Optical Coherence Tomography

User Manual

Version：A2

Please read this user manual carefully before using this product and keep it in a safe place.

Preface

Dear users,

Thank you for purchasing Optical Coherence Tomography. Our OCT is suitable for high-definition structural imaging of the fundus and anterior segment of the eye, using optical coherence tomography (OCT) technology, based on the principle of low-coherence optical interferometry, to obtain the reflected light signals of the biological tissues, and then through the optoelectronic conversion, digital image reconstruction and computational analysis, to provide the retina, the cornea, the image of the tissue and the thickness of the quantitative indexes of the ophthalmology.

Optical Coherence Tomography (OCT) is a fast, non-contact, non-destructive, high-resolution imaging technology that can obtain information on the depth direction of the biological structure, and then combined with one-dimensional and two-dimensional light scanning can be reconstructed to obtain three-dimensional stereo spatial information, in order to clearly distinguish the structural changes of the retina, the choroid, the cornea, the interlaminar layers, and the overall structure of the cornea. The product provides automatic imaging assistance function, which is convenient for operators to take high-quality images. At the same time, it provides efficient and reliable quantitative thickness analysis function, image management function, historical data query and comparison function.

This user manual to be used as a training, utilization and reference guide.

The user should be a trained medical professional or technician with extensive experience in the diagnostic interpretation of images generated by ophthalmic optical coherence tomography equipment. When training in the operation of this product is provided, no diagnostic guidance is provided on the interpretation of the images generated. This manual does not provide such knowledge.

Important note

1. Declares that

- Please read the contents of this manual carefully before using the instrument. Transportation, installation, use, maintenance, replacement of accessories and disposal should be carried out in accordance with the contents of this manual.
- The contents of this manual apply only to our OCT-1000Optical Coherence Tomograph product.
- This instrument should be operated by trained personnel only in accordance with the contents of the manual and the operating instructions. Before and during the operation of the instrument, be aware of the safety warnings and specifications.
- Maintenance of this instrument can only be performed by qualified service personnel authorized by manufacturer
- Ltd. reserves the right to change technical specifications without notice due to the continuous improvement of our products.
- Please keep this manual, the final interpretation of this manual belongs to manufacturer

2. Instrument installation

installation requirements

- This instrument must be installed in a ventilated room and must not obstruct the ventilated instrument cover that dissipates heat from the equipment.

	**CAUTION: Failure to provide proper ventilation may cause a heat buildup effect resulting in component failure and/or misfire conditions.**

- This instrument should be used with a dedicated power supply. Depending on your specifications, the instrument is shipped from the factory configured for use with 220 V line voltage.

3. Notes

In accordance with IEC 60601-1:2020, this instrument is classified as follows.

	• Class I equipment - protected against electric shock. • Type B - Degree of protection against electric shock for applicable components (forehead and jaw rest). • General Equipment (IPX0) - Degree of protection against liquid immersion (none). • Continuous Operation - Operation Mode.

	**CAUTION: When transporting or moving the instrument, please place it in the direction indicated on the instrument or the packing box, otherwise the instrument may be unbalanced.**
	**Note: When reboxing instruments, place them in the direction indicated and place them in a smooth and light manner.**
	**Note: The equipment must be properly grounded and connected to a qualified power supply in accordance with the operating voltage.**
	**Note: The instrument should be placed in a well-ventilated clean space, and keep a distance from other electronic equipment. The instrument should be protected from water, dust and corrosive liquids.**
	**Note: The table should not be tilted to prevent the instrument from slipping off the table during use.**
	**CAUTION: It should be stored, transported and used under the specified environmental conditions of temperature, humidity and air pressure, otherwise it may damage the electronic components and optical subsystems of the instrument, which may lead to incorrect diagnosis and treatment.**
	**Note: Please check under the guidance of a professional, non-professionals are prohibited from using this instrument without authorization.**
	**Note: Only manufacturer authorized technicians can disassemble**

	or repair this instrument, the user shall not unauthorized disassembly or repair. (outside of China, please contact your local distributor.)
	**Note: When it is necessary to connect peripheral devices to this instrument (e.g., printers, desks, network switches, etc.), it is necessary to ensure that the various devices of the system connected to the equipment meet the requirements of IEC60601-1.**
	**Note: Additional isolation transformers are required for accessing peripheral devices that do not have a certificate of compliance with the IEC60601-1 standard.**
	**Note: When the instrument is in use, the patient should only place his/her head on the jaw rest and forehead rest, and avoid the rest of the body or clothing and other objects from touching the instrument. In particular, do not touch the parts of the instrument during the movement of the instrument.**
	**CAUTION: Do not disassemble the instrument case without authorization, unauthorized opening of the instrument case may result in potential optical hazards.**
	**CAUTION: Do not scan patients who have been injected with photodynamic therapy (PDT) therapeutic agents (e.g., Visudyne®) within the previous 48 hours. Failure to follow this warning may result in unintended exposure and uncontrolled neovascularization.**

4、Electromagnetic compatibility (EMC)

The minimum immunity requirements for this product according to the IEC standard for electromagnetic compatibility are shown in the table below. Please use this equipment in an electromagnetic environment that follows the guidelines in the table below.

	**CAUTION: Use of accessories, sensors, and cables other than those specified herein may result in increased equipment radiation or reduced tolerance.**

⚠	**CAUTION: This product should not be placed next to or stacked with other equipment. If it is to be placed next to or stacked with other equipment, the equipment or system should be observed to ensure proper operation in the configuration in which it will be used.**

EMC（IEC 60601-1-2：2020）

Guidelines and Manufacturers' Statements - Electromagnetic Radiation		
The OCT-1000is intended for use in the electromagnetic environments described below, and the customer or user of the OCT-1000should ensure that the equipment is used in such		
Launch test	**Conformity**	**Electromagnetic Environment - Guidelines**
Radio Frequency Emission IEC/CISPR 11	1 group	The OCT-1000uses RF energy only for its internal functions. As a result, its RF emissions are very low and there is little potential for interference with nearby electronic equipment.
Radio Frequency Emission IEC/CISPR 11	Grade A	The OCT-1000is suitable for use in installations other than domestic installations as well as installations directly connected to the public low-voltage power supply network (supplying buildings used for domestic purposes).
Harmonic emission IEC 61000-3-2	Not applicable	
Voltage fluctuation/flicker emission IEC 61000-3-3	Not applicable	

guidelines and manufacturers' declarations - electromagnetic immunity			
The OCT-1000is intended for use in the electromagnetic environment specified below, and the			
immunity test	**IEC60601 test levels**	**Conformity level**	**Electromagnetic Environment - A Guide**
electrostatic discharge IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	The floor should be wood, concrete or tile, and if the floor is covered with a synthetic material, the

			relative humidity should be at least 30%.
electrically fast transient pulse clusters IEC 61000-4-4	±2 kV to power lines ±1kV for input/output lines	±2 kV to power lines Not applicable	The net power supply should be of a quality typically used in a commercial or hospital environment, the
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to ground	±1 kV line to line ±2 kV line to ground	The net power supply shall be of a quality typical of use in a commercial or hospital environment, the
voltage dips, short interruptions and voltage variations on the power input line IEC 61000-4-11	<5% U_T for 0.5 cycles (>95% transient drop at U_T) 40% U_T for 5 cycles (On U_T, 60% temporary drop) 70% U_T for 25 cycles (On U_T, 30% temporary drop) <5% U_T for 5s (>95% transient drop at U_T)	<5% U_T for 0.5 cycles (>95% transient drop at U_T) 40% U_T for 5 cycles (On U_T, 60% temporary drop) 70% U_T for 25 cycles (On U_T, 30% temporary drop) <5% U_T for 5s (>95% transient drop at U_T)	The net power supply should be of a quality typically used in a commercial or hospital environment. If users of the OCT-1000 require continuous operation during power interruptions, an uninterruptible power supply or battery power is recommended for the OCT-1000
Work frequency magnetic field (50Hz) IEC 61000-4-8	3A/m	3A/m	(a) The IF magnetic field shall be characterized by the level of the IF magnetic field typical of a site in a typical commercial or hospital environment
Note:U_T means the AC network voltage before applying the test voltage.			

<table>
<tr><th colspan="4">Guidelines and Manufacturer's Declarations - Electromagnetic Immunity</th></tr>
<tr><td colspan="4">The OCT-1000is intended for use in the following electromagnetic environments.The customer or user of the OCT-
1000should ensure that it is used in such electromagnetic</td></tr>
<tr><th>immunity test</th><th>IEC 60601 test level</th><th>Conformity level</th><th>Electromagnetic Environment - Guidelines</th></tr>
<tr><td>RF conduction
IEC 61000-4-6</td><td>3 V
150 kHz~ 80MHz</td><td>3 V
(RMS)</td><td rowspan="2">Portable and mobile RF communications equipment should not be placed closer to any utilized portion of the OCT-1000(including cables) than the recommended spacing distance. The distance should be farther than the recommended spacing calculated from equations applicable to the transmitter frequency.

recommended spacing
$d = 1.2\sqrt{P}$
d =1.2 80 MHz~800MHz
d = 2.3 800 MHz~2.5GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer; and d is the recommended spacing in meters (m).
The field strength of a fixed RF transmitter is determined by a survey of the electromagnetic fielda and should be lower than the compliance level in each frequency rangeb.
Interference may occur in the</td></tr>
<tr><td>radiofrequency radiation
IEC 61000-4-3</td><td>3 V/m
80 MHz~ 2.5 GHz</td><td>3 V/m</td></tr>
</table>

			vicinity of equipment marked with the following symbols. 
Note 1: At 80 MHz and 800 MHz, the formula for the higher frequency band should be used. NOTE 2: These guidelines are not applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and people.			
a Field strengths of fixed transmitters, such as base stations for wireless (cellular/cordless) telephones and terrestrial mobile radio, amateur radio, AM and FM broadcasting, cannot be predicted with theoretical accuracy. In order to assess the electromagnetic environment of a fixed RF transmitter, a survey of the electromagnetic field should be considered. If the measured field strength of the OCT-1000exceeds the above RF compliance levels, the OCT-1000should be observed to confirm normal operation. If abnormal performance is observed, additional measures may be required, such as reorienting or repositioning the OCT-1000. b In the entire frequency range from 150 kHz to 80 MHz, the field strength should be less than 3 V/m.			

Recommended spacing between portable and mobile RF communications equipment and the OCT-1000

The OCT-
1000is intended for use in electromagnetic environments where RF emissions are controlled. Depending on the maximum rated output power of the communication equipment, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF communication equipment

The rated maximum output power/W of the transmitter, the	**Spacing/m, based on transmitter frequency**		
	150 kHz ~80MHz	80 MHz ~800MHz	800MHz~ 2.5 GHz
	d = 1.2	d = 1.2	d = 2.3
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 the maximum rated output power of the transmitter not listed in the above table, the recommended isolation distance d, in meters (m), can be determined by the formula in the frequency column of the corresponding transmitter, where P is the maximum rated output power of the transmitter provided by the manufacturer of the transmitter, in watts (W). Note 1: At the 80 MHz and 800 MHz frequency points, the formula for the higher frequency range is used. Note 2: These guidelines may not be appropriate in all cases and electromagnetic propagation is affected by absorption and reflection from buildings, objects and the human body.			

Attachments

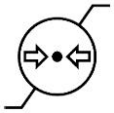
	**WARNING: Attachments connected to analog and digital interfaces must be verified according to the appropriate IEC standards (e.g., IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). In addition, all configurations should comply with the system standard IEC 60601-1-1. Anyone who connects additional equipment to the signal input section or signal output section configures the medical system and is therefore responsible for ensuring that the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, please consult the technical service department or your local representative.**

5. product compliance

National medical device laws and regulations.

6. Symbols and labels

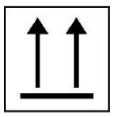
	It is important to read the user manual before using the device.
	Warning.

	Risk of electric shock. Note: Indicates a risk of electric shock due to the presence of uninsulated high voltage inside the instrument. Do not remove the cover or parts of the instrument.
	Fuses
	Type B applicable components.
	Manufacturer
	Serial number
	catalogue number
	Conformite Europeene
	Authorized representative in the European Community/European Union.
	Unique Device Identification.
	Temperature limitation.
	Humidity limitation.
	Atmospheric pressure limitation.
	Date of manufacture.

	Use by date

Protective packaging symbols

The protective packaging symbol specifies handling requirements and conditions of transportation and storage.

	This end up
	Handle with care
	Stay dry
	Fragile items, handle with care

Note: This instrument cannot be shipped disassembled from its original packaging.

8. Environmental impacts

This instrument will not produce pollutants that have an impact on the environment during normal use in accordance with the instructions, if the instrument exceeds its service life or is damaged or obsolete, please do not discard it at will, but dispose of it in accordance with the local and national (regional) requirements to avoid causing environmental pollution.

9. Instrument disposal

If you want to upgrade this instrument, please contact manufacturer. for the trade-in or upgrade price we offer. If you do not want to trade-in, please dispose of it

according to local and national (regional) requirements.

Content

PRODUCT OVERVIEW

The Optical Coherence Tomography is a precision optical instrument with automatic measurement assistance for tomographic imaging of the posterior and anterior segments of the eye. It utilizes near-infrared band low-coherence optical interferometric imaging technology, and through a variety of scanning modes, it can perform rapid and non-destructive imaging of the shape of biological structures and lesions in the posterior or anterior segment of the eye. It can be used in a variety of scanning modes

- **Principle**

This product uses near-infrared low-coherence light with a certain bandwidth to irradiate biological tissues, and through interferometric imaging methods, records and measures the light signals reflected or backscattered from biological tissues at different depths, so as to obtain high-resolution information in the depth direction. The one-dimensional scanning can obtain a cross-section of the biological tissue, and the two-dimensional scanning can obtain a three-dimensional view of the biological tissue.

This product adopts non-contact, non-invasive non-destructive optical measurement method. The frequency of the light wave used is so high that the amplitude of the light wave cannot be measured directly by existing electronic equipment, but can only be calculated by measuring the intensity of the light wave through interferometric imaging. By using a near-infrared light source with a bandwidth of 45 nm, an imaging resolution of better than 5 micrometers can be obtained.

This product adopts low coherence light source inside, the light beam is divided into a reference beam and a signal measurement beam by fiber optic interference module. The reference beam is reflected along the original path by a linear motor-driven mirror, forming a reference arm. The signal measurement beam is reflected by two orthogonal scanning mirrors through a set of mechanical zoom optics to irradiate the cornea or from the pupil into the irradiation of the fundus, different depths of reflection and backscattered light signals, through the same optical path back to form the sample arm. The optical signals returned from the reference arm and the sample arm are interfered and recorded by the spectrometer, and then the structural information of the biological tissues at different depths is calculated through the conversion, transmission and numerical

reconstruction of the optoelectronic signals. By controlling the rotation of the two galvanometer mirrors, the measurement of different regions of the fundus or anterior segment of the eye can be realized. Measurement images and analysis reports are stored in the mainframe database and can be exported or printed.

Intended use

Using the principle of optical coherence imaging, the information of tissue fault plane is obtained.

Intended patient populations

The measurement of posterior segment of the eye was performed in patients with -20 to +25 days without cataracts and without symptoms of ocular opacity.

Intended user

Hospital.

Side-effects/Complication

Not have.

- **Functionality**

- Non-invasive, non-contact observation of the shape of the fundus or retina or its lesions can be performed and analyzed for measurement and comparison.
- Non-invasive, non-contact observation of the shape of the anterior segment of the eye and analysis of measurements and comparisons provide auxiliary information for the diagnosis and treatment of ocular diseases.

- **Structural description**

This product consists of an optical main unit, a computer (including a monitor), a power supply, an eyelet adapter, and image processing software (release version V1).

- **Optical mainframe**

The optical host contains three major components: the XYZ motion platform component, the refractive system component, and the base support component. The optical head is the main measurement part of the optical host, realizing the core functions of refractive compensation, internal fixation, pupil localization and imaging scanning, etc. During the measurement, the

detected light signal enters the detection area of the human eye through the eyepiece, and the light signal reflected from the tissues of the human eye is collected by the optical head through the eyepiece, and then formed into the image of the tissues through signal processing.

The XYZ stage functions to align the center of the eyepiece to the center of the pupil in conjunction with a control algorithm or manually.

The chassis has an interface panel that provides external power input and switching, OCT signal transmission, optical host control signal transmission, pupil positioning signal transmission and other functions. Inside the chassis, there are voltage regulator circuits and master PCBA, which supply power to the optical host and respond to control commands. The front panel of the base has a honeycomb panel for transmitting the built-in speaker volume.

Figure 1-1 Optical main unit (front view)

Figure 1-2Optical mainframe (rear view)

Headstock

The patient's forehead can be gently rested against the forehead protector to stabilize the patient's head during image acquisition.

⚠Note: Before examining each patient, please clean the frontal rest and use a frontal rest pad.

- **Eyepieces**

If the eyepiece is contaminated with fingerprints, oil, or dust, the results of image acquisition will be affected. Be sure to check the eyepieces for contamination before image acquisition. Cover the eyepieces with an eyepiece cover when image acquisition is not in progress.

- **Jaw rest**

During image acquisition, the patient's jaw rests on the jaw rest. The height of the jaw rest can be adjusted for each patient.

- **Interface Panel**

1) power switch and jack

Make sure that the power cord is securely plugged into the socket and the switch is set to the "ON" position before use.

2) data transmission port

The DB-9 port is for optical host control signal transmission and the USB port is for data transmission. These two port cables will be connected and configured by the manufacturer's personnel during installation of the unit.

⚠CAUTION: Do not connect unknown cables to these ports, and do not exchange the wires of these ports, otherwise the device will not work properly and may cause damage to the device.

Figure 1-3 Bottom Interface Panel

- **Base**

Product base, support the whole machine work.

- **Speaker panel**

Deliver the voice prompt sound.

- **XYZ Platform**

Complete the optical head XYZ movement so that the eyepiece is away from or close to the human eye to complete the shot

- **Optical head**

The optical imaging mirror is composed of optical components integrated together to complete optical imaging.

- **Computer (with monitor)**

The control of the equipment, as well as the processing and display of data, is carried out by a computer and a monitor with a keyboard and mouse as input devices.

Figure 1-4 Computer cable locations.

⚠Note: Do not arbitrarily change the position of the port where the optical host is connected to the computer host, or the device may not work properly.

- **Power supply**

The power cords of the optical mainframe, computer, and monitor should be connected to the equipment's dedicated power supply, and the dedicated power supply should be connected to the network power supply.

⚠Note: You should not change the power cords of the optical mainframe, computer and monitor, or connect them directly to the network power supply without using a dedicated power supply. Failure to do so may result in reduced performance or damage to the equipment.

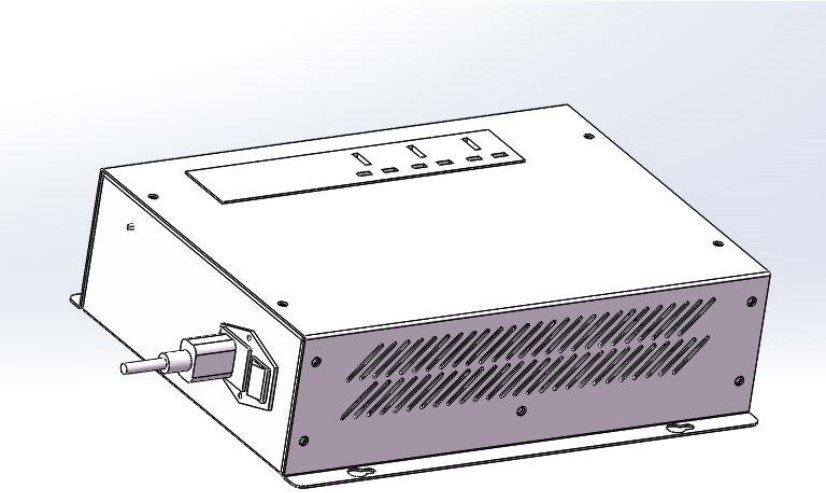


Figure 1-5 Device-specific power supplies that

- **The immediate section adapter**

The anterior segment adapter is an accessory that allows OCT image acquisition of the anterior segment of the eye by attaching the anterior segment adapter to the eyepiece.

Note: OCT-1000, OCT-1000shipping configuration list contains anterior eye joint adapter;

BV1000T shipping configuration list does not contain anterior eye joint adapter, if you need, please contact with manufacturer to buy.

Figure 1-6 Diagram of the structure of the eyelet adapter

- **Product installation**

This instrument should only be installed by manufacturer, so detailed assembly and installation instructions are not provided here. In this section, we only introduce the assembly method of some basic accessories that may be used by users, such as the front section module and

external indicator light.

- **Connecting the optical mainframe, the computer mainframe and the monitor**

1. Place the optical mainframe, monitor and computer mainframe on a smooth workbench in the layout shown in Figure 1-6.

2. Connect the cables of the optical main unit, monitor and computer main unit to the corresponding ports, and connect the mouse and keyboard.

3. Check that the power switch is in the "OFF" (O) position. Then, connect the power cords of the optical host, computer and monitor to the dedicated power outlet.

⚠Note: Be sure to connect the power cord to a power outlet with a protective grounding terminal. Otherwise, in the event of system failure or leakage, electric shock or fire may result.

4. Connect the special power supply to the network power. The connection is completed.

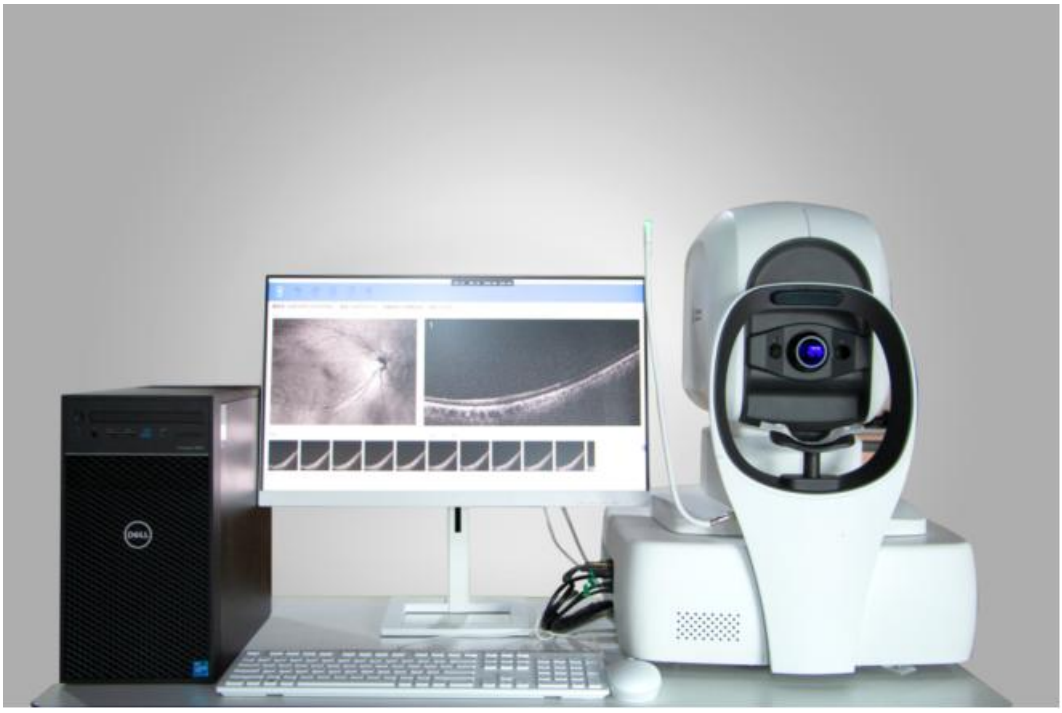


Figure 1-7 Schematic diagram of the completed installation

5, press the power switch, wait for the equipment startup is complete.

6, click the computer host desktop software icon, wait for the software to start and self-test through, you can start using.

- **Installing the front eyelet adapter**

1. Take the front eye joint adapter out of the storage box.

⚠Note: When taking out the front section adapter, do not touch the front section lens with your hand, otherwise fingerprints and other smudges will be easily left on the lens.

2. Check that the anterior segment adapter lens is not contaminated.

If the lens is contaminated, the image effect obtained will deteriorate. It is recommended that you check for stains on the lens before performing the inspection, and if there are any stains, clean the lens as described in "5.4.1 Cleaning the anterior eye section adapter".

3. Fix the wider end of the aperture of the anterior eyelet adapter to the eyepiece by aligning it with the objective lens of the host.

Once the anterior segment adapter is aligned with the host objective, the anterior segment adapter will be firmly attached to the eyepiece holder.

⚠Note: The lens must be operated slowly during operation, otherwise it will be easily damaged.

Figure 1-8 Schematic diagram of the installation of the anterior eye section

- **The shutdown of equipment**

The unit should be shut down when it is no longer in use. The following steps should be followed for shutdown.

- Save the data and exit the client software.
- Use the Windows shutdown button on the computer's mainframe to turn off the computer, do not power down the computer directly.
- Press the on/off button of the monitor and optical main unit to disconnect the power.

- Press the on/off button of the dedicated power supply to disconnect the power.

• DESCRIPTION OF THE SOFTWARE INTERFACE

The software interface will begin withTable 2-1The symbols shown illustrate the areas present in each sector.

Table 2-1 Description of the software interface symbols

Symbol	Description	As an example
[]	pages, windows, modules	[Login] screen, [Settings] window
<>	button	<Close> button, <Start> button
【】	options, text boxes	[Language] drop-down box, [Path] text box

This software is divided into 8 interfaces, all sectors can be basically divided into [navigation bar] (egFigure 2-1①), [information column] (egFigure 2-1②) and [core functional areas] (egFigure 2-1(③) Three parts.

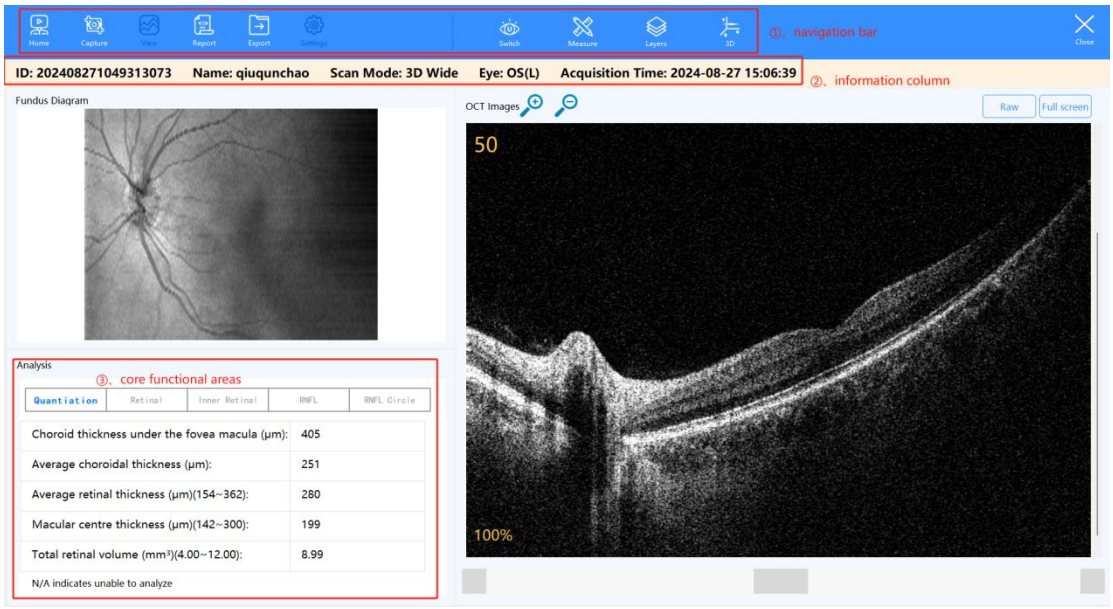


Figure 2-1 A three-part schematic of the interface

The [Navigation Bar] is located at the top of the interface, providing quick navigation jumps to the main interfaces and quick access to the functions of each interface. For the function of the [Navigation Bar] icon, seeTable 2-2。

The [Information Bar] displays basic information about the currently selected examinee.

[Core Functional Area] provides the core functions of the current interface.

Table 2-2Functions of the icons [in the navigation bar]

	The default screen after launching the program and logging in, the screen for filtering subjects or creating new subject profiles, and the preview function for OCT images and reports.
	After selecting a subject, click this icon to jump to the [Capture] screen to capture an image for that subject
	After selecting an image, click this icon to jump to the [Image Browse] screen to view the image
	After selecting a report, click on this icon to jump to the [Report View] screen to view the report
	After clicking it, it will prompt that the export data is successful and the data will be downloaded to the folder in the specified path
	Click it to open the [Settings] screen

The elements and functions of each sector or window are described next in the order in which they are likely to be encountered in actual use.

- **Launching the [Login] screen**

Launch the software and wait until the loading is complete, the first visible is the [login] interface, such asFigure 2-2Shown.

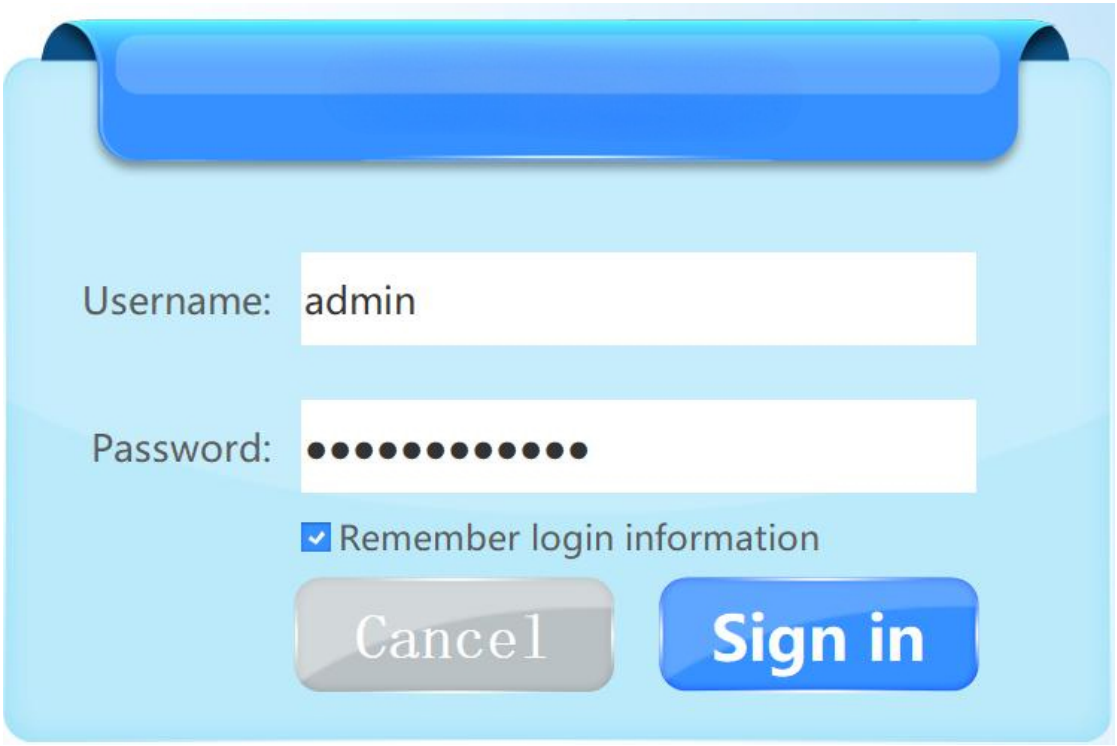


Figure 2-2 The login screen

In the [Login] screen, users can enter their user name and password to obtain permission to continue accessing data, capturing images, viewing images, printing reports, and other functions.

- **[Start] screen**

After successful login, the software switches to the [Start] main screen. IfFigure 2-3shown, is divided into 6 panes.

Figure 2-3 Starting the interface

- The [Subject Registration] pane: Figure 2-3 ①. Click on the Register button to enter the registration window for the examinee information register.

- [Prosecutee Inquiry] pane: egFigure 2-3The case number, name, and enrollment time were searched. Retrieving historical examinees by case number, name and enrollment time.

  It also provides a registered examinee function.
- [List of examinees] pane: egFigure 2-3③. Lists all eligible examinees for user selection.
- [OCT List] pane: egFigure 2-3of ④. Lists all OCT image previews of the selected subject for the user select.
- [Report List] pane: egFigure 2-3⑤. Lists thumbnails of all reports for the selected examinee for user selection.
- The [User Management] pane is shown in Figure 2-3 ⑥. You can batch upload the examinee information, edit and delete the information and corresponding images in the examinee list, and also bind the QR code to the applet to view the images.

- **[Registration] and [User Management] screens**

Click the <Register> button on the main screen (Figure 23(①), you can open the [Registration] interface of the examinee, as shown in Figure 2-4. Fill in the information such as name, gender, continent, date of birth, age, case number, cell phone number, ID number, e-mail, address and comments, etc. and click "Save" to complete the registration. The case number, name, gender, and date of birth will be displayed in the [Subject List] (Figure 2-3(③)).

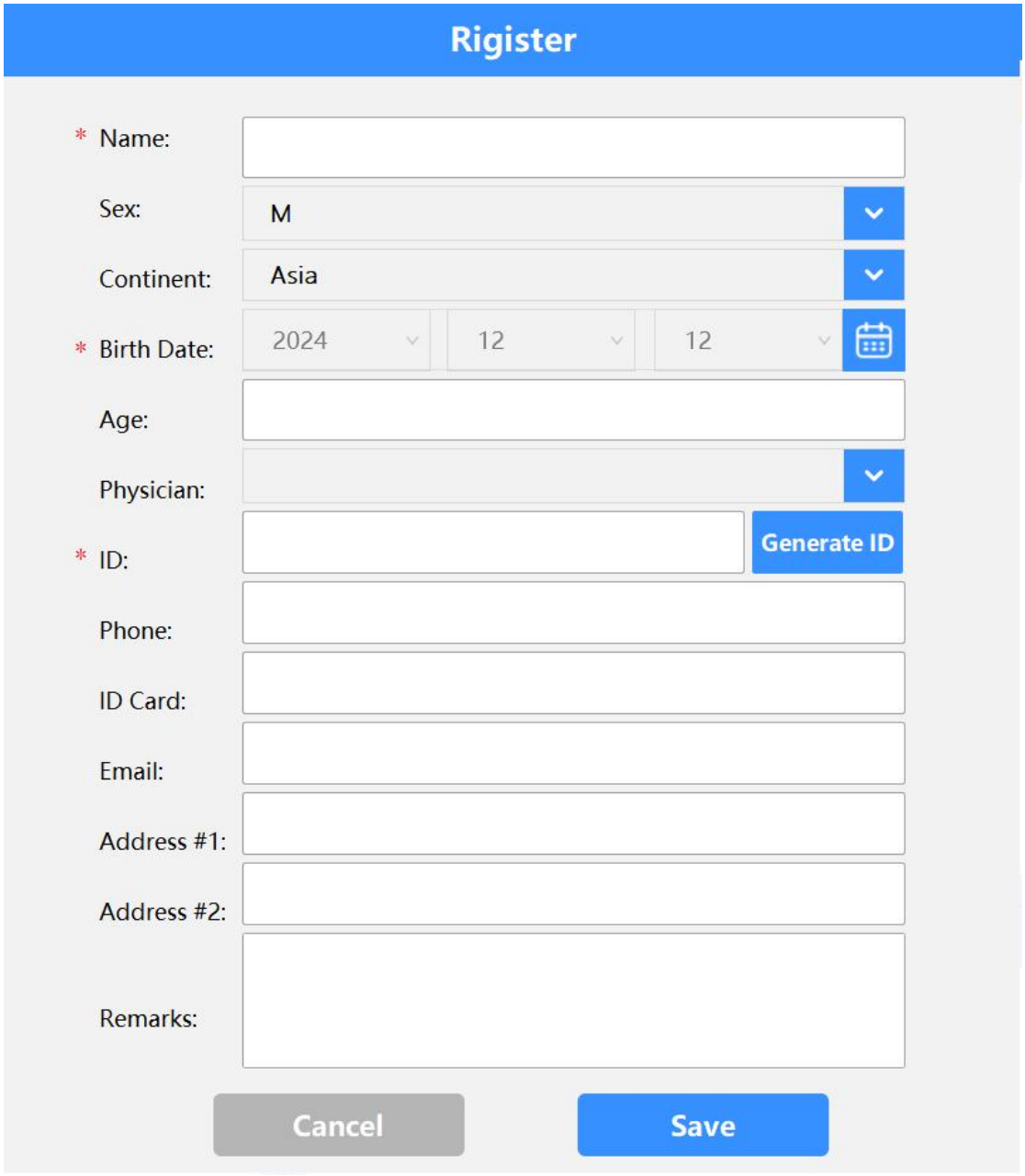


Figure 2-4 New case interface

When it is necessary to modify examinee information or delete images and reports, click the <User Management> button on the [Start] main screen (egFigure 2-3(之⑥), you can open the [user management] interface, such asFigure 2-5This interface allows you to update the examinee's information, delete the examinee's data, and delete the examinee's OCT images and corresponding reports. In this interface, you can update the information of the examinee, delete the data of the examinee, delete the OCT image and the corresponding report of the examinee, and export the

report to the specified path.

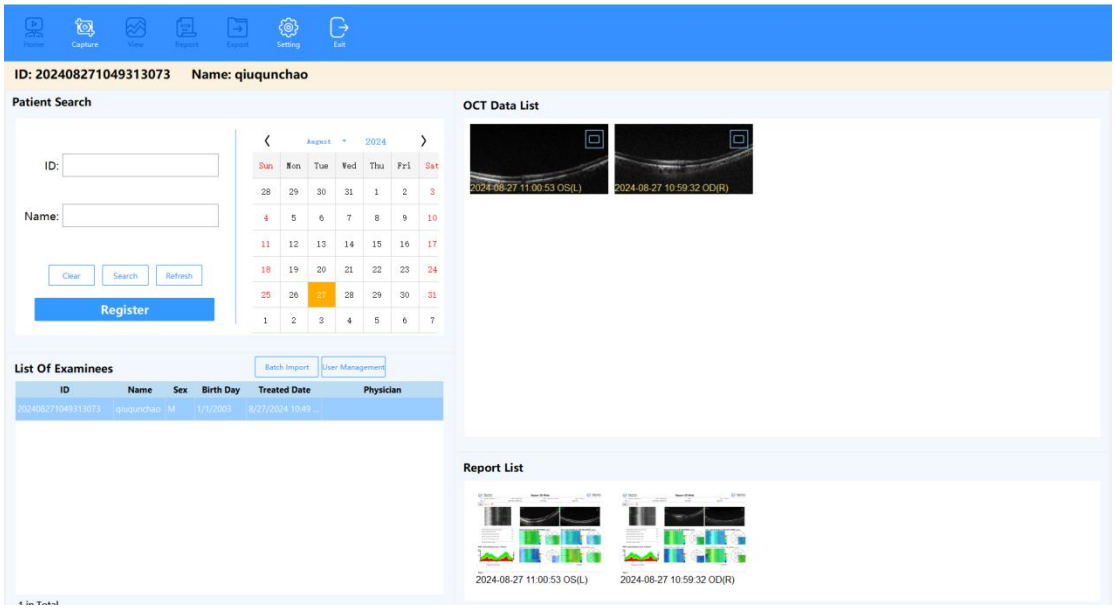


Figure 2-5 user management interface

• [Capture] interface

When you open the software for the first time, select the examinee, click the <Acquisition> icon to enter the [Acquisition] interface, initialize the device and select the acquisition mode to start image acquisition.

After selecting the examinee, click the <Acquisition> icon to enter the [Acquisition] interface and start image acquisition. The acquisition interface is divided into four sub-interfaces, namely [mode selection] interface, [pupil localization] interface, [fundus focusing] interface and [result preview] interface. The four interfaces are described below.

[Mode Selection] screen such asFigure 2-6Shown.

The interface is divided into two panes, namely.

- [Mode Selection] pane: Selects the mode of acquisition and the eye being acquired.
- [Pupil Preview] pane: Previews the position of the pupil.

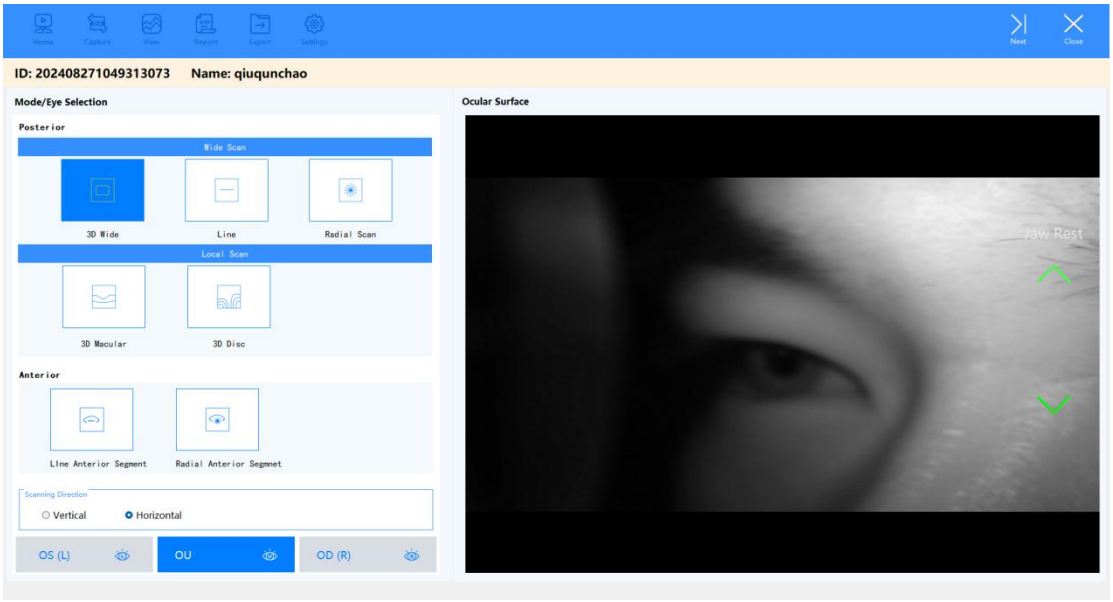


Figure 2-6 [Mode Selection] screen

After selecting the shooting mode and adjusting the jaw rest, click the <Close> button to close the current page and enter the main interface; click the <Next> button to enter the [Pupil Positioning] interface, and begin to automatically locate the pupil of the examinee, and follow the voice prompts of the device to do so, such asFigure 2-7The center pane of this screen is used to display the eye image and pupil localization. The middle pane of this screen is used to display the eye image and pupil localization.

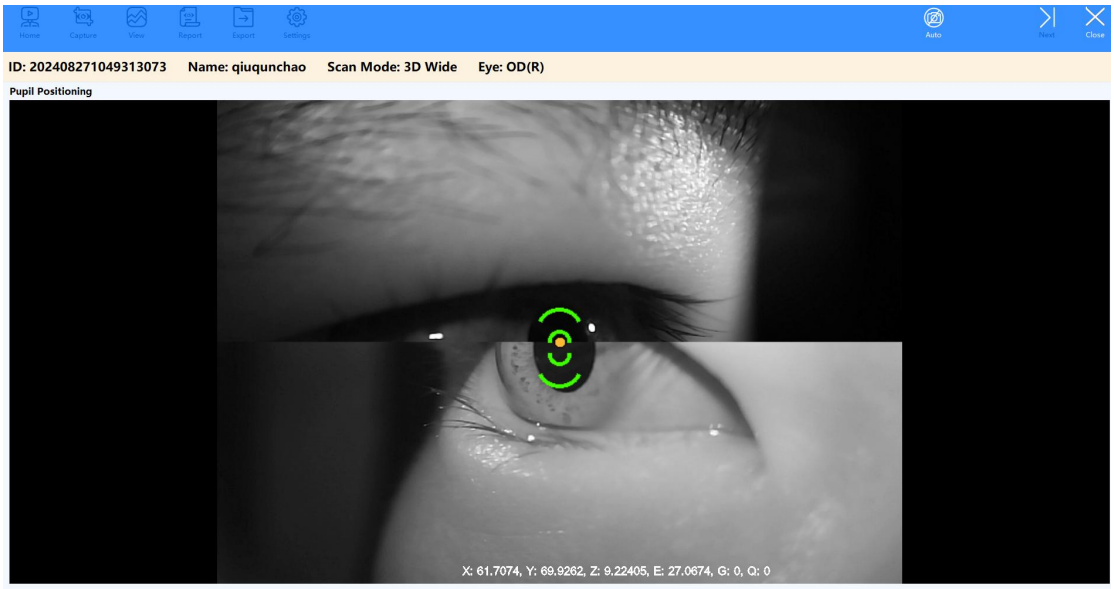


Figure 2-7[Pupil autopositioning] screen

If the automatic pupil positioning fails, you can click the <Auto> button to enter the [Manual Positioning] interface such asFigure 2-8Shown.

Figure 2-8Pupil Manual Positioning Interface

Click the buttons listed in Table 2-3 to complete the pupil positioning.

Table 2-3Pupil Manual Positioning Button Function

Figure 28The serial number of the button in the	Function
①	Controls the scanning probe to move in the direction of greater height
②	Controlling the movement of the scanning probe in the direction away from the subject's eyes
③	Controlling the movement of the scanning probe in the direction of the subject's right side, the
④	Controlling the movement of the scanning probe in the direction close to the subject's eye
⑤	Control of jaw rest elevation
⑥	Control the scanning probe to move in the direction of the subject's left side, the
⑦	Control of jaw rest lowering
⑧	Controls the scanning probe to move in the direction of decreasing height, the

After the pupil positioning is completed (click the <Next> button for manual positioning), enter the [Fundus Focus] interface to start the fundus autofocus, such asFigure 2-9This interface is divided into 2 panes. This interface is divided into 2 panes which are.

- [Two-Sided View] pane: Displays the fundus preview image.
- [OCT Map] pane: Displays the OCT preview image.

Figure 2-9[Fundus Focus] interface

After entering the auto capture interface, the system will automatically focus and capture the image; when the auto focus fails and enters the manual mode, by clicking onTable 2-4The following buttons are available for manual control of the device.

Table 2-4 Manual button functions of the fundus focus

•	Coarse upward adjustment of the image position
•	Coarse downward adjustment of the image position
•	Positive adjustment of refractive error
•	Negative adjustment of refractive error
•	Adjusting the focus position backward
•	Adjusting the focus position forward
•	Adjust the focus position to the right
•	Adjusting the focus position downward
•	Adjusting the focus position upward
•	Adjust the focus position to the left
▲	Cancel shooting, enter the main interface
☆	Cancel automatic shooting
★	Starting to take images manually

When image acquisition is complete, enter the [Result Preview] screen. If Figure 2-10Shown.

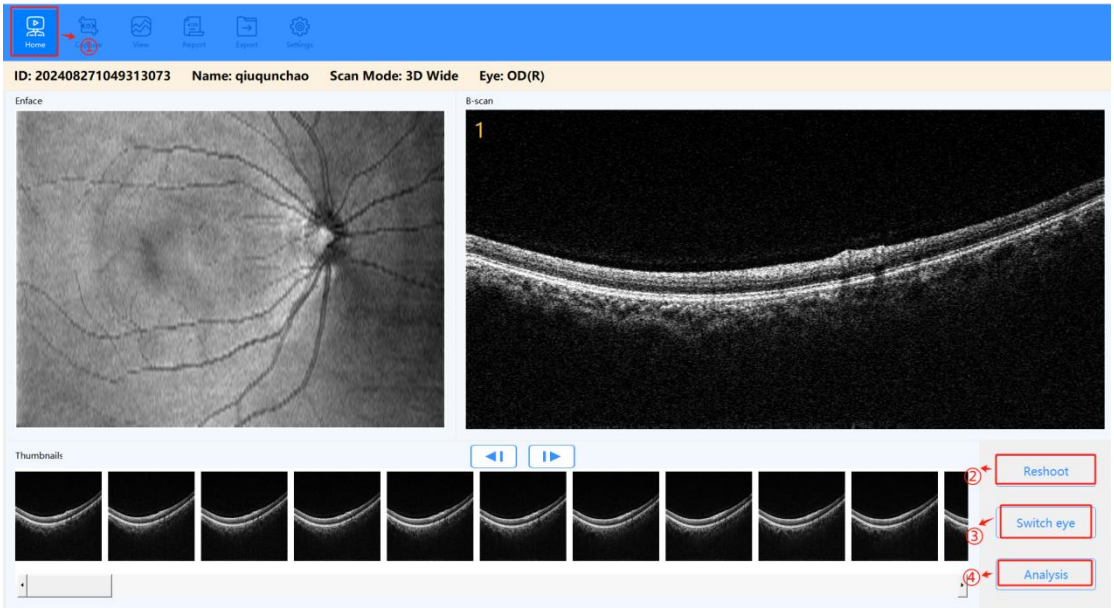


Figure 2-10[results preview] screen

The interface is divided into three panes which are.

- [Fundus View] pane: displays a preview of the fundus view and shows the position of the scan lines on the view.
- [Thumbnails] pane: This pane displays thumbnails of each slice of the current OCT image.
- [OCT Image] pane: This pane displays the OCT image selected in the [Thumbnail] pane.

Click the buttons listed in Table 2-5 to proceed to the next step.

Table 2-5 Functions of buttons on the [Result Preview] screen

①	Start button, whether to save the image, save the image to go to the next screen, do not save the image to go to the main screen
②	Re-acquisition of the current eye
③	Acquisition is complete, switch to the other eye for acquisition (effective when the other eye has not been acquired).
④	After the acquisition is completed, enter the [Image Browsing] interface for software analysis

- **[Image View] screen**

Select an image of the subject in the [Start] screen and click the <Image> button in the [Navigation Bar], or jump to the [Image Browsing] screen after completing all image acquisition

in the [Acquisition] screen. For exampleFigure 2-11Shown.

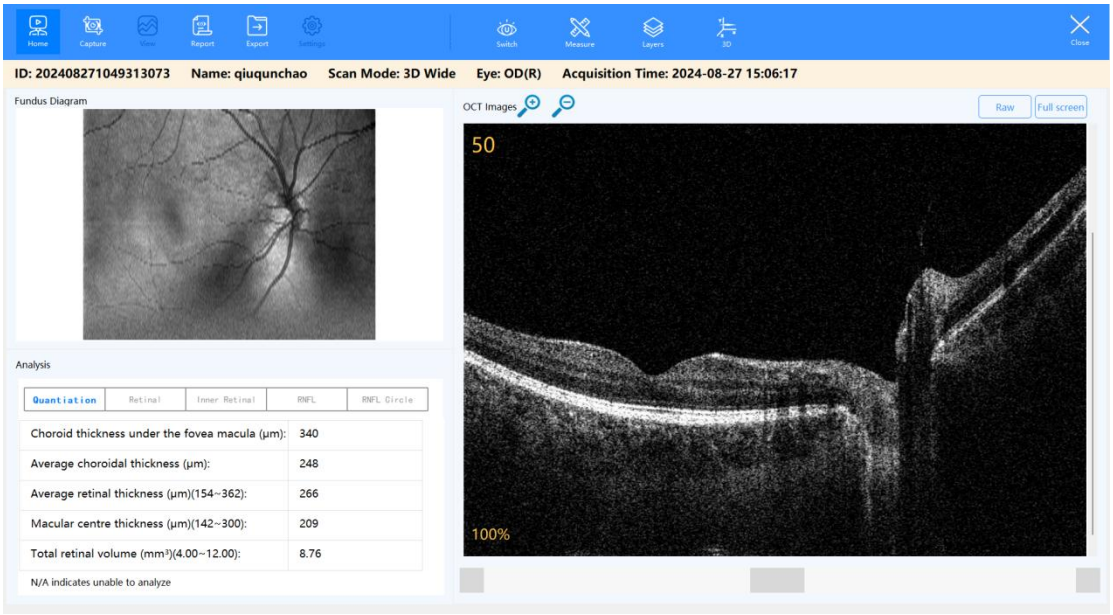


Figure 2-11The image viewing interface

The [Image View] screen is divided into three panes, namely.

- [Fundus Pane: Displays the En Face image generated during the selected image acquisition and the scan line position of the image in the current [OCT Slices] pane. If there are multiple OCT slices, click on the fundus image to switch to the corresponding OCT slice and display the scan line position of that OCT slice on the fundus image.
- [OCT Plot] pane: Displays a slice of the OCT obtained from the selected image acquisition. Click on the <Full Screen> button or double-click on the [OCT Plot] pane to display the OCT plot full screen.
- [Software Analysis] pane: display the selected image by the analysis of the analysis of the map (according to different scanning modes, the analysis of the functions can be displayed slightly different), such as Figure 2-12.

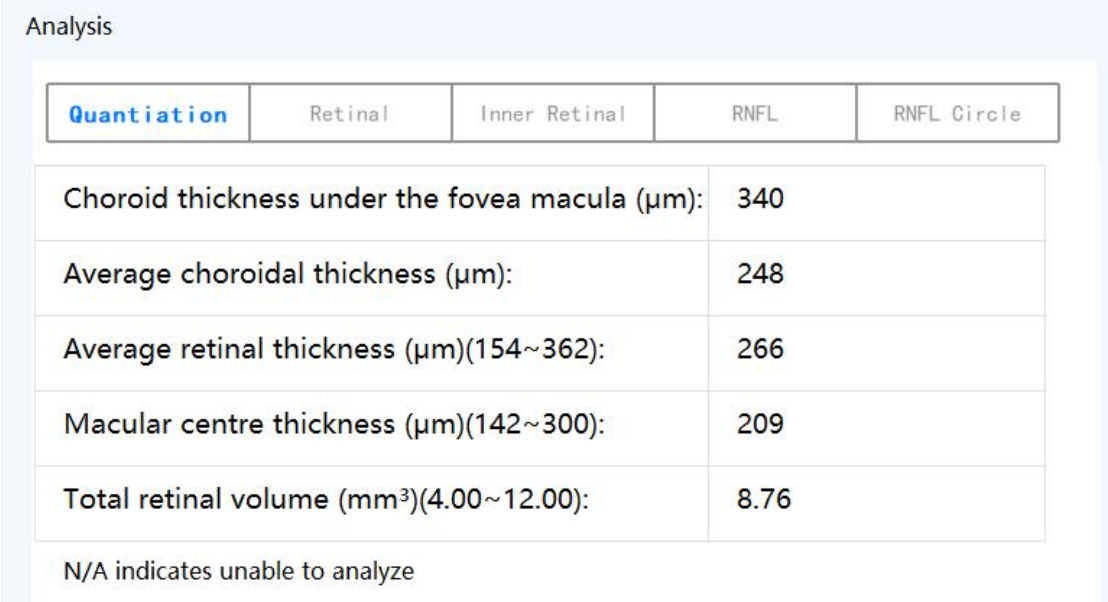


Figure 2-12Analyzing the graphs

Add a series of tool buttons on the right side of [navigation bar], the function of each tool button is shown in Table 2-6.

Table 2-6 Image Browsing Interface [Navigation Bar] Tool Button Functions

Switch	Toggle Eye Levels: Toggles between different eye levels in the same group of images.
Layers	Stratification Line:When turned on will display the OCT stratification results (if any) in the OCT slice pane.
Measure	Measurement:Click to open the measurement interface.
3D	3D Reconstruction: Clicking on this will open the 3D display window, which will reconstruct the layered results into a 3D image (if available).

- **[Image Measurement] screen**

Click the <Measurement> button in the image browsing interface to open the [Image Measurement] interface such asFigure 2-13Shown.

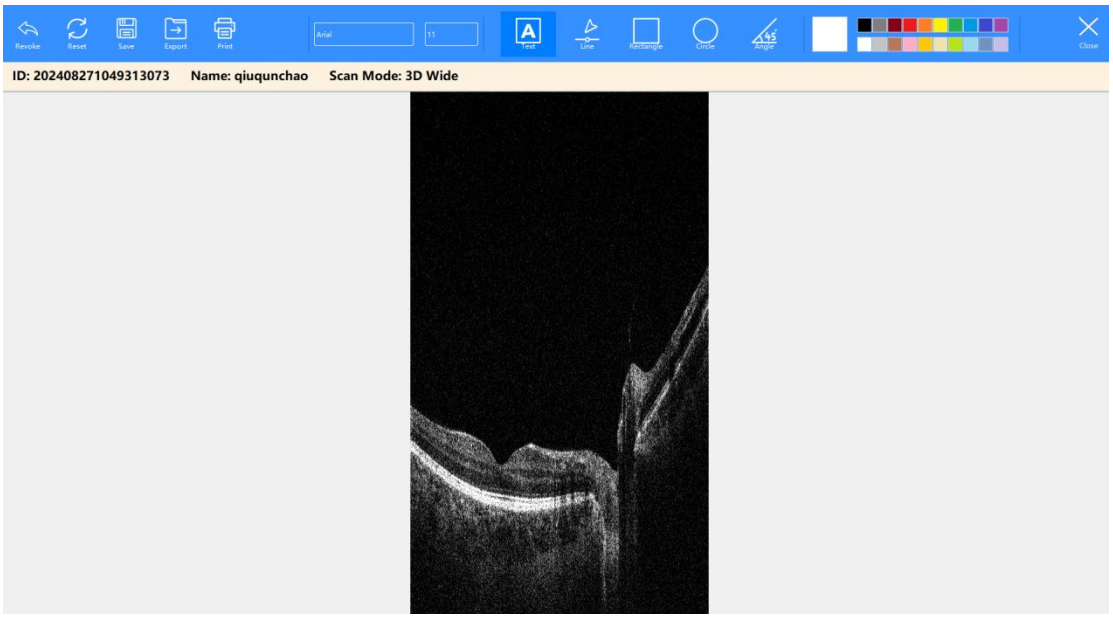
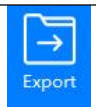
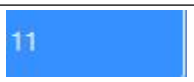
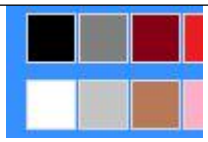


Figure 2-13[Image Measurement] screen

In the [Image Measurement] interface, the user can click on the buttons in the upper [Toolbar], and measure and label the lower image. The functions of the buttons in [Toolbar] are shown in Table 2-7.

Table 2-7 [Image Measurement] screen [Toolbar] button function

	Undo: Undo the previous step
	Reset: Undo all operations
	Save: Save all current operations
	Export: exports the current image
	Print: prints the current image
	Text: Inserts text annotations on the OCT image
	Straight lines: Inserts straight line segment length annotations on the OCT image

	Rectangle: inserts a rectangular area labeling on the OCT image
	Circle: Inserts a circular area labeling on the OCT image
	Angle: Inserts an angle annotation on the OCT image
	Close: Closes the image measurement interface and returns to the parent interface.
	Font: Select a system font as the font for the next labeled text.
	Font Size: Select a font size to be used as the font size for the next labeled text.
	Current Color and Preset Palette: Select a preset color from the preset palette to override the current color, and use the current color to draw the text and pattern of the next markup.

- **The [report view] screen**

Click the Report button in the [Image Browser] screen or select a report in the [Start] screen to open the Report Browser screen, egFigure 2-14Shown.

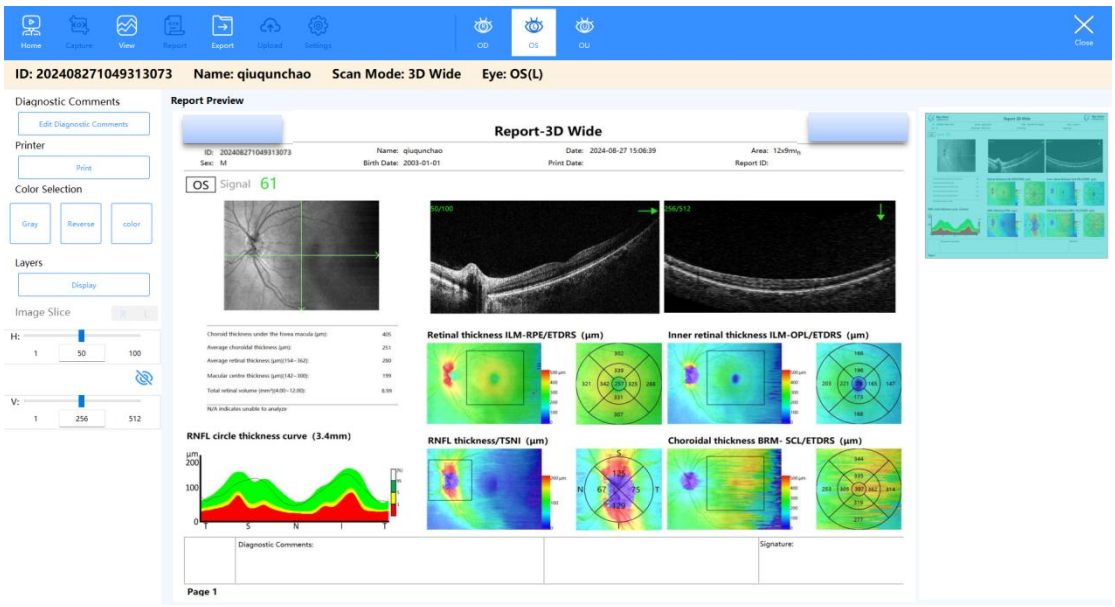


Figure 2-14The [report view] screen

The [Report View] screen is organized into three panes, namely.

- [Function] pane: Provides functions for setting up reports, editing diagnostic comments, selecting the print color mode, and performing printing.

  Select the Bscan slice.
- [Report Preview] pane: Shows the selected page in the current report.
- [Report Page Thumbnails] pane: Displays preview images of all the pages in this report.

Click the <Print> button to bring up the system's own [Print] dialog box, which will change somewhat depending on the system.

By clicking the Image Color Selection <Grayscale> <Artifact Color> <Anti-color> button, the slice image of the OCT analysis report is displayed in the corresponding color.

By clicking the <Show Stratification> button, the slice image of the OCT analysis report shows the stratification lines.

Click the <Edit Diagnostic Opinion> button to bring up the [Edit Diagnostic Opinion] dialog box, as shown in the figure 2-15 Shown.

Figure 2-15editing diagnostic comments

Clicking on the <Both Eyes> button in the navigation bar displays the report for both eyes, as shown in the figure 2-16 Shown.

Figure 2-16 [Binocular Report] screen

ACQUISITION OPERATION INSTRUCTION

The general operating procedure for capturing images is as followsFigure 3-1This is shown in the figure. In general, the process follows the flow of opening the software and logging in, registering or selecting a subject, selecting the acquisition mode and taking a picture, observing the image and marking it appropriately, and finally giving a diagnosis and printing the report.

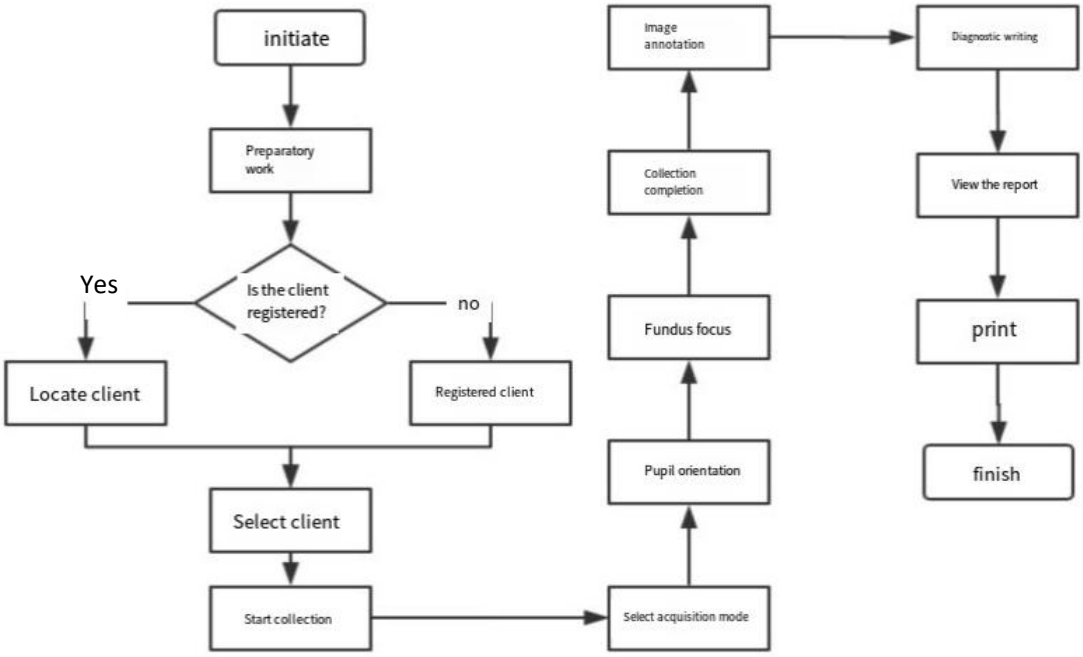


Figure 3-1operation flowchart

- **Pre-operational preparations**

Before starting, the user of the instrument should make the following preparations.

- Understanding of medical conditions. Before starting the examination, the user should read the case and examination documents, check the subject's information, and get a preliminary understanding of the condition.
- Check the power supply. Before beginning the check, the user should ensure that the unit is powered on and switched on.
- Open the lens cap. Remove the lens cap when you are ready to capture and keep it in place. When you stop using the equipment or turn off the camera, you should close the lens cap in a timely manner. If the lens is stained after opening the lens cap, clean the objective lens with a special tool and cleaner.
- Forehead and jaw rest cleaning. Wipe the forehead and jaw rests with a clean gauze moistened with water.

- **Subject registration and selection**

Once you have logged in, there are two ways to select a subject in the [Start] screen. These

are searching for an existing examinee and registering a new examinee. This step is done in the Start screen, egFigure 2-3Shown.

After selecting the target subject, you can view the thumbnails of its historical images and historical reports on the right side. You can also click the <Acquisition> button to acquire a new image for the subject, click the <Image> button to view the selected historical image, and click the <Report> button to view the selected historical report in the [Navigation Bar].

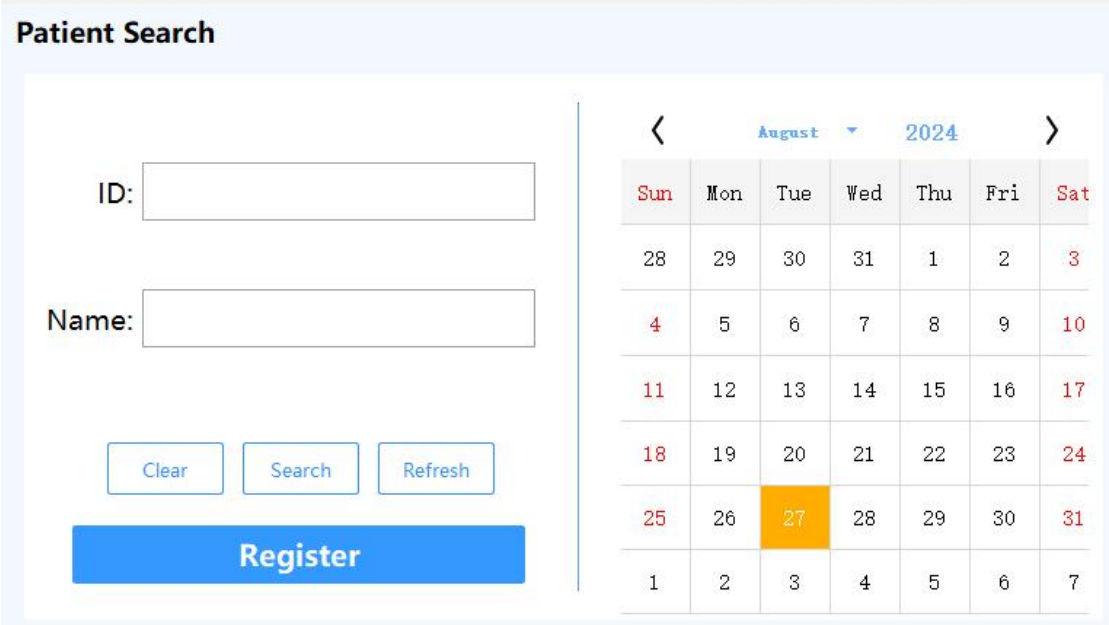
Note: After selecting a subject, the first image and the first report in the list will be selected by default if there are historical images and historical reports.

- **Searching for people who have already been examined**

If the examinee to be selected has had an image captured on this device before, the examinee that meets the corresponding conditions can be found and selected through a conditional search.

Note: If the examinee is deleted by the method in 2.3, it will also not be searched and will have to be re-registered.

such as Figure 3-2 shown, the software currently provides three conditions: case number, name, and registration date. Among them, case number and name must be queried precisely, i.e., enter the complete contents of the relevant fields to be retrieved. The registration date can only be selected precisely by clicking on a specific date. And the relationship between these fields for the "and" relationship, that is, will only be listed to meet the conditions of all the fields have been filled in the examinee (not filled in the field does not judge).



3-2The examinee query interface

Note: An example of an exact query. At present, there is a case number 123456, name "Zhuge Kongming", registration date "July 19, 2019" in the list of subjects. If you want to search out this person, if you know the case number, you must enter 123456 in the [case number]; if you know the name, you must enter "Zhuge Kongming" in the [name]; if you need to limit the conditions of a number of conditions, the fields should be entered correctly and completely, otherwise it is not possible to correctly retrieve the results.

Once you have filled in all the known information, click on the <Query> button and all the eligible examinees will be listed in the examinee list pane below.

- **Registering new examinees**

If the examinee has never been collected on this device (or was registered but has been deleted through the data management function), examinee registration is required.

Click the <Register> button at the top of the examinee search pane to open the [Register] screen. Fill in the examinee information in order. Currently, the following fields are available for the user to fill in.

- Case number
- Name

- Gender (optional)
- The continent to which it belongs
- Date of birth (optional)
- Age
- cell phone number
- Documentation number
- Email
- Address 1
- Address 2

After filling in the form, click the <Save> button to return to the start screen, and in the list of examinees, the newly registered examinee is automatically selected.

- **Batch import of examinee information**

Click the <Batch Import> button on the main screen (Figure 2-3If you select [User Registration Data Import Template.xlsx], you can upload the file successfully, and then the [Examinee List] (Figure 3-4) will display the file. Select the [User Registration Data Import Template.xlsx] document, and after uploading the file successfully, the successfully imported examinee information is displayed in the [Examinee List] (Figure 3-4).

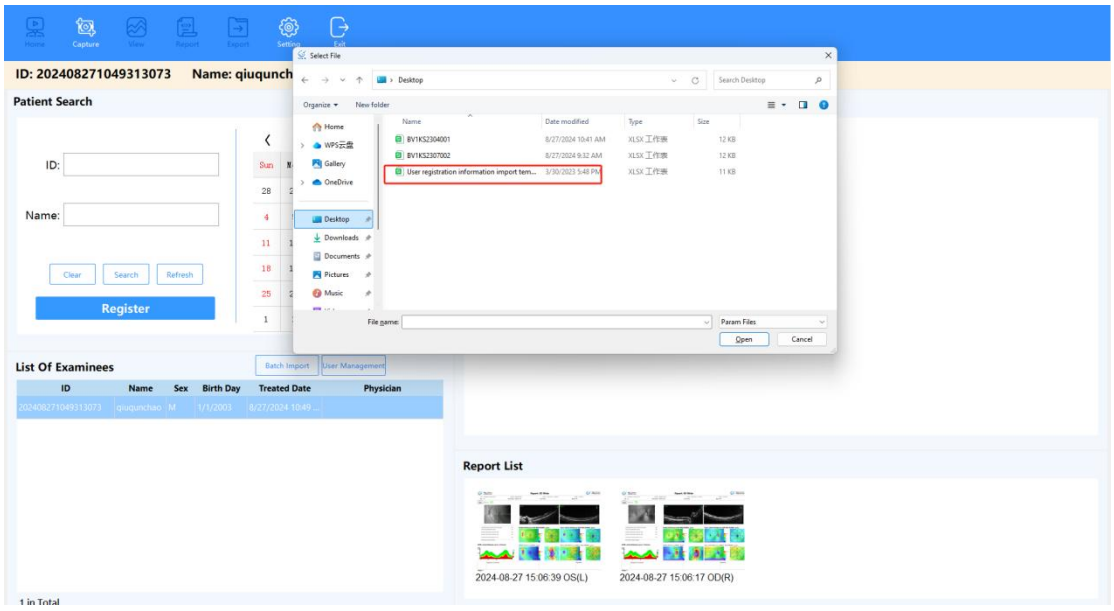
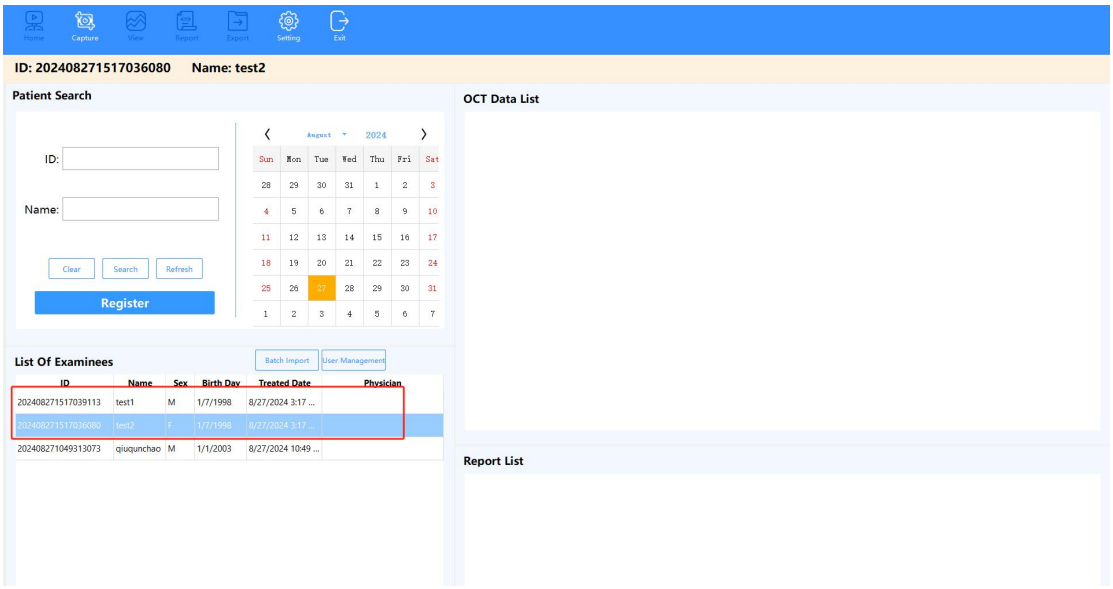


Figure 3-3 Selecting a File



3-4 Import Case Success Screen

- **Image Acquisition**

The image acquisition procedure is divided into three steps. First, select the mode and the eye, then the pupil localization to find the pupil, and finally, the retinal focusing imaging and acquisition. After selecting the mode and the eye, the product can automatically locate, focus and acquire, and when the automatic process fails or the user wants to manually intervene, it can be switched to manual mode to adjust the relevant parameters.

- **Mode selection and jaw rest adjustment**

Enter the [Pupil Positioning] screen, and the [Mode Selection] pane is at the top left. In this version, there are three modes and seven scanning methods for users to choose. The properties of each mode and scanning method are shown inTable 3-1。

Table 3-1A summary of the scanning patterns that

model	Scanning mode	Physical dimensions	Slicing direction
The big picture	HD Linear	12mm	Level
	radiating six lines	9mm	Every 30°
	Region	12mm×9mm	Horizontal or vertical
Localized	macular region	6mm×6mm	Level

	The optic disk area	6mm×6mm	Level
Immediate section	HD Linear	6mm	Level
	radiating six lines	6mm	Every 30°

At the same time, the user can select the eyes of the subject to be captured; OS (), OD (), and OU () mean only the left eye, only the right eye, and both eyes are captured, respectively. When OU is selected, the shooting will be done in the order of left eye first and then right eye. OU is selected by default.

NOTE: When selecting Eye Saving Mode, the Eye Saving Peripheral should be installed in place, as described in Section 1.4.3.

After selecting the mode and the eye, the acquisition proceeds to the pupil localization process. The purpose of this process is to align the lens with the pupil so that the light path can pass through the pupil into the fundus. Once the device is ready, the user instructs the subject to place the chin on the jaw rest, the forehead against the forehead protector, and to look straight ahead.

Note: The examinee should remove glasses or contact lenses during use. When there is a large difference between the jaw rest and the subject's chin height, the lift button on the motorized lift table (if available) can be used to move the jaw rest up and down in the vertical direction.

At this point, the software will automatically search for the subject's pupil and automatically adjust the jaw rest so that the subject's pupil is located approximately in the middle of the pupil image pane, e.g., the pupil of the subject is located approximately in the middle of the pupil image paneFigure 33The green semi-circle pattern in the figure is the position of the pupil in the field of view of both iris cameras. The green semi-circular pattern in the figure is the position of the pupil in the field of view of the two iris cameras.

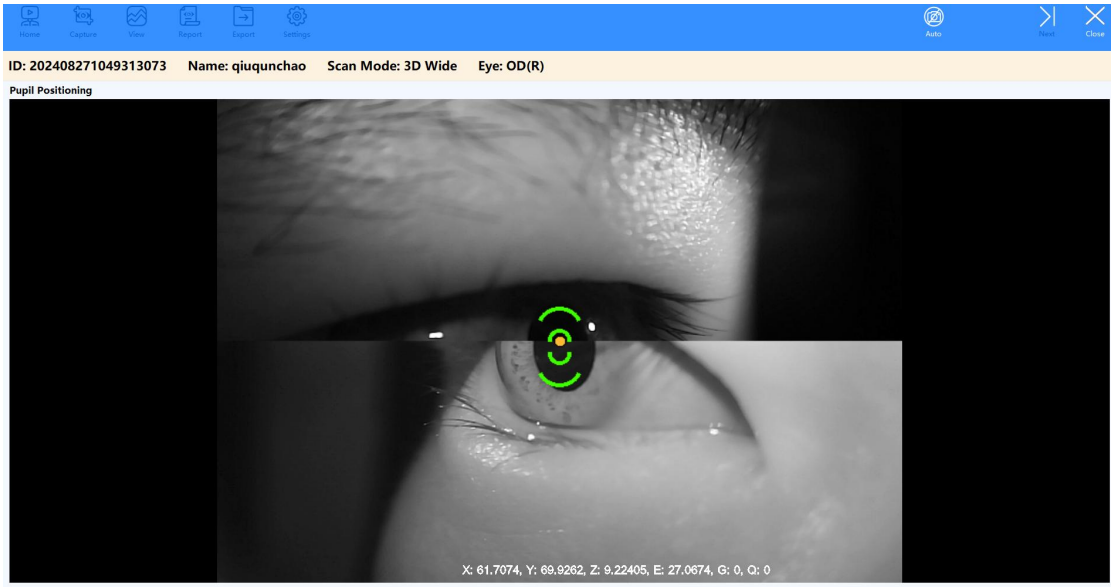


Figure 3-3Schematic diagram of the pupillary area, the

- **Pupil localization**

The system adopts the automatic positioning function by default. When the pupil position of the subject's target eye is correct, the automatic positioning function is activated, and the system will automatically fine-tune the position of the camera body until it meets the conditions for fundus focusing.

If the user wishes to intervene in pupil localization, he/she can click on the <Auto> button to switch it to <Manual> and enter the manual mode. At this point, depending on theFigure 28ClickTable 23Positioning of the pupil is accomplished by pressing the buttons listed in the

- **Fundus focusing and acquisition**

Once the pupil is positioned, the acquisition proceeds to fundus focusing. This process is designed to focus the device's optical path completely on the subject's retina to maximize clarity. When the equipment is ready, the system will automatically focus, at this time the user should remind the examinee with the eyes to be examined to look at the center of the green reticle in the lens; automatic focusing is completed, the device voice prompts to start shooting the eyes, please do not blink, after the completion of the shooting, the voice reminds the examinee to complete the shooting, please relax both eyes. The page jumps to the [Result Preview] interface.

Note: The position of the reticle may change depending on the mode selected and the eye level currently being photographed, so please prompt the examinee to look for the direction of the reticle according to the actual situation.

During shooting, you can use the eye-level focusing interface pane byFigure 29① andFigure 29The two buttons (②) are used to adjust the up and down position of the retinal OCT image (i.e., the front and back position of focusing) so that the retinal structure is in the middle of the image, so that the image position is not too close to the top or the bottom of the image, which may result in the retinal structure being refracted.

The system defaults to autofocus. If the user wishes to intervene in the fundus focusing process, he or she can switch to manual mode by clicking the <Auto> button before the acquisition is completed. At this time, you can use the buttons on the side of the fundus image pane to adjust the refractive error (from -20D to 25D), and adjust the up and down position of the retinal OCT image. When you are satisfied with the image quality in the fundus image pane and the preview image pane, click the <Shoot> button to acquire the acquired image after the countdown.

- **Completing the collection**

After the image acquisition is completed, depending on the quality of the image and the actual needs, the user can clickFigure 210The 4 buttons in the next step.

<Start> button: prompts the box whether to save the image or not, choose to save the image: goes to the [Image Preview] screen, choose not to save the image: goes back to the [Start] screen, the image is not saved.

<Retake> button: This acquisition will not be recorded and you will return to the [Pupil Localization] screen to restart the acquisition process.

<Switch Eye> button: Records the image acquired at this time and returns to the [Pupil Localization] screen for acquisition of the next eye.

<Enter Analyze> button: Records the acquired image, completes the acquisition, and jumps to the [Image View] screen.

Note: After clicking the <Re-shoot> button, the captured image will be deleted and

cannot be recovered, so please be careful.

Note: If you select Binocular Acquisition, but click the <Enter Analysis> button after the first eye is acquired, it will skip the acquisition of the second eye and go directly to the [Image Browsing] interface.

- **Image browsing**

After the image acquisition is completed, enter the [Image Browsing] screen. Select the image you want to browse in the [Image Sequence] pane, and the OCT and fundus images will be displayed in the [OCT Slices] pane and [Fundus Images] pane respectively. As shown in Figure 2-11, the green line on the fundus image marks the actual position of the OCT slice in the right OCT slice pane. By using the mouse wheel in the [OCT Slices] pane, the position of the green line in the [Fundus Image] pane will change at the same time. Clicking the scroll bar in the [OCT Slices] pane to switch the OCT image slice by slice also switches the position markers in the [Fundus] pane; clicking the [][] buttons adjusts the brightness of the image.

Click <False Color> button, you can change the color of the OCT image, currently support grayscale (the lowest brightness is black, the highest brightness is white) and pseudo-color (brightness from low to high from green to red) and inverse color. Refer to Figure 2-11 and Figure 3-4 for details.

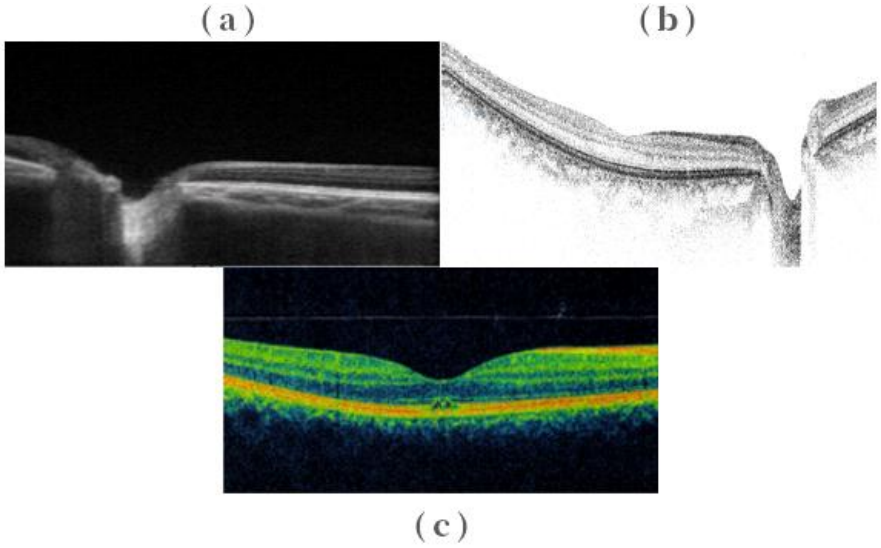


Figure 34 Schematic diagram of grayscale with inverse color and pseudo-color (a) grayscale (b) inverse color (c) pseudo-color, the

- **Analyzing data view**

The lower left corner of the image viewing screen is the analysis pane. The different modes support types of analysis results such asTable 3-2Shown.

Table 3-2The types of analysis supported by the different scanning modes

model	Scanning mode	inner retinal thickness maps	external retinal optical density maps	ETDRS	Viewing the cup and saucer segmentation diagram	Layering	Three-dimensional Reconstruction
The big picture	HD Linear	X	X	X	X	○	X
	radiating six lines	X	X	X	X	○	X
	Region	○	○	○	X	○	○
Localized	macular region	○	○	○	X	○	X
	The optic disk area	X	○	X	○	○	X
Immediate section	HD Linear	X	X	X	X	○	X
	radiating six lines	X	X	X	X	○	X
Where ○ is supported and X is not supported;							

The 3D reconstruction results will be displayed after opening the [3D Reconstruction] window via the <3D> button () in the [Navigation bar] tool buttons section on this page.

Note: The accuracy of the analyzed results is related to the quality of the images, so users are advised to use the analyzed data in conjunction with the actual quality of the images and the actual physical structure of the retina.

The 3D reconstruction results are shown in 3-5.

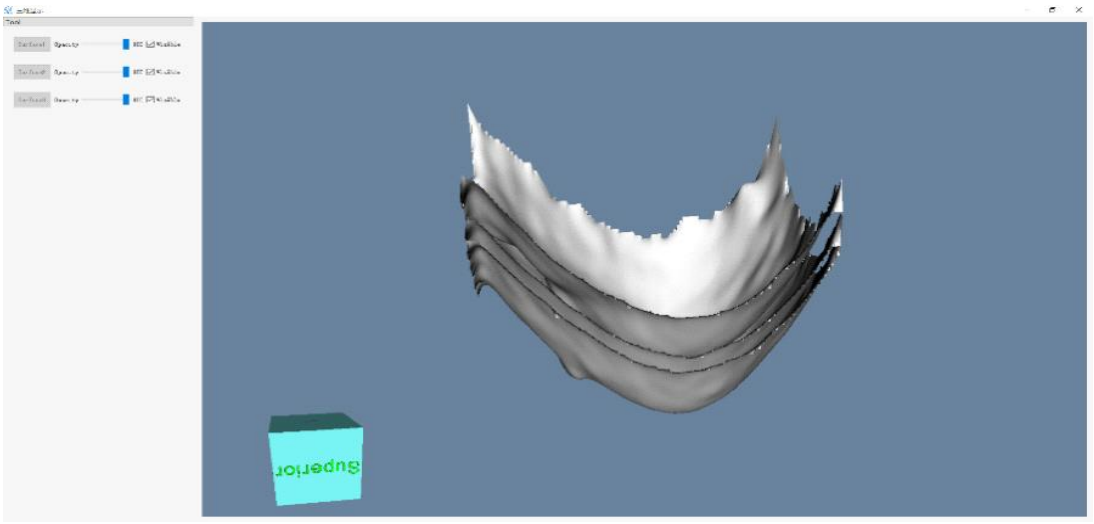


Figure 3-5 Three-dimensional reconstruction of the rendering

- **Image editing and labeling**

When you feel that the current OCT slice has a labeling value, you can click the <Measurement> button (button) to enter the [Image Edit] interface.

In the [Image Edit] section, the user can mark the OCT image with text and length.

When it is necessary to label the text, proceed as follows.

- Set the text color. Select a preset color or select a color from the color palette. (The currently selected color is the default color, which is inherited from the color selected in the Color panel of the [Navigation bar] of the image annotation screen)
- Set the text font. Click the Font drop-down box to select the appropriate font for the text.
- Set the font size of the text. Click the Font Size drop-down box to select the appropriate font size for the text.
- Select the insertion location. Insert the cursor by clicking on the image where it needs to be labeled
- Enter text content. Enter text content in a WYSIWYG fashion after the cursor.

When it is necessary to mark the length, proceed as follows.

- Start marking the length. Click the <Linear> button (button), start marking the length.
- Set the marker color. Select a preset color or choose a color via the color palette.
- Set the starting point of the marker. Click the start position of the marker on the OCT image.

- Set the marking endpoint. Click on the OCT image to mark the endpoint position.

When it is necessary to mark the area, proceed as follows.

- Start marking the length. Click the <Rectangle> or <Circle> button (orbutton), starts marking the area of a rectangular or circular area.
- Set the marker color. Select a preset color or choose a color via the color palette.
- Set the starting point of the marker. Click the start position of the marker on the OCT image.
- Set the marking endpoint. Click on the OCT image to mark the endpoint position.

When it is necessary to mark an angle, proceed as follows.

- Start marking the length. Click the <Angle> button (button) to start marking the angle.
- Set the marker color. Select a preset color or choose a color via the color palette.
- Set the starting point of the marker. Click the start position of the marker on the OCT image.
- Set the position of the corner. Click on the OCT image to mark the position of the corner.
- Set the marking endpoint. Click on the OCT image to mark the endpoint position

Finally, when you finish the image labeling, click <Save> button in [Navigation Bar] to save this editing. If you are not satisfied with the previous step during the drawing process, you can click the <Undo> button to cancel the previous step; when you need to clear all the annotations, click the <Reset> button.

Note: The <Undo> function does not work if the previous operation does not exist at the moment.

Note: The reset function cannot be undone, once clicked it will clear all operations, please be careful. Please be careful

- **Generating reports**

In order to facilitate the user to issue the image and diagnosis to the examinee, the system provides report generation and printing functions.

- **Viewing the report**

Clicking the Report button in the Navigation bar on the Image View screen will take you directly to the Report View screen. Of course, after selecting an image or report in the start screen, you can also click the <Report> button in the [Navigation Bar] to enter the [Report View] screen.

In the left [Function] pane, users can click <Grayscale> or <False Color> or <Anti-color> to convert the color of the OCT image in the report to grayscale or color or anti-color according to the actual need.

In the [Report View] screen, the [Report Preview] in the center is updated in real time based on the user's edits to the report.

In the [Report View] screen, click on Binocular Mode to display a binocular report, for exampleFigure 3-6 Shown.

In the [Report Browser] screen, enter the number of images in the image slice, and the corresponding images will be displayed on the right side.

Figure 3-6 Binocular report

- **Exporting the report**

Clicking the [Export Button] button, the images under the eye are exported to the folder in the selected path, as shown in the figureFigure 3-7 as shown;

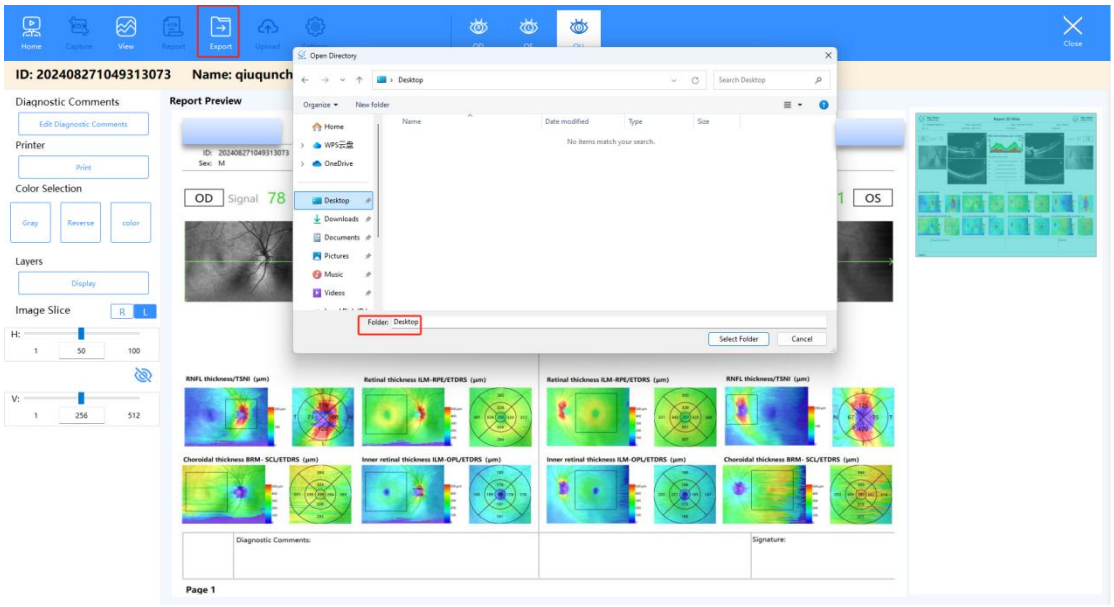


Figure 3-7 exporting the report

- **Writing diagnostic opinions**

On the [Report View] screen, click the <Edit Diagnostic Comment> button to enter a diagnostic comment directly into the dialog box. You can also click on a diagnosis template to select a preset diagnosis comment.

- **Print the report**

Click Print in the Report Browsing interface, as shown in Figure 3-7, and the print setting window will pop up, as shown in Figure 3-8. Click Print to print the report of the current eye.

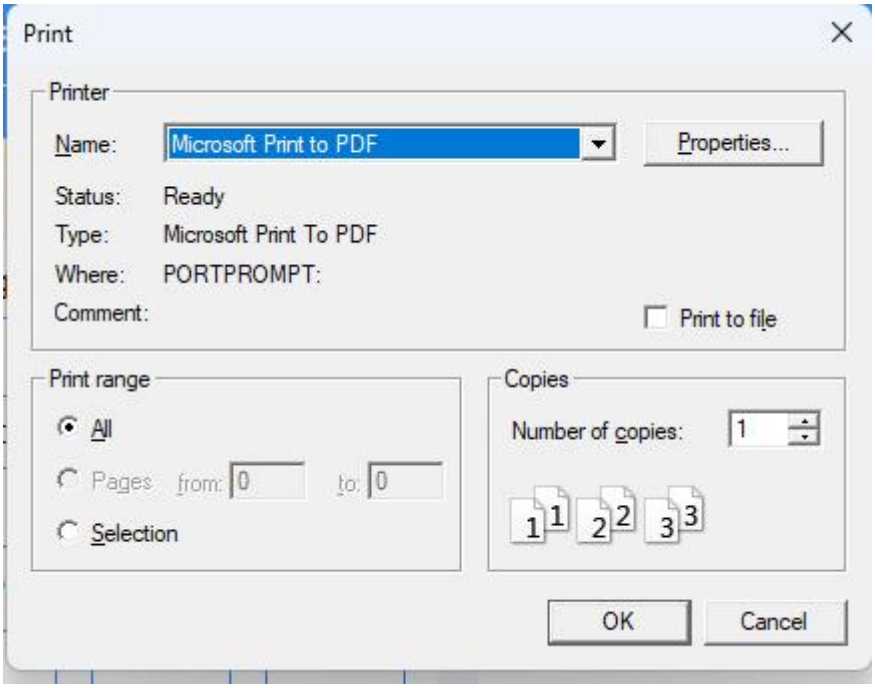


Figure 3-8 report printing

Note: The list of printers in the [Print] window may be different from the list of printers actually in use. Please pay attention to the identification.

- **Changes in reporting information**

In the [Basic Settings] interface, click < Report Settings > to open the [Report Settings] dialog box. As shown in figure 3-9 shows. In the [Report Settings] dialog box, users can enter the [Hospital Name] of the report, and can < add > or < delete > the hospital logo.

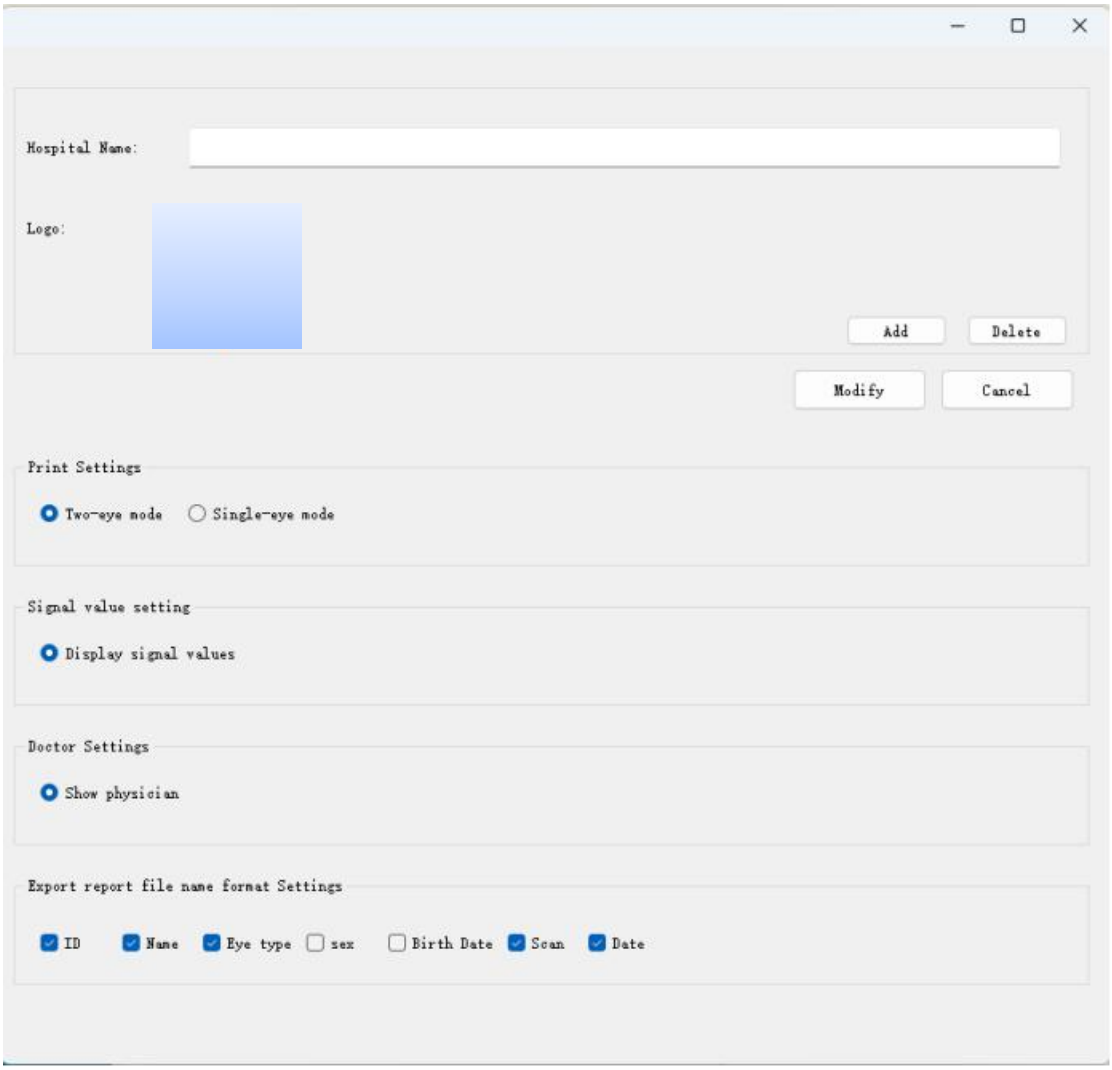


Figure 3-9 Report Settings

- **MANAGEMENT OF EXAMINEE INFORMATION, IMAGES AND REPORTS**

This system provides the management function of the examinee, the images collected by the examinee and the reports of the examinee.

- **image export**

When images need to be exported to other DICOM services, this function can be realized by the following methods.

Export in the [Start] interface. After selecting a patient, select the image to be exported in the [OCT List] pane on the right, click the < Export > button in the [Navigation Bar] to pop up the [Export] dialog box, confirm the information and click the < Send > button.

- **Export dialog box data export that**

Click the [Export] button, and the data will be imported into the address in [Settings] and [Export Path].

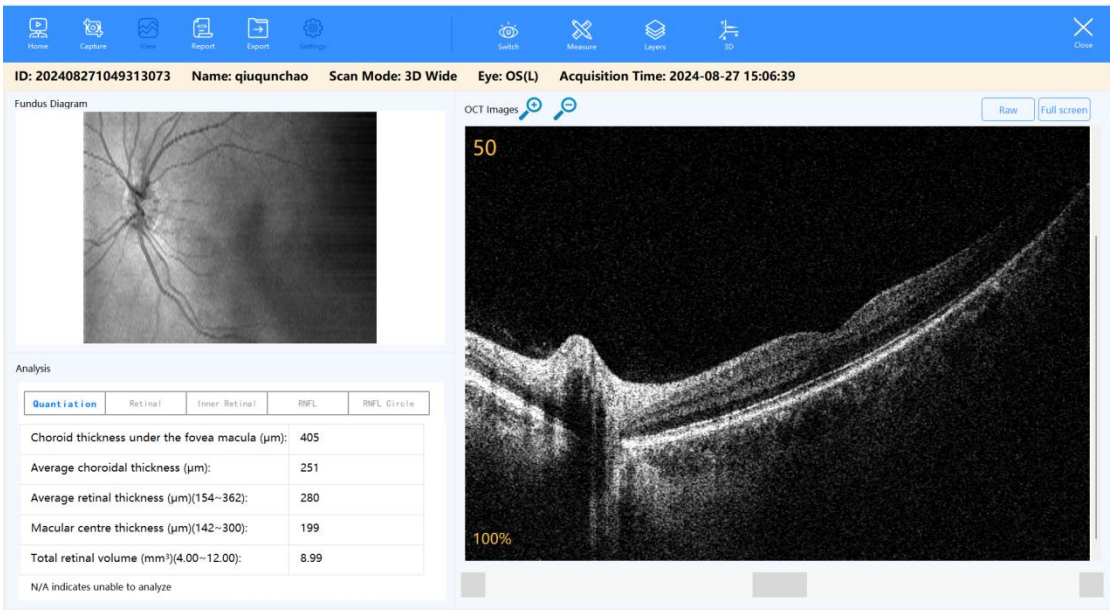


Figure 4-1 Export data interface

- **ROUTINE MAINTENANCE**

The ophthalmic optical coherence tomography scanner needs to be cleaned routinely after examining patients, and other maintenance should be carried out as needed.

- **Imaging troubleshooting**

If the instrument can't image normally or the imaging can't achieve the expected effect, please check it according to the following table, and then contact manufacturer. or local authorized dealers for maintenance.

Table 5-1 imaging troubleshooting

Phenomenon	Remedial measure
Image edge loss	The imaging lens is not aligned with the pupil center or beyond the scanning range, and the patient's pupil is repositioned for measurement.
Location is often unsuccessful.	Check whether the patient's eyelids or eyelashes are blocked, and prompt the patient to open his eyes wide.

	Check whether the ambient light is too strong and adjust the lighting brightness.
OCT image is poor and unclear.	Check the imaging lens for fingerprints, dust and other pollution, and clean it with mirror wiping paper. Switch to manual mode, adjust refractive compensation and measure again.
Fundus images cannot be collected.	Prompt the patient to look at the green target and keep posture during the test (don't blink and move the head); Check whether the part to be collected is beyond the imaging scanning range of the instrument.
Prompt "Hardware connection failed"	Complete the remedial measures according to the prompt guidance. If there is no guidance, you can try to restart OCT and the software.

- **Replacement of fuses**

The instrument host has two fuses. Instructions for checking and replacing the fuse in the instrument are as follows:

⚠Note: Except for replacing fuses, other operations of disassembling instruments and replacing parts can only be carried out by authorized service engineers of manufacturer.

⚠Note: Please strictly follow the following instructions to ensure safe inspection and replacement of fuses. Be sure to turn off the instrument and unplug the power cord before continuing the following operations. When completing each step, always use the minimum force necessary to avoid damage or injury.

1. Make sure to cut off the power supply of the equipment;

2. Unplug the power cord of the host power supply from the power socket;

3. Open the fuse cover，Figure 5-1 Fuse cover plate；

4. Take out the fuse;

5, check whether the fuse is damaged, throw away any defective fuse;

6. Insert a new fuse and cover the cover plate. Rating of two fuses: 10A 250V.

⚠Warning: Please be sure to switch to the fuse of the same type and rating. Otherwise, it may lead to fire hazard.

- **Fixed jaw rest pads**

Please follow the following steps to fix the chin rest pad paper.

- Pull out two paper-pad pins of the jaw support from the jaw support.
- Take out a certain amount (about 4~6mm) of pad paper from a pack of jaw rest pad paper.
- Align the positioning holes on both sides of the chin rest pad paper.
- Fix the chin rest pad paper on the chin rest and lock it.

- **Cleaning**

If the instrument case is stained, please wipe it with a soft cloth. For stubborn stains, please wipe them with a soft cloth dipped in water-diluted neutral detergent, wring them out and then wipe them with a soft cloth.

⚠Note: This instrument can only be wetted with a soft cloth, and no water drops can drip or flow out. No spray can be used on or near the instrument to prevent liquid from entering the instrument and causing damage and safety risks. Do not use the organic solution without authorization (if necessary, please consult the after-sales service first) to prevent the spray paint on the instrument surface from being dissolved.

- **Cleaning the objective/eye front section lens**

The objective lens/anterior segment lens is easy to be contacted by fingers, eyelashes and eye skin, and it is easy to stick fingerprints, secretions and oil stains, thus affecting the effect of image acquisition.

If there are stains on the lens surface, please follow the following procedures to clean it.

1. Observe whether there is dust or dirt on the whole surface of the mirror by using the reflection of the lens surface at different angles.

2. Blow off the large particles of dust on the lens surface with a balloon.

3. Please gently wipe the fingerprints and oil stains on the lens surface with a clean cotton swab or lens paper

dipped in acetone or alcohol. Should be wiped in the same direction or from the center of the lens to the edge along the circumference, cotton swabs or lens paper that have been stained with stains can not be reused to avoid damaging the lens.

⚠Note: The stains on the lens should not be scraped with nails, tweezers and other hard objects, otherwise the lens film may be damaged.

4. Check whether there is dust or dirt on the objective lens with naked eyes again.

- **Cleaning the frontal and jaw rests**

The forehead support and jaw support are the parts that often contact the patient on the instrument. After the examination is completed, the patient's sweat or cosmetics may remain on the forehead support or jaw support. Therefore, it is necessary to clean the forehead support and jaw support after each inspection.

⚠Note: before and after using the instrument every day, please use clean gauze or a rag dipped in disinfectant alcohol to clean the forehead support and jaw support. After each patient's examination, please use clean gauze or a rag with disinfectant alcohol to clean the places that patients may come into contact with. For stubborn stains, please wipe them with a rag dipped in disinfectant alcohol instead of a dry cloth.

⚠Caution: Never use dry cloth to wipe the forehead or chin rest repeatedly and forcefully.

- **Storage**

⚠ When the instrument is not used for a long time, please place it in the following environment:

● Ambient temperature -30℃ ~ 55℃

Low relative humidity 10% ~ 95%

● Atmospheric pressure is 86 kPa~106 kPa.

● A well-ventilated room without corrosive gas.

• SPECIFICATIONS AND CONFIGURATIONS

• Classification

- According to the classification of the type and degree of electric shock protection in IEC 60601-1:2020, this scanner belongs to Class I, Type B and movable common equipment.
- According to the classification of lasers in ISO 15004-2:2012, the signal light source of this scanner belongs to Class 1 laser.

• Specification parameters

Function	OCT-1000
Axial resolution:	5 m (in organization)
Horizontal resolution:	20 m (in organization)
Scanning speed:	≥80000scan/sec
Scanning depth:	≥2.3mm
Refractive adjustment range:	Not less than -20D to +25D (posterior segment of eye)
Peak wavelength of light source:	840 nm
Optical power at cornea:	≤750μW
Scanning field angle	≥45°

- External fixation

  Led fixation lamp
- System input device

  Keyboard, mouse
- Physical specification

  Size (instrument only):

  Length: 503(mm)

Width: 458(mm)

Height: minimum 578(mm) and maximum 608(mm)

Weight: 29.5 kg

- Environmental conditions

  Transportation and storage

  Temperature: -30 ~ +55℃

  Relative humidity: 10% ~ 95%

  Air pressure: 86kPa~106kPa

  Work conditions

  Temperature: +10 ~ +35℃

  Relative humidity: 30% ~ 90%

  Air pressure: 86kPa~106kPa

- Electrical requirements

⚠**Warning:** Please be sure to switch to the fuse of the same type and rating. Otherwise, it may lead to fire hazard.

Power supply: AC 11-220v 50-60hz.

Fuse rating: 10A 250 V

- Unit of measure
- All measurement units in this product are in the international system of units format. Unless otherwise specified, the units of measurement are microns.
- Computer (minimum configuration requirements)

  Cpu: the main frequency is 2.70GHz.

  Hard disk: 1T

  Memory: 16G

  Monitor: 23.8 inches

  Graphics card: 12G memory

  Operating system: Win11 64-bit

- **Configuration**

Standard fittings

Table 6-1 Standard parts list

Name	Quantity	Unit
OCT host	1	set
Indicator	1	platform
Mainframe computer	1	platform
Power supply	1	individual
The immediate section adapter	1	set
User manual/guide/handbook	1	basis
Product warranty card	1	share
Certificate	1	share
Power cord	1	strip
Whole machine protective cover	1	individual
Eyepiece protective cover	1	individual
Fuses	4	individual

- **Software information**

Software Name: Image Processing Software

Release version: V1

Full version: V1.3.0.4

Release date: October 22, 2021

• LEGAL NOTICE

- **Limited warranty**

This guarantee provides you with specific legal rights, and you may have other rights depending on your place. Within one year from the date of delivery (hereinafter referred to as "warranty period") warrants to the original buyer (hereinafter referred to as "You", "Yours" or "Buyer") that this product is free from defects in materials or workmanship. In case of failure, the seller's responsibility is limited to repairing or replacing the parts that are immediately reported as defective by the buyer within the warranty period and confirmed by the seller during inspection. Unless otherwise specified herein, this warranty covers all parts, labor, travel and expenses during the warranty period. This guarantee is only applicable to the original purchaser and should not be transferred or distributed in any way.

The warranty claim process should be carried out as follows: when you think this product is defective, report the defect to manufacturer immediately. Whenever possible, we will provide "at the customer's site" service to repair your instrument. However, we will decide whether the maintenance can be carried out in our maintenance department. In this case, we will pay all the transportation costs, unless we find that your instrument is not qualified for maintenance according to this guarantee during inspection, in which case, you will be responsible for paying half of the transportation costs. If your instrument is not qualified for maintenance according to the warranty, we will inform you, and any maintenance you authorize will be charged according to our standard price. All replaced parts are owned by manufacturer.

This warranty covers the ophthalmic optical coherence tomography scanner, but does not cover consumables such as operating consumables, paper or storage media, or any service to external printers. These items will be covered by the manufacturer's guarantee, and service arrangements must be made through the manufacturer. This warranty does not apply if the parts need to be repaired or replaced due to accidents, negligence, misuse, force majeure, transportation or other reasons other than general use, or consumables or accessories do not meet manufacturer's correct operating specifications. This warranty does not apply to any items that have been repaired or modified by non-manufacturer.

All data stored on the hard disk, magneto-optical disk and/or floppy disk are the records of the buyer, and you are responsible for maintaining the integrity of these files. Manufacturer is not responsible for the loss of patient files stored on hard disk, floppy disk, backup magneto-optical disk or backup floppy disk.

For the quality and performance of the software, you will bear all risks. Manufacturer does not guarantee that the software will meet your requirements, that the software operation will be uninterrupted or error-free, and that all software errors will be corrected. You are responsible for the installation and use of instruments and programs and the results obtained from them.

This warranty does not extend to any removable media that is damaged due to accidents, misuse, abuse, or services or modifications made by people other than manufacturer. If this kind of software proves to be defective after purchasing it, you (not manufacturer) will bear the full cost of all necessary services, repairs or corrections. Manufacturer has no responsibility or obligation for any claim, loss, responsibility or damage directly or indirectly caused or claimed by any software provided with this product or by manufacturer.

We have made a lot of reasonable efforts to ensure that the product manuals and promotional materials accurately describe the specifications and performance of this product when released. However, due to continuous improvement and product update, we cannot ensure that the printed materials will remain accurate after the publication date, and we will not be responsible for changes, errors or omissions. All instrument specifications are subject to change without prior notice.

Limitation of liability

The warranties contained herein are in lieu of and exclusive of all other express or implied warranties, except as required by law, including but not limited to the implied warranties of merchantability and fitness for a particular purpose. Manufacturer and any other party involved in the creation, production or transportation of this equipment or software (collectively referred to as "the related party") shall not be responsible for any damage, loss of use or any such loss, regardless of whether such damage or loss is caused by natural disasters, your purchase, possession or failure to fulfill your responsibilities for the correct installation, management, supervision or use of ophthalmic optical coherence tomography scanner or software; And whether such liability is based on tort, contract or other aspects.

If the above restrictions are deemed unenforceable, Manufacturer's (and "related parties") maximum liability to you should not exceed the cost you paid for the equipment. Under no circumstances shall manufacturer (and/or related parties) be liable for direct, indirect,

consequential or accidental damages (including damages caused by loss of relevant business and expected profits, business interruption, loss of business information, etc.), even if manufacturer or related parties have been informed that such damages may be caused. In some places, the exclusion or limitation of limited warranty or corresponding damages or accidental damages is not allowed, so the above limitation or exclusion may not apply to you.

• Service contracts

In China, the guarantee extension agreement (service contract) is executed according to its stipulated time limit.

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• Software license agreement

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Admit

You acknowledge that you have read all the provisions in this chapter (including this license and limited warranty), understand them and agree to be bound by their terms and conditions.

SERVICE COMMITMENT

Thank you again for purchasing and using our ophthalmic optical coherence tomography scanner.

Our company has established a series of complete and strict quality control systems, and the quality of the products produced is excellent. However, because it is a high-tech and complex instrument, if it is not operated in accordance with the regulations, it will inevitably make mistakes and may damage the instrument. Therefore, we must remind you that you must read and understand this manual in detail and operate in strict accordance with our operating regulations.

If you have any questions when using our instrument, please call us.

If you feel that our instruments need to be improved, please call us.

If there is anything wrong with our instrument, you are welcome to call us.

If you have any good suggestions or criticisms about our products or work, please feel free to ask us.

If you no longer use our instrument, please dispose of it according to local and national laws.

All employees of our company will welcome your call with the highest enthusiasm, answer your questions with the most sincere attitude, solve your problems with the fastest speed, and sincerely accept your criticisms and suggestions.

Thank you for your choice. Please contact us if you have any questions!

Revision date: April 12, 2023