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| Project | Picasso |
| Name | Medical Image Management And Processing System |
| Title | Product instruction |
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| Department | Software |
| Author | Mi Zhang |
| Approval | Shuai Zhou |
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SVision Imaging, Ltd.

Revision History

| Doc. version | Version description | Date | Author | Approval |
|--------------|---------------------|-----------|----------|------------|
| 1. 0. 0 | Initial release | 2024/11/4 | Mi Zhang | Shuai Zhou |
| | | | | |

Abbreviations / Acronyms

| Abbreviation | Description |
|--------------|------------------------------|
| OCT | Optical Coherence Tomography |
| Angio | Angiography |

Symbol Identification Description

| Symbol | Symbol Title |
|--------|--|
| | Warning, refer to the IFU. Note: Ignoring this warning may result in personal injury or instrument damage. |
| | Caution |
| | Must follow Instructions for Use |

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1. Introduction

1.1 Product name

Medical Image Management And Processing System.

1.2 Trade name

Picasso.

1.3 Model

Picasso.

1.4 Version

V1.0.

1.5 Intended use

Medical Image Management And Processing System is a comprehensive software platform designed to transmit, process, analyze, measure, store, display, and output ophthalmic clinical images, patient data, and examination data from computerized digital imaging devices through computer networks.

1.6 Patient Profile

This product is suitable for all users who wish to remotely access patient information, ophthalmic data, and images collected by the examination device, provided that the system has been connected to any of our company's own branded examination devices.

1.7 Contraindications

no.

1.8 Instrument Overview

This product is medical image management and processing system developed by SVision Imaging, Ltd. (SVI in short). The purpose is to use this software to meet the remote analysis needs of domestic and overseas clinical doctors, connect the product with doctors, and enable more doctors to directly use the analysis function.

Medical image management and processing system is a comprehensive software platform that adopts the B/S technology framework. This software utilizes computer networks to transmit, process, store, display, and output ophthalmic clinical images, patient data, and examination data from computerized digital imaging devices. And it supports data fusion from multiple collection devices, remote viewing, and supports concurrent use by multiple users.

1.9 Security

The security of medical image management and processing system is medium.

According to the latest regulation Guidelines for Software Registration Technical Review Edition 2022, the software security is divided into minor, medium, or severe (minor, medium, severe correspond to A, B, C defined by YY / T0664). The minor refers to the software being unable to cause harm, the medium refers to the software being able to directly or indirectly cause minor (not serious) harm, and the severe refers to the software being able to directly or indirectly cause serious harm or death.

This product is developed and tested in accordance with the SVision Imaging, Ltd. safety standards and it complies with the applicable national and international standards, regulations and guidelines as well to ensure that the instrument is highly secure. Please make sure you fully understand all safety warnings and cautions provided in the manual before using the device. It does not contain any substance at risk of chemical hazards.

1.10 Security software

Use the security software and firewall that come with the Windows 10 operating system.

It is not recommended to install antivirus software and firewalls from other vendors. If antivirus software and firewalls from other vendors have already been installed, it is recommended to turn off the corresponding security software.

1.11 Regulatory standards

- The laws and regulations that this software complies with are as follows:
Guiding Principles for Technical Review of Medical Device Software Registration (2022 Revised Edition) No. 9 of 2022;
Guiding Principles for Registration and Review of Medical Device Network Security (2022 Revised Edition) No. 7 of 2022;
Guiding Principles for Naming Medical Software Common Names (2020 No. 41).
- The standards referenced by this software are as follows:
YY/T 0316-2016 "Application of Medical Device Risk Management to Medical Devices";
YY/T 0287-2017 "Medical Device Quality Management System for Regulatory Requirements";
YY/T 0664-2020 Medical Device Software Life Cycle Process;
YY/T 1406.1-2016 Medical Device Software Part 1: Guidelines for YYT 0316 Application in Medical Device Software.

1.12 Requirements

1. 12. 1 Train

Our company is responsible for providing training or on-site guidance to 1-2 operators of the product, with the ultimate goal of enabling users to proficiently use the product.

1. 12. 2 Requirements

The operator shall be medical workers with professional training or relevant knowledge of medical imaging, such as ophthalmologists, optometrists or equivalent, ophthalmic nurses, medical practitioners, etc.

Skills that the operator must possess, including the use of a computer, and a basic knowledge of ophthalmology. The operator must be able to perform the following actions:

- Open the browser
- Check the inspection equipment is online
- Login the medical image management and processing system
- Data analysis and save
- Logout the medical image management and processing system
- Close the browser

2. Safety Instructions and Warnings

2.1 Delivery method

U disk.



2.2 Safety Messages

2.2.1 Before you start using the software, make sure that you already know the correct login and logout process (Chapter 4, operation instructions).

2.2.2 Read the instructions for use carefully before proceeding any operation. Any operation beyond the intended use may cause software abnormalities and prevent normal operation of the product.

2.2.3 If an abnormal situation occurs during operation, please contact with the SVision Imaging, Ltd. in time.

2.2.4 This software uses network transmission to transmit eye images to the user's computer. If you encounter user information leakage, network intrusion, or other situations during use, please shut down the computer in a timely manner and contact technical service personnel.



2.3 Warnings

2.3.1 This product is a unified remote data platform, which supports remote analysis and viewing, and shall be used in cooperation with the company's own brand inspection equipment.

2.3.2 The disease diagnosis is the responsibility of the licensed ophthalmologist. This product is not a diagnostic device that can identify and classify diseases alone. This instrument provides data in conjunction with other information to assist the ophthalmologist in confirming the diagnosis.

2.3.3 The diagnosis should not be solely performed with a single examination. Various information and medical history data, etc. should be referred to help performing the final diagnosis.

2.3.4 Computers and accessories not approved by visual microimages should not be used. So as not to affect the product operation and use, resulting in the wrong inspection results.

2.3.5 The operating environment of the instrument should be confirmed to meet the requirements. Otherwise, the instrument may be damaged or the image quality may be

jeopardized.

2.3.6 When using this product to view, analyze and diagnose, if any alarm or error prompts appear, please reload the data or restart the software to avoid the wrong diagnosis caused by data errors.

2.3.7 When using the product to print the report, make sure that the computer or laptop is correctly connected to the printer, otherwise the printing error will occur.

2.3.8 This product shall be used in the network and login state.

2.3.9 Do not use images with artifacts as it may lead to the erroneous diagnostics.

2.3.10 The software deployment environment or database information should not be changed without permission, otherwise the software may be inaccessible.



2.4 Precautions

2.4.1 Before using the product, the operator should determine that the dependent software is installed on the server, the server software configuration is completed, the medical image management and processing system can be started normally, and the browser can access the server. Incorrect installation or configuration can cause the remote software to be not properly accessible.

2.4.2 Please read the section of "4 Operating Instructions" carefully before starting and using, so that users can quickly and reasonably use the software for remote data viewing, analysis and diagnosis.

2.4.3 Only authorized users can access and process the data of the subjects, otherwise the loss of the data will affect the subsequent analysis and lead to the wrong diagnosis.

2.4.4 Ensure that the subject data is regularly backup and checked for successful backup to prevent data loss.

2.4.5 When the use environment changes, make sure that the dependent software installation, configuration is completed, restart and access the server to prevent analyze the wrong image results and cause the wrong diagnosis.

2.4.6 When accessing the server, make sure you are correctly connected to the network.

2.4.7 When the network is busy or occupied, the browser may fail to access the server normally. Please wait for the network or change the network environment to access to prevent the wrong image results and cause the wrong diagnosis.

2.4.8 Sudden computer failure during image acquisition and image viewing can lead

to incorrect image results.

2.4.9 When logging in, you can select “Chinese” or “English” in the upper right corner of the login area.

2.4.10 For the installation, configuration, operation, adjustment and maintenance of this product, please read this manual in detail and follow the manual.

2.4.11 Do not divulge sensitive personal information in case of malicious network attack.

2.4.12 Do not change the product dependence environment and configuration requirements without permission. In case of failure or abnormal use, please contact the technical service personnel in time to provide further technical guidance.

2.5 Network security

According to the Guidelines for the Review of Cyber Security Registration of Medical Devices (2022 Revision, No.7, 2022), Medical device cybersecurity risk management activities usually include: identifying assets (Asset, Physical and digital entities of value to individuals or organizations), a threat (Threat, Potential causes and occurrence of unexpected events that may cause damage to individuals or organizations) and vulnerability (Vulnerability, Weaknesses in assets or risk control measures that may be exploited by the threat), To assess the impact of threat and vulnerability on medical devices and patients and the possibility of being utilized, Determine the risk level and take adequate, effective and appropriate risk control measures.

When developing the risk acceptability criteria for network security, our company set the acceptability criteria for network security risk management according to Appendix D of IEC / TR 80001-2-1:2012, and set the definition of Guidelines of Network Security Registration Review of Medical Devices (2022), including confidentiality (confidentiality), integrity (integrity) and availability (availability) as the three security attributes of evaluation assets, which are defined as follows:

Confidentiality refers to the characteristics that the information is not obtained or known by unauthorized entities (including products, services, individuals, organizations), that is, the medical device product itself and related data can only be accessed and used by authorized users at the authorized time.

Integrity refers to the characteristics of the creation, transmission, storage, and display of information that have not been changed by unauthorized means (including deletion, addition), that is, the data related to the medical device is

accurate and complete, and is not tampered with.

Availability refers to the characteristics that the information can be accessed and used upon the requirements of the authorized entity, that is, the medical device itself and related data can be accessed and used in the expected manner.

2.6 Potential safety hazards and usage restrictions

2.6.1 Potential safety hazards

May cause patient data leakage, hospital information leakage, and doctor information leakage. In response to these potential security hazards, the system has conducted a risk analysis and implemented risk measures to reduce the risk, ultimately achieving an acceptable level of overall residual risk. For details, please refer to the Software Risk Management Plan

2.6.2 User usage restrictions

- 1) Users need to enter at least 8 characters and must include both letters and numbers when changing their password;
- 2) The default validity period for user passwords is 1 year.
- 3) When a piece of data is being used, other users will not be able to load it simultaneously.
- 4) The user account can only remain logged in to one browser at a time. Logging in again without logging out or logging in to another browser without logging out will automatically log out of the previous login.
- 5) If a user stays on a certain page for more than 30 minutes without taking any action, they will be logged out by default.

2.7 User accidental operation protection measures

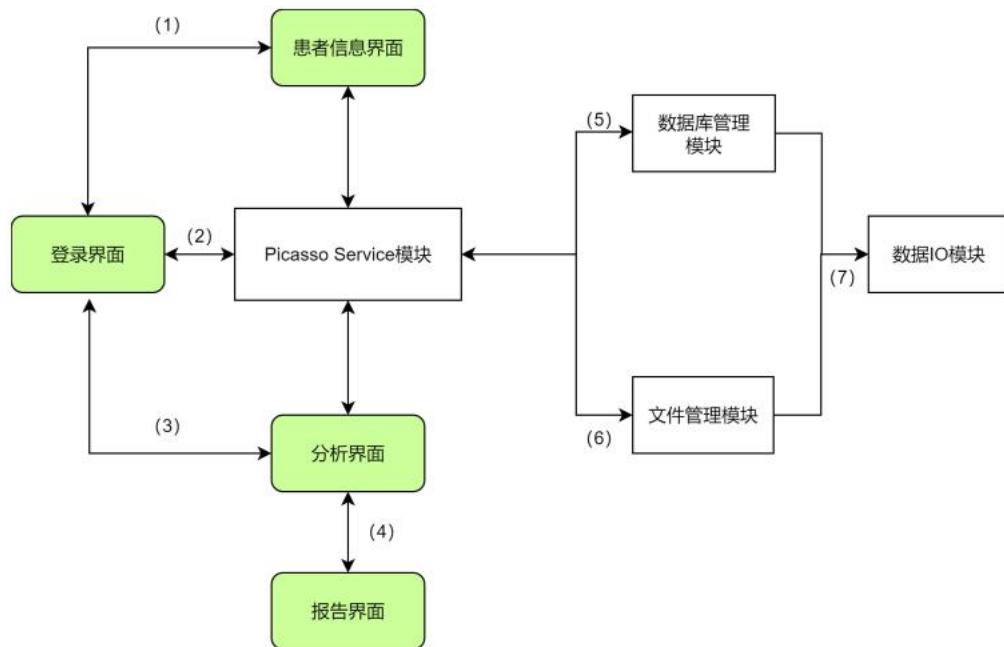
This software provides accidental operation protection measures. The software marks user actions that may cause serious consequences with a red button. When performing user actions with serious consequences such as deletion or cancellation, a warning message will pop up again, and confirmation is required before execution.

2.8 Precautions for waste disposal

This product is an independent software and does not require uninstallation. Users can directly access the software website through a browser to log in and use it. The hardware device is a remote server and does not require disposal.

3. Product description

This product is a software medical product. The medical image management and processing system is a unified remote data platform, which supports the data fusion of multiple collection devices, adopts B/S technology framework to realize remote viewing, and supports the concurrent use of multiple users.



3.1 Server

| name | model |
|---------------------|--|
| CPU processor | Performance is not less than 4 cores, and the main frequency is 3.0GHz |
| Memory | Not less than 128 GB |
| Built-in hard disk | Solid-state hard disk: not less than 250 GB; Mechanical hard disk: not less than 3 TB |
| Network card | Recommended ten gigabit network card, the lowest 2.5G network card |
| Network connections | 10 Gbps (recommended), 1 Gbps (minimum) |
| Other | Connect to the hospital LAN. |
| Support software | MySQL 5.7.17 |

3.2 Software environment

| name | edition |
|----------------------|-----------------------------|
| Operational software | Windows10 Version and above |

| | |
|-------------------|----------------------------------|
| Memory | ≥ 16 GB |
| Monitor | Not less than 1920×1080 |
| Browser | Google Chrome 80.0.0.0 and above |
| Network type | LAN |
| Network bandwidth | ≥ 1 Gbps |

3.3 Interface requirements

| name | require |
|-----------|---------|
| Indicator | HDMI |
| Keyboard | USB |
| Mouse | USB |

3.4 Installation



In order to ensure that the product can be accessed normally, the product can only be installed by qualified personnel authorized by the visual microimage.



Before the installation of this product, the hospital IT needs to provide 2 IP addresses and 2 port numbers (ophthalmic image management software server, Capture PC), and open the firewall whitelist.



This product has certain requirements for dependent environment and configuration. Before installation, it is necessary to determine whether the hardware environment, software environment and interface requirements mentioned above can be met.

3.5 Accessories

This product is an independent software and does not require installation or uninstallation. Users can directly access the system website through a browser to login. The server required for this software is provided by our company. This software have to used together with the capture devices provided by our company.

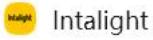
3.6 Service life

When there is a significant change in the product, the software cannot meet the expected use of the product, and the registrant/manufacturer/manufacturer is unable to provide maintenance services, the product lifecycle ends and the product cannot

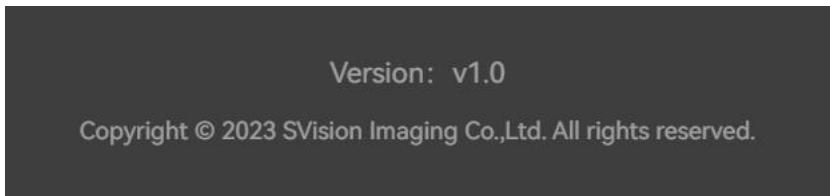
continue to be used

3.7 Product label

- 1) Enter the browser URL (such as 10.80.60.194) to enter the login interface, where the browser displays tags containing the company logo and name.



- 2) Enter the patient management page, click on "About" in the upper right corner, and a label containing the version and copyright will be displayed



3.8 Maintenance

- 1) This product is a remote data platform, and the installed computer equipment needs to ensure normal network operation to avoid being unable to use due to network abnormalities.
- 2) It is recommended to reload when using the current patient information again to avoid data expiration or updates for a long time.
- 3) It is recommended to reload the current patient information when using it again to avoid data that has not been used for a long time, expired, or has been updated.
- 4) Only the authorized technical service personnel can carry out the product maintenance. Do not change the product system configuration and use dependencies that do not meet environmental requirements. If there is a fault during using, please contact the technical support department of visual microimage.
- 5) Regular feedback and version upgrade maintenance of the product are received and maintained by professional personnel from the SVision Imaging to ensure the normal and good operation of the product

3.9 Network Connections

The user is responsible for network setup and maintenance, including the installation and configuration of all necessary hardware and software. The SVision Imaging technology support department is only responsible for testing the network connectivity of the medical image management and processing system and is not

responsible for troubleshooting or repairing network connectivity issues.



When connected to the Internet, the product may suffer serious security risks, including viruses and worms that may cause system failure or negatively affect its performance. There may also be third-party software, software drivers either automatically or purposefully downloaded to your computer. Installing any unapproved software, including drivers, can reduce computer performance and affect diagnostic or treatment information.

If the system is connected to Internet, it is recommended to install all the operating system patches and patches. Frequent viral scanning is also recommended.

Prohibited activities

Prohibited activities when using the equipment include:

- Do not relocate the device database to a network file server.
- Do not share device folders with other computer systems over the network.
- If a printer is installed on the device, do not share that printer.

Network configuration requirements

- 1) If you transfer data over the network, connect the source and the target system to the network using standard cables. If it is transmitted through a direct connection between the source and the target system, use cross cables to connect both.
- 2) Source and target systems must share the same network protocol set.
 - Microsoft Network client
 - Microsoft Network file and printer sharing
 - Internet protocol (TCP/IP)
- 3) On the destination system, create a network mapping disk to receive the imported data and access the destination system from the source system.
- 4) On the source system, map the network drive to a shared folder created on the target system in step 4. If the target system is password protected, it must be accessed using a user account with Windows 10/11 computer Administrator privileges.

3.10 Version upgrade

This product is a unified remote data platform. According to the problems or abnormalities encountered in the use of the product, visual microimage professionals will receive feedback regularly. If the product is upgraded, an upgradable version will be provided to ensure the normal use of the product.

3.11 Technical descriptions

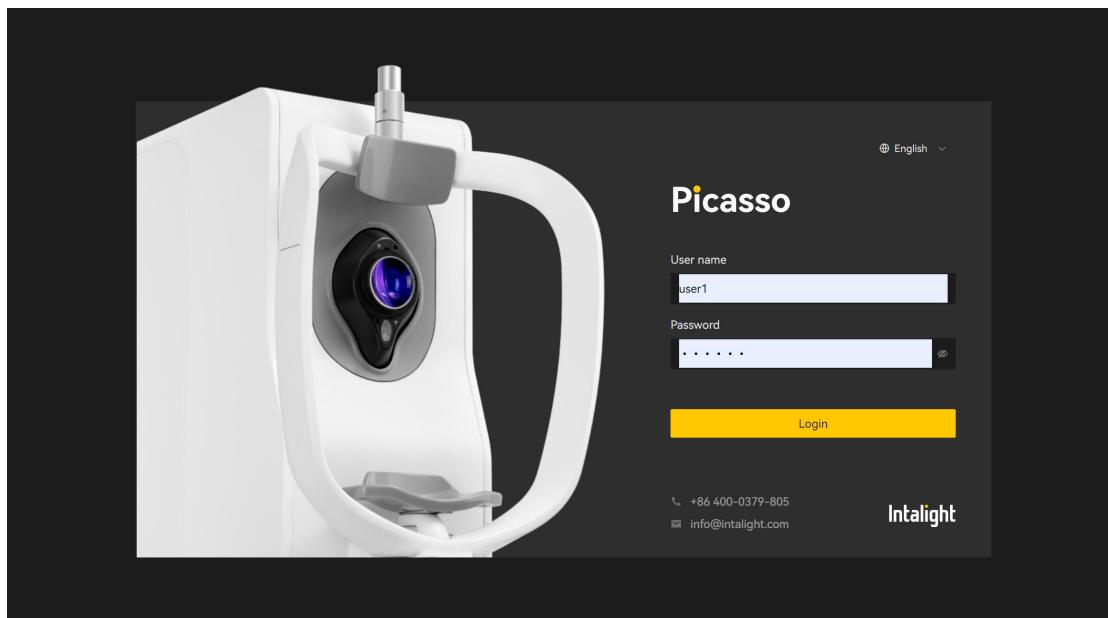
This product specification contains use instructions and technical instructions, such as software design documents, software test report and other technical documents, only the engineers who have obtained the SVision Imaging authorization and receive formal training are qualified to obtain the SVision Imaging contact.

4. Instructions

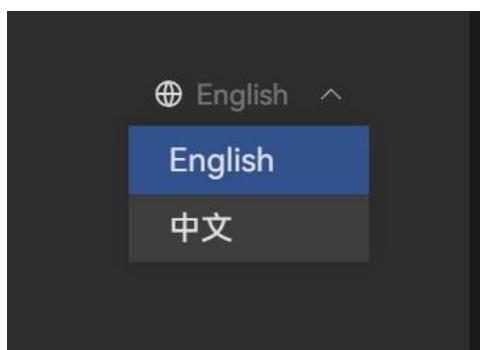
4.1 Basic operations

4.1.1 Login

- 1) Turn on the computer, and enter the Windows operating system.
- 2) Open the Google Chrome, enter the server address of the medical image management and processing system, and wait for the website to load until the following login page appears:



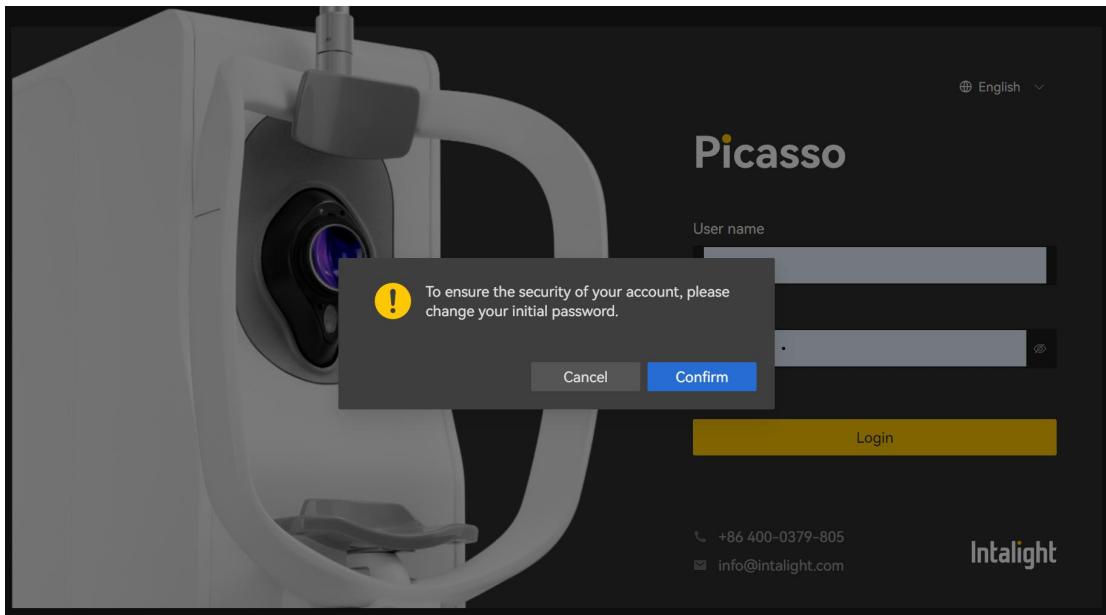
- “Chinese” and “English” switch: in the upper right corner of the page’s login area, click the upper right corner to switch the language, default is English.



- Enter the user name and password to login.

4.1.2 First login

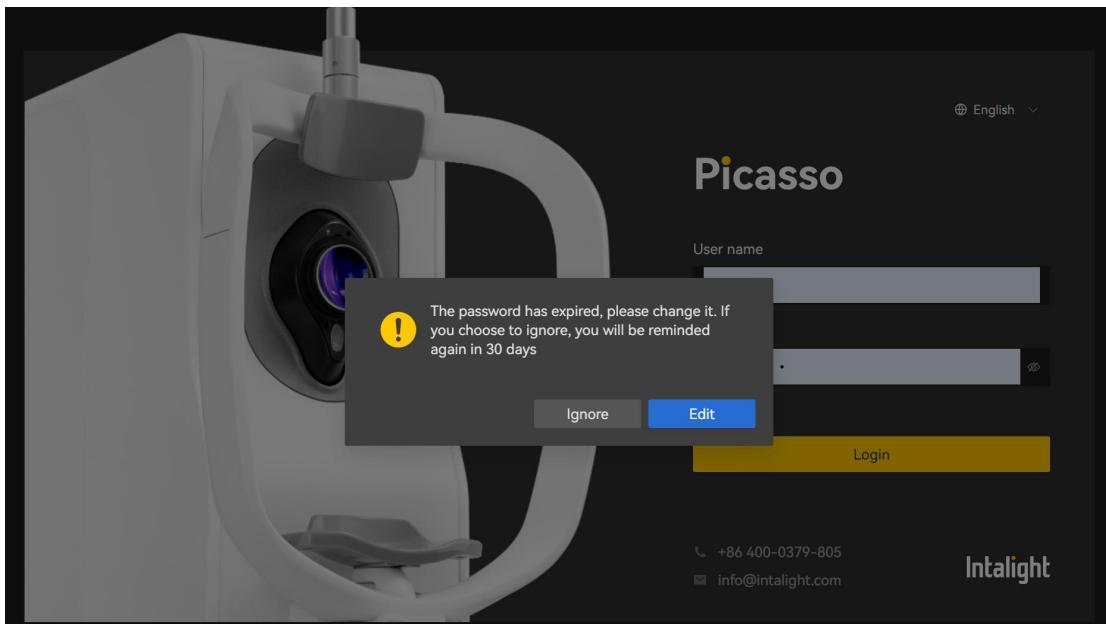
Follow the above steps, enter the correct user name and password, and click “Login”. If you are logging in the medical image management and processing system for the first time, it will prompt you to change the password after clicking:



- Click “confirm” will jump to modify password page and support users to reset the password.
- Click “Cancel” will jump to the patient management page. It should be noted that if your initial password is not changed, it will still prompt “change the initial password” when you login again.

4.1.3 Password expires

The default user password expiration time of the medical image management and processing system is set to 1 year. When the password expires, the user clicks “login” and will prompt to change the password after clicking:

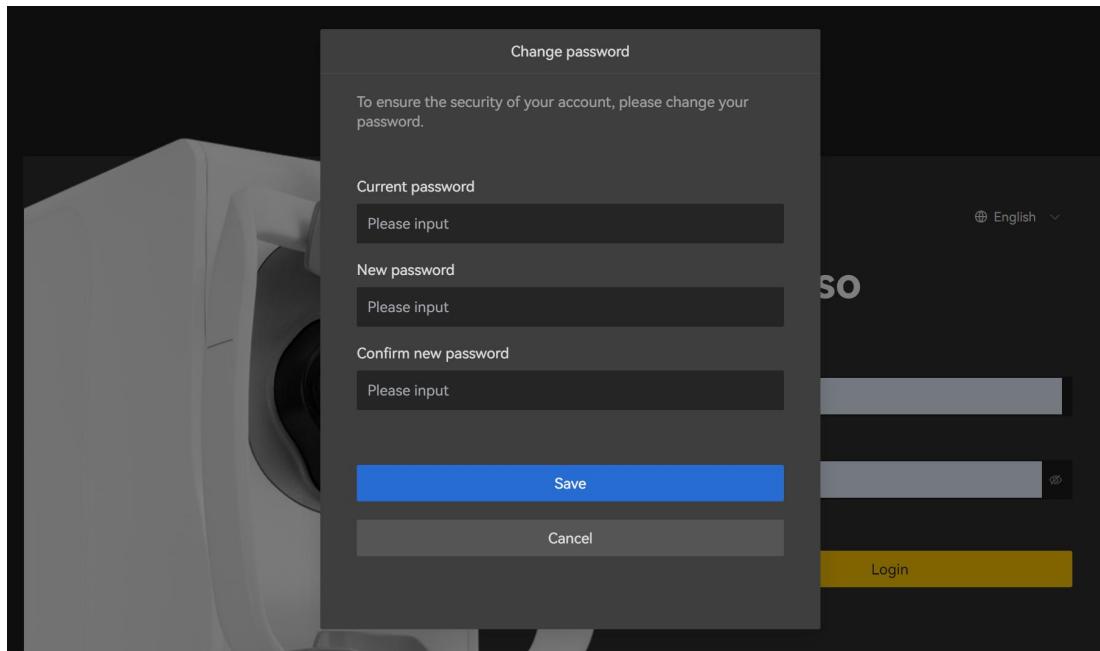


- Click “Edit” will jump to modify the password, support users to reset the password.

- Click “ignore” will jump to the patient management page. It should be noted that if your password is not changed, the password expiration time will be set to “30 days” by default, which means that after “30 days”, you will be prompted again with “password expiration”.

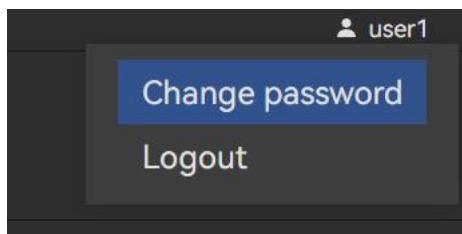
4.1.4 Change password

In the modified password page, you need to enter the original password, the new password, confirm the new password, it should be noted that the new password needs to meet the “at least 8 characters, including letters and numbers” conditions.



- Click “Save”, confirm to change the password, jump to the login page of the medical image management and processing system, enter the new password you set and click “Login” .
- Click “Cancel”, without any modification, jump to the patient management page or stay on the original page.

In addition to the two ways mentioned above, in the upper right corner of the user operation page, provides the user “change the password” entrance, you can set your new password at any time.

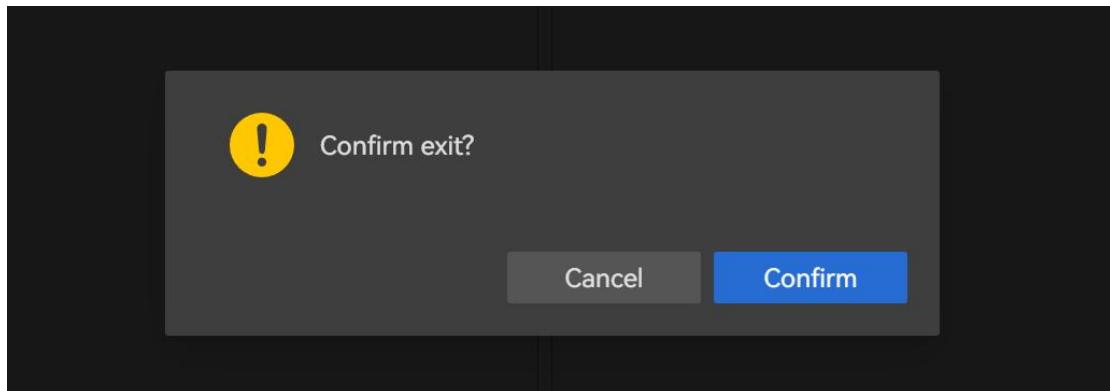


4.1.5 Logout

- Click the avatar of the character in the upper right corner of the user

operation page, and the drop-down selection menu will be expanded, where you can choose “logout”

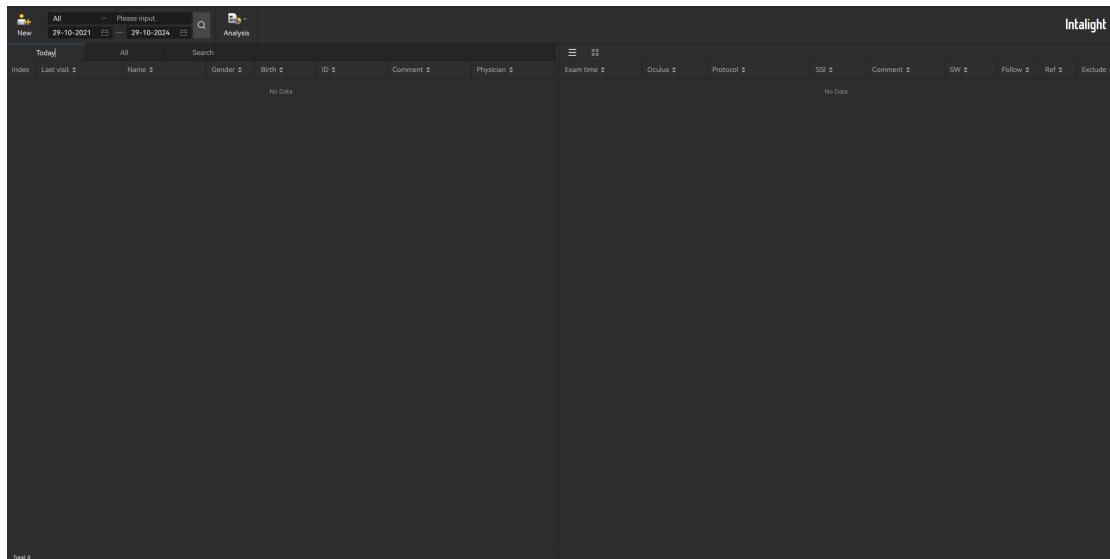
- 2) After clicking, the second confirmation box of “whether to logout” will pop up:



- Click “Confirm” to check out and jump to the login page of the medical image management and processing system. You can choose to login again or close the webpage of the medical image management and processing system.
- Click “Cancel” to close the second confirmation box and stay on the original page.

4.2 Patient management

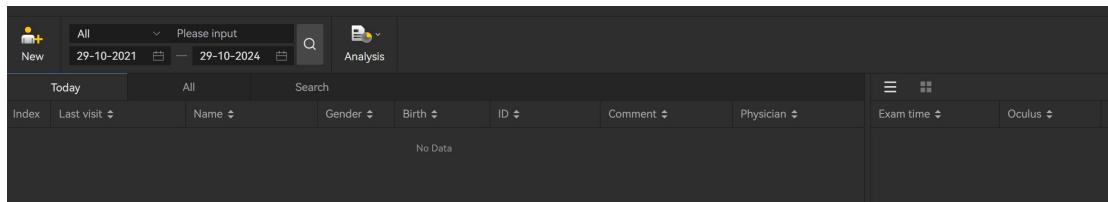
Patient management page includes the patient list, the patient capture list, the patient search, the analysis page entrance, the editing patient remarks, and editing capture remarks:



4.2.1 Add patients (not supported)

4.2.2 Patient list

- 1) The “Today” shows the list of patients who completed the day:



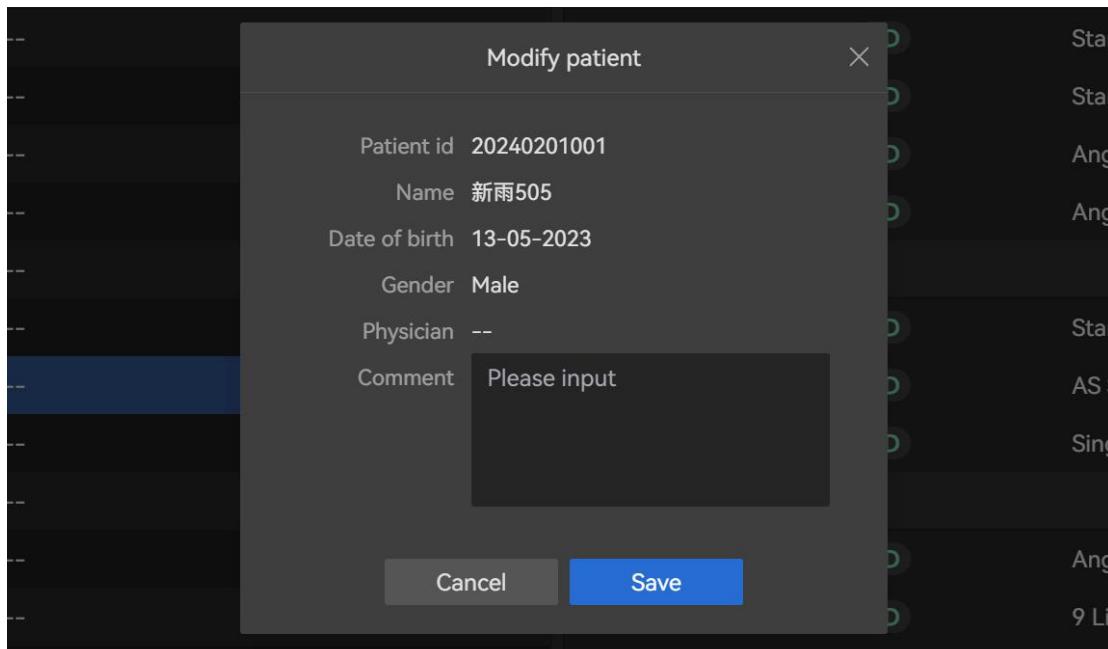
2) The “All” shows the list of all captured patients:

| Index | Last visit | Name | Gender | Birth | ID | Comment | Physician | Exam time | Oculus |
|-------|---------------------|---------------|--------|------------|-------------|---------|-----------|------------|--------|
| 1 | 28-10-2024 16:56:11 | 猪眼 | Male | 28-10-2024 | 20241028002 | -- | aa | 28-10-2024 | OS |
| 2 | 21-10-2024 16:15:50 | 眼底曲率-不同工作距... | Female | 21-10-2024 | 20241021001 | -- | aa | 16:51:46 | OS |
| 3 | 21-10-2024 11:09:21 | test | Male | 18-09-2023 | 20230918001 | -- | aa | 16:43:59 | OS |
| 4 | 18-10-2024 15:53:56 | 眼底曲率-Monica | Male | 18-10-2024 | 20241018007 | -- | aa | 16:42:38 | OS |
| 5 | 18-10-2024 13:24:25 | 大视野FAZ test | Male | 18-10-2024 | 20241018003 | -- | aa | 16:37:10 | OS |
| 6 | 18-10-2024 12:33:07 | test | Male | 18-10-2024 | 20241018004 | -- | aa | | |

3) The “Search” shows the list of patients queried by condition:

| Index | Last visit | Name | Gender | Birth | ID | Comment | Physician | Exam time | Oculus |
|-------|---------------------|--------------|--------|------------|-------------|---------|-----------|-----------|--------|
| 1 | 21-10-2024 11:09:21 | test | Male | 18-09-2023 | 20230918001 | -- | aa | 11:09:21 | OD |
| 2 | 18-10-2024 13:24:25 | 大视野FAZ test | Male | 18-10-2024 | 20241018003 | -- | aa | 18:43:12 | OD |
| 3 | 17-10-2024 15:52:01 | test111 | Male | 17-10-2024 | 20241017003 | -- | aa | 18:42:02 | OD |
| 4 | 12-10-2024 13:42:52 | 眼底曲率xyy test | Male | 19-09-2024 | 20240919001 | -- | -- | 18:41:03 | OD |
| 5 | 29-09-2024 14:46:16 | 16x16test | Male | 29-09-2024 | 20240929001 | -- | aa | 18:34:27 | OD |
| 6 | 20-09-2024 12:45:34 | zy | Female | 27-12-2023 | 20231227002 | -- | aachen | | |

Right click a patient to display Modify Comments, click “Modify Comment” will show popup window, which supports modifying patient remark:



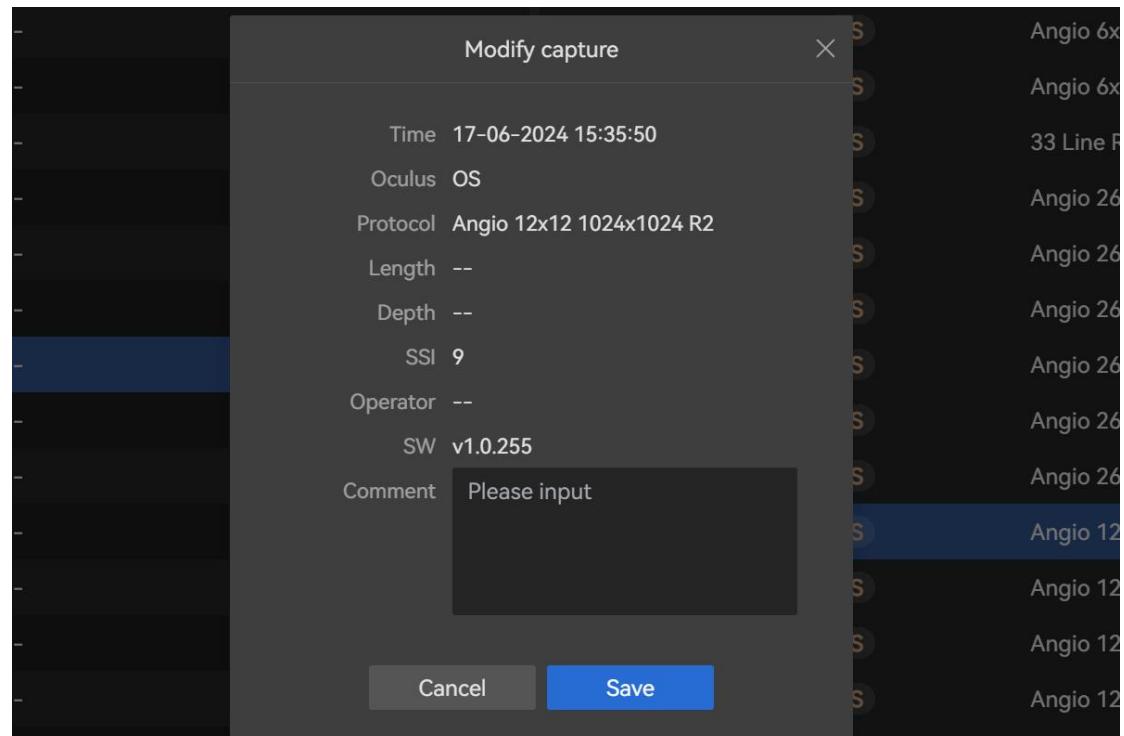
4.2.3 Patient capture list

After a patient data is selected in the patient list, the patient capture list will display all the captured informations of the patient, supporting the “List”

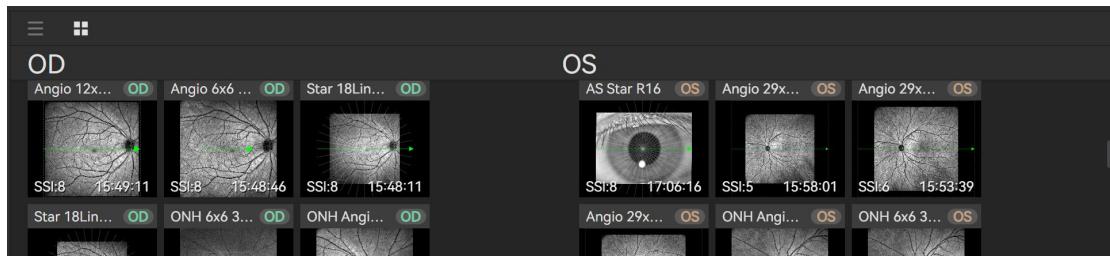
and the "card", and in the "List" mode, support the right click to modify the capture remarks. The "List", the "card" can be switched in the upper left corner of the capture list:

The screenshot shows a software interface for managing medical images. At the top, there is a header bar with various icons. Below it is a table-like "capture list" with columns for Exam time, Oculus, Protocol, SSI, Comment, SW, Follow, Ref, and Exclude. The list contains several entries, with the last one from 14-06-2024 highlighted. Below the list are two rows of thumbnails. The first row shows five grayscale fundus photographs of the retina. The second row shows four other types of medical images, possibly OCT or angiograms. A green dashed box highlights the first image in the first row.

The "List" mode includes the capture list on the upper side and the thumbnails on the lower side. Right click a capture data to display modify comments, click "Modify comment" will show popup window, which supports modify capture remarks:



Click to switch the "card" to display:



The “card” includes the OD list on the left and the OS list on the right.

4.2.4 Search patients

The upper side of the patient management page includes the patient search area, where you can select the condition and the time you want to query to search the patient.

| | Name | Gender |
|-------------|--------|--------|
| 白随访 | Male | |
| 小鼠BatImport | Male | |
| 切换协议测试 | Male | |
| 人眼动物眼测试 | Male | |
| 张娇直眼505 | Female | |

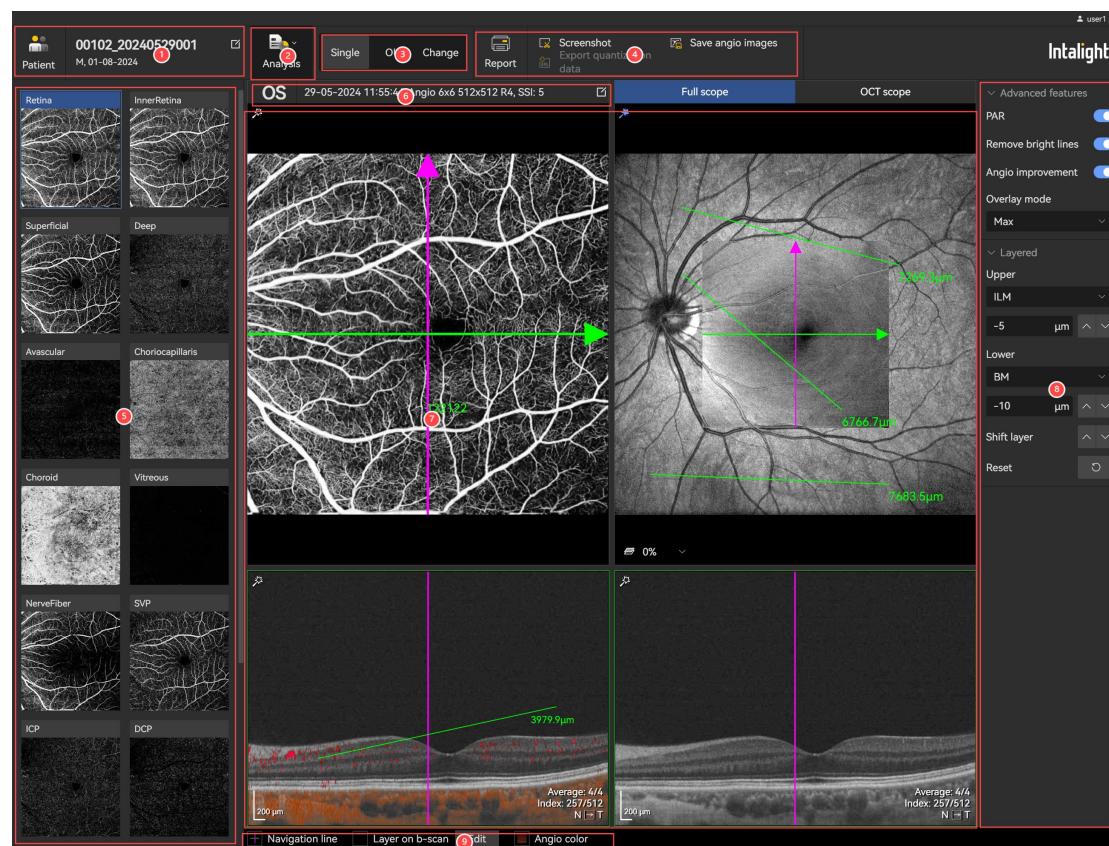
4.2.5 Jump to the analysis page

The upper side of the patient information management page includes the analysis page entrance. According to the patient capture information you have selected, the medical image management and processing system provides an analysis interface that can be switched, or you can jump to the default analysis page by double-clicking the patient capture, such as:

| Exam time | Oculus | Protocol | SSI |
|-----------|--------|------------------------|-----|
| 13:04:37 | OD | Angio 12x12 512x512 R4 | 9 |
| 15:39:32 | OD | Angio 6x6 512x512 R4 | 6 |
| 15:37:45 | OD | 9 Line R16 | 6 |
| 16:56:31 | OD | Angio 16x16 680x680 R4 | 6 |

4.3 Scan images

By clicking on the entrance of the analysis page or double clicking on the patient capture information, you can jump to the analysis page and view the scanned images. According to the capture's protocol is different, the scans supported for viewing are not completely consistent. In general, including "Angiography", "Angio-Retina enhanced view", "Structural projection", "Advanced segmentation", "Cube", "OCTA montage", "Line scan", "B-scan". The following instructions take the angiography page as the example.

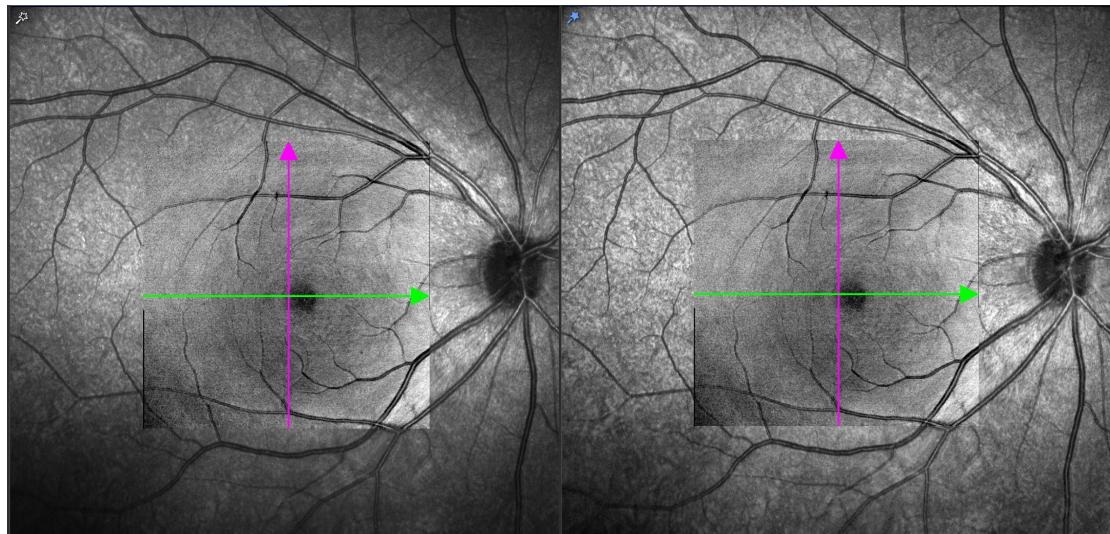


- 1) Patient information: Click "Patient" will return to the Patient Management page; click "Edit" icon will display the "Modify Patient" popup window, which supports to modify the patient remark.
- 2) The entrance of analysis page: supports free jumping to view other scan images within the analysis page.
- 3) "Single", "OU", "Change": supports switching to view the scan images within the angiography protocol, or the line-scan protocol.

- 4) Operation buttons: including “screenshot”, “report”, “save angio images”, “select data”, “synchronize”, etc.
- 5) Thumbnails: supports clicking to switch layer.
- 6) Patient capture information: including basic information such as oculus, capture time, protocol, etc. Clicking the “Edit” icon will display the “modify capture” pop-up window, which supports to modify the captrue remarks.
- 7) Scan images: take the angio page as the example, the current display is Angio, OCT, Slow B-scan with angio color, Slow B-scan.
- 8) Operable list: take the angio page as the example, including remove bright lines, angio improvement, modify layers, reset, etc.
- 9) Bottom control: including bottom operation buttons to adjust the scan images, such as navigation line, layer on bscan, angio color, etc.

4.3.1 Image enhance

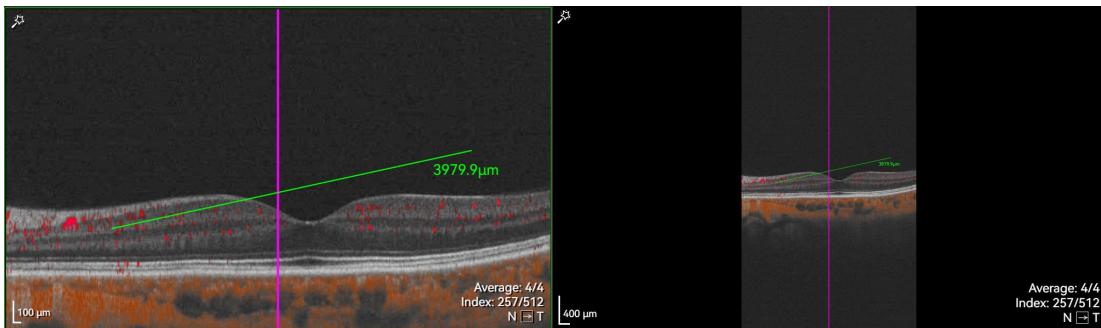
 The upper left corner of the scan images is the “image enhance” icon, and click to view the rendering effect.



4.3.2 Scale

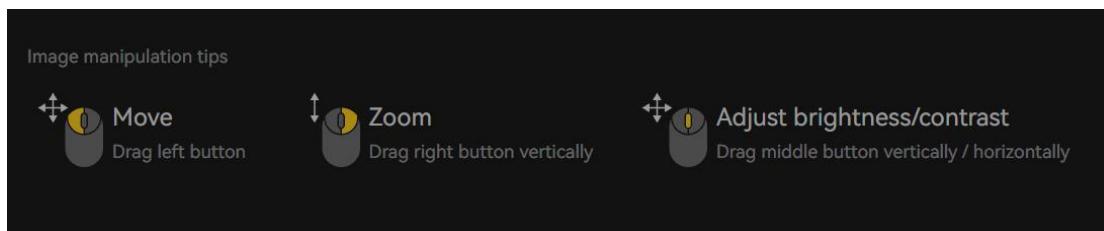
The B-scan image displays the scale of the image in the current scene, representing the ratio of the displayed size to the actual size of the image. When

the user adjusts the B-scan display, the scale bar will dynamically adjust the display.



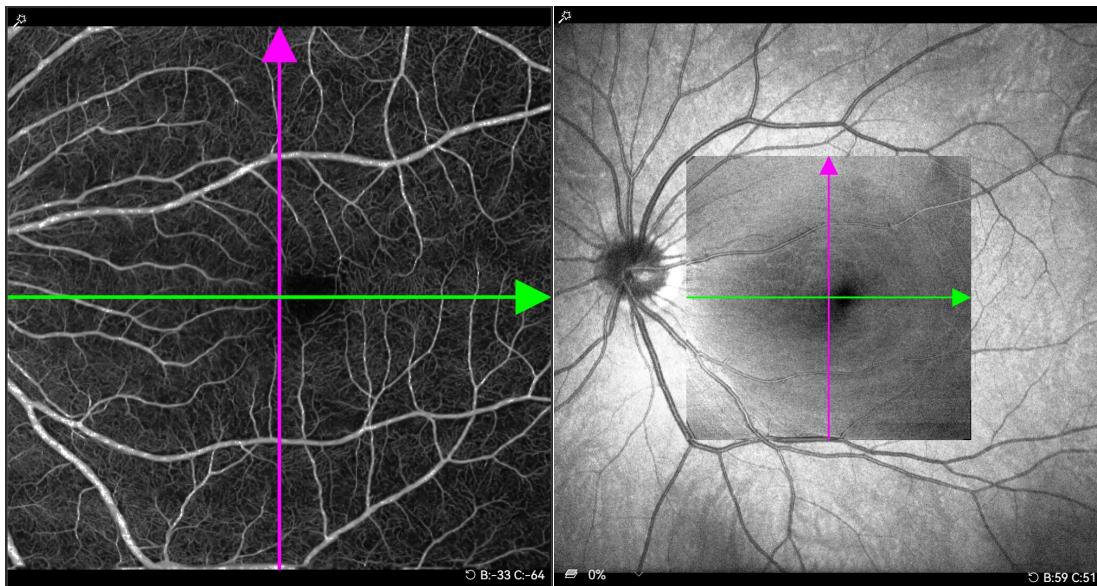
4.3.3 Shortcuts

For the convenience of users, the medical image management and processing system has customized part of the shortcut operations, and users can also see some shortcut key guidance when entering or switching the analysis page.



- 1) Left mouse click: take the angio page as the example, Clicking the left mouse button on Angio or OCT will trigger navigation line repositioning.
- 2) Left mouse long press: In the current image, pressing the left mouse button will trigger the image drag. It should be noted that drag behavior is only effective in scenarios where the image is enlarged.
- 3) Left mouse double-click: double-click the left mouse button. If the mouse is located in the scan image, it will trigger the current scan image to be full screen and exit the full screen.
- 4) Middle mouse long press: Long press the middle mouse button will trigger the brightness and contrast adjustment of the current scan image, in which the upward is to increase the brightness, the down is to reduce the brightness, the right is to increase the contrast, and the left is to reduce the contrast. It should be noted that brightness and contrast adjustment are not triggered

in image-enhanced scenes, and in scenes where brightness and contrast are zero, brightness and contrast are not displayed.



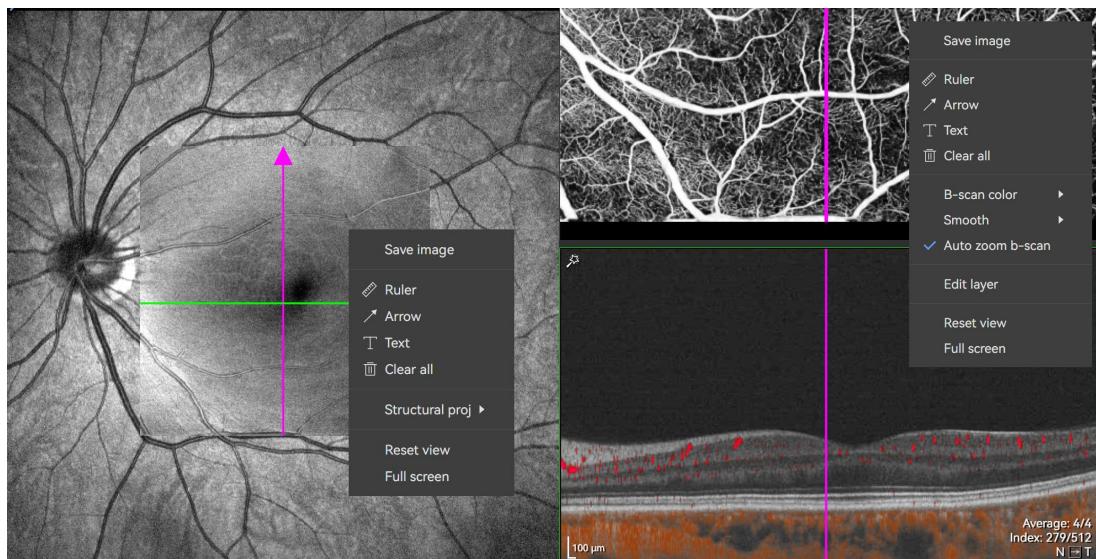
- 5) Right mouse click: clicking the mouse right button to trigger the right-click menu.
- 6) Right mouse long press: long press the mouse right button will trigger the sacn image to zoom. Take the current trigger point as the center, zoom in upwards and zoom out downwards..
- 7) Mouse wheel: Place the mouse cursor in the image, and sliding the mouse wheel will trigger the position change of the x-axis navigation line.
- 8) Keyboard: Up and down will trigger the x-axis navigation line position change, and to the left and right will trigger the y-axis navigation line position change.



The right mouse long press zoom in Edge browser conflicts with Edge's gesture, resulting in reduced usability of right mouse zoom. The solution is to disable "mouse gesture" in Edge browser or replace with Google Chrome.

4.3.4 Right click menu

Place the mouse in the image, the right click will trigger the right-click menu, containing the current image executable action buttons, take OCT, Slow B-scan as examples.



- 1) Save image: Download the scan image, which contains changed information such as brightness, contrast, color, etc.
- 2) Measure tools: including ruler, arrow, text, all clear, in 4.3.5.
- 3) B-Scan color: change the scan images display, support gray, reverse, classic, rainbow, etc.
- 4) Smooth: Change the smooth of B-scan images, which ranging from 0 to 3.
- 5) Auto zoom b-scan: Change the display scale of B-scan images.
- 6) Edit layer: click to trigger “edit layer” popup window, in 4.5.
- 7) Reset view: Change the scan images display to adapt the current window.
- 8) Full screen, exit the full screen: change the scan images full screen, or exit the full screen display.

4.3.5 Measure tools

Measure tools supported by the medical image management and processing system includes ruler, arrow, text, all clear.

- 1) Ruler

Select “ruler” to draw the ruler in the current scan image. The ruler is determined by 2 points, including 2 endpoints, measure line and measure value. After determining the 2 points, double-click the scan image or the right button to

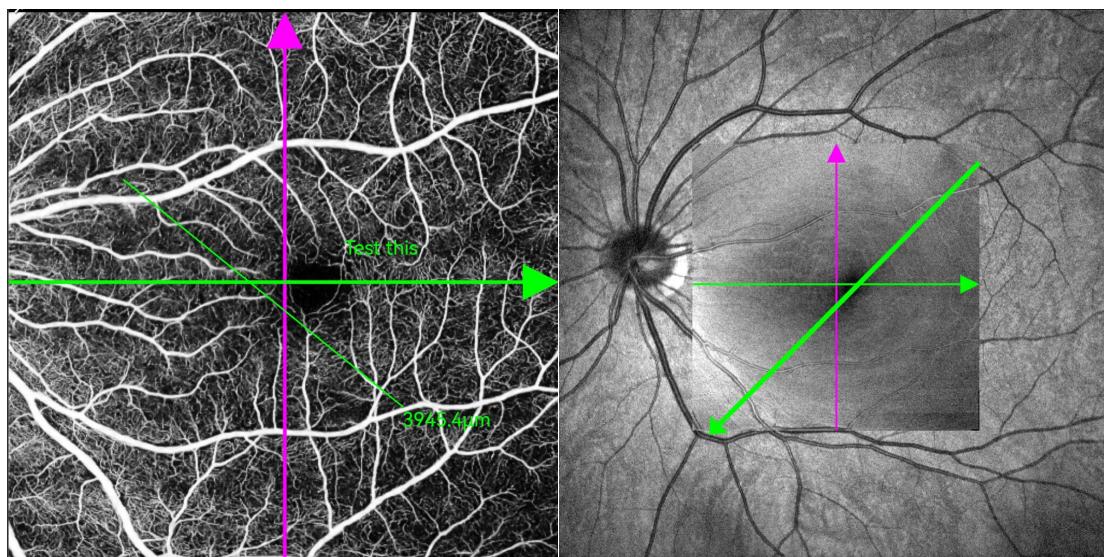
exit the drawing state. A double-click on the ruler you want to edit will select this ruler and enter the drawing state of the ruler. When a ruler is selected, you can dynamically change the display position or size of endpoints, measure line, and measure value by dragging and dropping.

2) Arrow

Select “Arrow” to draw the arrow in the current scan image. The arrow is determined by 2 points, including 2 endpoints and arrow line. After the 2 points are determined, double-click the scan image or the right button to exit the drawing state, and double-click the arrow you want to edit will select this arrow and enter the drawing state. When an arrow is selected, you can drag and drop to dynamically change the endpoint, the arrow line with position and size.

3) Text

Select “Text” to draw the text in the current scan image. Click on the scan image somewhere, will trigger the text box display, you can enter the text you want to add in the text box, after the addition, left button or double click the blank area, right button can exit the drawing status, double click on the text you want to edit will pop up the text modification box, enter the text drawing state.



4) Clear all

Select “Clear All” to delete all measures for the current scan image, including ruler, arrow, text.

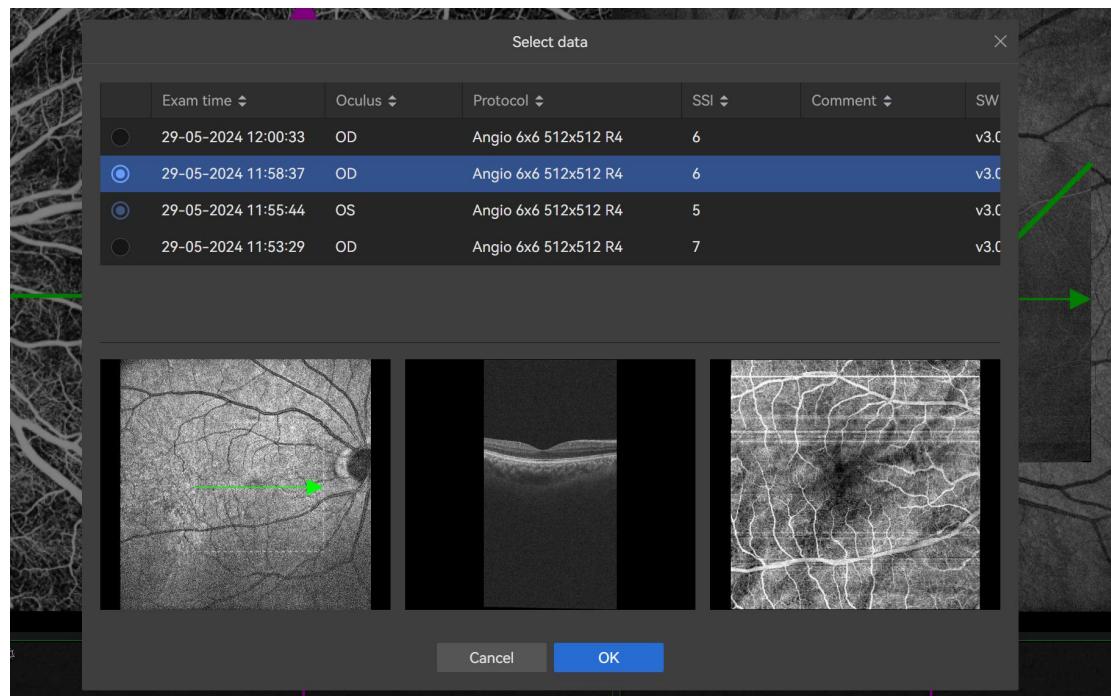
5) Save

The measures is not saved in real time and is triggered when you switch the analysis page or return to the patient management page.

4.4 OU/Change

After entering the analysis page, for the first time click “OU” or “Change”, the default trigger select data pop-up window. The current check information is the main data and cannot be changed by default. The other selected data is auxiliary data recommended by the system, which can be switched by clicking the radio button in front of the list.

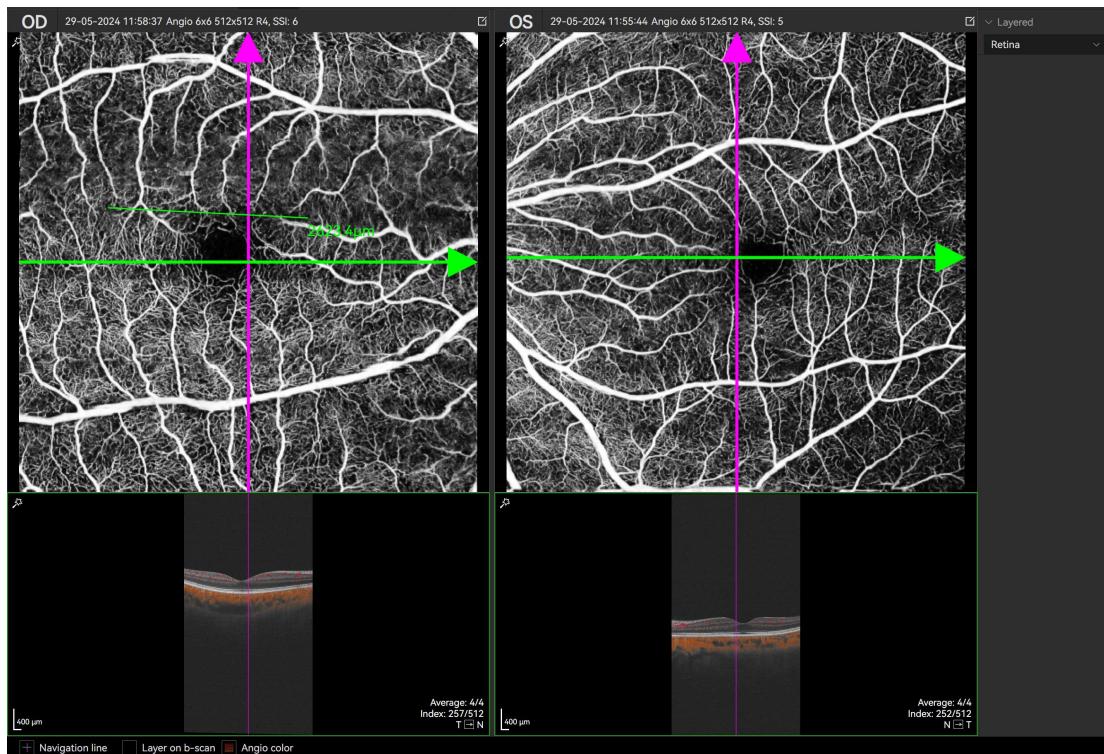
If the selected main data and subsidiary data already exist in the “OU” and “Change” page, when clicking “OU” or “Change” again, the page will directly jump to the corresponding page to display the selected data. The following figure will take the angio protocol as the example. If you want to change the current selected subsidiary data, you can trigger the select data pop-up window through the “Select Data” button on the analysis page.



4.4.1 OU

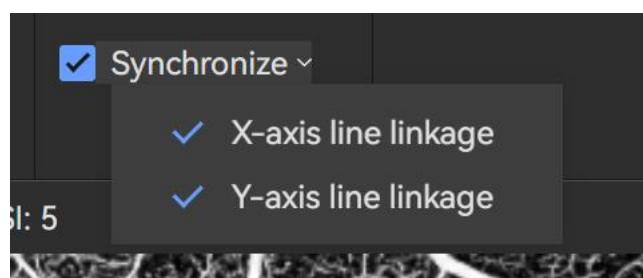
Contrast information between the left and right eyes, shown by default as OD on the left side and OS on the right side. Angio and Slow B-scan are included. It

should be noted that the operations of the navigation lines between the main data and auxiliary data are asynchronous, the main data changes are synchronized to the single page, and the auxiliary data changes do not affect the display of the main data.



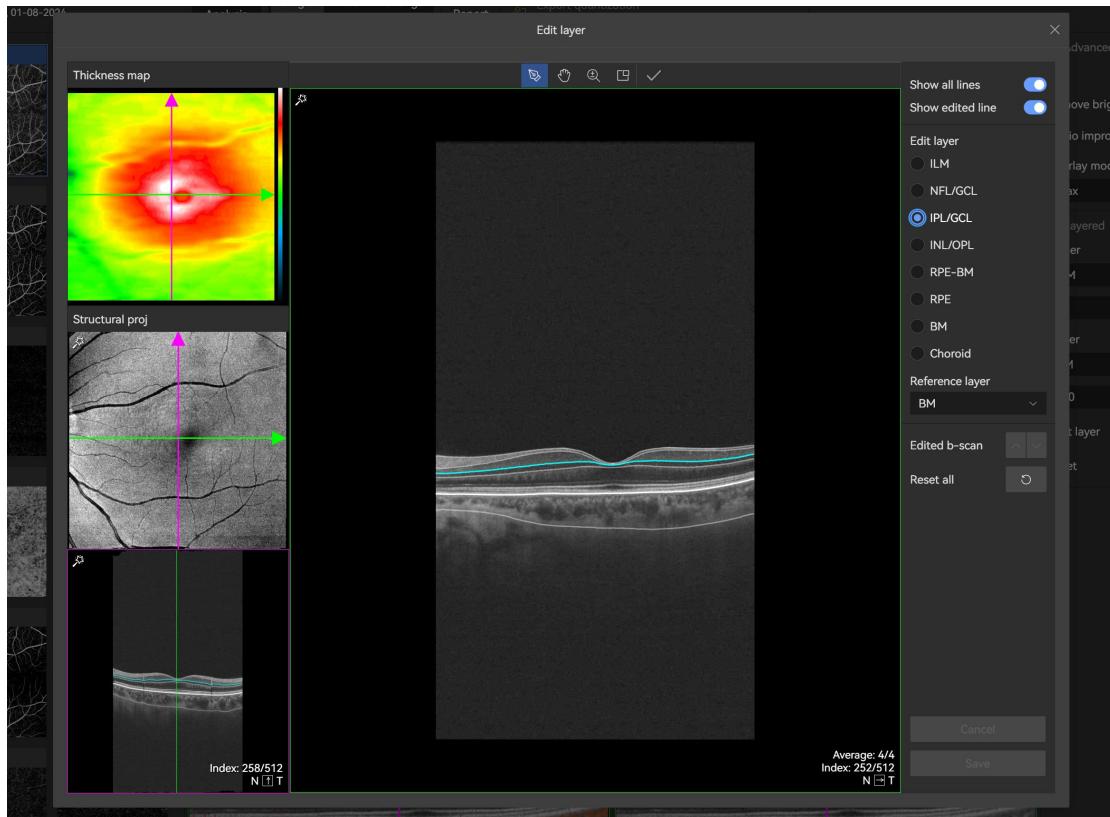
4.4.2 Change

The change page is similar to the OU page, and is displayed by default in reverse order of capture time. Angio and Slow B-scan are included. It should be noted that the operation of the main data and auxiliary data can be set synchronous or asynchronous. By setting the “synchronize” on the upper side of the page, you can control whether the navigation line's x-axis and y-axis change synchronously. the main data and auxiliary data adjust the navigation line changes according to the synchronization length, When asynchronous, the main data and auxiliary data do not affect each other.



4.5 Manual layer

Clicking on the “Edit Layer” in the B-scan right-click menu or clicking on the “Edit” in the bottom control will trigger the manual layer pop-up window.



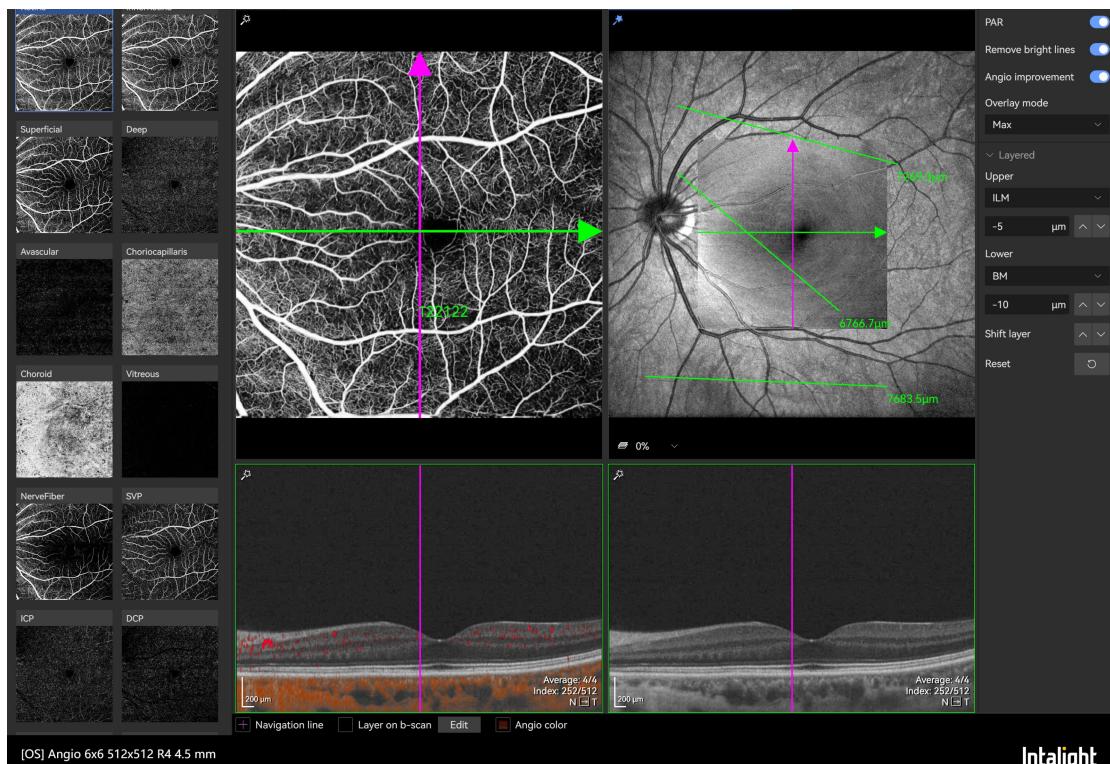
- 1) Left: including thickness topographic map, structural projection map, fast B-scan, each map changes with editing layers on the b-scan, and operating on the right side.
- 2) Edit: including toolbar, B-scan image. Select the toolbar action icon and switch to the appropriate edit status. It indicates the current editing state, left click on the layer line to modify its position, and right click to temporarily store the edited layer information. It indicates the current dragging state, long pressing the left mouse button to drag the image. It indicates the current zooming state, long pressing the left mouse button to zoom the image. It indicates the full screen or exit the full screen; it indicates temporary storage, the button is available when there is unsaved editing information on the layer line.
- 3) Right: including display control, layer switch, save, reset and other operation buttons. Select the icon button “reset”, and the edited layered

information will be reset to the default state. After being edited, the lower right “Cancel”, “save” button is available, select the button “save”, and the edited layered information will be saved to disk.

- 4) Exit: Closing the manual layer requires you to click  in the upper right corner of pop-up window.

4.6 Screenshot

Click the “Screenshot” button on the analysis page to trigger the full-screen screenshots. After generating the screenshots, download the screenshots to the local folder of the browser by default. The generated screenshots include the scan images and watermark, and the watermark content is not completely consistent according to the size of the screenshots.

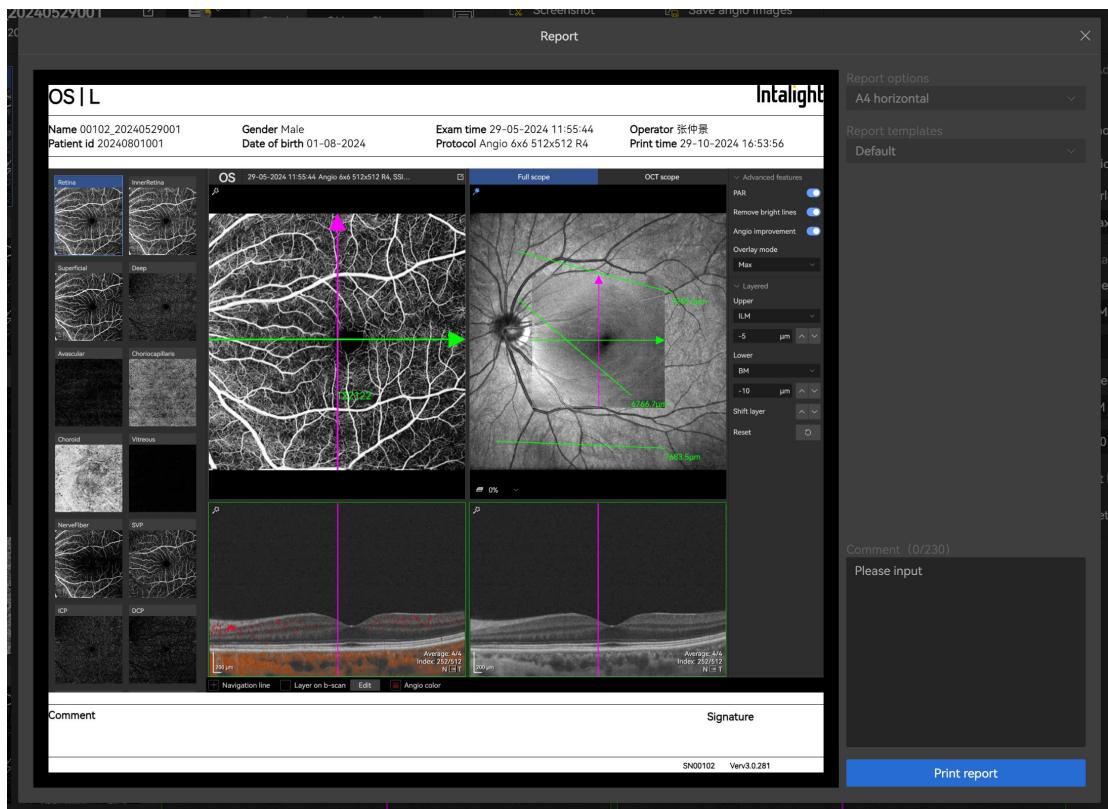


4.7 Report

Click the “Report” button on the analysis page to trigger the display of the report popup window. The window includes reports, report options, and comments.

- 1) Report: This section is the printed content, where the “description” changes in real-time with the input on the right side.

- 2) Report options: default report size is A4 and report template is default.
- 3) Comments: support input, line breaks, etc., the input is synchronized to display in the report content.
- 4) Print: Click the “Print” button to trigger the browser print preview.



matters need attention:

- The printer uses non-standard parts for this product. In case of printing errors, please try restarting the printer or contact the printer manufacturer for resolution.
- The printed results are not intended for independent identification or proactive classification of diseases. They only assist ophthalmologists in confirming diagnoses.
- Operators should check whether the printed results are clear and free from contamination.

5. Product quality

5.1 Functional

5.1.1 User usage restrictions

- 1) Users need to enter at least 8 characters and must include both letters and numbers when changing their password;
- 2) The default validity period for user passwords is 1 year.
- 3) When a piece of data is being used, other users will not be able to load it simultaneously.
- 4) The user account can only remain logged in to one browser at a time. Logging in again without logging out or logging in to another browser without logging out will automatically log out of the previous login.
- 5) If a user stays on a certain page for more than 30 minutes without taking any action, they will be logged out by default.

5.1.2 Key defects and solutions

1) Data loss

User operation: During the process of saving data, the network was interrupted, resulting in data loss.

Solution: After restoring the network, restart the browser, log in to the software again to operate and save data.

2) Service unavailable

User operation: Server downtime, network disconnection, power outage, or shutdown of server-side services, resulting in unavailability of client software services.

Solution: Use UPS uninterruptible power supply on the server side and secure and stable network.

3) Software crash

User operation: During software operation, opening multiple apps simultaneously can cause the client's CPU utilization to reach 90% or memory utilization to reach 90%, resulting in browser crashes and software crashes.

Solution: Clean up cache, close unnecessary apps, uninstall unnecessary apps, close unnecessary startup programs, restart the browser to restore normal use.

4) Interface response timeout

User operation: The client exceeds the maximum concurrency limit; The server CPU utilization rate reaches 90% or above, and the memory utilization rate reaches 80% or above.

Solution: Clean up the cache on the server side, and restart the browser on the client side to restore normal use.

5.1.3 System timeout

This software provides timeout control function. After reaching the preset idle time interval (30 minutes), the system will automatically log out to prevent users from obtaining permanent authorization.

5.2 Efficiency

| quota | requirement |
|----------------------------|---------------------------------|
| Software startup time | Response time within 10 seconds |
| Patient page loading time | Loading time within 5 seconds |
| Analysis page loading time | Loading time within 1 minutes |
| Server memory usage | <= 80GB |

5.3 Usability

5.3.1 Knowledge required to operate

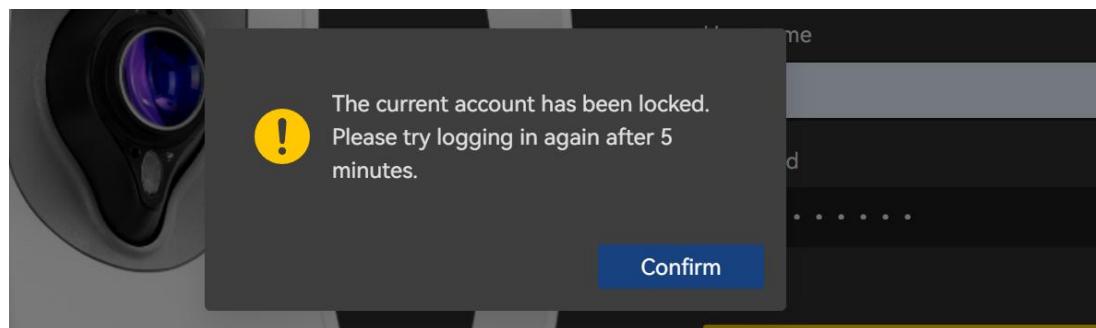
The users of this software need to be medical personnel with normal vision and basic keyboard operation ability, as well as knowledge of imaging, computer usage, or industry requirements.

5.3.2 Error defense

1) Illegal user operation prompt

This software will provide prompts for illegal user operations. When a piece of data is being used, other users will be prompted to load it. When the user inputs the password incorrectly more than 5 times, a prompt will be given. When the user wants to write and save due to insufficient disk, a prompt will be given.

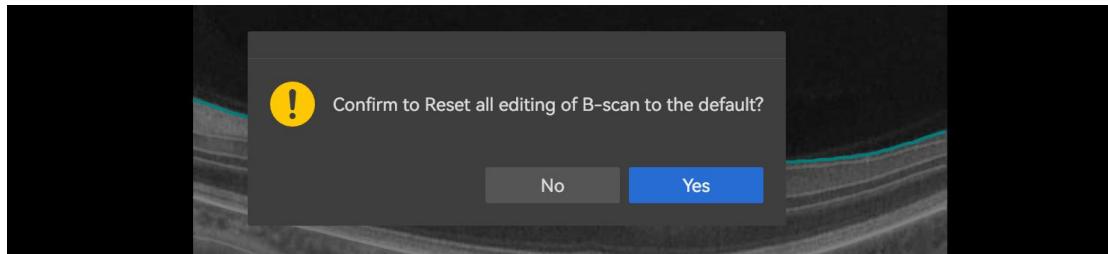
For example, if the password is entered incorrectly more than 5 times, it will be locked:



2) Serious consequences warning

This software marks operations with serious consequences using a red button. When performing operations with serious consequences such as resetting, saving, and canceling, a warning message will pop up again. Only after confirmation can the operation be executed.

When resetting the editing layer:



5.4 Compatibility

5.4.1 Compatibility

Users of this software client are recommended to use Google Chrome or the Edge browser that comes with the Windows 10 operating system. The browser version should be compatible with the software operating environment. Not recommended to use other browsers (such as IE, Safari) as they may not be compatible. One thing to note: The right mouse long press zoom in Edge browser conflicts with Edge's gesture, resulting in reduced usability of right mouse zoom. The solution is to disable "mouse gesture" in Edge browser or replace with Google Chrome.

5.4.2 Software environment parameter configuration

The server-side requires installation of services, configuration of environment and parameters. The installation of server-side services and configuration of environment and parameters will be carried out by our professional personnel.

5.5 Reliability

5.5.1 Ability to continue operating with errors

When the user inputs incorrectly, the software will provide corresponding prompts. When encountering server side service unavailability, the software will report an error. In the event of a network failure, the software will report an error. When the interface response exceeds the time limit, the software will report an error. The backend log will capture the reason for the error. After repairing or restoring the network in the backend, restart the software to continue running.

5.5.2 Data backup

See 6. Data Management for details

5.6 Security

1) Confidentiality

This software uses username and password for user identity authentication and prohibits unauthorized users from accessing.

2) Integrity

This software performs data integrity verification to ensure the integrity of the data.

3) Verifiability

This software operation has backend logs that support viewing.

4) Authenticity

Users save image files in their original format to ensure the authenticity of the image data.

5) Security level

The security level of this software is moderate, which means that the software may directly or indirectly cause minor (not serious) harm, as detailed in 1.8.

5.7 Maintainability

- 1) Users need to keep their accounts and passwords safe and regularly update them to prevent accidental password leaks.
- 2) When users do not need to operate, they should log out in a timely manner to prevent malicious use by others.
- 3) Before using the system, users should clean up the cache to avoid running out of memory.
- 4) Real time monitoring of system resource utilization through task manager to avoid high CPU/memory/disk utilization.
- 5) Real time monitoring system network bandwidth to avoid the phenomenon of low network bandwidth and slow system operation.
- 6) Close and exit unnecessary apps, uninstall unnecessary apps, and disable unnecessary startup programs.
- 7) Pay attention to ventilation and heat dissipation, regularly check whether the power fan of the host and the CPU fan inside the motherboard are running normally.
- 8) It is strictly prohibited to copy files to the hard drive without authorization, as file damage caused by this may also lead to system crashes.

5.8 Portability

5.8.1 Operating environment

See 3.1 and 3.2 for details.

5.8.2 Incompatible browsers

This software recommends using Google Chrome, but you can also use Edge browser. It may not be compatible with other browsers such as IE and Safari.

6. Data management

6.1 Backup of database

The software provides a regular database backup mechanism. The backup strategy is to back up once a day, with a maximum of seven backups retained. If the number exceeds seven, the oldest ones will be deleted. Check whether backup is required during software startup, every 6 hours and 4 times a day to ensure correct backup and inspection on the same day. The database backup file location is D:\picassoBackup. The software encrypts the backup database.

| data (D:) > picassoBackup | | | | |
|---------------------------|--------------------------|-----------------|--------|------|
| | 名称 | 修改日期 | 类型 | 大小 |
| ↗ | Picasso_20240904.sql.enc | 2024/9/4 17:16 | ENC 文件 | 7 KB |
| ↗ | Picasso_20240905.sql.enc | 2024/9/5 17:16 | ENC 文件 | 7 KB |
| ↗ | Picasso_20240906.sql.enc | 2024/9/6 17:17 | ENC 文件 | 7 KB |
| ↗ | Picasso_20240908.sql.enc | 2024/9/8 17:18 | ENC 文件 | 7 KB |
| ↗ | Picasso_20240909.sql.enc | 2024/9/9 18:04 | ENC 文件 | 7 KB |
| ↗ | Picasso_20240910.sql.enc | 2024/9/10 18:05 | ENC 文件 | 7 KB |
| ↗ | Picasso_20240911.sql.enc | 2024/9/11 0:52 | ENC 文件 | 7 KB |

6.2 Data encryption

Patient data information is identified in combination with patient ID number and data source IP, and does not reflect other patient information. Patient data information is encrypted, which needs to be read or analyzed by the company's product software.

| 此电脑 > 本地磁盘 (D:) > Capture > 20220530001 > 2022-05-30_11-34-23 | | | | |
|---|--|-----------------|---------|-----------|
| | 名称 | 修改日期 | 类型 | 大小 |
| ↗ | 20220530001(2022-05-30 11.34.23)_analysis.encg | 2022/6/14 15:14 | ENCG 文件 | 15,890 KB |
| ↗ | 20220530001(2022-05-30 11.34.23)_large.encg | 2022/5/30 11:34 | ENCG 文件 | 21,788 KB |
| ↗ | 20220530001(2022-05-30 11.34.23)_small.encg | 2022/5/30 11:34 | ENCG 文件 | 6,652 KB |

6.3 Operation log

When the software starts, it will automatically start recording logs, and the log files will be saved to in the user data directory by default. The log file has been encrypted and needs to be decrypted by decryption software before it can be viewed.

| 文件夹 | | | |
|----------------|-----------------|-----|----|
| 路径 | | | |
| 名称 | 修改日期 | 类型 | 大小 |
| AppData | 2024/10/25 0:00 | 文件夹 | 0B |
| Roaming | 2024/10/25 0:00 | 文件夹 | 0B |
| SVision | 2024/10/24 8:57 | 文件夹 | 0B |
| Log | | | |
| PicassoHost | 2024/10/25 0:00 | 文件夹 | 0B |
| PicassoService | 2024/10/25 0:00 | 文件夹 | 0B |
| VanGoghService | 2024/10/24 8:57 | 文件夹 | 0B |

7. Error code

| code | category | Meaning |
|-------|----------------|---|
| 10101 | Request Error | The request path is not acceptable. |
| 10102 | Request Error | Invalid parameters provided. |
| 10103 | Request Error | The protocol of request capture can not be handled. |
| 20101 | Data Error | The data to be processed is invalid. |
| 20102 | Data Error | The data to be processed is empty. |
| 20103 | Data Error | Load capture failed. |
| 20104 | Data Error | Save capture or analysis file failed. |
| 20105 | Data Error | The data has been opened by other user. |
| 20106 | File Error | The file has been closed by release interface. |
| 30101 | Analysis Error | Analysis failed. |
| 30102 | Analysis Error | Server load is too heavy to do analysis. |
| 30103 | Analysis Error | Server resource are insufficient for analysis. |
| 40101 | Database Error | Failed to connect to database. |
| 50101 | Server Error | Internal error occurred. |
| 60101 | Server Error | save userInput to file failed. |

8. Specification

| | |
|--------------------------------|---|
| Manufacturer | SVision Imaging, Ltd. |
| Size and weight | Server (Length x Width x Height) : 356mm x169mm x 385mm, Approximately 7.2 kg; |
| Power Supply | 220V 50Hz |
| Power Output | 700W |
| Environmental Condition of Use | Temperature: 10° C~30° C Relative Humidity: 30%~70% Atmospheric Pressure: 80~1060 kPa |
| Storage Condition | Temperature: -20° C~60° C Relative Humidity: 10%~100% Atmospheric Pressure: 700~1060 hpa |
| Altitude | ≤2000m |
| Server configuration | CPU: performance is not less than 4 cores, and the main frequency is 3.0GHz Memory: not less than 128 GB Solid-state hard disk: no less than 250 GB Mechanical hard disk: not less than 3 TB Monitor: not less than 1920×1080 Network card: recommended ten gigabit network card, the lowest 2.5G network card Operational software: Windows10 and above Browser: google Chrome 80.0.0.0 and above |

9. Manufacturer Contact Information

SVision Imaging, Ltd.

Room 302, Building 1, NO. 2 Penglai Road, Jianxi District, Luoyang, Henan, CHINA,
471000

Tel. : +86 0379-6300-2345

Service Hotline: +86 400-0379-805