Optical Biometer
User Manual

Model: AL550, AL551, AL552

Shanghai MediWorks Precision Instruments Co., Ltd.

Contents

Preface

Thank you for choosing the optical biometer produced by Shanghai MediWorks Precision Instruments Co., Ltd.

Below is an overview of some basic facts and feature parameters of this product.

Overview

This manual is an integral part of the optical biometer and contains instructions for use and technical specification. The manufacturer information is listed on the last page of this manual.

This manual consists of user instructions and technical specification. The equipment classification of the optical biometer according to IEC 60601-1-1 standard is also included in this manual.

The applicable marks specified in IEC 60601-1-1 have been permanently affixed to the device, and are explained in this manual.

This product provides auto positioning of the pupil, corneal topography capturing, saving, real-time observation, analysis and calculation, as well as axial thickness measurement of intraocular multi-layer parts.

This is a Class 1 laser product.

The laser may radiate to the human eye and should not be directed at the human eye for more than 2 hours.

Structure and Composition

This product is composed of the main device, chin rest, power cord and software (release version: R1.1).

Scope of Application

The product is intended for the ocular measurement of corneal thickness, anterior chamber depth, lens thickness, axial length, vitreous thickness, axial angle, white-to-white distance, pupil diameter, and corneal curvature topography, as well as for the IOL power calculation of the requested intraocular lens to be implanted in the eye.

Intended Population

This product is suitable for adults or children with fixed vision, and requires that the patient's eye is free of vitreous hemorrhage, retinal detachment, and other diseases that make measurement by optical methods impossible.

Contraindications

No known contraindications.

Main Safety Features of the Product

Classification of the type of protection against electric shocks	Class I equipment
Classification of the degree of protection against electric shocks	Type B applied part
Classification of the degree of protection against harmful liquid	IPX0
Classification of the degree of safety when used in a flammable anesthetic mixture with air, or a flammable anesthetic mixture with oxygen or nitrous oxide	Non AP/APG equipment
Operating mode	Continuous operation
Rated voltage and frequency of the equipment	~ 100 - 240 V, 50/60 Hz
Rated power of the equipment	180 VA
Whether the equipment has defibrillation-proof applied parts	No
Whether the equipment has signal output or input	Yes
Permanently or non-permanently installed equipment	Non-permanently installed equipment

Performance Parameters

Projection ring diameter	> 9.8 mm
Radius of curvature	32.14 dpt - 61.36 dpt (5.5 mm - 10.5 mm)
	Precision: ± 0.1 dpt (± 0.02 mm)
White-to-white range	8 - 16 mm, tolerance: ± 0.1 mm
Principal meridian direction	0 - 180°, tolerance: for principal meridional differences in radiiof curvature ≤ 0.3 mm: ± 4° for principal meridional differences in radii of curvature > 0.3 mm: ± 2°
Pupil diameter	1 - 13 mm, tolerance: ± 0.1 mm
Left and right eye (OD&OS) recognition	Automatic
Axial length	Maximum measuring length: 40mm, tolerance: ± 10 μm, resolution: 1 μm
Corneal thickness	0.2 - 1.2 mm, tolerance: ± 10 μm, resolution: 1 μm
Anterior chamber depth	0.7 - 8 mm, tolerance: ± 10 μm, resolution: 1 μm
Lens thickness	1.5 - 6.5 mm, tolerance: ± 10 μm, resolution: 1 μm
Corneal thickness	0.2 - 1.2 mm, tolerance: ± 10 μm, resolution: 1 μm
Adjustment range	Travel range: X direction (left/right): ≥ 90 mm; Y direction (forth/back): ≥ 60 mm; Z direction (up/down): ≥ 30 mm. Chin rest (up/down): ≥ 60mm
Service life	8 years
Display	10.1" touchscreen
Power supply	~ 100 - 240 V, 50/60 Hz

Focus mode	One-click operation, auto focus and measurement in X,Y and Z directions
Placido light source	Dual mode, 850 nm infrared LED and 620 nm red light
Wavelength of the light source for axial measurement	1000 - 1150 nm
Data output	USB, Wi-Fi
Image format	JPEG
Data interface	USB, DP
Radiation output	The wavelength range of the light source used by this equipment to measure each intraocular interference surface is 1000 - 1150 nm. Its light power projected on the cornea is less than 1.5 mW and is Class 1 laser.

Product Models

Model / Performance Indicator		AL550	AL551	AL552
Axial length measurements		Applicable	Applicable	Applicable
Corneal thickness measurements		Applicable	Applicable	Not applicable
Anterior chamber depth measurements		Applicable	Applicable	Not applicable
Lens thickness measurements		Applicable	Applicable	Not applicable
Corneal topography	Area measurement	Applicable	Applicable	Not applicable
	Sample density measurement	Applicable	Applicable	Not applicable
	Performance measurement and reports	Applicable	Applicable	Not applicable
	Results shown in colors	Applicable	Applicable	Not applicable
Radius of curvature measurement		Applicable	Applicable	Applicable
Measurement of principal meridian direction		Applicable	Applicable	Applicable
Pupil diameter measurement range		Applicable	Applicable	Applicable
White-to-white measurement range		Applicable	Applicable	Applicable
Projection ring diameter		Applicable	Applicable	Not applicable
Software Features				
Settings	General	Applicable	Applicable	Applicable
	Date and time	Applicable	Applicable	Applicable
	Network	Applicable	Applicable	Applicable
	Report	Applicable	Applicable	Applicable
	Capture	Applicable	Applicable	Applicable
	Corneal topography	Applicable	Applicable	Not applicable
	DICOM	Applicable	Applicable	Applicable
	Third-party software	Applicable	Applicable	Applicable
	Refractive index	Applicable	Applicable	Applicable
	Contact lens management	Applicable	Applicable	Not applicable
	Account	Applicable	Applicable	Applicable
	Storage	Applicable	Applicable	Applicable
	About	Applicable	Applicable	Applicable
Patient information management	Add patients	Applicable	Applicable	Applicable
	View patients	Applicable	Applicable	Applicable
	Edit patients	Applicable	Applicable	Applicable
	Export data	Applicable	Applicable	Applicable
	Third-party software	Applicable	Applicable	Applicable
Record	Create new records	Applicable	Applicable	Applicable

management	Delete records	Applicable	Applicable	Applicable
	View records	Applicable	Applicable	Applicable
Capture	Automatic image data capture	Applicable	Applicable	Applicable
	Manual image data capture	Applicable	Applicable	Applicable
Corneal topography and axial measurement	Overview	Applicable	Applicable	Applicable
	Topographic maps	Applicable	Applicable	Not applicable
	Four maps	Applicable	Applicable	Not applicable
	Shape factor	Applicable	Applicable	Not applicable
	Zernike	Applicable	Applicable	Not applicable
	Contact lens	Applicable	Applicable	Not applicable
	Pupil & Cornea	Applicable	Applicable	Applicable
	Axial measurement	Applicable	Applicable	Applicable
	IOL calculation	Applicable	Not applicable	Not applicable
	Comparison	Applicable	Applicable	Applicable
	Report	Applicable	Applicable	Applicable

Weight and Dimensions

Dimensions: 297 mm (L) x 546 mm (W) x 583 mm (H)
Weight: 25 kg

Operating Environment

Temperature	+5℃ ~ +40℃
Relative humidity	≤ 80%, no condensation
Atmospheric pressure	800 hPa ~ 1060 hPa

Storage and Transport Environment

Temperature	-40℃ ~ +55℃
Relative humidity	≤ 90%, no condensation
Atmospheric pressure	700 hPa~1060 hPa

Precautions

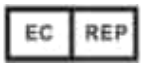
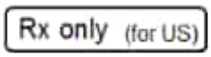
Please read this manual carefully before using the product to avoid accidental or mechanical hazards caused by improper use, resulting in unclear images, diagnostic errors and other results. Please observe the following safety precautions carefully to prevent product damage, user/patient injury, and other possible hazards and accidents.

- This product is a non-mobile device. Do not move the device during normal use.
- Do not disassemble or attempt to perform operations that are not described in this manual. Improper operation with excessive mechanical force may cause product damage or user/patient injury. In case of device failure, please read the troubleshooting guide carefully and follow the troubleshooting methods and steps to solve problems; if the problems remain unsolved, please contact MediWorks Service and professional service personnel will be arranged to solve your problems.
- Do not store or use the product in flammable, explosive, high-temperature, high-humidity, or dusty environments; use it in a clean room, and keep it clean and dry.
- Other medical instruments and equipment installed at the same site must be electromagnetically compatible with the device. Equipment that is not compatible or is known with poor electromagnetic compatibility must be installed at least 3 meters away from the device and must be powered by another power cable.
- Before connecting the device, unplug the power cord to avoid the risk of electric shock.
- Before using the device, make sure all the cables are correctly connected and the device is well grounded; otherwise, the device may be short-circuited, which may cause device damage and user/patient injury.
- If replacement of a power cord is needed, replace it with one specified in this manual.
- Turn off the power when the product is not in use.
- Dispose of waste from the product and end-of-life product and components in accordance with relevant laws and regulations.
- Read carefully the safety symbols and marks on this device to use the device safely.
- Use this product in strict accordance with the requirements and precautions in this manual.
- This is a Class 1 laser product with laser normally off and only turned on when the corneal topography is working.
- The marking for Class 1 laser product is affixed to the side of the device housing.
- The device is equipped with an optic cable service connector inside. If this connector is disconnected, laser radiation may exceed the emission limits of Class 1 laser product. Please observe laser protection safety precautions and wear goggles.
- Warning -- The lights emitted by this device are potentially dangerous. Longer exposure poses higher risk of ocular damage. Exposure to any of the red light, short infrared light, or medium infrared light for 300s, or to all the three types of lights simultaneously for 60s, at the maximum light intensity, will exceed the guided safety limits. Please protect your eyes while in use.
- Harmful radiation exposure may occur if control or adjustment units are not used or steps are not performed as required.

Description of Icons, Symbols, and Marks

The following icons, symbols and marks are used on this product. Refer to the table below for their specific meanings.

Icons/Symbols/Marks	Description
	Type B applied part
	Date of manufacture

	WEEE logo. Please dispose of waste from the device according to local laws and regulations.
	Located on the power switch, indicating that the main power supply is on.
	Located on the power switch, indicating that the main power is off.
	Class 1 laser product
	Crushing of hands
PN	Part Number, representing the code of parts or products
	Serial Number, representing the serial number of the product or part
	Refer to instruction manual / booklet
	This way up
	Fragile, handle with care
	Keep dry
	Stacking limit by number, 2
	Stacking limit by mass, 80 Kg
	Temperature limit, - 40℃ ~ + 55℃
	Humidity limit, 0%~90%, no condensation
	Atmospheric pressure limit, 700 hPa~1060 hPa
	Manufacturer
	Catalog number
	Authorized representative in the European Community / European Union
	USA Federal law restricts this device to sale by or order of a physician.
	Medical device
	Unique Device Identifier

Indicator Light Color

The power switch has an indicator light. When the light is green, it indicates that the power is on and the device is working.

Electromagnetic Compatibility Information

This product has passed the electromagnetic compatibility test, and complies with the International Electrotechnical Commission standards (IEC 60601-1-2) on medical equipment. These limits are intended to provide reasonable protection against harmful interference in typical medical installations. This product uses RF energy for its internal functions only and may cause harmful interference to other electronic equipment in the vicinity if not installed and used as directed. However, there is no guarantee that interference will not occur under specific installation conditions. If the product does cause harmful interference to other electronic equipment, the other electronic equipment can be restarted, and the user is advised to try the following measures to correct the interference:

1) Adjust the position of other electronic equipment.
2) Increase the spatial distance between this product and the interfered equipment.
3) Separate the connection circuit of the main power supply of the product from that of other electronic equipment.
4) Contact the manufacturer or regional technical support.

Guidance and Manufacturer's Declaration

Please use the cables and accessories supplied with this device. Cable information below is provided for EMC reference.

Cable	Length	Shielded / Unshielded	Qty	Classification
Power cord	1.8 m	Unshielded	1 set	AC power

Important information regarding Electromagnetic Compatibility (EMC)

This electrical medical device needs special precautions regarding EMC and put into service according to the EMC information provided in the user manual; The device conforms to this IEC 60601-1-2 standard for both immunity and emissions. Nevertheless, special precautions need to be observed:

- The device with Following ESSENTIAL PERFORMANCE is intended used in professional healthcare facility environment except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

  ESSENTIAL PERFORMANCE: The device does not crash and the screen displays normally.

- WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of the device and result in improper operation.

- WARNING: Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the device and the other equipment should be observed to verify that they are operating normally.

- WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.

- WARNING: If the use location is near (e.g. less than 1.5 km from) AM, FM or TV broadcast antennas, before using this device, it should be observed to verify that it is operating normally to assure that the device remains safe with regard to electromagnetic disturbances throughout the expected service life.

- When the AC input voltage is interrupted, the device will stop battery charging/shut down and if the power supply restored, it could be recovered automatically/by operator manually. This degradation could be accepted because it will not lead to unacceptable risks and it will not result in the loss of basic safety or essential performance.

- The following degradation caused by Electrostatic Discharge or Electrical fast transients/burst could be accepted because it will not lead to unacceptable risks and it will not result in the loss of basic safety or essential performance:

Vertical bars appear on the screen, it can recover to previous condition by operator manually by restarting the power switch.

Data transmission stopped, the transmission could be restarted by operator manually by restarting the power switch or re-insert the data cable.

EMI Compliance Table (Table 1)

Table 1 - Emission

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class A	Professional healthcare facility environment
Harmonic distortion	IEC 61000-3-2 Class A	Professional healthcare facility environment
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	Professional healthcare facility environment

NOTE: The EMISSIONS characteristics of this device make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this device might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

EMS Compliance Table (Table 2-4)

Table 2 - Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrostatic Discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table **3**
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz
Proximity magnetic fields	IEC 61000-4-39	Frequencies 134.2 kHz, 65 A/m, Pulse modulation 2,1 kHz
		Frequencies 13.56 MH, 7.5 A/m, Pulse modulation 50 kHz

Table 3 – Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18 Hz, 27 V/m
450	430-470	FM, ± 5 kHz deviation, 1 kHz sine, 28 V/m
710	704-787	Pulse modulation 217 Hz, 9 V/m
745		
780		
810	800-960	Pulse modulation 18 Hz, 28 V/m
870		
930		
1720	1700-1990	Pulse modulation 217 Hz, 28 V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217 Hz, 28 V/m
5240	5100-5800	Pulse modulation 217 Hz, 9 V/m
5500		
5785		

Table 4 – Input a.c. power Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrical fast transients/burst	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	± 0.5 kV, ± 1 kV
Surges Line-to-ground	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V, 0.15 MHz - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Voltage dips	IEC 61000-4-11	0% U_T; 0.5 cycle At 0º, 45º, 90º, 135º, 180º, 225º, 270º and 315º
		0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0º
Voltage interruptions	IEC 61000-4-11	0% U_T; 250/300 cycles

Table 5 – Signal input/output parts Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrical fast transients/burst	IEC 61000-4-4	± 1 kV 100 kHz repetition frequency
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V, 0.15 MHz - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz

FCC Compliance Information

Please take attention that changes or modification not expressly approved by the party responsible for

compliance could void the user's authority to operate the equipment.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) This device must accept any interference received, including interference that may cause undesired operation.

WEEE Precautions

Please dispose of waste from the device in accordance with relevant laws and regulations.

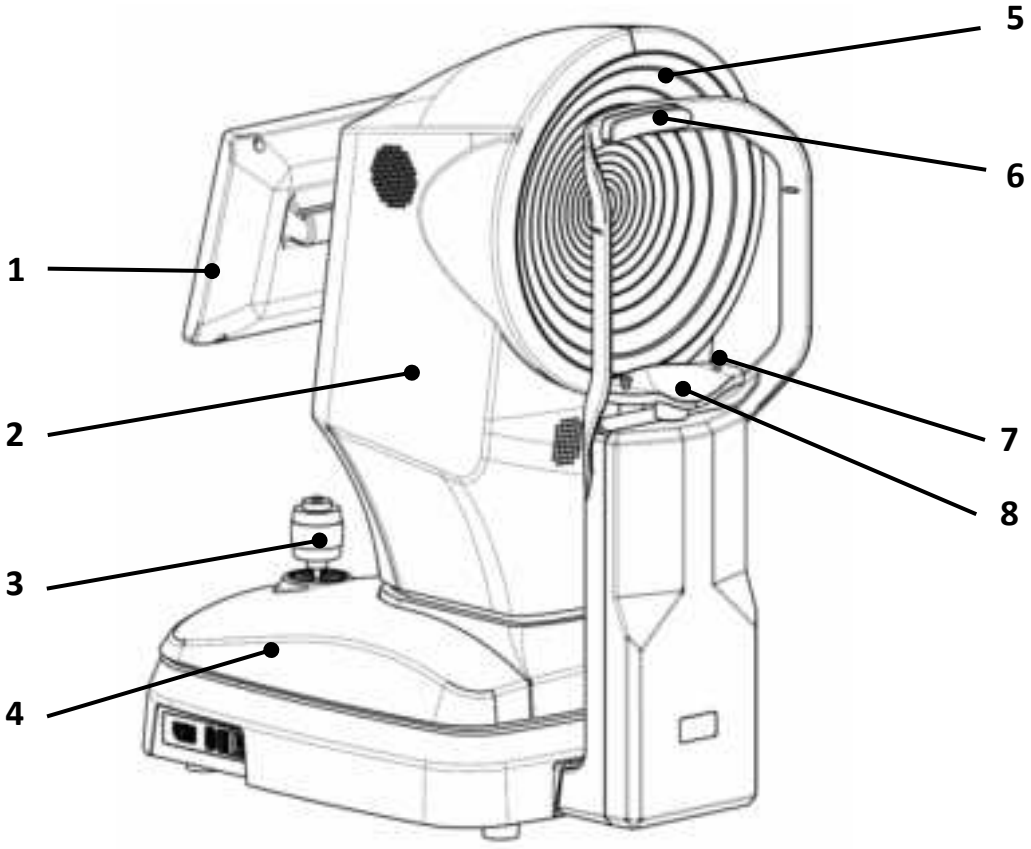
1. Installation

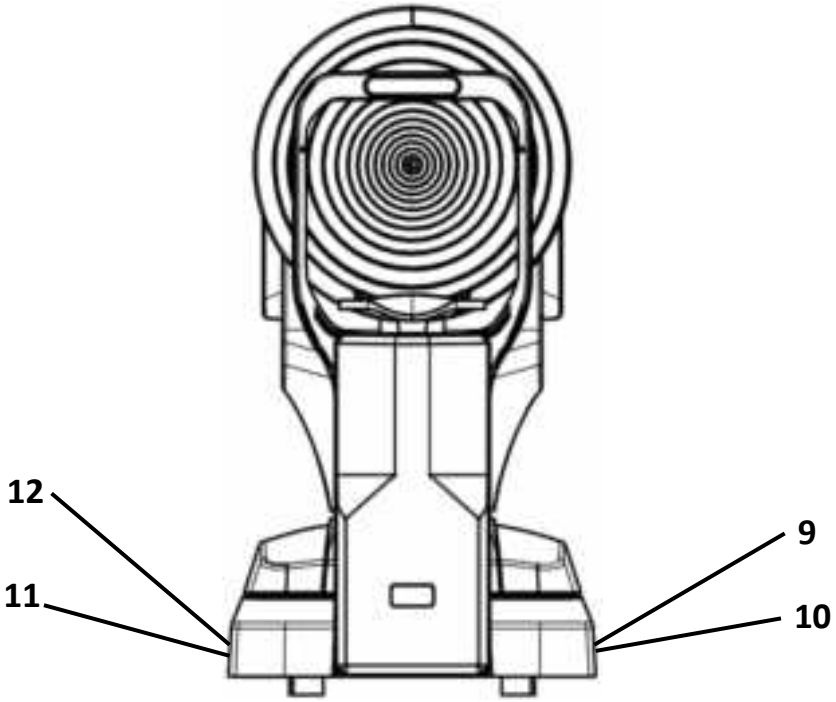
1.1 Product List

Before start using the product, check that all of the following items are included in the product packaging. If any item is missing, please contact our authorized distributors.

No.	Part Name	Qty
1	Optical biometer	1
2	Power cord	1
3	User manual	1

1.2 Illustration of Parts





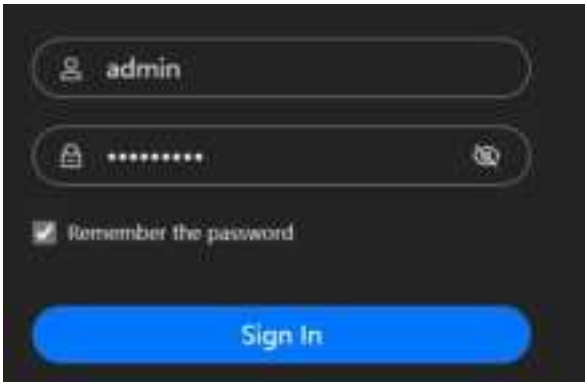
1. Touch screen, the angle can be adjusted by tilting the screen
2. Main shell
3. Joystick, to adjust the movement platform horizontally (X, Y) and vertically (Z, by turning)
4. Movement platform, can be electrically adjusted in X, Y and Z directions
5. Placido rings
6. Forehead rest, to keep the patient's head in the proper position
7. Chin rest paper fixing bolts, to secure chin rest paper
8. Chin rest, to support the patient’s chin
9. Power switch, I indicating on and O indicating off
10. Power socket
11. USB interface, to connect USB devices, such as wireless mouse and keyboard
12. DP interface, to connect display devices

1.3 Product Installation

1. Carefully take out the device and place it on the tabletop, and plug in the supplied power cord.
2. Press the power switch (I is on, and O is off) for the power indicator to light up and the device to turn on. If you want to turn off the device, press the power switch again.

2. Patient and Record Management

Turn on the device and enter the login screen, as shown below.



Enter the correct username and password and click **Sign In** to log in to the patient and record management interface. If wanted, tick the **Remember the password** checkbox before logging in and you will not need to enter your password the next time you log in.

After login, the patient management interface appears as the homepage, with the patient list in the left column and the selected patient's records in the right column.

Shutdown: shuts down the system.

Settings: enters the settings window (see Chapter 0 Settings).

Wi-Fi: displays the connected Wi-Fi configuration. This icon appears only after a Wi-Fi network has been connected (see Section 4.3 Network).

2.1 Adding Patients

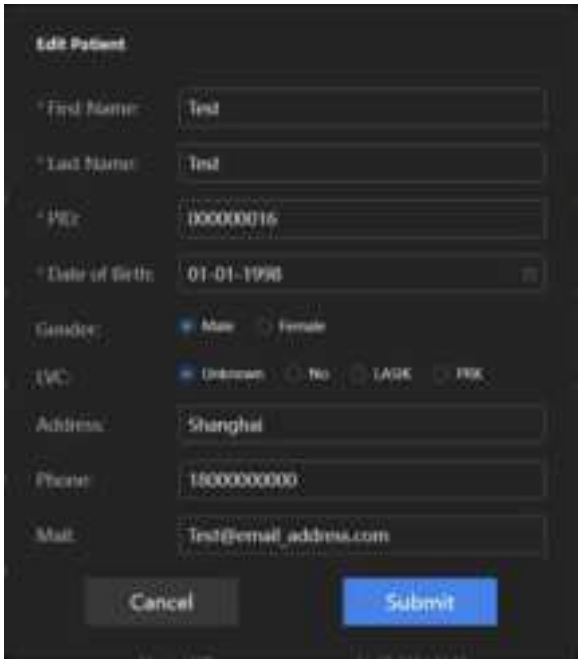
On the patient management interface, click New to add a new patient.

In the displayed window, enter patient information, such as the name, patient ID (PID), gender, date of birth, laser vision correction (LVC) type, address, phone and mail, and then click Submit. The patient information is saved and the patient is displayed and selected in the patient list. You can click **Edit** to view and edit related information of the patient.

NOTE: PIDs will be automatically assigned if PID auto assignment is enabled in the settings window (see Section 4.1 General).

2.2 Editing Patients

Select a patient from the patient list, and click Edit to edit information of the patient (e.g., correct the patient's gender). Then, click Submit. The changes will be saved.



2.3 Exporting Data

Connect a removable storage device (e.g., a USB drive) to the product.
Click Select in the patient column. A checkbox appears before each patient in the patient list.
Select patients whose data you want to export by checking their checkboxes. Then, click Export Data.
Data of the selected patients will be exported to the removable storage device.

2.4 Sharing Data with Third-party Software

The Third-party button allows you to share data with the third-party software after the software information is properly set in the settings window (see Section 4.8 Third-party Software).

Click Select in the patient column and select the desired patients.

Then, click Third-party and choose an operation as required:

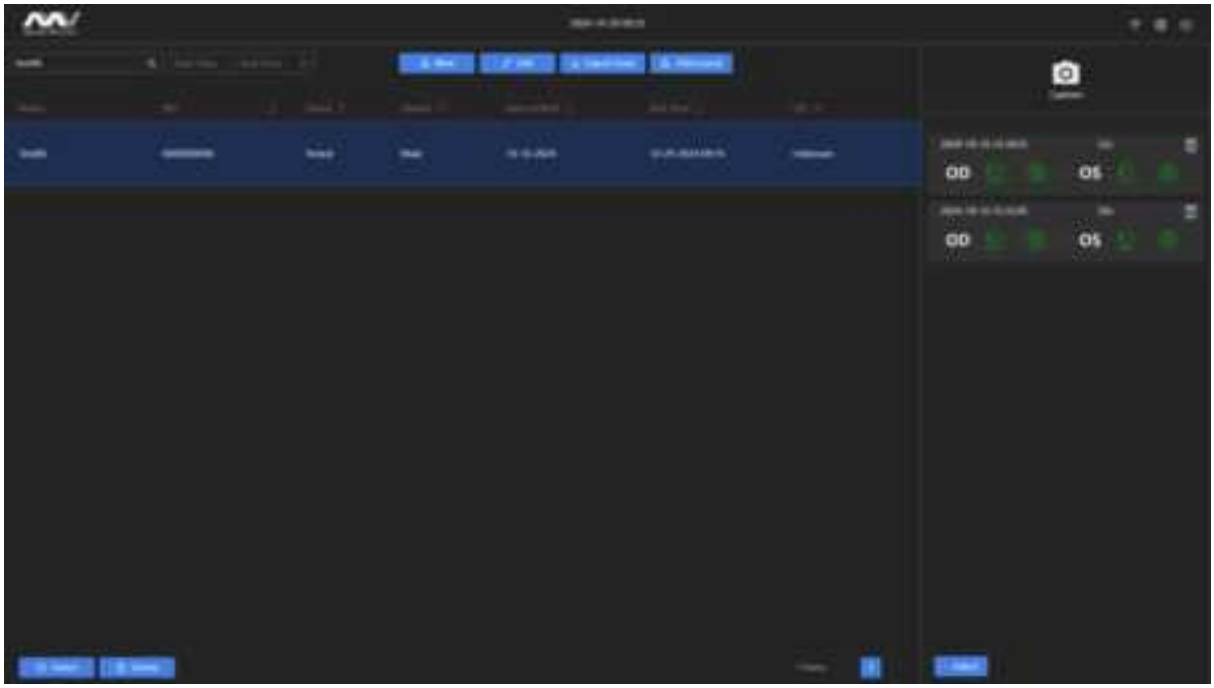
- Retrieve Patient Data: imports patient info from third-party software.
- Export To Third-Party: exports patient info and measurement data to third-party software.

2.5 Deleting Patients

Click Select in the patient column and select patients that you want to delete. Then, click Delete to delete the selected patients and all their records, or click Cancel to cancel the selection.

2.6 Searching for Patients

In the search box, enter the search criteria to search for patients.



2.7 Managing Patient Records

After a patient is selected, you can manage his/her records in the right column.

To delete a single record, click  at the end of the desired record.

To delete multiple records, perform the following steps:

1. Click Select in the right column. A checkbox appears at the end of each record, as shown below.

2. Check the checkboxes of records that you want to delete. Alternatively, click Select All to select all the records.
3. Click Delete to delete the selected records.

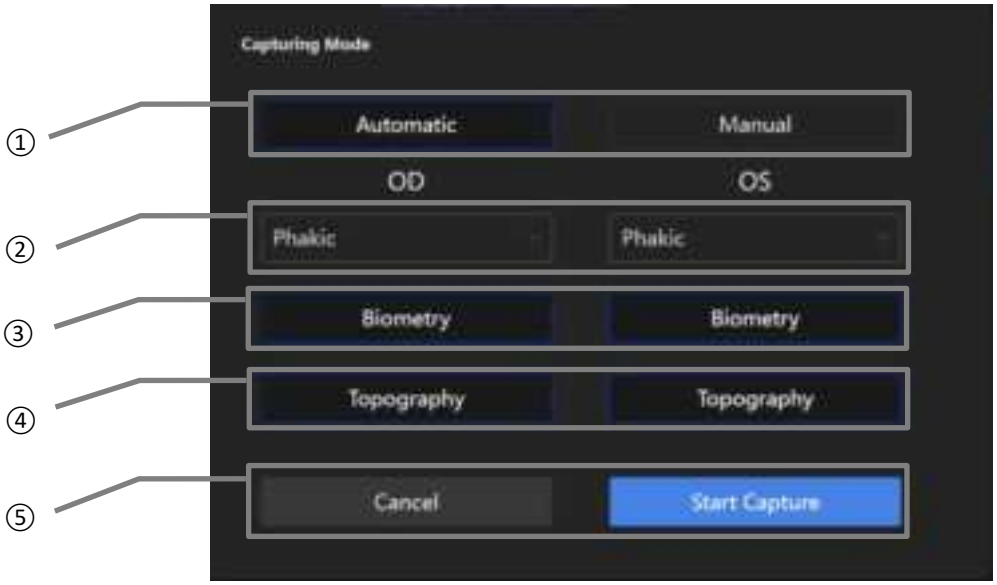
3. Measurement Function Modules

3.1 Full Data Measurement

3.1.1 Capture Mode Selection

After selecting a patient, click  . The capture mode selection window is displayed.

Select the eye (OD/OS) to be measured and capture items. After the selection is completed, click Start Capture to start the capture.



① Automatic / Manual

Automatic capture: The device automatically locates and focuses the eye, and captures the images.

Manual capture: Manual focusing and capture are required during the capture process.

② Eye status: Select the status of the eyes to be measured from the drop-down list. Correct selection of eye status is mandatory for successful and accurate measurement of the axial length, since the refractive indices of the lens and aqueous humor vary according to eye status. Refractive index values can be viewed in the refractive index tab of the settings window.

Capture items include ③ **Biometry** and ④ **Topography**. If the automatic mode is selected, the desired capture items can be selected for the left and right eyes respectively in the window above. If the manual mode is selected, capture items will need to be selected and captured one at a time in the capture window.

③ **Biometry** includes measurement of axial data such as corneal thickness (CCT), anterior chamber depth (ACD), lens thickness (LT), vitreous thickness (VT), and axial length (AL), and of white-to-white distance and pupil diameter.

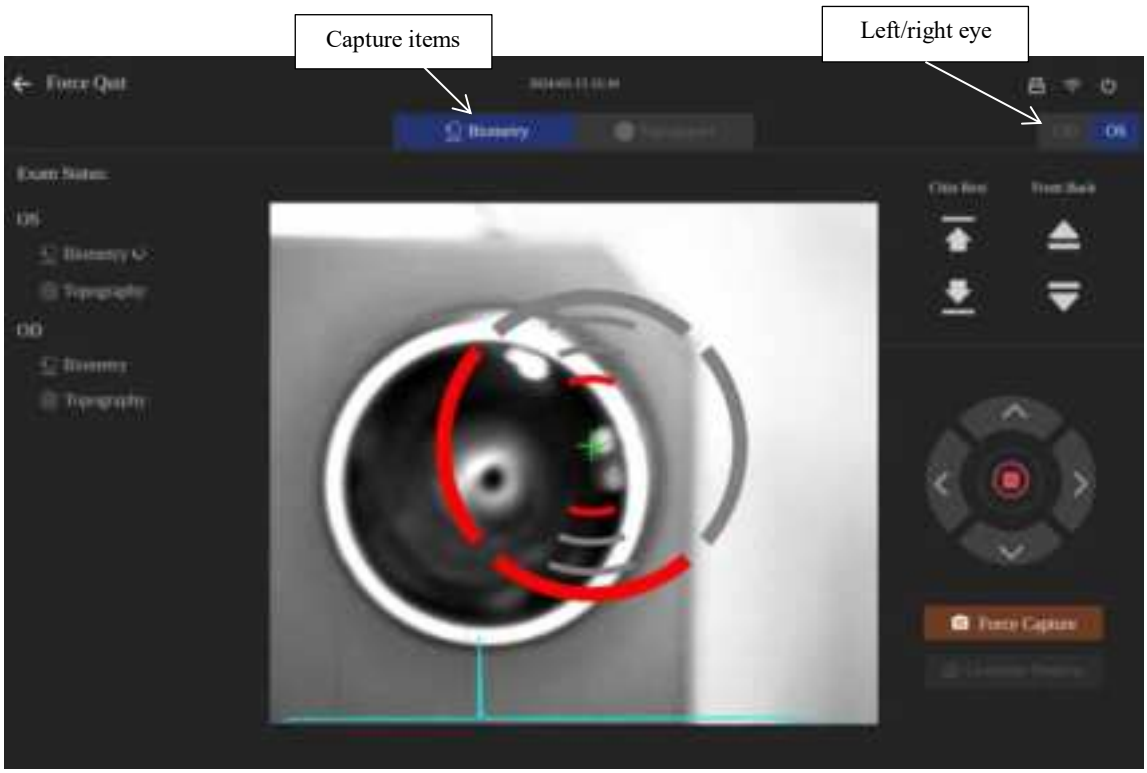
④ **Topography** includes measurement of corneal curvature, principal meridian direction, and other parameters.

⑤ **Cancel** / **Start Capture**: Click Cancel to cancel the capture, or click Start Capture to enter the capture window.

3.1.2 Capture Procedure

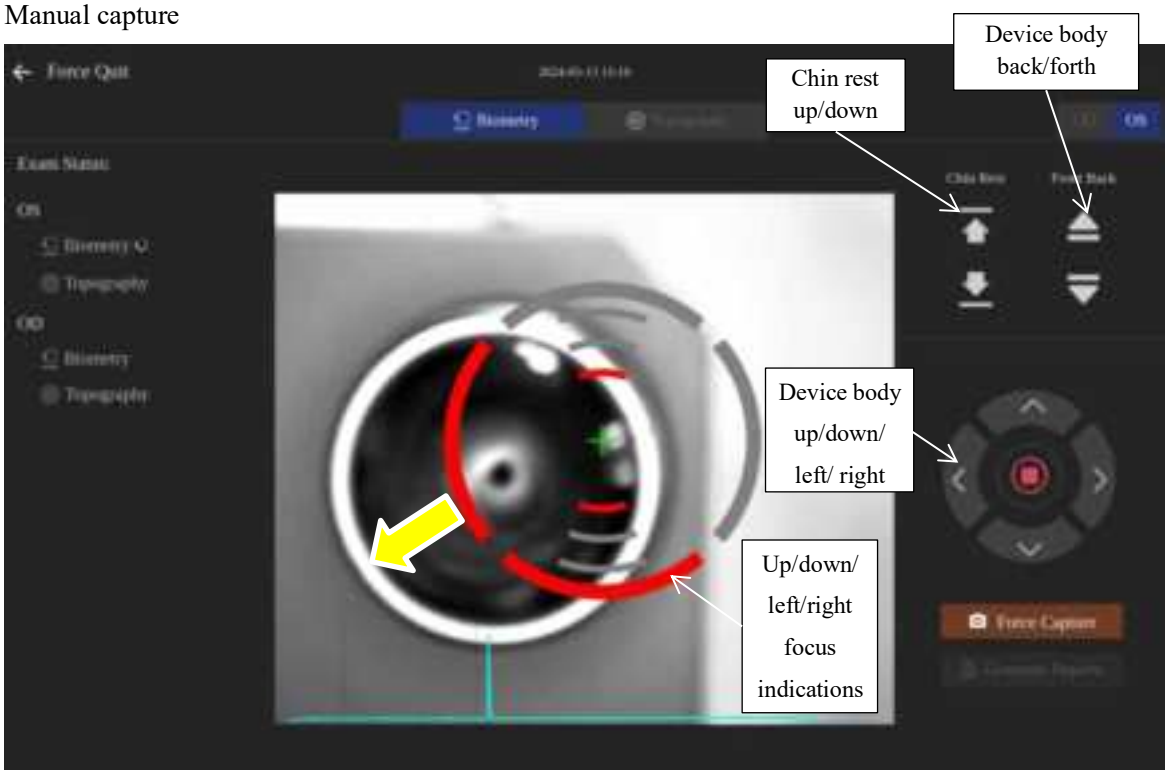
In the capture mode selection window, click Start Capture to enter the capture window, as shown below.

1. Adjust the height of the chin rest using the **Chin Rest** buttons on the screen until the patient's eye is aligned with the mark line on the chin rest.
2. Ask the patient to keep his/her eye wide open and look at the circular fixation point during the capture.
   - Automatic capture

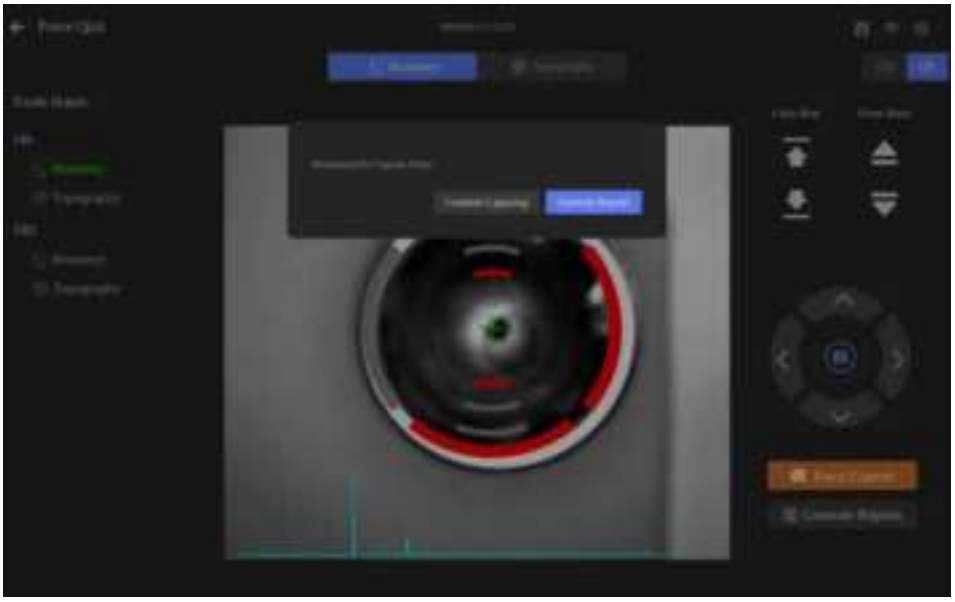


1) The device automatically finds the center of the pupil. After finding the center, it moves back and forth until the sclera becomes clear, and then captures images and records the white-to-white distance of the pupils. It also adjusts X, Y and Z positions in real time, continuously collects axial signals during this process, and automatically stores axial data after the requirements are met.
2) Wait for the device to acquire sufficient axial length data.
3) During the process, ensure that the patient remains as still as possible.
4) Then, corneal topography starts.
5) The red light and the laser positioning light automatically turn on.
6) The device automatically adjusts the position so that the capture range of the camera stays in the center of the pupil, then moves back and forth until the laser positioning light is at the corneal vertex and automatically captures and records corneal topography.
7) The result page is displayed after the capture is completed.

➢ Manual capture



1) Select a desired capture item. Click OD or OS (or use left/right arrow keys) in the window to move the device to the position of the eye to be captured.
2) Move the device body according to the focus indications (red indicates that the device body should move towards that direction). After the focus is successful (all focus indications turn green), click **Capture**.
3) After one capture item is completed, a window will be displayed asking if you want to continue capturing. Click Continue Capturing if the other capture item or capture of the other eye is required.

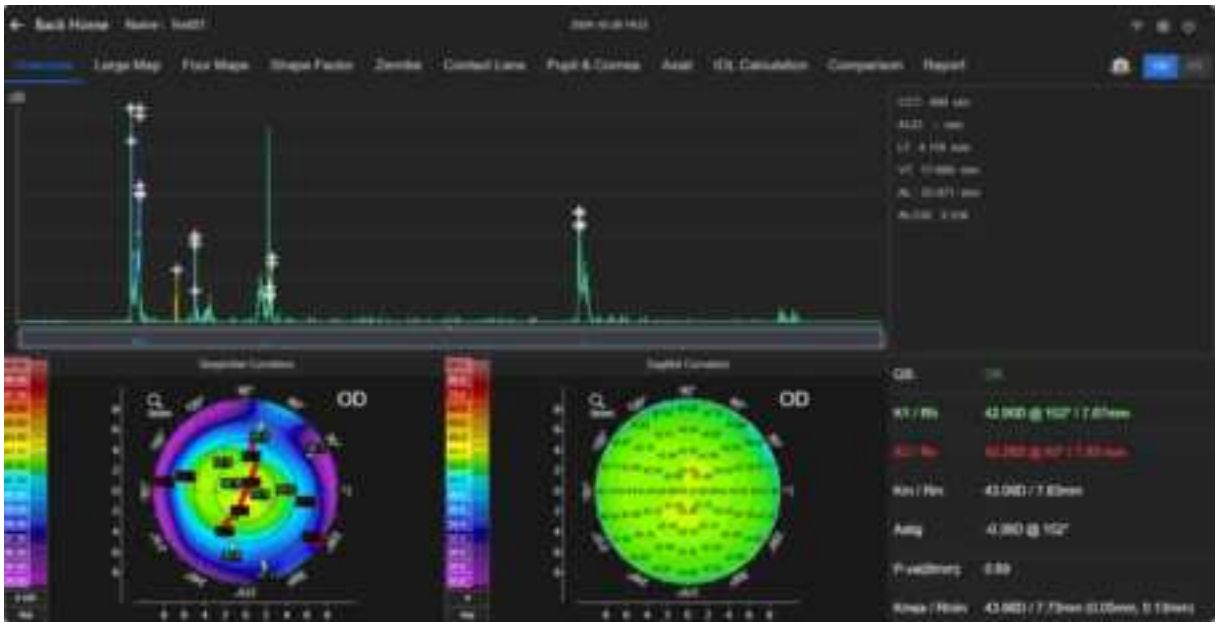


a. If the other capture item for the same eye is required, select the other desired capture item, and then repeat step 2);
b. If capture items for the other eye are required, repeat steps 1), 2).

4) When all desired capture items are completed, click Generate Reports to generate the report and enter the result page.

NOTE: Face Capture allows images to be captured regardless of whether exact focus is achieved. You can use it to capture images if exact focus could not be reached after a long time.

3.2 Function Interface Introduction



If the capture is successful, the system automatically enters the **Overview** interface, showing measurement data of the selected capture items for analysis. You can also enter this interface by clicking a saved record on the record management interface.

The **Overview** interface mainly shows a axial signal chart, topographic maps, and summarized measurement data (which will not be calculated and displayed if the related capture item is not selected).

3.2.1 Function Column

This column contains all the function modules provided by the software with detailed measurement data. You can check the data under the corresponding function modules as required.

3.2.2 Interpretation of Summarized Measurement Data

The summarized measurement data characterize axial thickness of intraocular parts, axial lengths, and anterior corneal data, etc.

Anterior Segment Data	
K1/Rh	Indicates flat k-dioptric value and curvature radius value, and @ describes the meridian direction
K2/Rv	Indicates steep k-dioptric value and curvature radius value, and @ describes the meridian direction
Km/Rm	Indicates mean dioptric value and curvature radius value

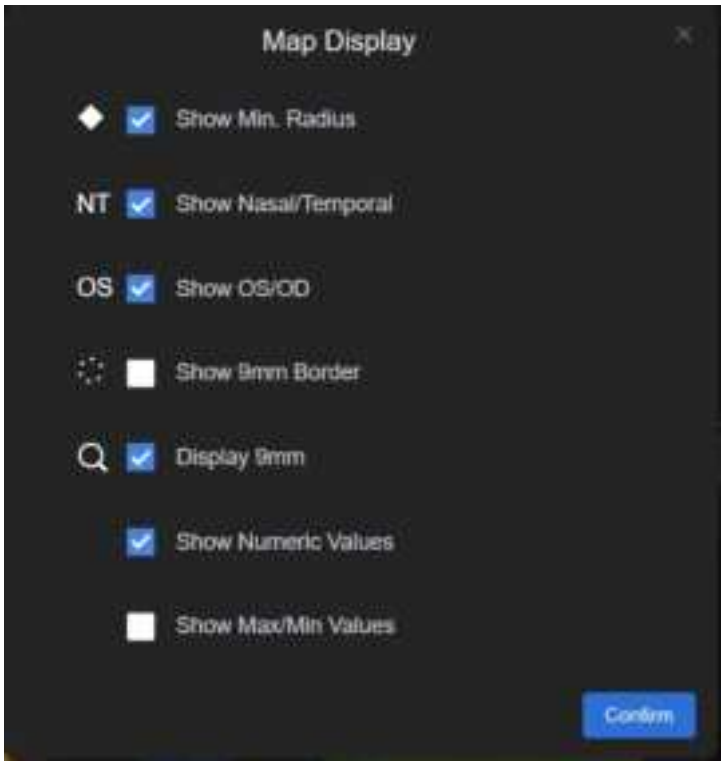
Astig	Indicates astigmatism
Ecc (E, Q, P)	Indicates corneal shape factor values of a diameter ring centered on the corneal vertex
Kmax/Rmin	Indicates maximum dioptric value and minimum curvature radius value, and the values in the brackets indicate the polar coordinates of such point
Corneal curvature	/
Pupil diameter	/
Pupil center	/
White to white	Indicates corneal diameter
Axial Data	
CCT	Central corneal thickness
ACD	Anterior chamber depth
LT	Lens thickness
VT	Vitreous thickness
AL	Axial length
AL/CR	Axial length / corneal radius ratio

When image capture is completed, the system automatically presents the results after calculation, which include overview, topographic maps, the four maps, the shape factors, Zernike, Keratoconus, contact lens, pupil & cornea, axial data, IOL calculation, trend, comparison, and report.

3.3 Introduction to Functions of Axial Measurement and Corneal Topography

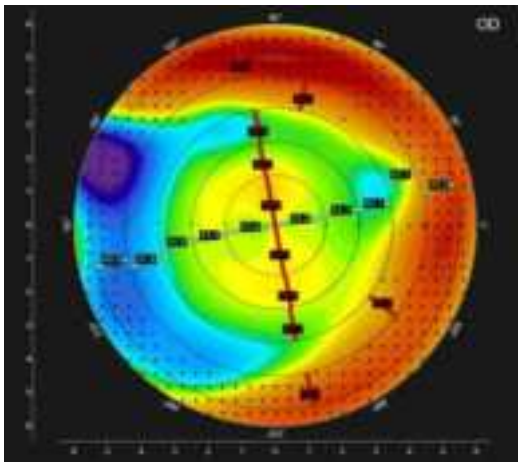
3.3.1 Topographic Maps

3.3.1.1 Topographic Map Display Settings



Be it the Topographic map module or the Four map module or other modules, as long as there is an interface presenting the topographic map, right-click or long-press on the topographic map opens the topographic map display setting window. You can check or uncheck feature checkboxes to display or hide corresponding features on the topographic map, where,

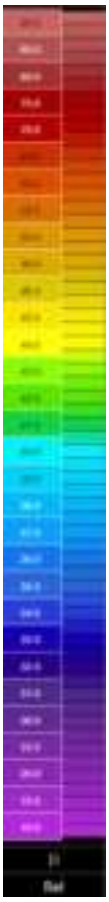
- **Show Min Radius**: the white solid diamond represents the point with maximum curvature on the corneal surface;
- **Show Nas/Temp**: the letters "T" and "N" on the bottom left and right of the topographic map indicate the temporal side and the nasal side, respectively, to facilitate distinction and positioning;
- **Show OS/OD**: on the top of the topographic map, "OS" indicates the left eye, and "OD" indicates the right eye, to facilitate distinction and positioning;
- **Show 9mm Border**: the white and black dotted line is used to represent the ring with a radius of 4.5mm from the vertex;
- **9mm Display**: only the topographic map of the cornea diameter of 9 mm is available.
- **Show Numeric Value**: numeric values are displayed every 1 mm in the radial direction of the color topographic map.
- **Show Max/Min Value**: it displays the maximum and minimum values of the corresponding topographic map and their directions in the corneal diameter ranges of 3, 5, 7, 9, and 11 mm, only applicable to sagittal curvature topographic maps and tangential curvature topographic maps of the cornea.



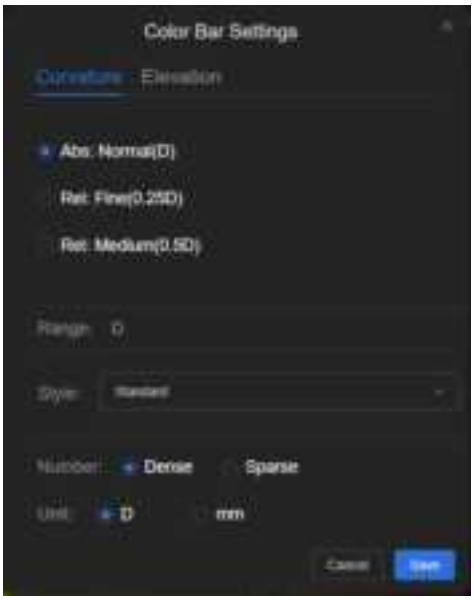
3.3.1.2 Topographic Map Color Bar Settings

A topographic map uses different colors to represent the distribution of data. The value of data is represented by color bars on the topographic map.

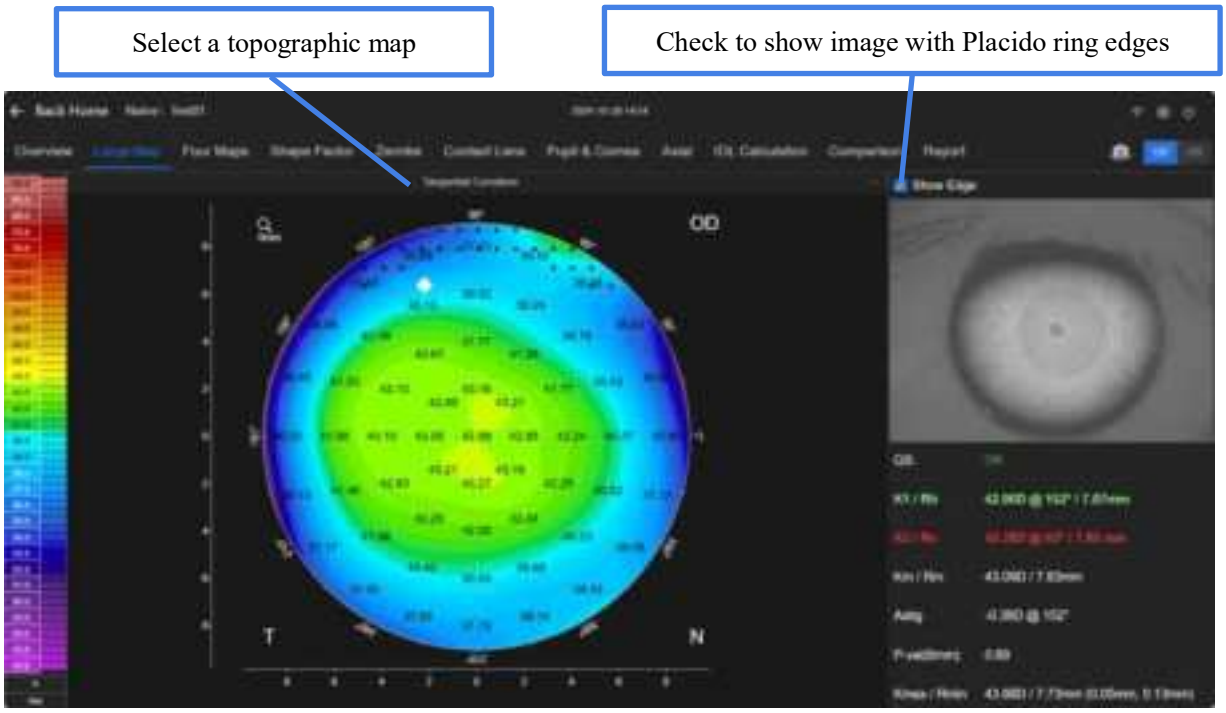
Each topographic map in the software has a corresponding color bar. In addition, the color scale is marked on the color bar, below which there is the unit for the values on the current topographic map and the color bar mode (shown below).



When clicking on the color bar, the window for setting the current topographic map color bar is displayed. You can change the color level interval (relative or absolute), color bar style, density, and measurement unit (only applicable to curvature-related topographic maps) according to your preferences or for better reflection of the changes in the current topographic map.



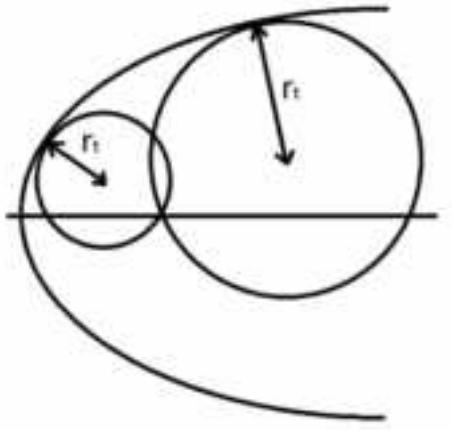
3.3.1.3 Tangential Curvature Topographic Maps



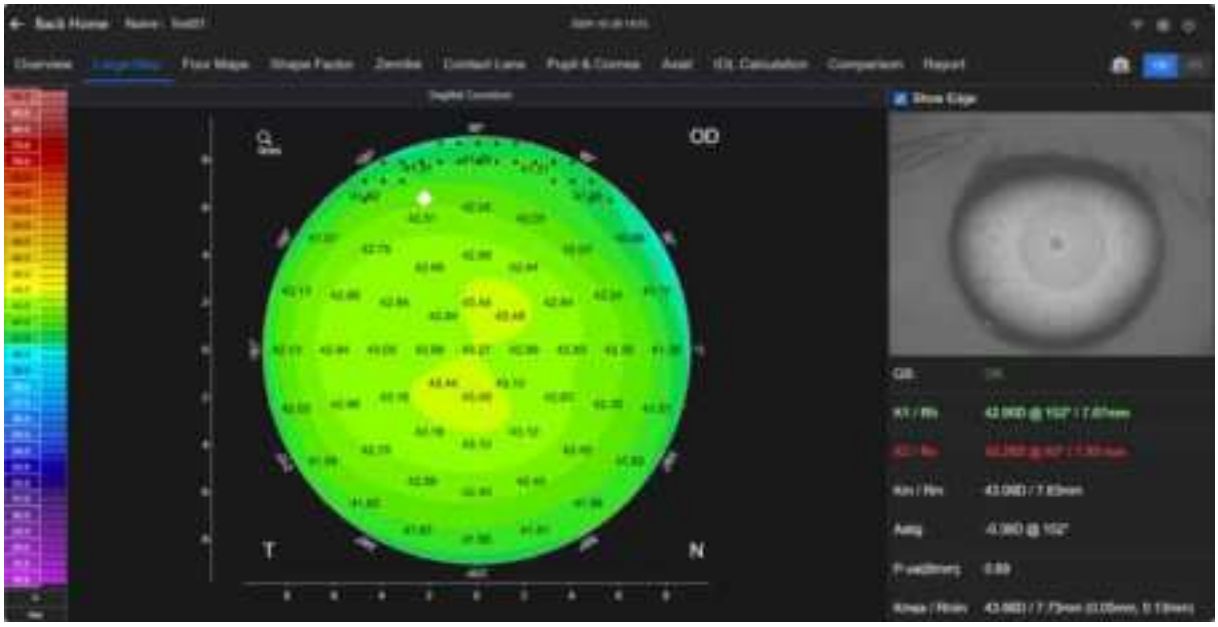
This topographic map depicts the tangential radius of curvature at various points on the anterior corneal surface. You can click on the color bar to display it in diopters.

Definition of the tangential radius of curvature at a certain point: it is calculated according to the following definition after the radial arc passes through the measuring point and the corneal vertex is found.

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

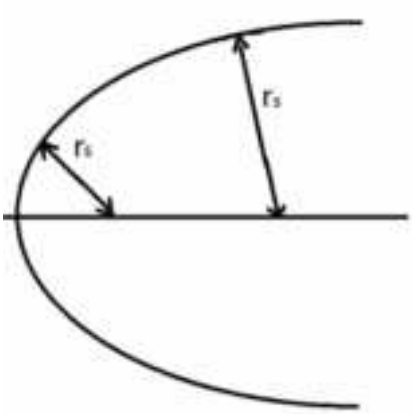


3.3.1.4 Sagittal Curvature Topographic Maps



This topographic map depicts the sagittal radius of curvature at various point on the anterior corneal surface. You can click on the color bar to display it in diopters.

Definition of the sagittal radius of curvature at a certain point: it is calculated according to the following definition after the radial arc passes through the measuring point and the corneal vertex is found.

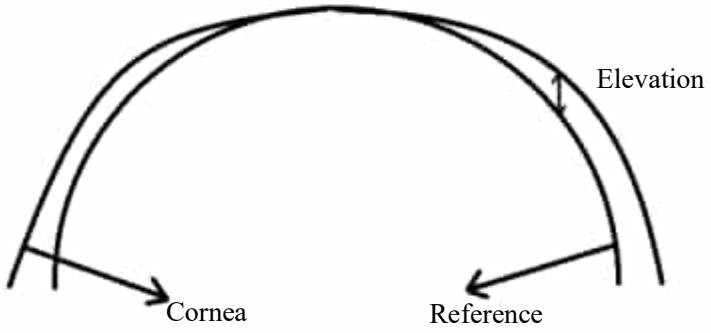


The radial (or sagittal) curvature is equivalent to the distance between the measuring point and the intersection of the following two lines: (1) the perpendicular to the tangent of the measuring point, and (2) the axis. In the radial display mode, the curvature value depends on the slope of the measuring point, and the position of the optical axis should be considered. The sagittal display mode allows for better analysis of the cornea impact on the visual acuity of patients.

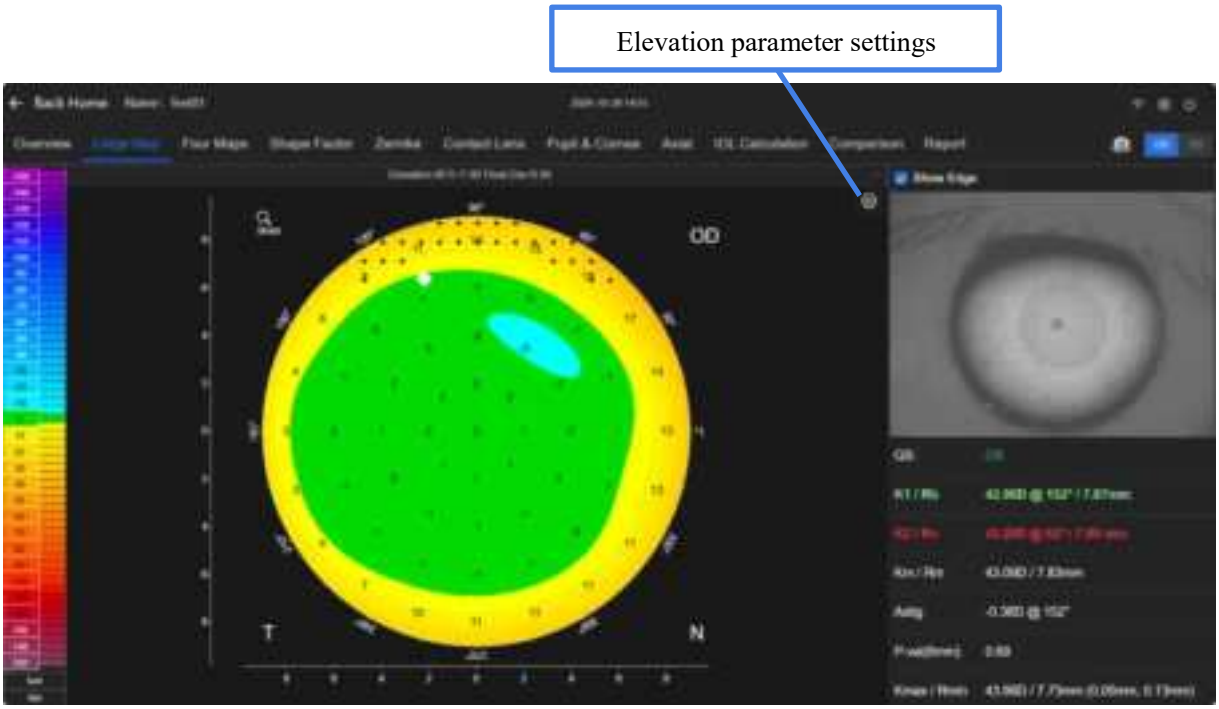
3.3.1.5 Elevation Map

Description of elevation map

In terms of elevation, there must be a reference, namely a relative object, which can be a plane or any curved surface. The elevation topographic map depicts the difference in elevation between the cornea and the reference.



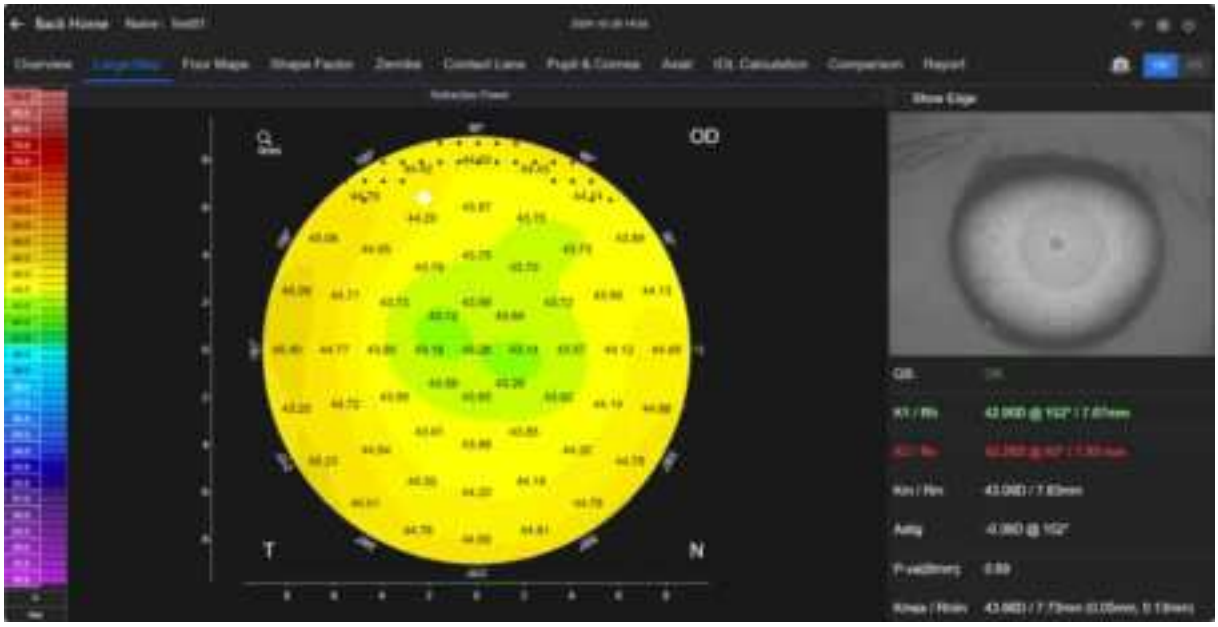
The value can be positive (cornea above the reference) or negative (cornea below the reference).



This topographic map depicts the elevation data for the anterior corneal surface.

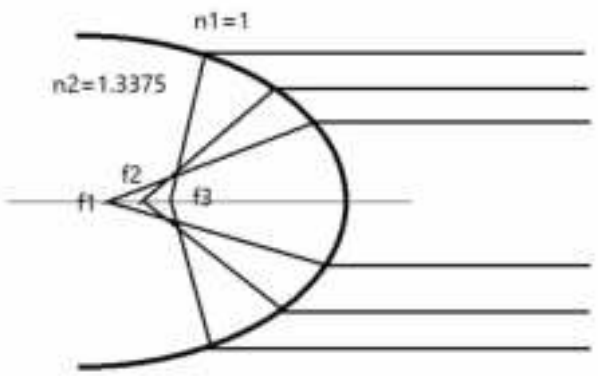
The elevation here is a relative concept. For the specific meaning, refer to the explanation of the elevation data and the reference above. “BFS” in the topographic map title represents the Best Fit Spherical radius of the anterior corneal surface, while “Dia” represents the minimum diameter sampled on the cornea.

3.3.1.6 Refractive Power Map



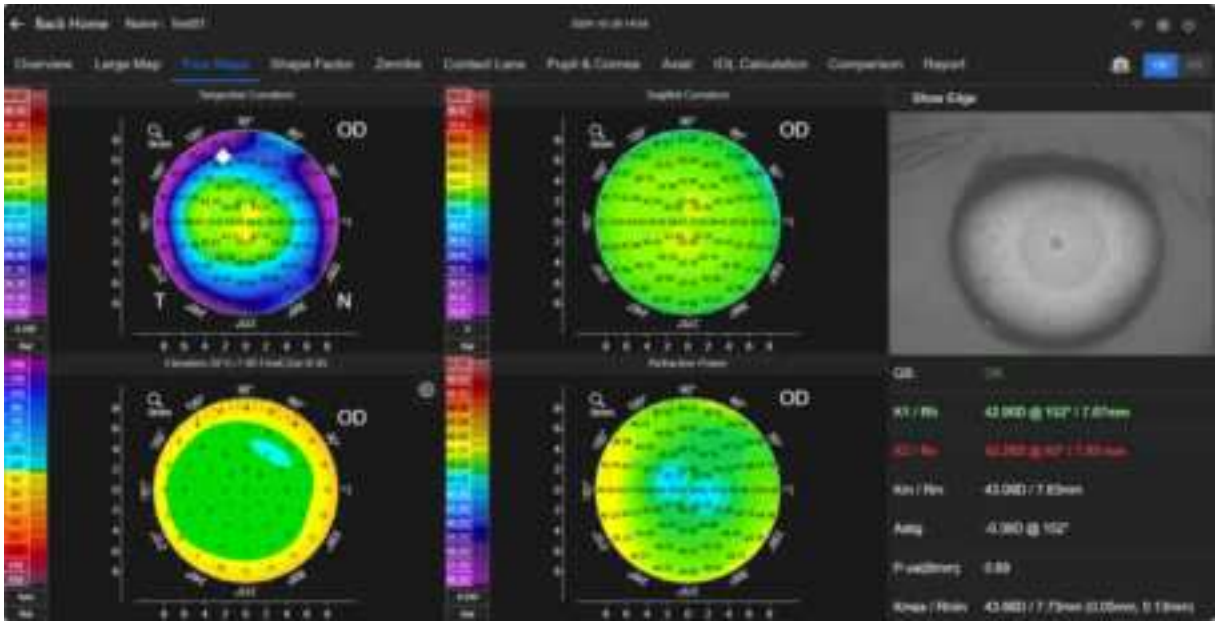
To estimate the optical effects of the anterior corneal surface, this topographic map uses focal length instead of curvature value to calculate the refractive power. The focal length is calculated using Snell's law (ray tracing method), to take the spherical aberration effect into account. Take a standard sphere as example, the refractive power calculated by Snell's law is significantly different from the one obtained by the method of traditional curvature topographic map, due to difference in refractive index caused by spherical aberration, that is:

1. Traditional curvature topographic maps show only one refractive power because the curvature of the sphere is the same at every point.
2. Given the spherical aberration effect, the refractive power at the periphery (f3) of the refractive power map under this definition will be greater, while the refractive power in the middle (f1) will be less.



3.3.2 Four Maps

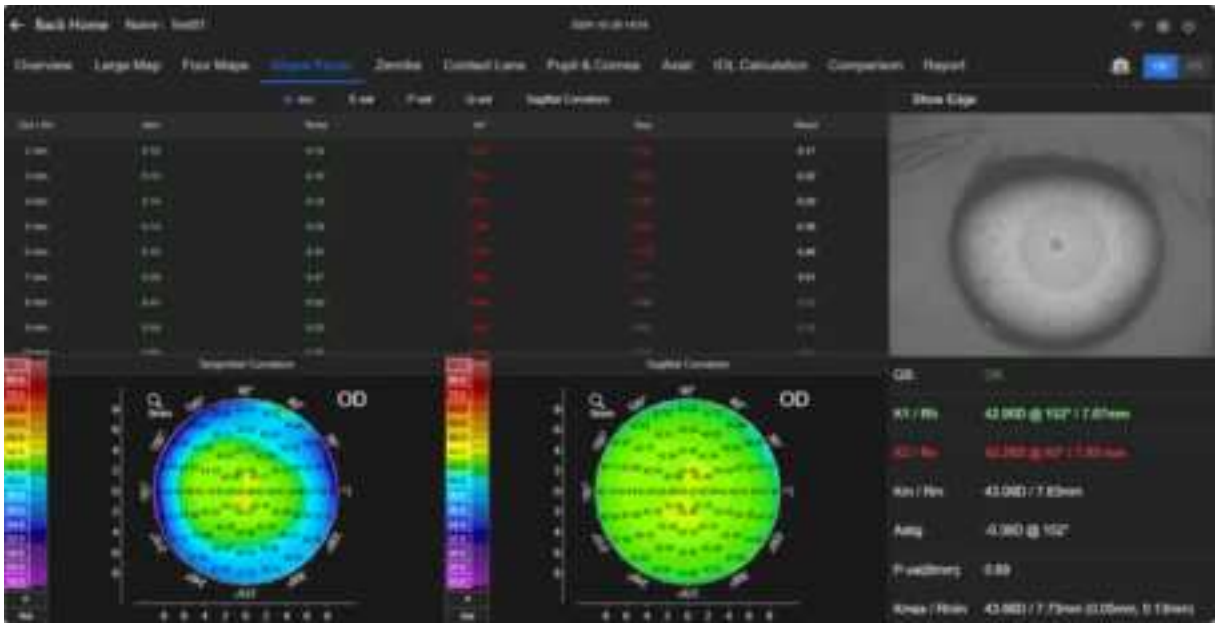
Click on **Four Maps** to enter the interface containing Tangential Curvature, Sagittal Curvature, Elevation, and Refractive Power maps, as shown below.



The types of the presented four topographic maps are fixed. They can be used to aid ophthalmologists in diagnosis of corneal abnormalities.

3.3.3 Shape Factor

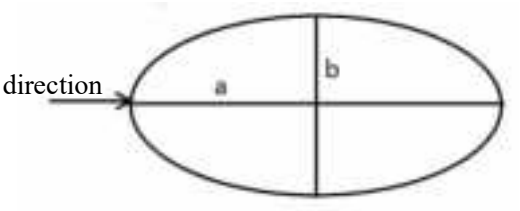
Click on **Shape Factor** to enter the Shape Factor module.



This module shows the tangential and sagittal curvature topography of the cornea.
The charts above shows the corneal shape factors and the curvature values of the anterior corneal surfaces at each radial sagittal ring and the intersection of the four radial directions.
The corneal shape factors include Ecc, E-val, P-val and Q-val. You can select which shape factor to display

in the topography map by setting it in the topography tab of the settings window.

The cross-section of the cornea is not an exact ellipse. Therefore, it is necessary to find the best fitting ellipse in a certain direction in the calculation. The following definitions of shape factors are described based on the definition of an ellipse.



➢ Shape factors

- Ecc

  It follows the standard mathematical definition of elliptical eccentricity, and is calculated as

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

  Be noted that whether an ellipse is oblate or not cannot be distinguished by the eccentricity e.

- P

  The purpose of this shape factor is to solve the limitation of Ecc value, which is defined as

$$P = \frac{b^2}{a^2}$$

  Using this shape factor, a circle can be described as p=1, an oblate ellipse be described as p value less than 1, and a circular ellipse be described as p value greater than 1.

- Q

  This shape factor can be used to indicate the deviation between a specific curve and the sphere. It is defined as

$$Q = P - 1$$

  The Q value of the spherical surface is 0, the Q value of the oblate ellipse is negative, and the Q value of the circular ellipse is positive.

- E

  This shape factor is similar to the Q value, but the difference is that the E value of an oblate ellipse is positive, and that of a circular ellipse is negative. It is defined as

$$E = 1 - \frac{b^2}{a^2}$$

Shape factors are helpful in partially quantifying eye shape characteristics. These factors are calculated from an elliptical shape that approximates 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 *Corneal Asphericity: The Es, Ps, and Qs of Corneal Shape* by Swarbrick, H. in Refractive Eyecare for Opthalmogologist in December 2014. At the bottom is the display of the mean values of the corneal shape factors at the location of corneal astigmatism.

3.3.4 Zernike

3.3.4.1 Overview

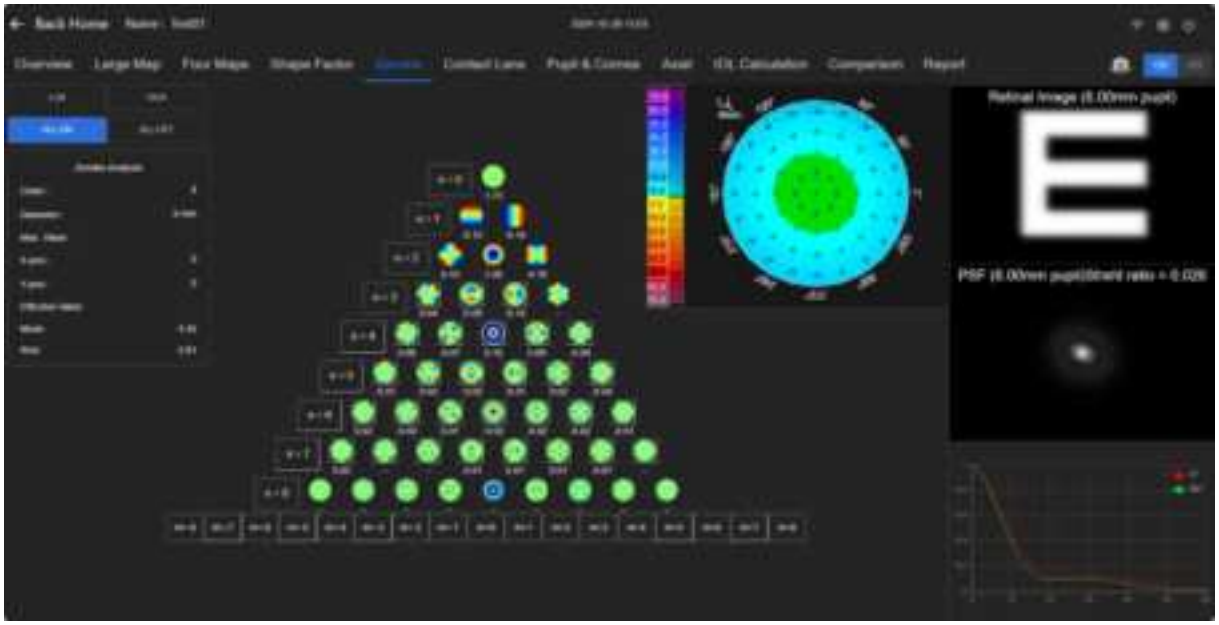
Zernike polynomials are commonly used to describe wavefronts. Each beam contains a sinusoidal oscillation, and points in the entire sinusoidal oscillation array having the same phase direction form a refractive surface that is perpendicular to the plane wavefront of the propagation direction.
Ideally, the incident wavefront, parallel to each other, are deformed to form spherical waves that accurately satisfies the focal length F. However, 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 Zernike (1888-1966, the inventor of the aberration microscope) successfully gave a mathematical expression of the deviation between the true wavefront and the ideal value by polynomial fitting. Each polynomial is named according to the image defect represented (e.g., coma, spherical aberration). Zernike polynomials are also known as ring polynomials because they refer to circles with a radius of 1, and are expressed in polar coordinates. Mathematically, each Zernike polynomial is expressed as the product of multiple powers of radius r and multiple powers of the angle variable θ.
A Zernike polynomial has the following definitions:

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

3.3.4.2 Zernike

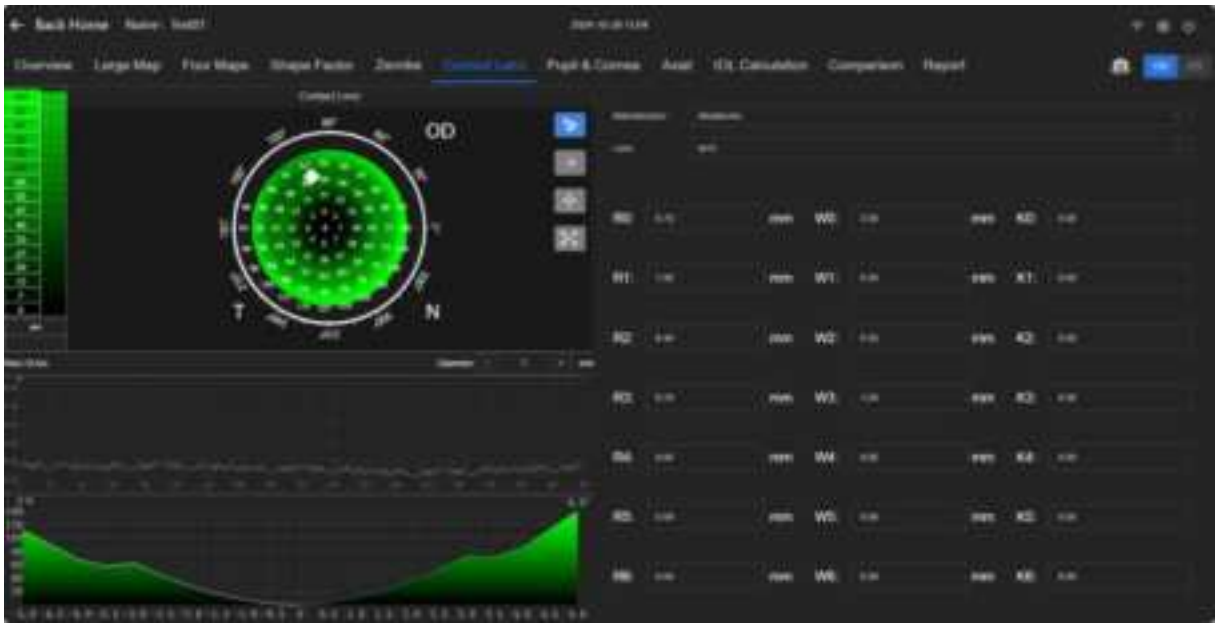
Click on **Zernike**. The Zernike module appears as below.



This module provides Zernike analysis based on the measured elevation data of the anterior corneal surface. It calculates a coefficient for each Zernike polynomial term, which describes the contribution of this polynomial to the elevation data.

3.3.5 Contact Lens

Click on **Contact Lens** to simulate the results of a contact lens correction.



The contact lens module is used to help design suitable contact lenses. By making subtractions based on lens design parameters input by users and corneal sagittal elevation data acquired by the device, it obtains wearing effects by means of fluorescein patterns. In the meantime, you can create or import parameters of existing lenses in the contact lens tab of the settings window.

This module simulates fluorescein staining images on the cornea. The device provides corneal topographic data. Without taking corneal deformation caused by contact lens into account, when the geometric input parameters of the lens are determined, it simulates and calculates the clearance between the posterior surface of the contact lens and the anterior surface of the cornea, thus realizing the simulation image of fluorescent tear film thickness under the lens. This module enables you to design the most suitable lens type according to your customized fitting parameters. You can create multiple lens designs for each examination to simulate different wearing effects by means of fluorescein staining images. Fluorescein staining images are simulations that can only be used as reference for expected effects. It should be noted that the area of the simulated fitting image is larger than the area of data captured, which may be inaccurate because it is based on extrapolated data. The lens trial-wearing should always be conducted to confirm the results of the simulation.

This module contains a fluorescein staining image, a chart of cross-sectional tear thickness under the lens, a corneal sagittal elevation chart, and a list of lens parameters. You can create or import parameters of existing lenses in the contact lens tab of the settings window. After a lens is created, you can select its manufacturer and model directly from the lens list in the contact lens module.

A fluorescein staining image simulates fluorescent results of tear film thickness (between the posterior surface of the contact lens and the cornea) of the currently selected lens. Color scale (μm) is marked on the color bar displayed on the left. The tear film is thicker in the darker green area, and thinner in the lighter green area. The default initial position of the contact lens is at the geometric center of the cornea. You can use the drag button  to move the position of the lens and view corresponding fluorescent results.

3.3.6 Pupil & Cornea

On the interface below, the green circle identifies the pupil and the yellow arc identifies the cornea. On the right side, pupil diameter, corneal diameter, pupil center coordinates, and corneal center coordinates are displayed.

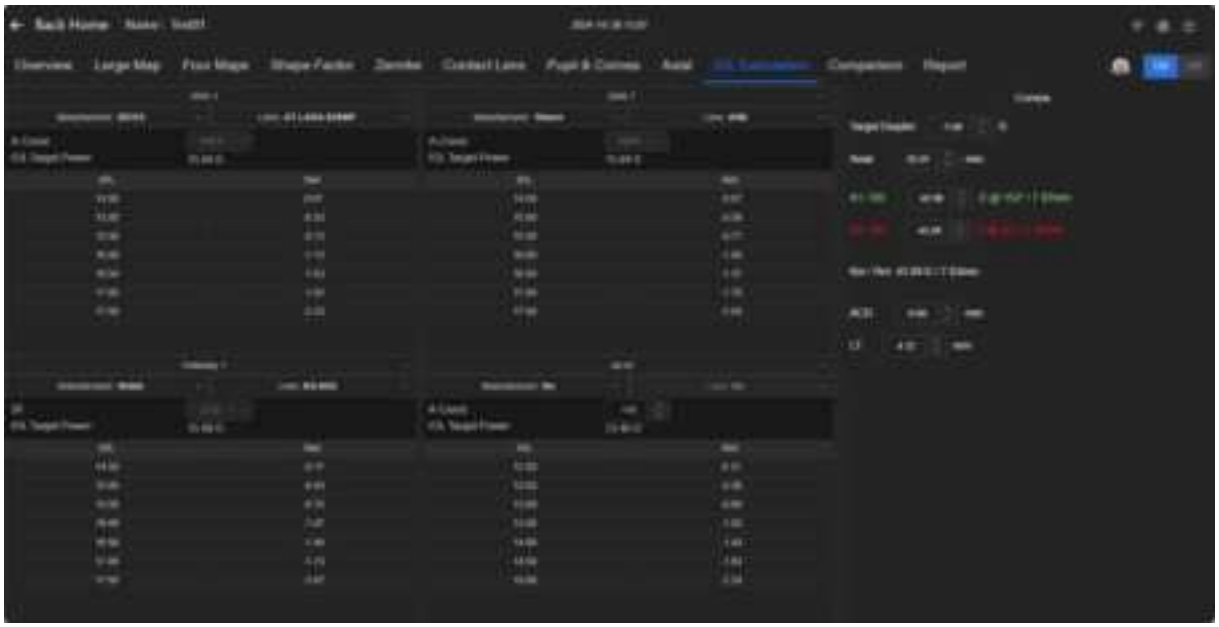
3.3.7 Axial Measurement

The **Axial** interface displays axial measurement results, including the measured values of multiple measurements and standard deviations.

3.3.8 IOL Calculation

This function module is designed to calculate IOL powers. It provides calculation formulas such as SRK 1/2/T, Holladay 1, Binkhorst 2, Hoffer Q, Haigis. The A-constant for each formula is provided by lens manufacturers. When using this module to calculate IOL powers, the target diopter in the upper right corner of the interface is set to -1.00 D by default, and you can modify it to the actual value required. Parameters involved in the calculation in this patient record (e.g., axial length, K1 / Rf, and K2 / Rs) are provided by the measurement data.

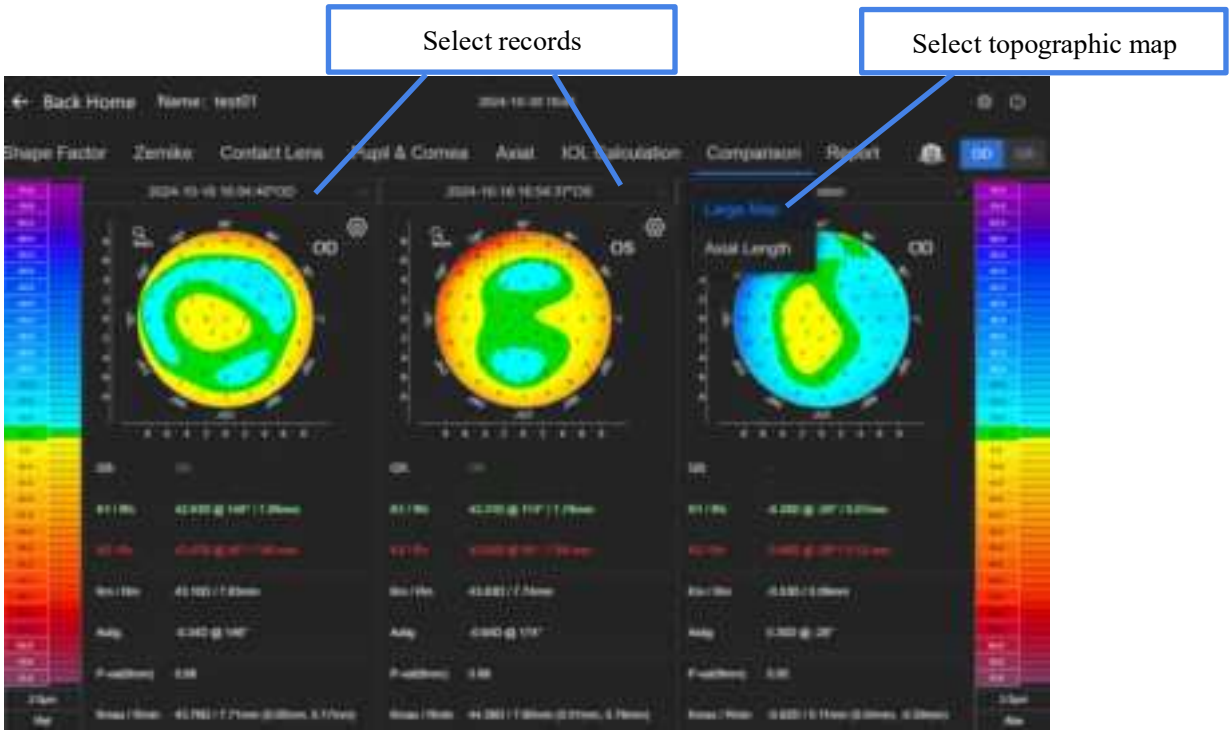
In each table, **IOL Target Power** indicates the calculated IOL power based on respective formula that satisfies the target diopter. IOL powers are listed at 0.5 D intervals in the **IOL** column, and the corresponding diopters are listed in the **Ref.** column. You can select the desired manufacturer and lens from the manufacturer and lens lists to check IOL target power for the selected lens.



3.3.9 Comparison

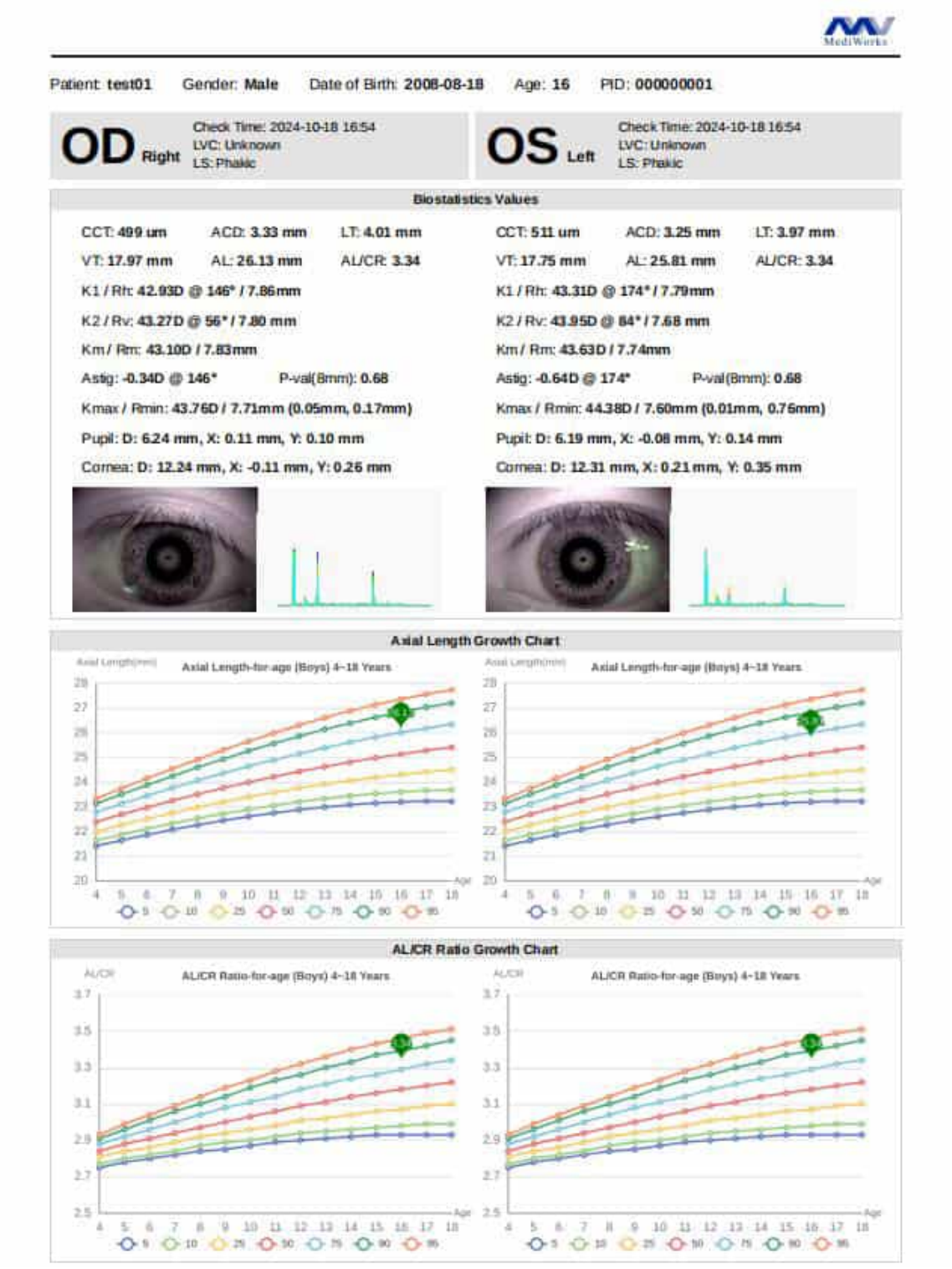
Select **Comparison** to compare both eyes or to compare the measurement results of the same eye taken at different times.

Comparison of topographic maps or axial lengths can be selected as shown below.



3.3.10 Report

An example of the report is shown below.



Patient: test01 Gender: Male Date of Birth: 2008-08-18 Age: 16 PID: 000000001

OD Right — Check Time: 2024-10-18 16:54 — LVC: Unknown — LS: Phakic

OS Left — Check Time: 2024-10-18 16:54 — LVC: Unknown — LS: Phakic

Biostatistics Values

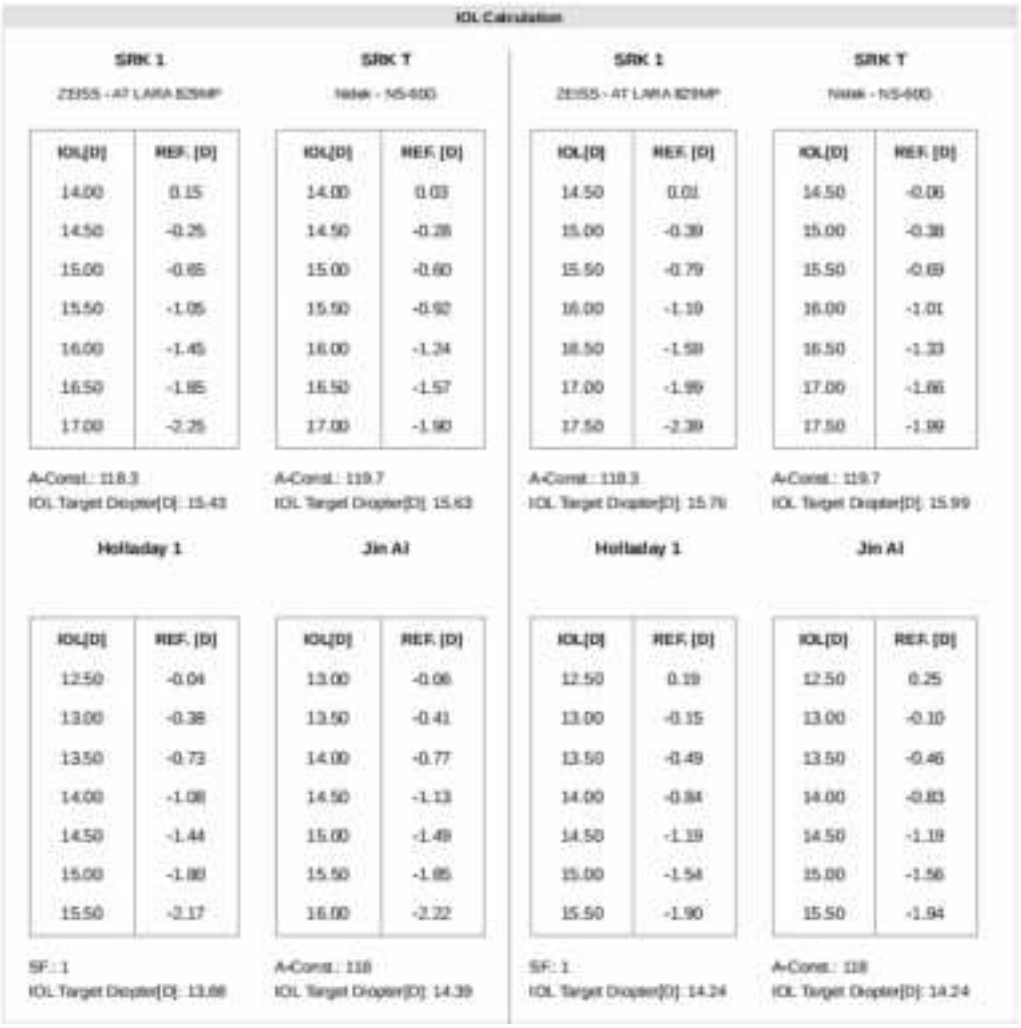
OD	OS
CCT: 499 um ACD: 3.33 mm LT: 4.01 mm	CCT: 511 um ACD: 3.25 mm LT: 3.97 mm
VT: 17.97 mm AL: 26.13 mm AL/CR: 3.34	VT: 17.75 mm AL: 25.81 mm AL/CR: 3.34
K1 / Rh: 42.93D @ 146° / 7.86mm	K1 / Rh: 43.31D @ 174° / 7.79mm
K2 / Rv: 43.27D @ 56° / 7.80 mm	K2 / Rv: 43.95D @ 84° / 7.68 mm
Km / Rm: 43.10D / 7.83mm	Km / Rm: 43.63D / 7.74mm
Astig: -0.34D @ 146° P-val(8mm): 0.68	Astig: -0.64D @ 174° P-val(8mm): 0.68
Kmax / Rmin: 43.76D / 7.71mm (0.05mm, 0.17mm)	Kmax / Rmin: 44.38D / 7.60mm (0.01mm, 0.76mm)
Pupil: D: 6.24 mm, X: 0.11 mm, Y: 0.10 mm	Pupil: D: 6.19 mm, X: -0.08 mm, Y: 0.14 mm
Cornea: D: 12.24 mm, X: -0.11 mm, Y: 0.26 mm	Cornea: D: 12.31 mm, X: 0.21 mm, Y: 0.35 mm

Axial Length Growth Chart

Axial Length-for-age (Boys) 4~18 Years

AL/CR Ratio Growth Chart

AL/CR Ratio-for-age (Boys) 4~18 Years



IOL Calculation

SRK 1

ZEISS - AT LARA 829MP

IOL[D]	REF. [D]
14.00	0.15
14.50	-0.25
15.00	-0.65
15.50	-1.05
16.00	-1.45
16.50	-1.85
17.00	-2.25

A-Const.: 118.3
IOL Target Diopter[D]: 15.43

SRK T

Nidek - NS-600

IOL[D]	REF. [D]
14.00	0.03
14.50	-0.28
15.00	-0.60
15.50	-0.92
16.00	-1.24
16.50	-1.57
17.00	-1.90

A-Const.: 119.7
IOL Target Diopter[D]: 15.63

SRK 1

ZEISS - AT LARA 829MP

IOL[D]	REF. [D]
14.50	0.01
15.00	-0.39
15.50	-0.79
16.00	-1.19
16.50	-1.59
17.00	-1.99
17.50	-2.39

A-Const.: 118.3
IOL Target Diopter[D]: 15.76

SRK T

Nidek - NS-600

IOL[D]	REF. [D]
14.50	-0.06
15.00	-0.38
15.50	-0.69
16.00	-1.01
16.50	-1.33
17.00	-1.66
17.50	-1.99

A-Const.: 119.7
IOL Target Diopter[D]: 15.99

Holladay 1

IOL[D]	REF. [D]
12.50	-0.04
13.00	-0.38
13.50	-0.73
14.00	-1.08
14.50	-1.44
15.00	-1.80
15.50	-2.17

SF.: 1
IOL Target Diopter[D]: 13.88

Jin Al

IOL[D]	REF. [D]
13.00	-0.06
13.50	-0.41
14.00	-0.77
14.50	-1.13
15.00	-1.49
15.50	-1.85
16.00	-2.22

A-Const.: 118
IOL Target Diopter[D]: 14.39

Holladay 1

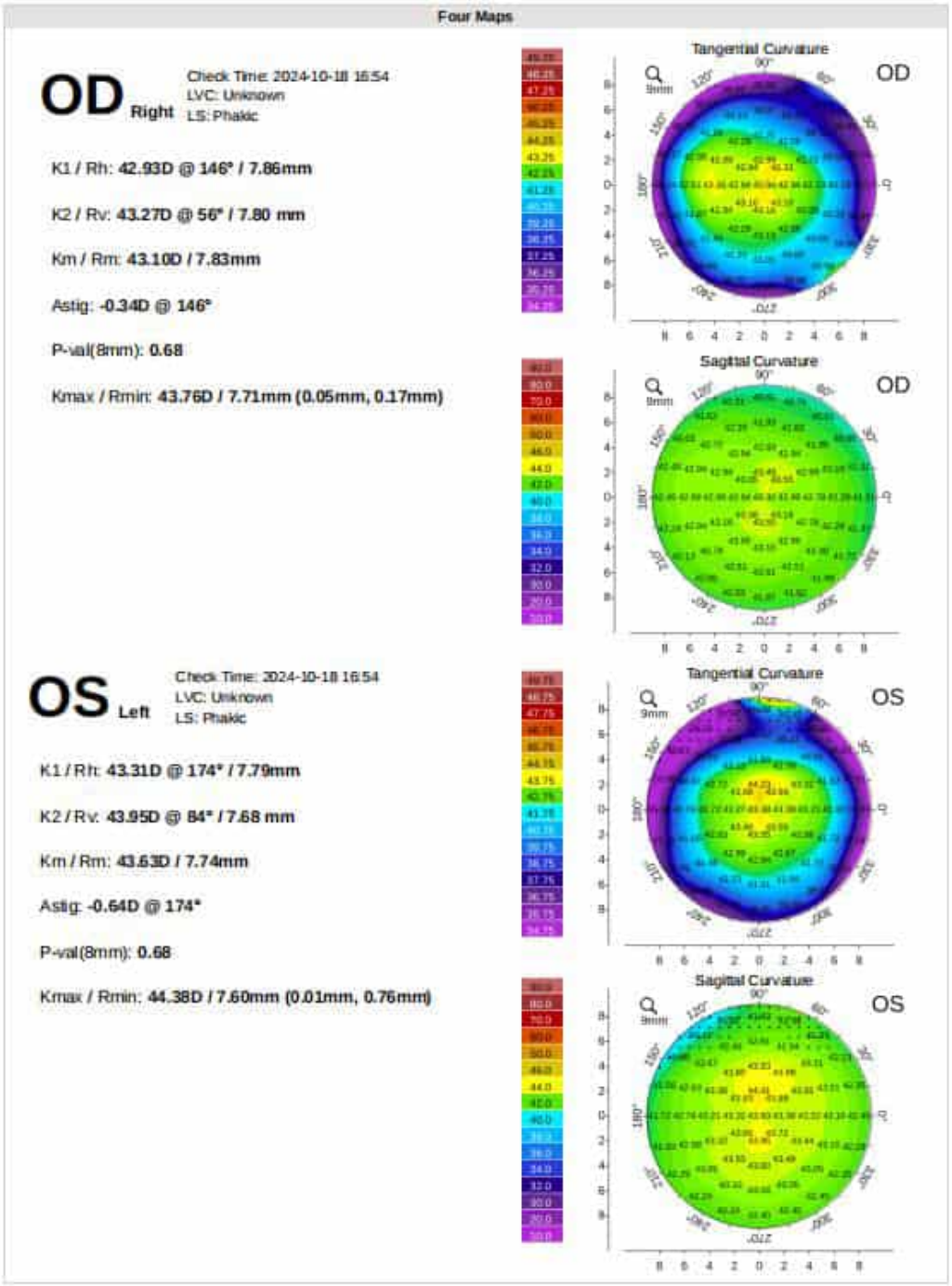
IOL[D]	REF. [D]
12.50	0.19
13.00	-0.15
13.50	-0.49
14.00	-0.84
14.50	-1.19
15.00	-1.54
15.50	-1.90

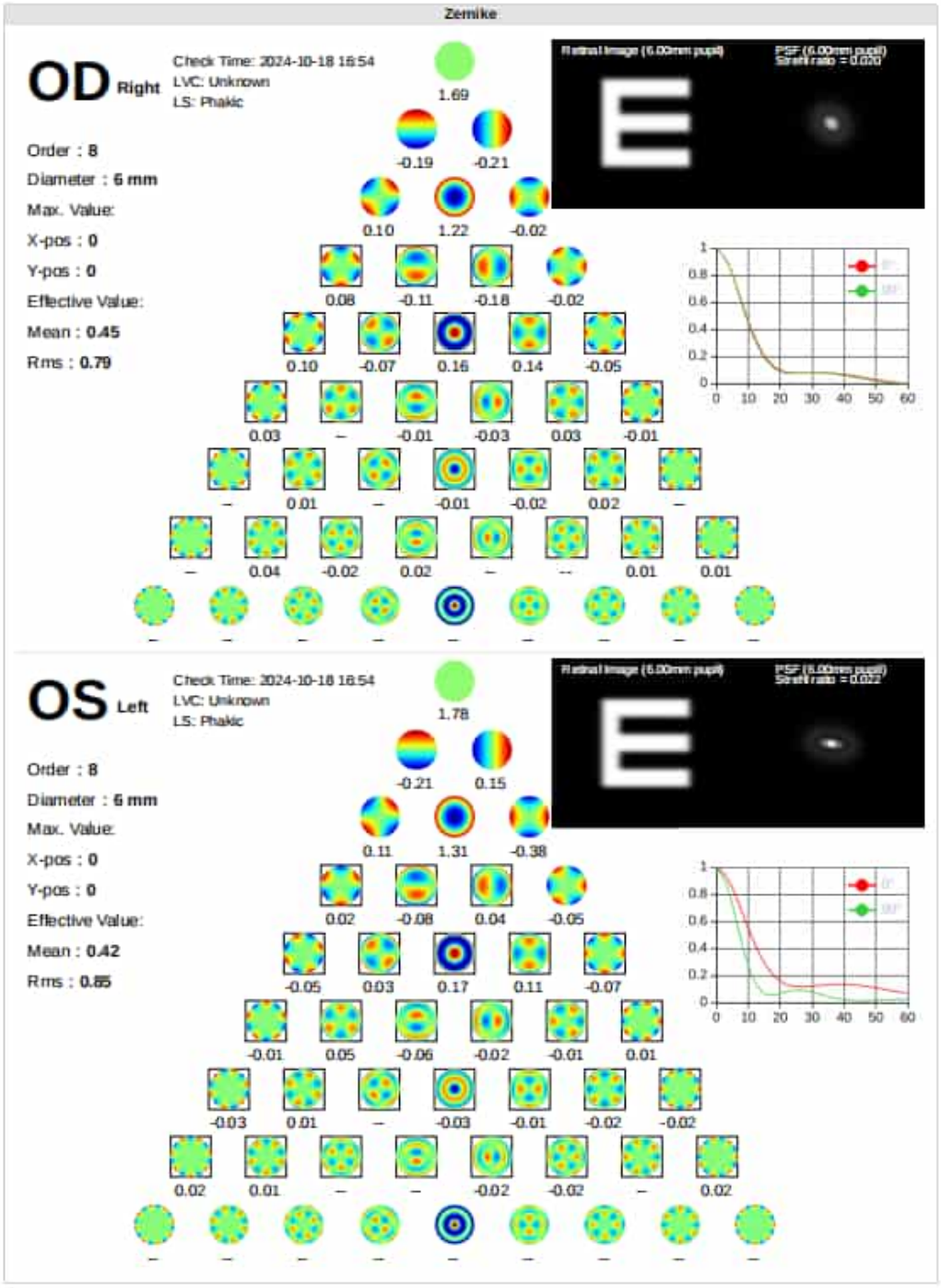
SF.: 1
IOL Target Diopter[D]: 14.24

Jin Al

IOL[D]	REF. [D]
12.50	0.25
13.00	-0.10
13.50	-0.46
14.00	-0.83
14.50	-1.19
15.00	-1.56
15.50	-1.94

A-Const.: 118
IOL Target Diopter[D]: 14.24


Four Maps
OD Right
Check Time: 2024-10-18 16:54
LVC: Unknown
LS: Phakic
K1 / Rh: 42.93D @ 146° / 7.86mm
K2 / Rv: 43.27D @ 56° / 7.80 mm
Km / Rm: 43.10D / 7.83mm
Astig: -0.34D @ 146°
P-val(8mm): 0.68
Kmax / Rmin: 43.76D / 7.71mm (0.05mm, 0.17mm)
Tangential Curvature
OD
Sagittal Curvature
OD
OS Left
Check Time: 2024-10-18 16:54
LVC: Unknown
LS: Phakic
K1 / Rh: 43.31D @ 174° / 7.79mm
K2 / Rv: 43.95D @ 84° / 7.68 mm
Km / Rm: 43.63D / 7.74mm
Astig: -0.64D @ 174°
P-val(8mm): 0.68
Kmax / Rmin: 44.38D / 7.60mm (0.01mm, 0.76mm)
Tangential Curvature
OS
Sagittal Curvature
OS


Zernike
OD Right
Check Time: 2024-10-18 16:54
LVC: Unknown
LS: Phakic
Order : 8
Diameter : 6 mm
Max. Value:
X-pos : 0
Y-pos : 0
Effective Value:
Mean : 0.45
Rms : 0.79
Retinal Image (6.00mm pupil)
PSF (6.00mm pupil)
Strehl ratio = 0.020
1.69
-0.19 -0.21
0.10 1.22 -0.02
0.08 -0.11 -0.18 -0.02
0.10 -0.07 0.16 0.14 -0.05
0.03 – -0.01 -0.03 0.03 -0.01
– 0.01 – -0.01 -0.02 0.02 –
– 0.04 -0.02 0.02 – – 0.01 0.01
OS Left
Check Time: 2024-10-18 16:54
LVC: Unknown
LS: Phakic
Order : 8
Diameter : 6 mm
Max. Value:
X-pos : 0
Y-pos : 0
Effective Value:
Mean : 0.42
Rms : 0.85
Retinal Image (6.00mm pupil)
PSF (6.00mm pupil)
Strehl ratio = 0.022
1.78
-0.21 0.15
0.11 1.31 -0.38
0.02 -0.08 0.04 -0.05
-0.05 0.03 0.17 0.11 -0.07
-0.01 0.05 -0.06 -0.02 -0.01 0.01
-0.03 0.01 – -0.03 -0.01 -0.02 -0.02
0.02 0.01 – – -0.02 -0.02 – 0.02

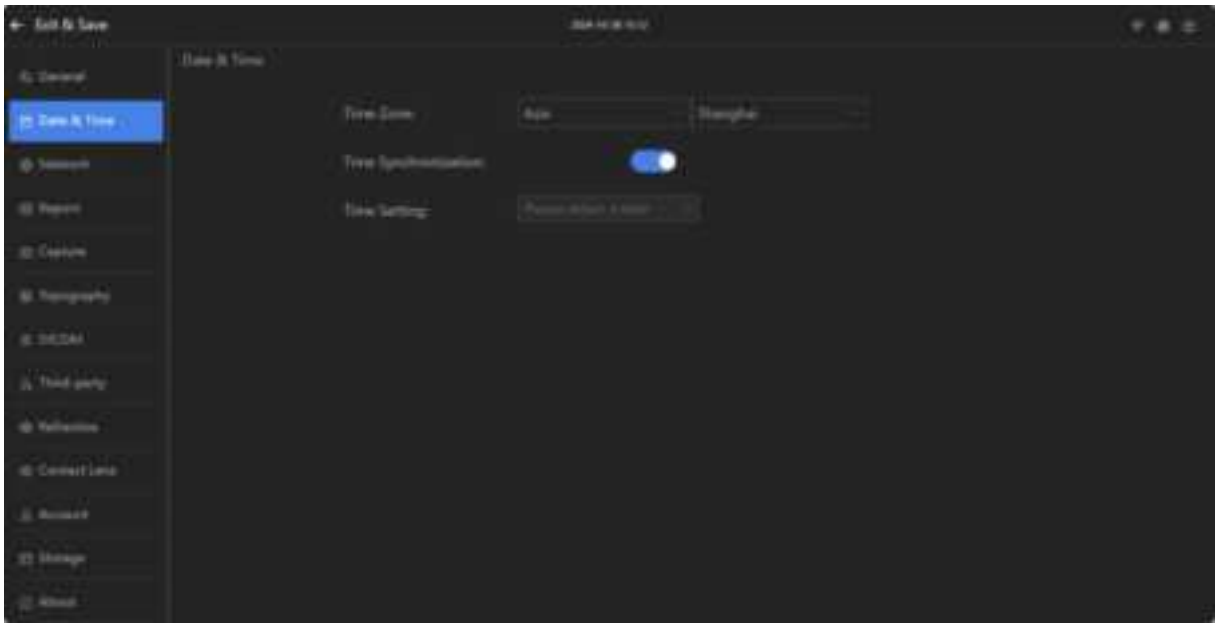
4. Settings

Click the **Settings** button  on the top right of the interface. The settings window is displayed.

4.1 General

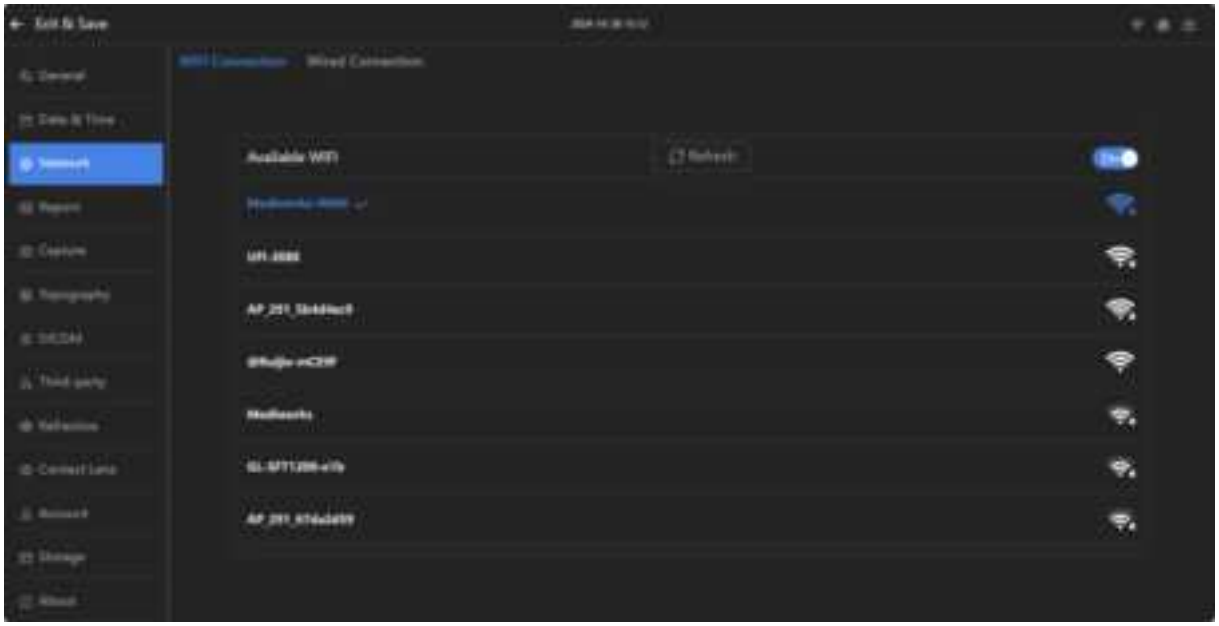
- **Language**: currently supports Chinese and English.
- **Date Format**: currently supports six date formats, which are YYYY-MM-DD, MM-DD-YYYY, DD-MM-YYYY, YYYY/MM/DD, MM/DD/YYYY, and DD/MM/YYYY.
- **Standby Time**: sets standby time of the device, values available: 5, 15, 30, 60 and Never.
- **Hide Keyboard**: hides/displays the soft keyboard on the interface.
- **Patient Auto ID**: sets the prefix and the number of digits for the PID, and enables/disables auto ID assignment.

4.2 Date and Time



- **Time Zone**: sets the region and city where the device is currently located.
- **Time Synchronization**: enables/disables network time synchronization.
- **Time Setting**: allows you to manually set the device time.

4.3 Network



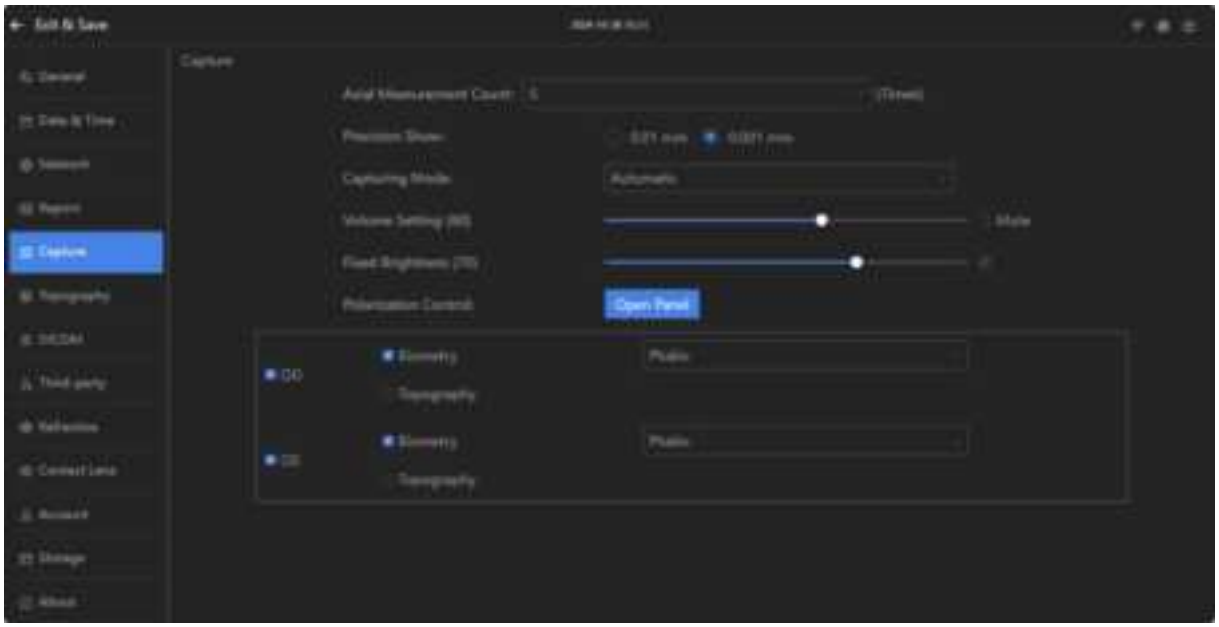
- **WIFI Connection**: After the Wi-Fi connection switch is set to **ON**, select the Wi-Fi network that you want to connect in the available Wi-Fi list, and enter the password in the displayed password input box to connect to the Wi-Fi network.
  After a WI-FI network is connected, is displayed on the top right of the interface. You can click the connected WI-FI in the list or to view Wi-Fi configuration information.
- **Wired Connection**: View the configuration of the wired connection.

4.4 Report

- Hospital information: sets the title, hospital, phone, and logo to be shown in the printed report.
- **Options**: selects print items, including Maps, Zernike, Biostatistics Values (including pupil and cornea, axial data, etc.), Myopia Prediction, and IOL Calculation. Tick the checkboxes of desired items to show them in the report. A checkbox ticked (with √) indicates that the related item is selected.
- Connect To Bluetooth: displays the Bluetooth list for connecting to a Bluetooth printer. You can select a desired Bluetooth device in the list and enter the password to connect to it.

- Open Settings Page: enters the printer settings webpage if a printer has been connected. For specific printer settings, see printer setting instructions.

4.5 Capture



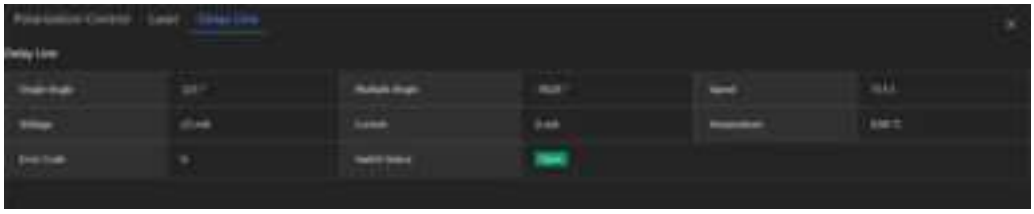
- **Axial Measurement Count**: sets the number of axial measurements. Values available: 1, 2, 3, 4 and 5.
- **Precision Shown**: sets displayed data precision. Values available: 0.01 mm and 0.001 mm.
- **Capturing Mode**: specifies the capture mode. Values available: Automatic and Manual.
- **Volume Setting**: sets volume, ranging from 0 to 100. You can also check **Mute** to mute the device.
- **Fixed Brightness**: sets brightness of the fixation light, ranging from 0 to 100. You can also click to restore the brightness to the default value.
- Capture item selection area: specifies OD, OS, and their capture items, and eye status for capture.
- Open Panel for Polarization Control: enters the polarization control panel, which contains the **Polarization Control**, **Laser** and **Delay Line** tabs, as shown below.

On the **Polarization Control** page, you can calibrate polarization of the motors.

- Initialization buttons Init 1 and Init 2: After you click an initialization button, the system automatically initializes related polarization motor position. The text on the initialization button will change to "Auto Configuration" after initialization is completed. Then, click Auto Configuration and wait until the system displays the message "save successfully". The automatically adjusted polarization motor position is saved.
- Return to last position: returns the related polarization motor to its last position.
- Return To Factory: returns the related polarization motor to the factory position.
- Save: saves the polarization motor position that manually adjusted by using the navigation keys.

The **Laser** page displays laser status.

The **Delay Line** page displays delay line motor status.



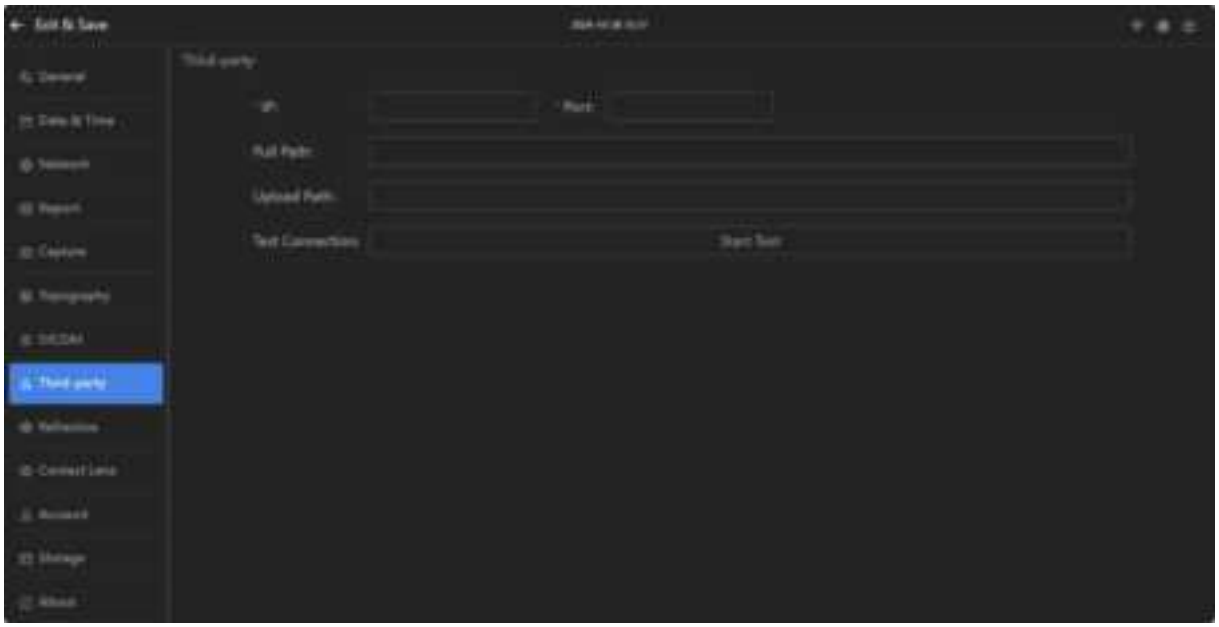
4.6 Corneal Topography

- **R Value**: sets the value display type in the corneal topographic map. Types available: Rh/Rv and Rf/Rs.
- **Coordinate System**: sets the type of coordinate system in the corneal topographic map. Types available: rectangular coordinate system and polar coordinate system.
- **Map Scale**: sets scale display type in the topographic map. Types available: diameter and radius.
- **Shape Factor**: sets the value display type in the topographic map. Types available: Ecc, E-val, P-val and Q-val. After a value display type is selected, you can set **Corneal Diameter**, ranging from 2 mm to 9 mm.

4.7 DICOM

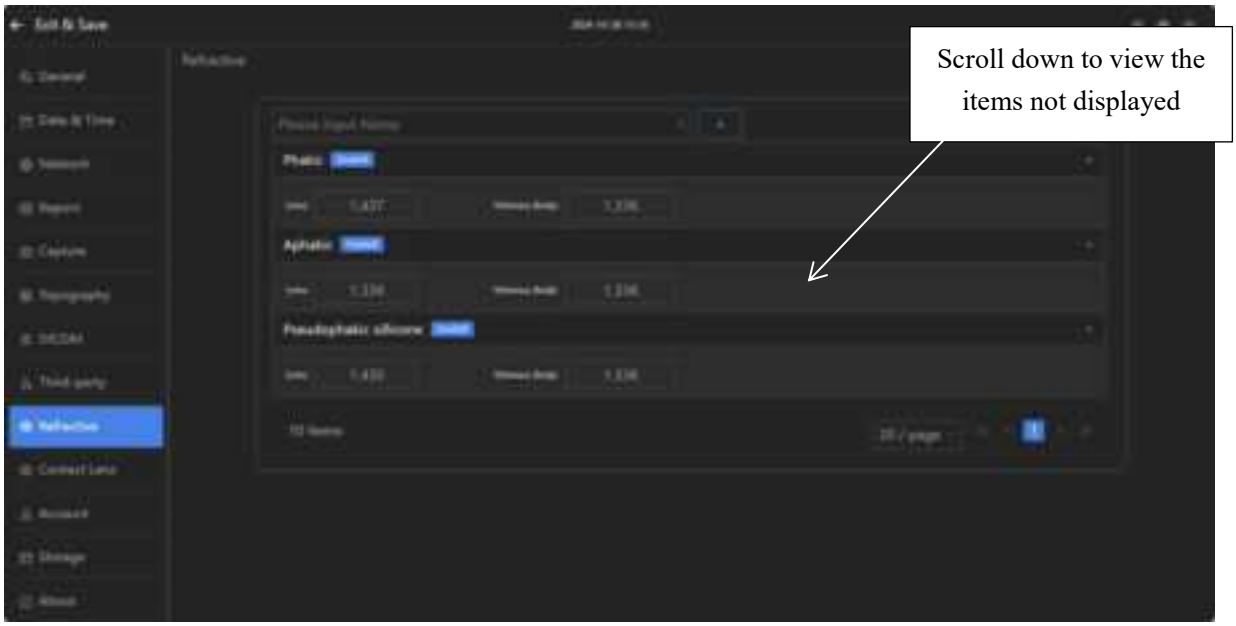
Configure information of the **Work List** server and the **PDF** server as required on the respective tabs, and select **Enable DICOM** to enable download of patient information from the DICOM server.

4.8 Third-party Software



Configure information of third-party software, such as the IP address, port, and customized paths for sharing data with the third-party software.

4.9 Refractive Index



- Refractive indices of the following eye status are provided by default: phakic, aphakic, pseudophakic silicone, pseudophakic memory, pseudophakic PMMA, pseudophakic acrylate, silicone-filled phakic, silicone-filled aphakic, silicone filled pseudophakic, and test eyes.
  Refractive indices of the default eye status can be modified. You can select an eye status in the list and click  , then modify refractive indices as required in the displayed window, and click 

  to save the modifications.

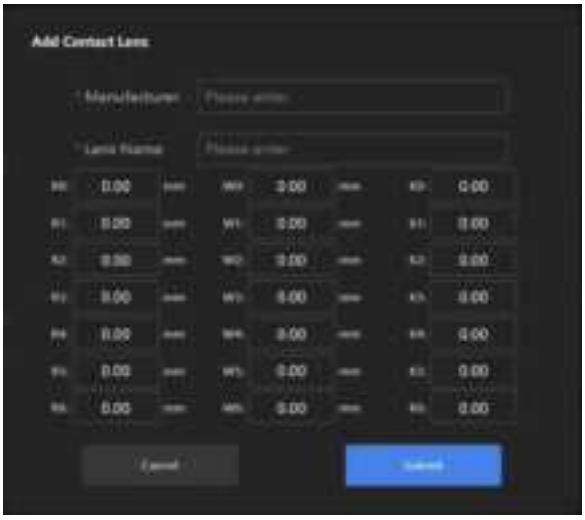
- Add new lenses: New lens types are allowed to be added. You can click +, and enter the lens name and refractive indices in the displayed window, and click Submit to save the new lens type.

- Refractive index:

  According to the measurement principle, biometric measurement directly obtains information about optical path length. As distance = optical path length / refractive index, an accurate refractive index is indispensable for accurate measurement of various distances (corneal thickness, anterior chamber depth, lens thickness, vitreous thickness, axial length). The default refractive index is 1.376 for cornea and 1.336 for aqueous humor. The refractive indices of the lens and vitreous body vary depending on the eye status. The measured distance changes as the refractive indices of the lens and vitreous body change. The default refractive indices of lens and vitreous body for various eye status have been given in the refractive index tab of the settings window. When measuring a test eye used for verifying accuracy, the refractive indices can be configured and adjusted based on the actual data.

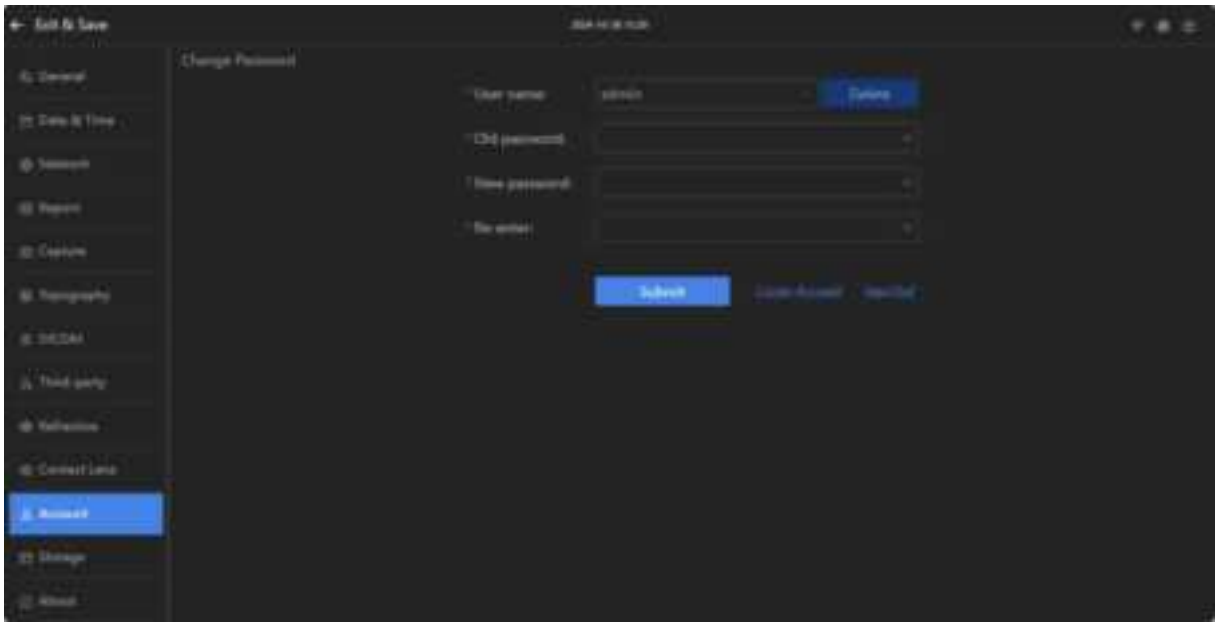
4.10 Contact Lens Management

- Add: Click  . In the displayed window, enter the manufacturer, lens name, and parameters and click  . The new lens is saved.



- Edit: Select the lens to be edited and click  . In the displayed window, edit the lens information.
- Delete: Select the lens to be deleted and click  . The selected lens is deleted.

4.11 Account



- The initial default account is **admin**, and the default password is **mediworks**.
- Change password: Select the username that you want to change password in the username drop-down box, enter the old and new passwords, re-enter the new password, and click  . The password is changed. You will be redirected to the login interface.
- Create user: Click **Create Account** on the interface above to create a user.

Enter the username and password, re-enter the password, and click Submit. The new user is added.

- Sign out: Click **Sign Out**. You will be redirected to the login interface.

4.12 Storage

- Disk Usage: It is displayed in used/total capacity.
- Backup Database: Click **Start Backup** to start database backup.
- Clean Up: Click **Clean up the recycle bin** to clear data in the database that is no longer in use.

4.13 About

The **About** interface allows you to view the product name, device model (i.e., software model), version and copyright information.

The device model and corresponding functions are determined by the device serial number. For example, the device serial number 550-J202201001-0-000000000002 determines that the device model is AL550; and the device serial number 551-J202201001-0-000000000002 determines that the device model is AL551.

NOTE: The data in the software interface above is only an example for demonstrating software functions. It should not be used as a basis for clinical diagnosis.

5. Cleaning, Protection and Maintenance

5.1 Cleaning Methods

Before cleaning, be sure the power supply is disconnected.

1. Clean and disinfect plastic parts: To clean plastic parts such as main device surface, chin rest and forehead rest, use a soft cloth dipped in soluble detergent or water to clean the dirt, and then wipe them twice with 75% ethanol and wait for 3 minutes. Note: Do not wipe with any corrosive cleaning agents to avoid damaging the surface.
2. Clean the screen: To clean dust on the screen, gently wipe it off using a clean soft cloth moistened with distilled water, or using a screen-specific cleaning cloth. Do not use organic solvents, such as alcohol, acetone or other soluble detergents.

   ⚠**Note: Do not wipe with hard objects.**

3. Replace chin rest paper: When the chin rest paper pad is used up, pull the two fixing bolts on the chin rest upwards, put a new paper pad in place, and then install the fixing bolts.
   Note: Do not clean the device with organic solvents such as diluent or corrosive cleaning agents to avoid damaging the device.

5.2 Cleaning Cycle

The optical biometer should be used in a relatively clean environment. To ensure normal use and observation, the operator should clean it regularly. The cleaning interval is recommended as follows:

1. For plastic parts such as chin rest and forehead rest:

   Cycle: Recommended to be cleaned every time after a patient is examined.

   These two parts are in frequent contact with patients and should be cleaned and disinfected in a timely manner. The cleaning and disinfecting cycle is only our recommendation. The forehead rest should be cleaned and disinfected, and the chin rest paper should be replaced after each patient is examined.

2. For the whole device and display screen:

   Cycle: Recommended every 6 months.

5.3 Maintenance

Proper cleaning and protection will help to extend the life of the product.

When the device is not used for a long time, the power supply should be disconnected.

5.4 Service Life

The service life of the optical biometer is 8 years.

The product is covered by a limited warranty granted by your seller.

5.5 Waste Disposal

The product is labeled with the  symbol and must not be disposed of as household waste. It must be disposed of in accordance with local laws and regulations.

If you have any questions, please contact us.

Troubleshooting

If a malfunction occurs, please check it according to the following table for guidance. If the malfunction is still not rectified, please contact MediWorks Service or our authorized distributors. Computer failures can also be resolved by contacting the customer service of the computer supplier.

Malfunction	Possible Cause	Solution
The device failed to turn on	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.	Put the switch in the I position.
Acquisition failed	Failure to maintain eye fixation as required during the capture.	Keep the patient's eyes staring at the fixation LED, with the eyeballs as still as possible for recapture.

When you contact us, please provide the following information.

Model: Model number of the product you purchased (see product label).

Serial Number: Serial number of the product you purchased (see product label).

Purchased Time: The date you purchased the product.

Malfunction: Malfunction details.

Disclaimers

1. Shanghai MediWorks Precision Instrument Co., Ltd. is not responsible for any damage caused by fire, earthquake, third party behavior, other accidents, carelessness, misuse, or use under abnormal conditions.
2. Shanghai MediWorks Precision Instrument Co., Ltd. is not responsible for any loss caused by the inability to use this product due to loss or suspension of business.
3. Shanghai MediWorks Precision Instrument Co., Ltd. is not responsible for any damage caused by operations not described in this manual.
4. Diagnosis is the responsibility of the doctor concerned, and Shanghai MediWorks Precision Instrument Co., Ltd. is not responsible for the results of the diagnosis.

Production Date: See label

Version: 1.0 20250117

Shanghai MediWorks Precision Instruments Co., Ltd.

No.7, Ming Pu Phase 2, No.3279 San Lu Road, Min Hang District, 201100, Shanghai, China

Tel: 0086-21-54260421; Fax: 0086-21-54260425

Email: international@mediworks.biz

www.mediworks.biz

EC REP

Company Name: CMC Medical Devices & Drugs SL

Company Address: C/ Horacio Lengo N18, Málaga, 29006, Spain

Email: info@cmcmedicaldevices.com