to set the Order of the Zernike fit and the pupil Maximum data Diameter.



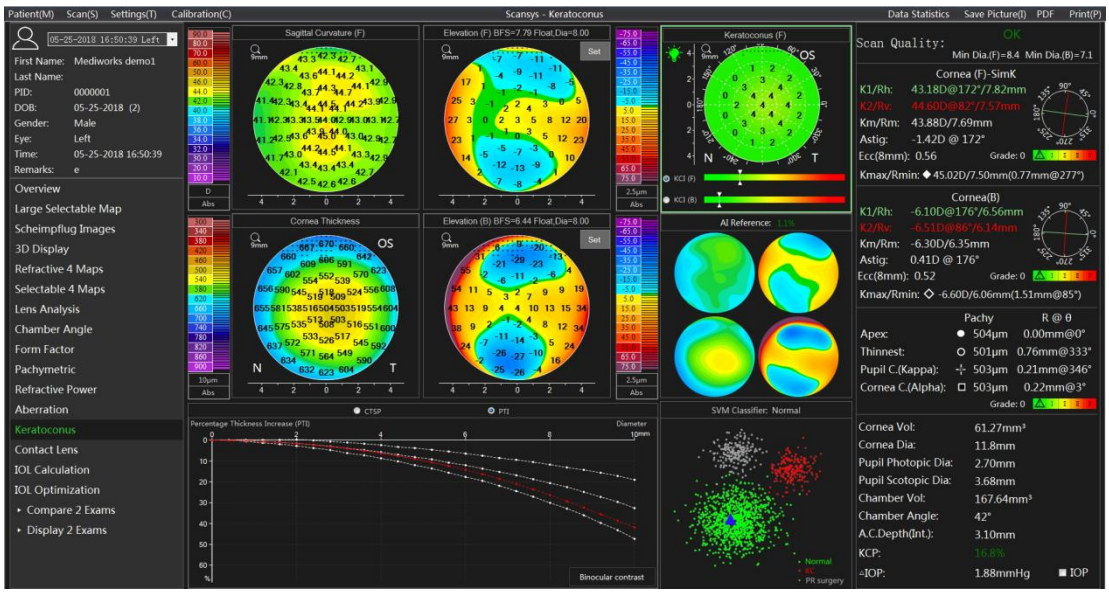
3. The four options in the upper left corner are low-order aberration, high-order aberration, full phase difference, and all the switch buttons are turned off. Of course, the user can manually click on a switch to determine whether the item participates in the data fit.

4. Mean and RMS means the average value and root mean square value of selected items.

At the far right of the interface are the Retinal Image, the PSF (Point Spread Function) distribution, and the MTF (Modulation Transfer Function) distribution graphs at 0 ° and 90 °. The introduction of these optical definitions and parameters more professionally describes the optical quality situation under the current aberrations (or combinations).

6.11 Keratoconus

Click on the "Keratoconus" module on the left and the following view appears.

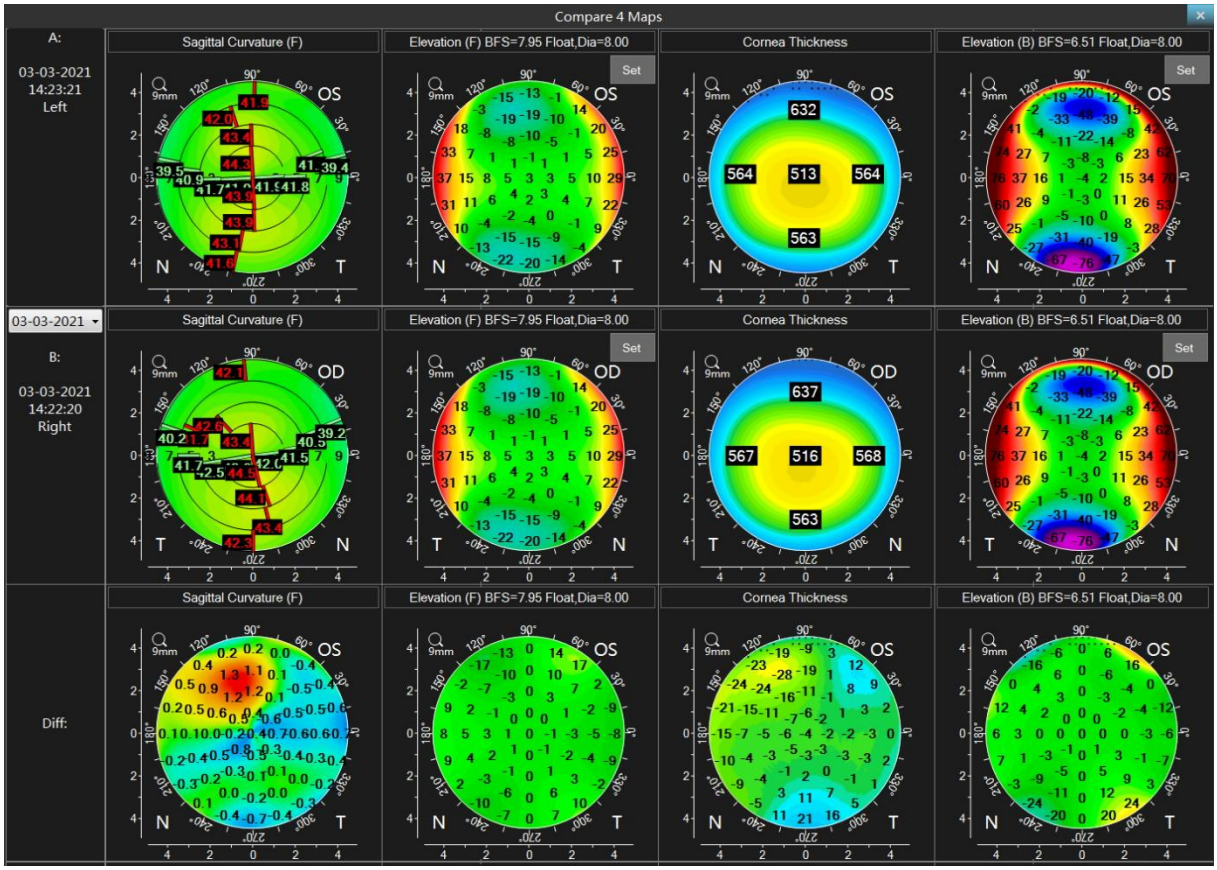


This section is mainly used to assist in the screening of keratoconus.

The above figure contains the topographic map of refractive 4 maps, and the trend distribution of the thickness map is also given. These are the key references for judging the keratoconus. The Scansys TA517 clinically collects a large amount of data from all over the world and introduces AI to intelligently distinguish all data in the four pictures and give the corresponding judgment result of keratoconus: AI Reference. Consider the severity coefficient (KCI) of keratoconus on the anterior and posterior surface of the cornea by the position of the cursor. At the same time, using the SVM method, the current case is classified into three categories: keratoconus, normal, and PR surgery through the selection of artificial feature vectors. The KCP parameter comprehensively considers all methods to give the possibility of keratoconus in the current case, and introduces the green, yellow and red non-polar color scale.

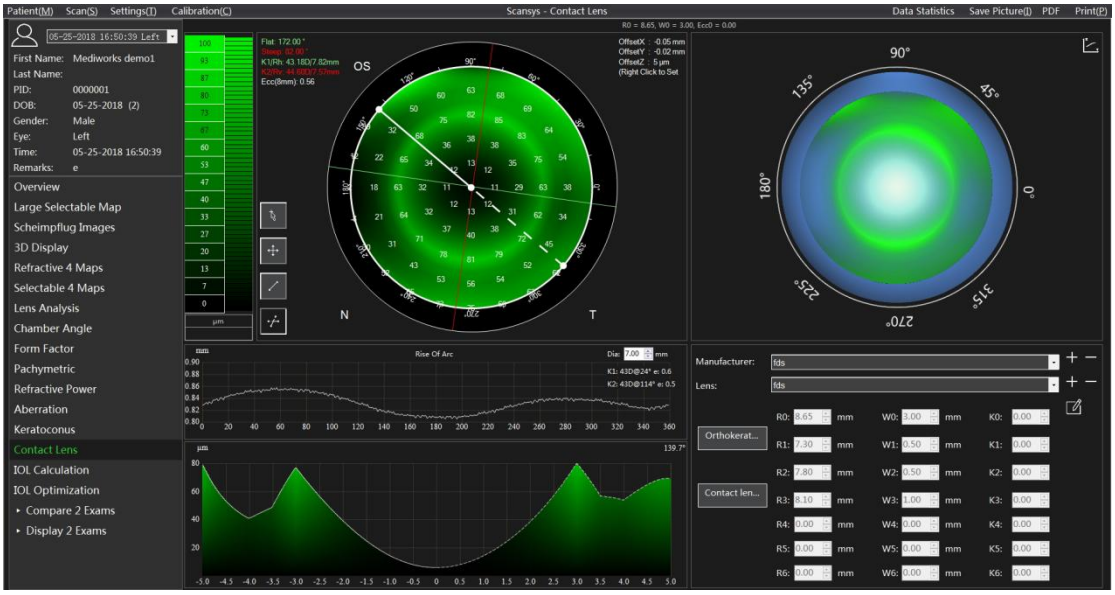
In order to give doctors more reference, click the icon below the AI Reference, and refractive 4 maps of the case with the sample set most similar to the current case feature vector will be displayed.

Under normal circumstances, the occurrence of keratoconus has binocular differences. Furthermore, The Scansys TA517 provides a binocular contrast function. Click the "Binocular contrast" button to obtain the compare 4 maps of the refractive 4 maps of the binocular after unifying the eye positions. As shown below:



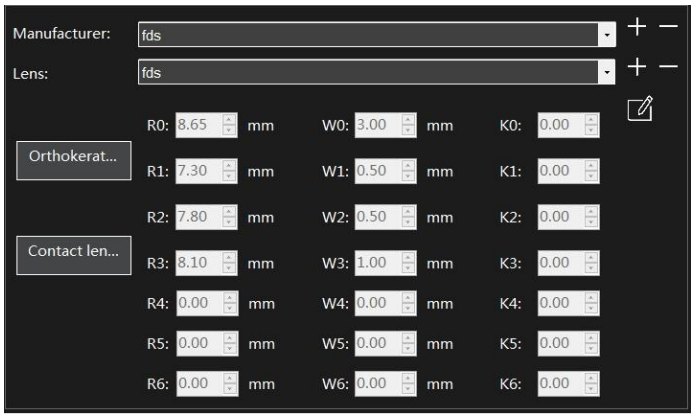
6.12 Contact lens

Click on the “contact lens” option in the left section to enter the contact lens fluorescence dyeing simulation system.

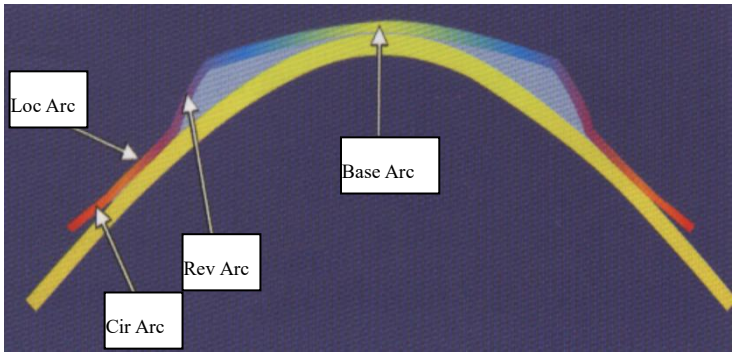


The Scansys TA517 system can collect detailed height data of the cornea, which is very helpful for the choice of contact lens. In order to simulate the suitability of the real wear, this section provides the fluorescence simulation of the patient wearing the contact lens. The basic parameters of the

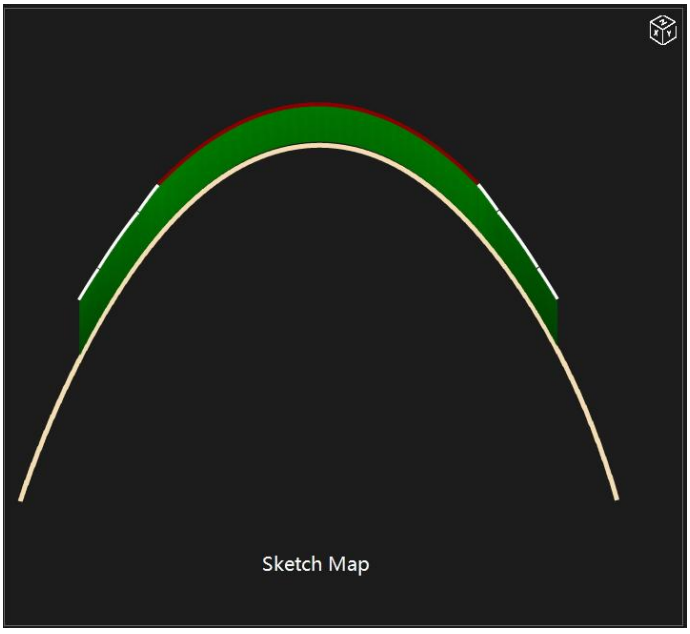
current lens base arc are displayed at the top of the right form, namely R0, W0, Ecc0.The lower right part of the interface is the lens data form.



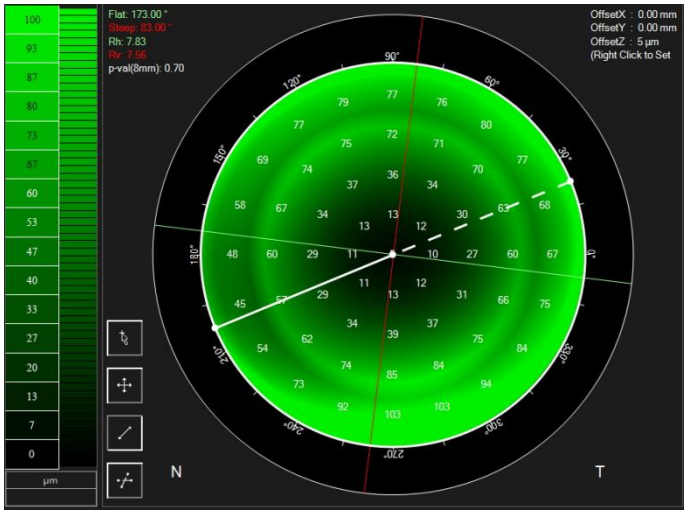
The user can choose the manufacturer and lens model in the database to simulate the patient directly, or can manually create new manufacturers and series of lens parameters. Scansys TA517 provides the user with at most 7-arc lens design form. The user can design the most suitable lens data for manufacturers according to their needs and patient corneal data and simulation results.



Where R represents the central radius of curvature of each segment of the arc, W represents the half width of each segment of the arc, and Ecc represents the eccentricity of each segment of the arc. When designing to change the lens parameters, the user can switch to the 2D schematic by clicking the icon  in the upper right corner of 3D simulation effect form in the upper right corner. Data changes in any arc of the lens will be highlighted on the schematic, which allows the user to more clearly understand the meaning of the detailed data of each segment of the arc, and the user will not easily mistake the data.

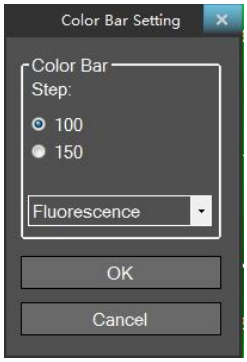


After editing the lens data and clicking the save button, the system automatically simulates the lens data and the wearing situation of the patient's cornea. At the upper left of the interface is image display of a fluorescent staining simulation of the tear thickness.



The program automatically calculates these values and represents them in a shaded green image, which can be inferred from the green bar graph. The upper left corner of the form gives the current K angle of the anterior surface of the patient's cornea (the green line in the 2d figure of the form), the steep k angle (the red line in the figure of form 2), the radius of curvature of the flat k, and the radius of curvature of the steep k. Value, and the Ecc value at 4 mm in the radial direction. These values can be used to know the choice or design of the lens data. The upper right corner shows the offset between the center vertices of the lens and the vertices of the cornea, which can be manually set by right-clicking. Click the color bar on the left side of the form to bring up the color bar setting option.

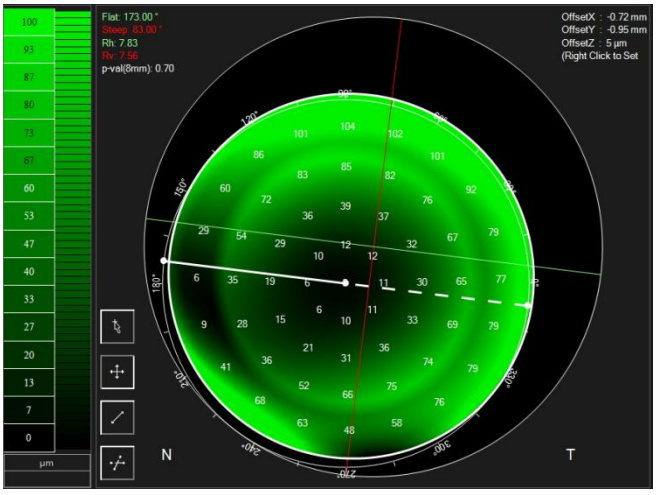
In this mode, the system provides two kinds of dyeing effects, namely fluorescent color and standard color, and two step options, 100 items and 150 items. The user can switch freely according to their preferences.



There are four function buttons below the form.

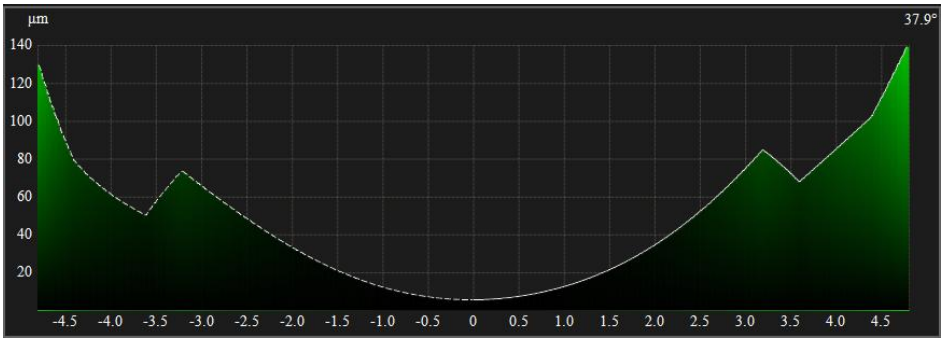
Activate  button: The value of the under-the-glass tear thickness at the current position can be viewed anywhere in the lens or cornea.

Activate  button: The user can drag the lens anywhere in the cornea, and the simulation will change at the same time.

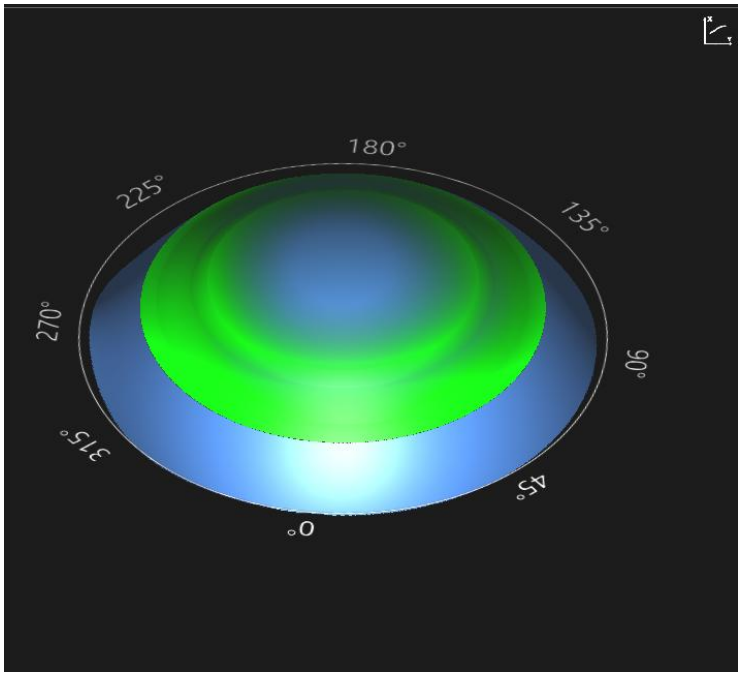


Activate  button: Measures the distance between any two points within the cornea on this form.

Activate  button: The user can use the mouse to drag the free line (white solid line + dotted line) in the main form to view the tear thickness distribution radically in this direction (default is flat k direction) under the arbitrary angle, display in the lower left form of the interface.



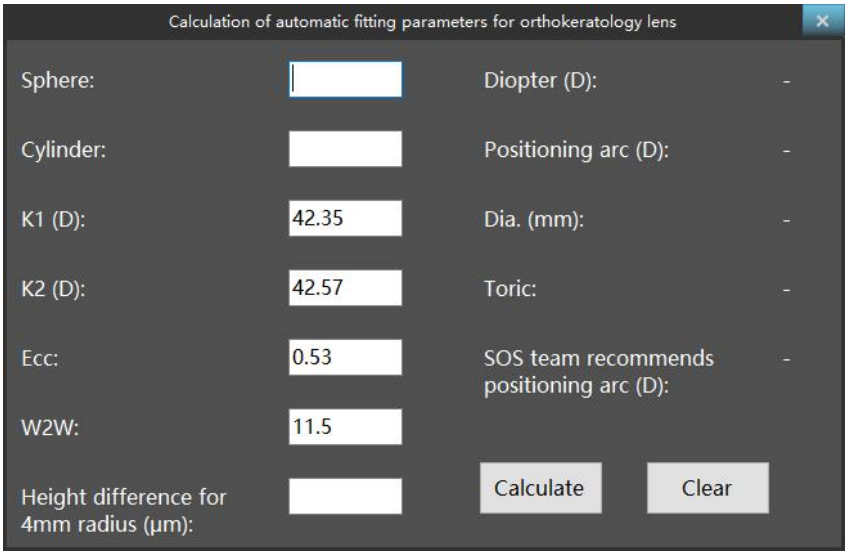
The top right of the interface is the 3D simulation wearing situation, and the simulation effect will follow the change of the lens position in the main upper left upper frame, making the wearing effect more intuitive, illustrative, real, and 3D wearing performance can be observed from any angle by dragging the mouse.

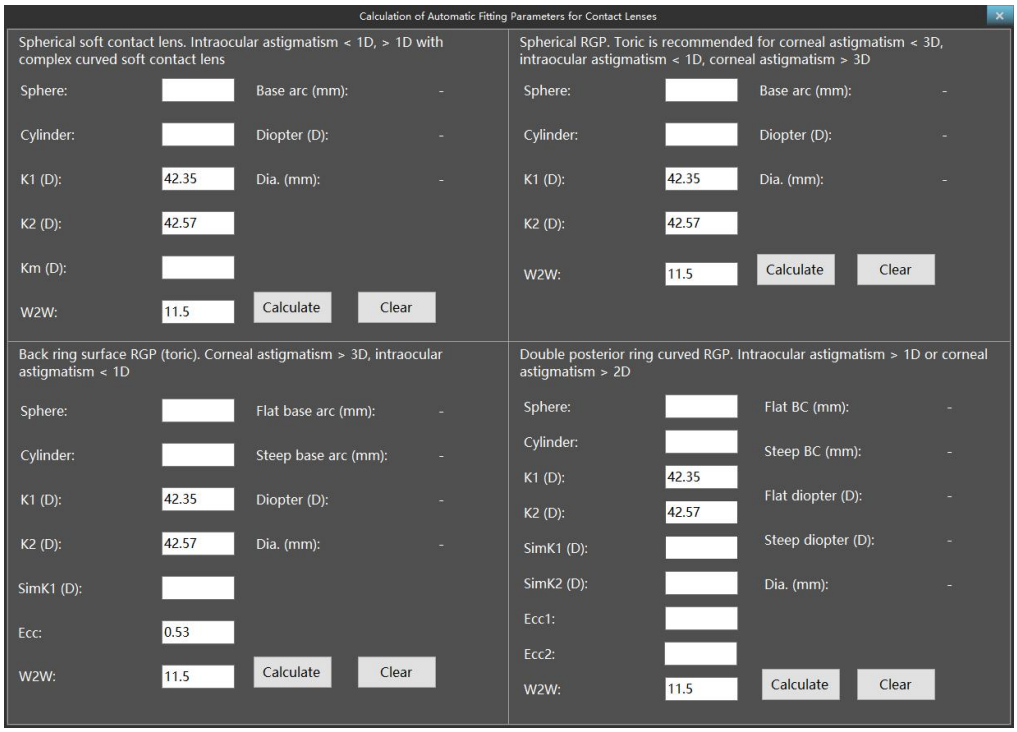


The simulation effect of the three forms is full of angles without dead angles. The user can judge whether the lens is suitable according to the comprehensive performance of the three forms to reduce the number of trials in the actual process.

In order to make it more convenient for customers to choose OK lens and RGP, The Scansys TA517 provides calculation of automatic fitting parameters for orthokeratology lens and calculation of automatic fitting parameters for contact lens. The user can automatically calculate the parameter configuration of the corresponding lens by entering the true refractive data.

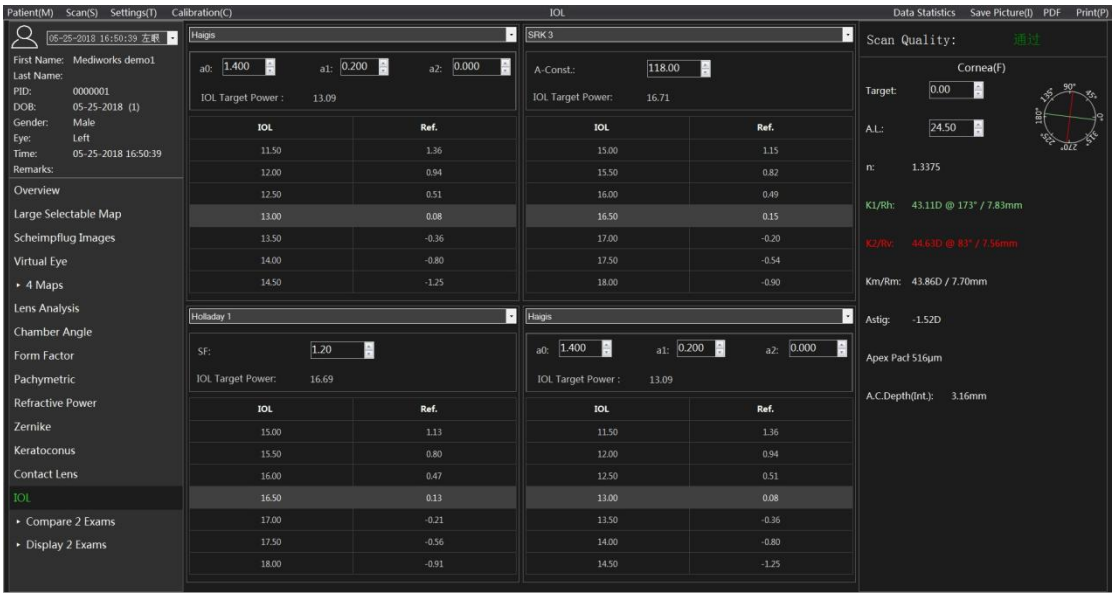
(The above application results are derived from the authorization and certification of Shanghai Research Center of Ophthalmology and Optometry (SRCO) of Eye & ENT Hospital of Fudan University).





6.13 IOL

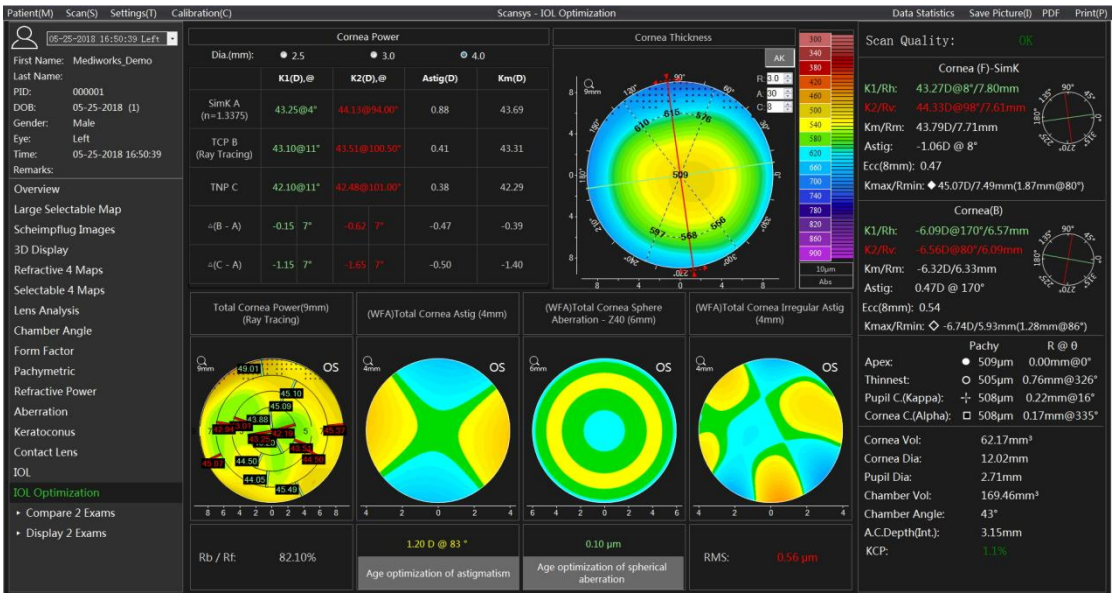
IOL is an optional purchasing module, user will see the interface below if successfully active this model when click “IOL” in the left section.



This module is aimed at calculating IOL power. We offered SRK1, SRK2, SRK3, Holiday1, Binkhorst2, HofferQ, Haigis etc. formulas to be selected by users, and the constant paras were offered by lens manufactures. The accurate IOL target power will be displayed in every table upper when users input target power and axis length in the up right corner, meanwhile IOL power(in 0.5D step) and Refractive power were listed one to one correspondence in the lower part of table.

6.14 IOL Optimization

“IOL Optimization” module is purchased separately. If there is no license for this function module, the module on the left side of the view is grayed out. If you have already purchased it, click on the "IOL Optimization" function module on the left, and the following view will appear:



The table on the upper left of the view gives the K1, K2, Km, and Astig values of the three types of corneal refractive power (Simk, total corneal power, true net refractive power), and the differences between them are calculated. The 2.5mm, 3.0mm, and 4.0mm in the setting items represent the collection diameter of corneal data.

Cornea Thickness is shown on the right side of the table. Click on the upper right corner to switch to AK mode. At this time, the topographic map shows the radius R (adjustable), the thickness average and boundary value on the circle of the cut angle A (adjustable). The parameter C represents the cut angle and is associated with the green line in the figure. By default, the red and green axes are the same as the K1 and K2 axis angles of the current case. You can also drag the dashed arrow at the border of the red axis to manually change the angle position.

The first image below shows the topographic map of total corneal refractive power in the range of corneal diameter 9mm, and Rb / Rf represents the posterior anterior corneal radius ratio.

The second image shows the total corneal astigmatism aberration (Z2, ± 2) in the range of 4mm corneal diameter. The values below are the actual calculated values and azimuth angles for this parameter in the current case.

The third image shows the total corneal spherical aberration (Z4, 0) in the range of 6mm corneal diameter. The lower value is the actual calculated value under this parameter in the current case.

The fourth image shows the total corneal irregular astigmatism within a range of 4 mm in corneal diameter. The lower value is the true RMS value of this parameter for the current case.

This module is specially designed for the “IOL Optimization" of refractive cataract surgery. It provides professional data and analysis support for solving spherical refractive errors, astigmatism, spherical aberration, and presbyopia in cataract surgery.

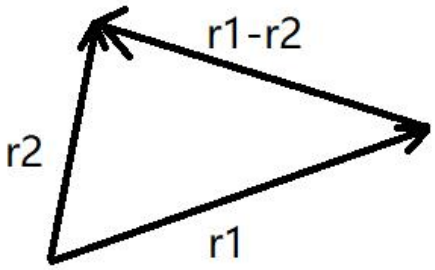
6.15 Compare 2 exams

Click the “Compare 2 Exams” function button in the left interface, which is divided into two options: Information and Maps.

6.15.1 Information difference

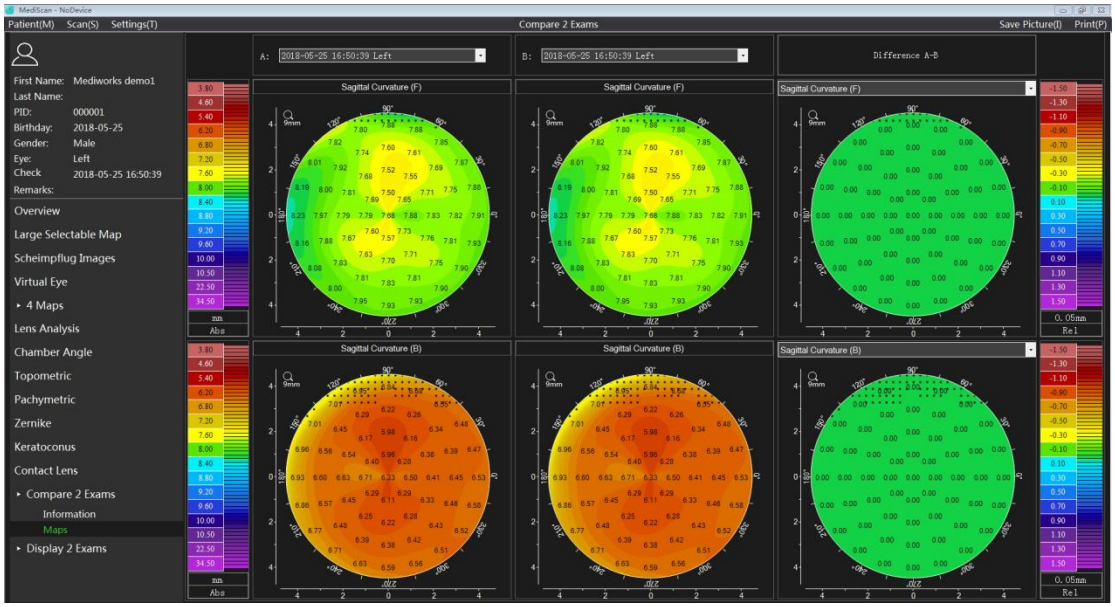
Information difference is shown as following

The user can select the cases to be compared in columns A and B. The column AB shows the difference of each detailed parameters, including the characteristics of the anterior surface of the cornea, the characteristic data of the posterior surface of the cornea, the thickness data, and the comprehensive data of the anterior segment, so the user can view the patient's case data difference before surgery and post-surgery. Or they can see the difference in any circumstance. It should be pointed out here that vector difference is used when calculating the position difference, instead of the corresponding subtraction of r and θ. In the specific calculation, the polar coordinate representation is first converted into a rectangular coordinate representation, and then the corresponding difference is calculated, and then converted into a polar coordinate expression.



6.15.2 Maps difference

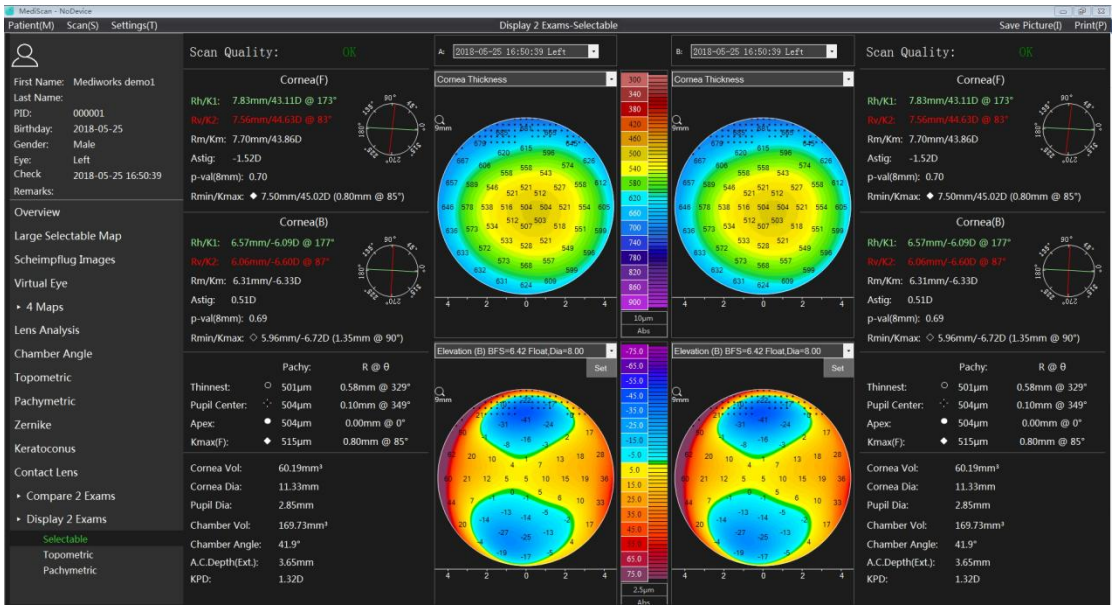
As shown below



Also select the cases to be compared in columns A and B, and the A-B column shows the difference between the maps. This interface also provides a comparison of two types of topographic maps, which can be switched between A-B columns. Then, the A and B columns will be followed by the topographic maps that need to be compared. The color bars of the Difference column and the columns A and B are independent of each other and can be set separately.

6.16 Display 2 exams

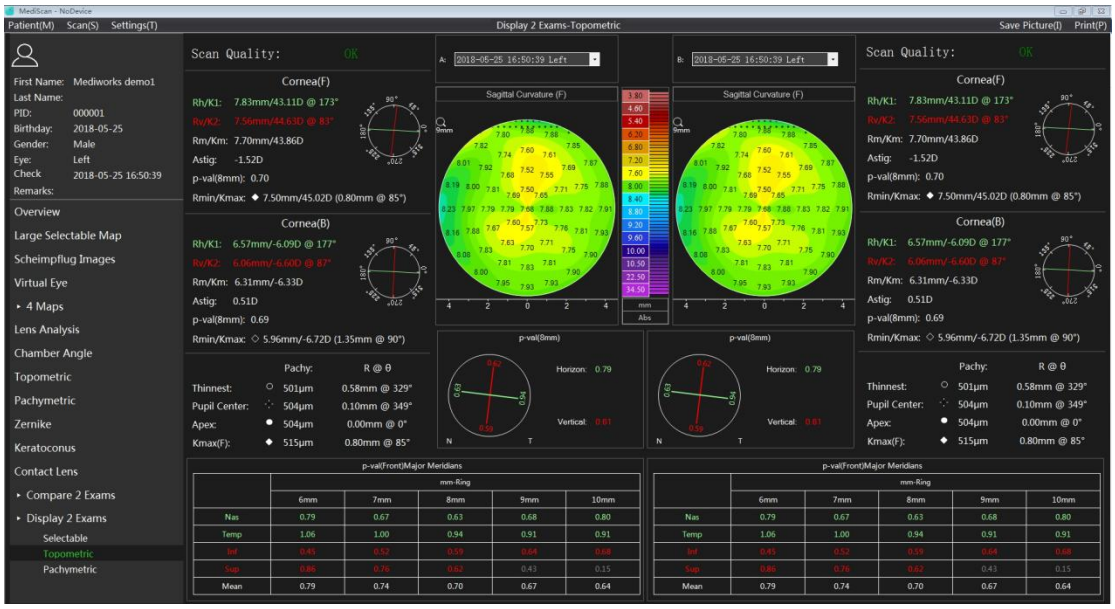
Click the “Display 2 Exams” section on the left side of the interface to compare the eyes or compare the same eye to check the results at different times. The section is divided into three options, which are “Selectable”, “Topometric”, and “Pachymetric”. When "Selectable" is selected, the effect chart is as follows



The user can open any two cases of data in columns A and B. This display mode can provide comparison and contrast of two alternative topographic maps, including corneal anterior surface feature data, posterior corneal surface feature data, thickness data, and other data in the anterior segment.

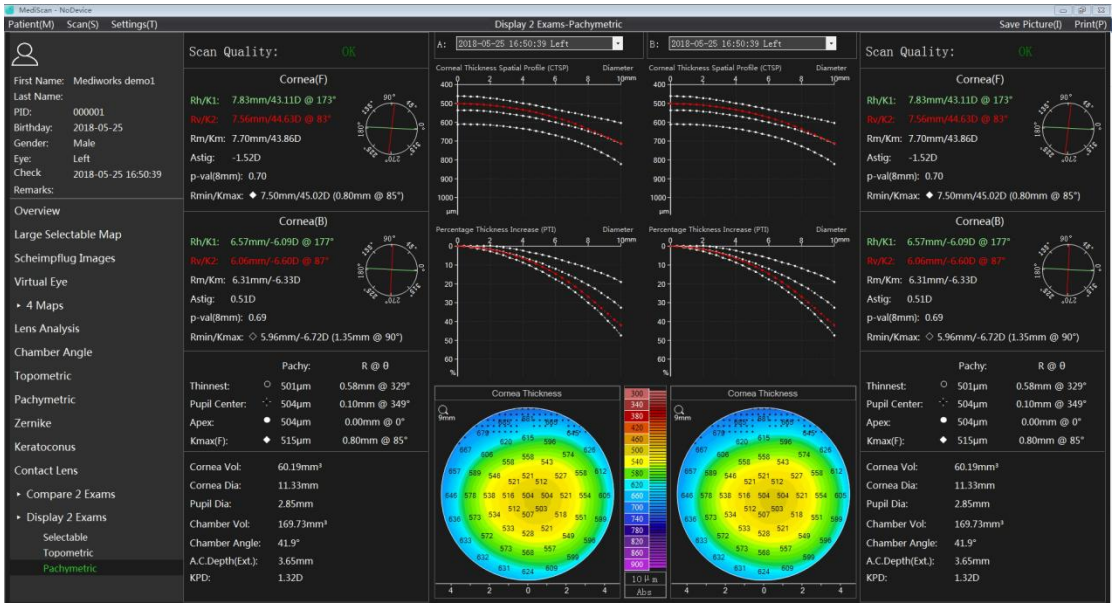
The two color maps in the middle of the screen are associated. Changing any topographic map type or right-clicking to change the Topometric map settings will affect the same change on the opposite side, and both maps use the same color scale bar. When the left mouse button moves anywhere on the topographic map to obtain the corresponding value at that location, the other topographic maps also display the value of the type of topographic map at the same location.

When "Topometric" is selected, the effect chart is as follows



The purpose of this contrast display option is to provide detailed corneal analysis and contrast for refractive and contact lenses.

When "Pachymetric" is selected, the effect chart is as follows



This option is used to compare the thickness of two eyes or the thickness of the same eye at different times. The detailed parameter meaning refers to the parameter interpretation in the Pachymetric section.

7. Product Installation

Before installation. Carefully remove all parts from the shipping container, then install.

7.1 Assembly of the Scansys TA517

Open the Anterior Segment device box and carefully remove all parts (see table below) from the shipping package and install them;

Serial No	Accessory name	QTY
1	Scansys TA517 Anterior Segment Instrument	1
2	Chin rest	1
3	Rack and pinion cover	1
4	Power cord, data cable	1
5	Dust cover	1
6	User Manual	1

Scansys TA517

Chin rest

1. Under the bottom plate, fasten the bottom end with two screws using a hex key, attach the chin support bracket with the bottom plate (see the figure below).

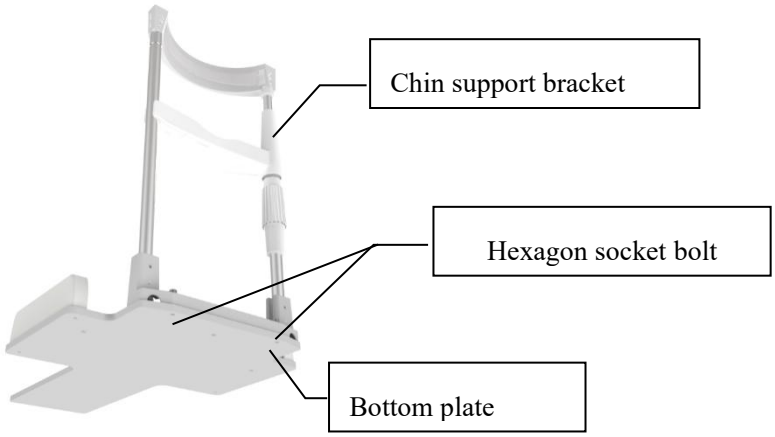


Figure 7.1.3

2. Take the main device out of the box and place it on the instrument table. Place every pinion on both sides of the rack. Please keep the distance between each pinion to the end of the rack rail as same as possible. Loosen the Base locking screw (see Figure 7.1.4), put the rack and pinion cover, and then push it in the direction of the rack rail until the pinion hits the end of the rack cover. Check if each pinion on both sides touches the end of the rack cover. If one of them has a distance, remove the cover and re-position the pinion on the rack rail until the same end of the rack cover is reached for every pinion. Then gently push the base back and forth to check whether the roller can smoothly

roll back and forth on the rack rail to make sure there is no problem with the base movement, and then tighten the base locking screw to lock the base (see Figure 7.1.5).

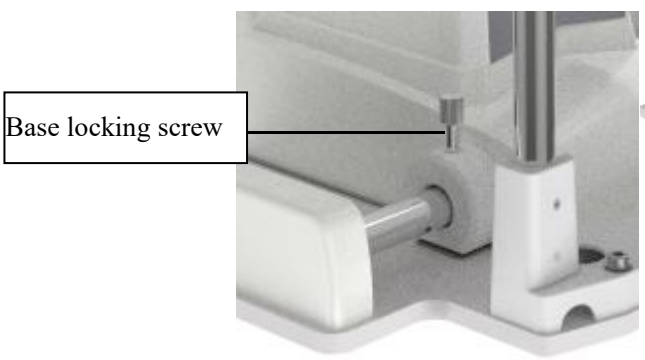


Figure 7.1.4

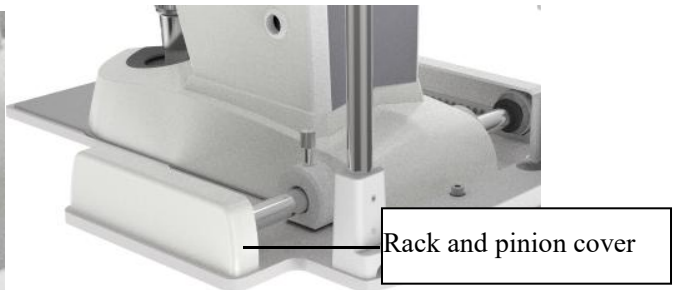
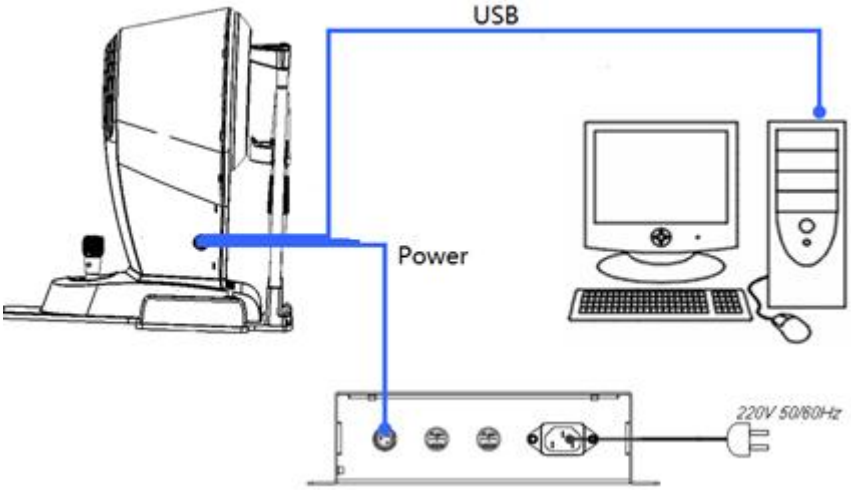


Figure 7.1.5

7.2 Device connection

The data cable connection method is as shown below



a) Please follow the connection method listed on the schematic installation diagram to connect the Scansys TA517 host and computer host with the data cable;

b) After installation, open the power box fuse box and confirm that the fuse is installed inside. The fuse size is F1AL250V.

c) Arrange the tools used in the installation and the spare parts in the box and place them in the drawer at the bottom right of the table top assembly.

⚠ **Attention: The wrongly installation of data cable of the Scansys TA517 may cause equipment damage. Please make sure all connections are correctly connected.**

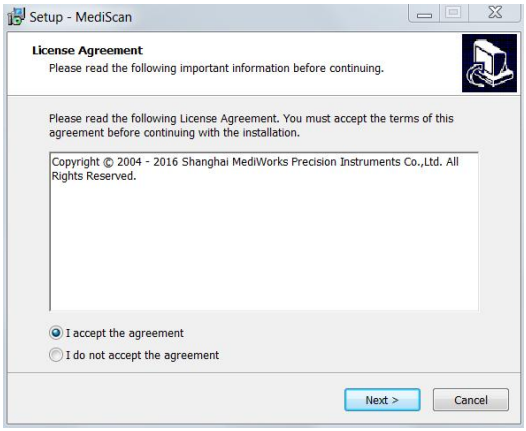
7.3 Software installation and registration

7.3.1 Software installation

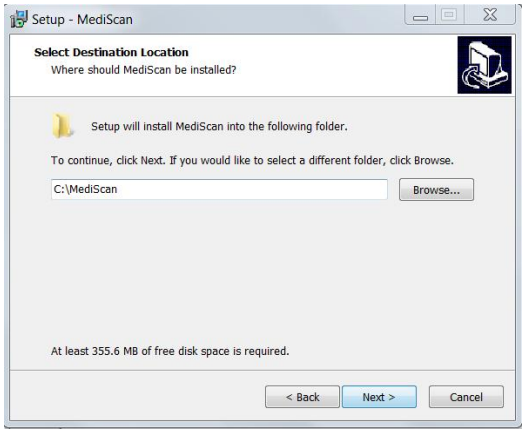
1. According to the 32/64 bit system, select the corresponding installation software. If the software installation file name has x64 type, it is 64-bit installation software; if it has x86 type, it is 32-bit installation software.

2. Double-click the software installation package. The pop-up interface is as follows. The user can choose to install the Chinese or English language.

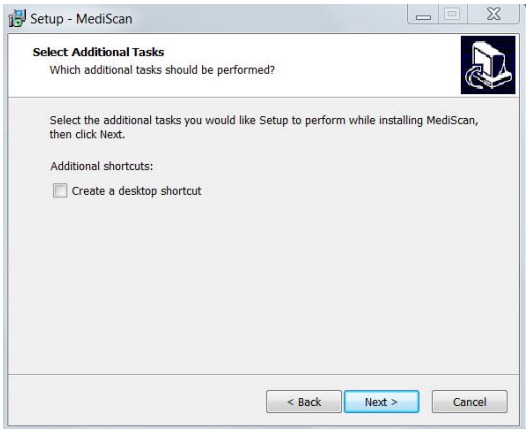
3. After selecting the installation language, click “OK”, the pop-up interface is as follows, select “I agree the agreement” and click “Next”.



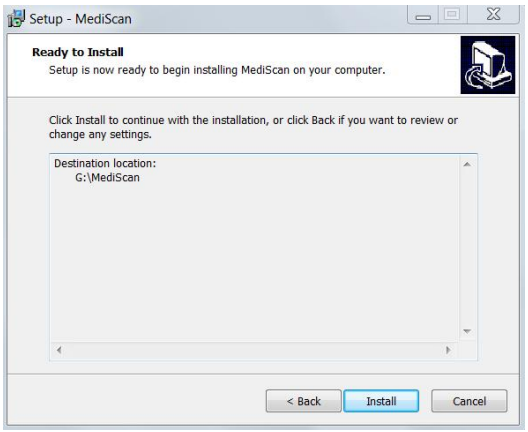
The following interface pops up, select the installation path as needed, and click “Next”.



4. The “Select Extra Task” window pops up. The user can confirm whether to select “Create icon on the desktop” as needed. It is recommended to check “Create desktop shortcut” and click “Next”.



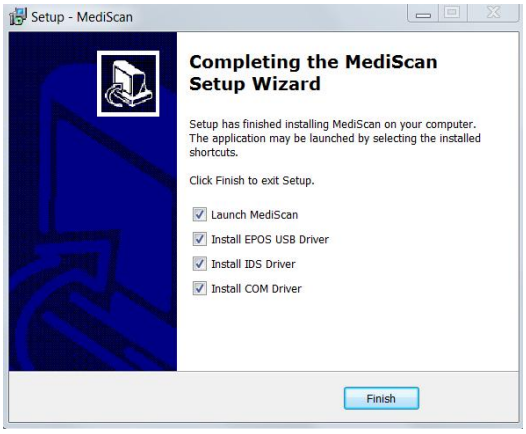
5. Continue to click "Install".



6. The installation screen pops up. Please wait for a while.

7. After the software installation is completed, the following interface pops up. If the user is installing for the first time, they must check the "Install EPOS USB Driver", "Install IDS Driver" and "Install COM Driver" options, click "Finish" to start installing the driver software; if it is not the first

time, uncheck the above Option, the user can directly select "Launch Scansys" and open the software. If the software is not registered, please refer to 7.3.2 Software Registration.



8. The pop-up interface is as follows, check "I agree to the license terms and conditions" to start the installation process;

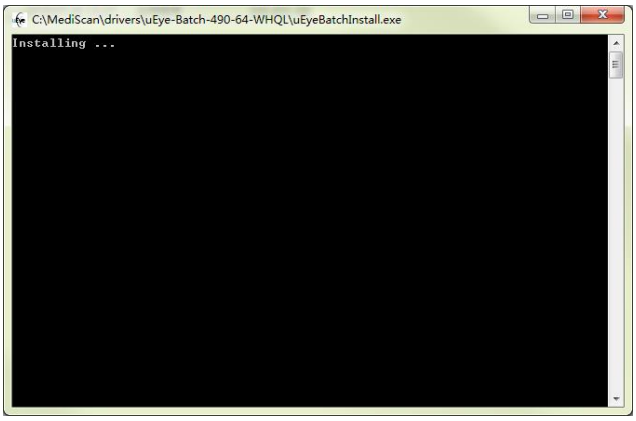
If the prompt interface pops up, just click "Close" and confirm the cancellation.

9. After the installation successful interface pops up, click the "Close" button.

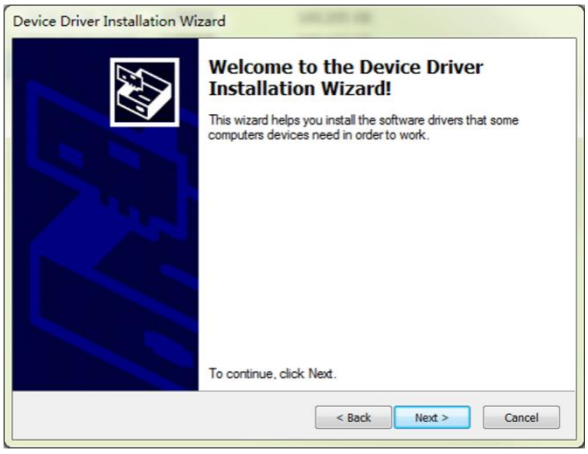
10. The “Device Driver Installation Wizard” interface pops up, click “Next”.

11. The following interface pops up to indicate that the current driver installation is successful. Click the “Finish” button.

12. The following interface pops up and waits for a while.



13. The following interface pops up, click “Next” and wait for a while.



14. The installation success interface pops up. Click “Finish” and the software installation is successful. If the software has not been registered, Please refer to 7.3.2 to register software.

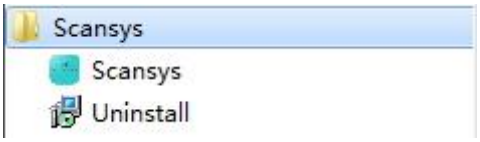
7.3.2 Software registration

Attention：

1).The software must have been successfully registered once Scansys TA517 system works.

2).The Registration license is unique corresponding to computer and instrument, so you need to re-register if software is installed on another computer.

1. Open the Scansys software from the desktop (when the icon is created on the desktop), or select “Scansys” under “Scansys” folder in the start menu, as shown below



2. If the software has not been registered or not registered successfully, the program will pop up prompt

Click "OK" to open the registration software, the interface is as follows, or you can activate it on the directory path ~:\Scansys\Register\Scansys_Register.exe

3. If you only want to activate the software just select No Device , and if device is also need to be activated you should make sure the device power on and connects computer well, then select Have Device. Click the “Get Request Code” button and the corresponding application code will be displayed in the text box of the interface, as shown below. It should be noted that the computer and device that obtained the application code and the computer and device that applied for registration must be the same.

4. Click the “Copy” button or manually copy the application code in the text box and send the application code to our staff via email.

5. After receiving the certificate file sent by the company's staff, open the registration software again, as described above. Click the "Register" button, the "Select Certificate File" interface will pop up

6. After selecting the certificate file, click the “Open” button. If the failed prompt interface pops up, the registration fails. Please confirm whether the registered computer and device and the computer that obtained the application code are the same, and whether the certificate file is selected incorrectly. If the confirmation is correct, please contact the relevant staff of the company.
If the success prompt interface pops up, the registration is successful. After clicking the "OK" button, the Scansys software should be able to use.

7.4 Operation precautions

1. During the operation, the operator should first understand the contents of the User Manual and master the structure and function of the Scansys TA517, so that correct operation and diagnosis can be performed.
2. During the operation, the different scales and different indication marks corresponding to the various knobs at different positions should be observed clearly, to prevent unnecessary misjudgments during the observation.
3. When the patient is examined by the Scansys TA517, a beam of slit lamp light is applied to the patient’s eyes. The long-term exposure may temporarily affect the patient's visual observation effect. If the patient feels uncomfortable, please inform the operator or actively seek help. Therefore, try to avoid illuminating the patient's eyes for a long time under strong light.
4. The chin support bracket has a bearing capacity of 6kg and factor of safety is 4 times.

8. Product Maintenance

8.1 Methods of cleaning

1. Clean the lens: If dust adheres to the lens, gently wipe it off with soft cotton dampened with absolute alcohol (see Figure 8.1.1).Note: Do not wipe with fingers or other hard objects.

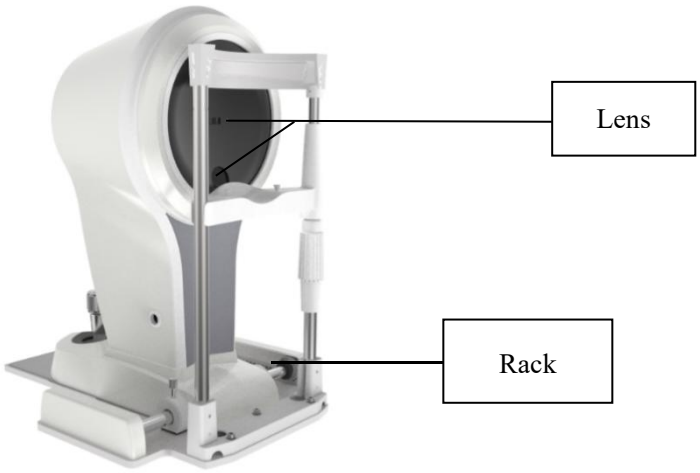


Figure 8.1.1

2. Cleaning the pads, rails, and shafts: If the pads, rails, and shafts are not clean, the horizontal and vertical movements will not be smooth. Wipe clean with a clean soft cloth (see Figure 8.1.1).

3. Clean and disinfect plastic parts: Clean plastic parts such as chin support brackets, forehand strap, etc. Use a soft cloth dampened with soluble detergent or water to clean the dirt, then wipe with medical alcohol. Note: Do not wipe with any corrosive detergent to avoid damaging the surface.

4. Clean the instrument table: Use a soft cloth dampened with a soluble detergent or water to clean the dirt. Do not use any corrosive detergent to avoid damaging the surface.

5. Clean the computer parts: Wipe with a clean, soft cloth. Do not use any corrosive detergent to avoid damaging the surface.

6. Replace chin rest paper：Pull out the two catches and put new chin rest papers on the chin rest, and then push in catches.

8.2 Product cleaning cycle

The Scansys TA517 Anterior Segment Analyzer system be used in a relatively clean environment. To ensure the normal use, and its ability of observation, operator should clean the Scansys TA517 regularly. The cleaning cycle is recommended as follows:

- For the turntable lens part: Cycle: It is recommended to clean it once every 2 months. Since the lens has an anti-reflection film and a reflection film, although the coating is sufficiently strong, frequent wiping tends to cause damage to the film, thereby affecting the optical effect of observation. This cycle is only a suggestion. If there is a lot of dust adhering to the lens that has affected the

quality of the observation, it is recommended to clean it immediately according to the prescribed method.

- For moving sliding plate, rails and shafts: Cycle: It is recommended to clean it once every month. The use of Scansys TA517 in a relatively clean environment in a hospital will not cause the sliding plates, rails and shafts to be unclean in a short period of time (within 1 year), nor will it affect the horizontal and vertical movement of the moving sliding plate. However, we still recommend that you clean the above parts with a clean soft cloth every 6 months for better movement and positioning.
- For chin support brackets, forehead strap and other plastic parts: Cycle: It is recommended to do it once after one patient exams done. These two parts are in frequent contact with the inspected patient. They should be cleaned and disinfected in time. The cleaning and disinfection cycle is only our recommendation; the forehead towed part should also be cleaned and the chin support bracket paper should be replaced after one patient exams done. Both parts should be cleaned and disinfected before the daily first use.
- Cleaning the instrument table components: Use a soft cloth dampened with a soluble detergent or water to clean the dirt. Do not use any corrosive detergent to avoid damaging the surface.
- For the whole device Cycle: It is recommended to clean it every 2 months.

8.3 Replace fuse

The Scansys TA517 is not a permanent installation device. According to the design specifications of the circuit, the electrical current rating can be determined. There is a clear fuse specification on the fuse location of the instrument power box. Once the fuse is blown, the user can replace the spare fuse. After the spare fuse is used up, it needs to be purchased from our company.

Attention: Turn off the main power switch when replacing the fuse, and unplug the input power cord from the power outlet (very important)!!!

The fuse of the Scansys TA517 is located in the 2 black fuse boxes in the middle part of the power box panel. The fuse type is F1AL250V. Press and hold the plug with a screwdriver or a coin. Rotate to remove the fuse and extract the fuse in use to see if it is intact. If it cannot be used, use the new fuse to replace the old one. All accessories should insert back into place after the replacement is completed.

⚠ Note: Please replace the fuse of the same model, specification and rating in strict accordance with the above requirements.

9. Troubleshooting

If a fault occurs, please check the following table for guidance. If the fault has not been eliminated, please contact MediWorks or its authorized distributors. The minor computer malfunction can also be resolved by contacting the computer supplier's customer service.

Fault	Possible Causes	Solution
Power supply does not provide power	The power cord is not properly connected to the power outlet.	Connect the power cord correctly.
	The main power switch is in the O position.	Place the switch in the I position.
	Loose plug on the power supply. box	Press tight the plug.
	Fuse blown.	Replace the fuse.
The Scansys TA517 malfunction	Please refer to the user manual.	Refer to user manual for troubleshooting, or contact the MediWorks or its authorized distributors.
Computer malfunction	Please refer to the manual of the Microcomputer.	Contact with MediWorks or its authorized distributors, or contact the computer supplier's customer service.
Software failure	Please refer to the user manual for reference information.	Please refer to the user manual for detailed solution, or contact MediWorks or its authorized distributors.
Lifting station malfunction	Power supply is not connected correctly or wrongly installation.	Follow the lifting station installation steps to check if the power supply is properly connected or contact MediWorks or its authorized distributors.

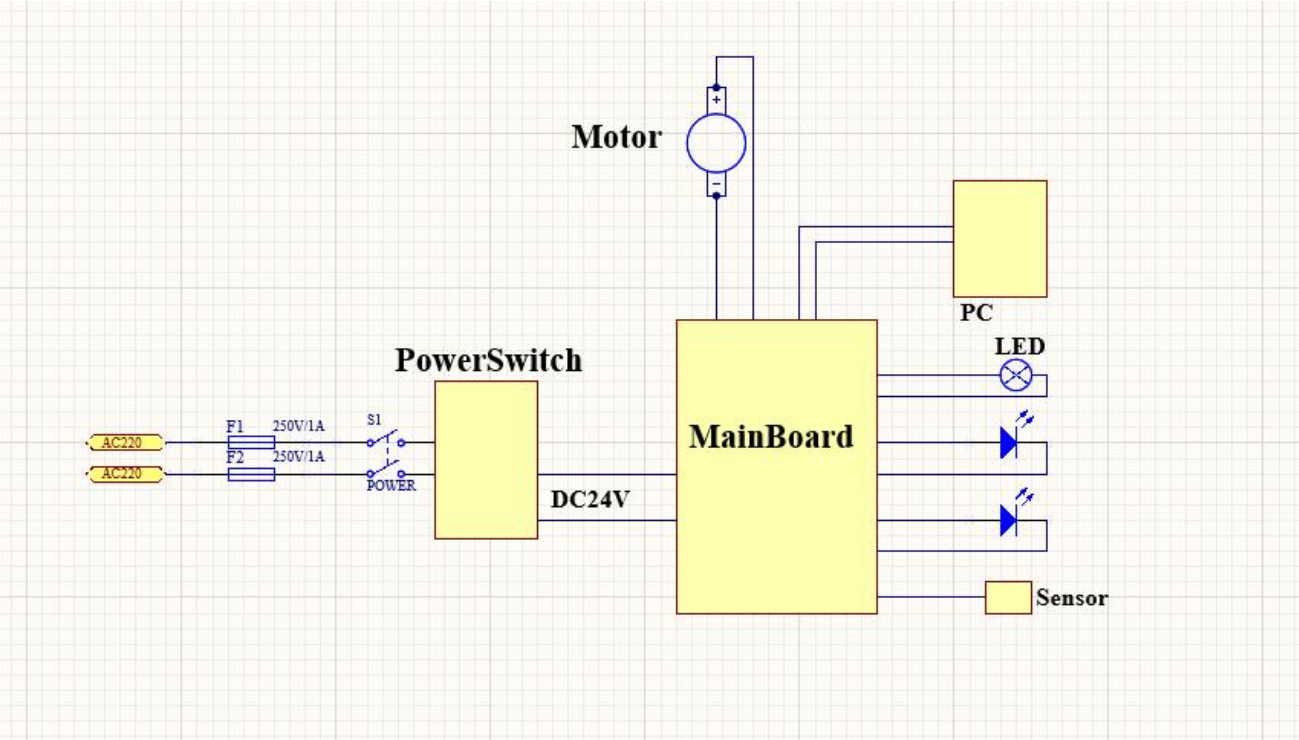
10. Final Disposition

This mark  is on the label. It means the product can't be disposed like the domestic garbage. It must be disposed according to the local laws and regulations.

If you have any questions, please connect with MediWorks or its authorized distributors.

11. Electricity Schematic

The electrical schematic is shown in the figure below.



Service Life：8 years 1

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