

OPTOMED HALO

Automated Portable Retinal Camera

User Manual



Reading through accompanying documents is a mandatory action before using this equipment



810-C2701-131 Rev. D

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1 Introduction

1.1 Outline

The Automated Portable Retinal Camera Optomed Halo is an auto 3D tracking, fast and easy to carry retinal imaging system. Optomed Halo is designed to provide images of the eye as an aid to clinicians in the diagnosis of diabetic retinopathy, AMD, glaucoma and other retinal diseases.

1.2 Intended use

Optomed Halo provides non-mydratic color retina and external images of the eye as an aid to clinicians in the evaluation and diagnosis of eye disease.

1.3 Indication for Use

Optomed Halo is a non-contact, high resolution digital imaging device which is suitable for photographing, displaying and storing images of the retina and external areas of the eye to be evaluated under non-mydratic conditions.



Optomed Halo is indicated for in-vivo viewing of the posterior and external area of the eye and the images are intended for use as an aid to clinicians in the evaluation, diagnosis and documentation of ocular health.





1.4 Proper instrument use




1. Optomed Halo is a medical device; it must be operated by properly trained and qualified person(s) only. The operation should be supervised by a physician. If abnormal behavior is observed due to EM disturbances, please relocate the device accordingly.
2. Please be sure to read the user manual to understand the safety precautions before operating this device.
3. Always enter patient information first.
4. Prepare patient contact surfaces (forehead and chin rest) according to the cleaning method in this manual.
5. Instantly turn off the power switch of this instrument and disconnect the power cable if uncertain problems arise.
6. Clean ocular lens frequently to ensure good image quality.
7. Adjust the height of motorized adjustable table properly to ensure patient's comfort during the examination.
8. Align the patient's eye position to the canthus indicator mark on the chin and forehead rest assembly.
9. Dim the room lights to allow natural dilation of the patient's pupil and to provide a comfortable visualization of the fixation target without glare.
10. Inspection of the system's functionality before use whether any repair is needed.






2 Safety information








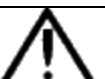

2.1 Displays for safety use

| <u>Display</u> | <u>Meaning</u> |
|--|---|
|  WARNING | “WARNING” indicates the presence of a hazard that could result in severe personal injury. |
|  CAUTION | “CAUTION” indicates the presence of a hazard that could result in minor injury. |
| NOTE | “NOTE” provides useful information for operation which is important. |






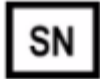


| | |
|--|--|
|  WARNING | Accessory equipment connected to the digital interfaces must be certified according to the respective IEC standards (e.g., IEC 60950 for laptop or IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1-1 and IEC 60601-1:2005. Any person who connects or installs devices to the system has responsibility to verify that compliance. If in doubt, consult the Optomed local representative or distributor. |
|  WARNING | To avoid risk of electric shock, this equipment must only be connected to the supply mains with protective earth. |
|  WARNING | Do not modify this equipment without authorization of the manufacturer. |
|  WARNING | THE Optomed Halo CANNOT REPLACE CLINICAL JUDGEMENT AND IS INTENDED TO BE USED ONLY IN CONJUNCTION WITH OTHER CLINICAL TOOLS CONSIDERED TO BE THE STANDARD OF CARE FOR MEASUREMENT AND DIAGNOSIS OF THE EYE. |

| | |
|--|---|
|  WARNING | <p>The Optomed Halo is a medical device. The software and hardware has been designed in accordance with U.S., European and other international medical device design and manufacturing standards. Unauthorized modification of the Optomed Halo software or hardware, or any addition or deletion of any application in any way can jeopardize the safety of operators and patients, the performance of the instrument, and the integrity of patient data.</p> <p><u>Any changes, additions or deletions to factory installed applications, operating system or modifications to hardware in any manner VOIDS the Warranty completely.</u></p> |
|  WARNING | <p>Optomed Halo is not intended for home use and may not be stored or operated in environment conditions other than those prescribed. (see <i>Specification</i>)</p> |
|  WARNING | <p>Phototoxicity</p> <p>Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged, and the brightness setting should not exceed what is needed to provide clear visualization of the target structures.</p> <p>The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. If the value of radiance were reduced in half, twice the time would be needed to reach the maximum exposure limit.</p> |

| | |
|--|--|
|  WARNING | Do not obstruct the mains power switch or position the equipment where the connection to the mains line can be accidentally disconnected. |
|  WARNING | Equipment is not suitable for use in the presence of a Flammable Anesthetic Mixture with Air, Oxygen, or Nitrous Oxide. |
|  WARNING | The Optomed Halo has no special protection against harmful ingress of water or other liquids (classified IPX0). To avoid damage to the instrument and cause a safety hazard, the cleaning solutions, including water, should not be directly applied to the device. Using a dampened cloth (without dripping), is a good method to clean the exterior surface of the enclosure. |
|  WARNING | The patient cannot touch any electrical device that is not powered by Optomed Halo with any part of his or her body while being examined. In addition, the Optomed Halo operator must not attempt to touch the patient and any electrical device that is not powered by Optomed Halo at the same time while examining the patient. Failure to do so could result in electrical shock to the patient and/or operator. |
|  WARNING | Do not connect the instrument with anything other than specified. Otherwise, it may result in fire or electric shock. For details of purchasing accessories, please contact a Optomed representative or distributor. |





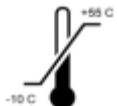



| | |
|--|---|
|  CAUTION | Be sure to hold the bottom of the base when Optomed Halo is moved. |
|  CAUTION | When adjusting chinrest, be careful not to pinch the patient's hand. |
|  CAUTION | The device need to install on the stable table. Do not install in location that are unstable or exposed to vibration |
|  CAUTION | Federal law restricts this device to sale by or on the order of a Physician or Practitioner (CFR 801.109(b)(1)). |
|  CAUTION | Careful consideration of this information is essential when stacking or collocating equipment and when routing cables and accessories. |
|  CAUTION | Please do not use any other cables or accessories not approved by the manufacturer in this manual to avoid negative influence on electromagnetic compatibility. |
|  CAUTION | This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments. |
|  CAUTION | Distance between Optomed Halo and wall not less than 22cm |
|  CAUTION | To ensure cleanliness, replace the chinrest paper whenever changing patients. |

2.2 Symbols and labels




| | |
|---|--|
|  | <p>Presence of electrical shock hazard.</p> <p>Note: Indicates risk of electrical shock due to the presence of uninsulated high voltage inside the instrument.</p> <p>Do not remove the instrument cover or parts.</p> |
|  | Circuit Breaker |
|  | <p>Type B applied parts.</p> <p>Note: This instrument complies with the specified requirements to provide protection against electrical shock, particularly regarding allowable patient leakage current.</p> |
|  | <p>Manufacturer</p> <p>Crystalvue Medical Corporation</p> <p>No. 116, Ln. 956, Zhongshan Rd., Taoyuan Dist., Taoyuan City 33072, Taiwan</p> |
|  | <p>Authorized Representative in the European Union</p> <p>Medical Device Safety Service (MDSS) GmbH</p> <p>Schiffgraben 41</p> <p>30175 Hannover, Germany</p> |
|  | Serial number |
|  | Catalog number / part number |
|  | Prescription Use |

2.3 Protective packing symbols

The protective packing symbols specify the handling requirements and the transport and storage conditions.

| | |
|---|---|
|  | Fragile, Handle with care |
|  | Keep dry |
|  | This end up |
|  | Relative Humidity |
|  | Temperature |
|  | Do not stack |
|  | 2 Layers only |
|  | <p>Waste Electrical and Electronic Equipment (WEEE)</p> <p>Recycling Instructions</p> <p>When determined that the device is ready for disposal, it is to be recycled following the policies and procedures reflecting respective country's requirements. Do not dispose of device as general waste.</p> |

Product compliance

| | |
|---|---|
|  | 93/42/EEC/M5 Medical Device Directive |
|  | Indicates this equipment contains Type B applied parts |
|  | <p>The Optomed Halo is classified as follows:</p> <p>Class I Equipment – Protection against electrical shock.</p> <p>Type B – Degree of protection against electric shock of applied part (chin and forehead rests).</p> <p>Ordinary Equipment (IPX0) – Degree of protection against ingress of liquids (none) (4th edition).</p> <p>Continuous Operation – Mode of operation</p> <p>Electromagnetic Compatibility (EMC): EN 60601-1-2:2015 (4th edition)</p> <p>The Optomed Halo™ device has been tested to comply with the emission and Immunity requirements of EN60601-1-2:2015 (4th edition). The Optomed Halo™ is intended for use in an electromagnetic environment where radiated RF disturbances are not beyond the standard defined in EN60601-1-2:2015 (4th edition).</p> |

Certification: under IEC 60601-1

| Guidance and manufacturer’s declaration – electromagnetic emissions | | |
|---|------------|--|
| The Optomed Halo is intended for use in the electromagnetic environment specified below. The customer or the user of the Optomed Halo should assure that it is used in such an environment. | | |
| Emissions test | Compliance | Electromagnetic environment – guidance |
| RF emissions CISPR 11 | Group 1 | The Optomed Halo uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class A | The Optomed Halo is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. WARNING: The Optomed Halo is intended for use by healthcare professionals only. The Optomed Halo may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the system, or shielding the location. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | |


Manufacturer's declaration-electromagnetic immunity

The Optomed Halo is intended for use in the electromagnetic environment (for professional healthcare) specified below.

The customer or the user of the Optomed Halo should assure that it is used in such an environment.

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment-guidance (for professional healthcare environment) |
|--|---|---|---|
| Electrostatic discharge(ESD) IEC 61000-4-2 | Contact: ± 8 kV Air ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV | Contact: ± 8 kV Air ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30% |
| Electrical fast transient/burst IEC 61000-4-4 | ± 2 kV for power supply lines ± 1 kV for input/output lines | ± 2 kV for power supply lines Not applicable | Mains power quality should be that of a typical professional healthcare environment. |
| Surge IEC 61000-4-5 | ± 0.5 kV, ± 1 kV line(s) to line(s) ± 0.5 kV, ± 1 kV, ± 2 kV line(s) to earth | ± 0.5 kV, ± 1 kV line(s) to line(s) ± 0.5 kV, ± 1 kV, ± 2 kV line(s) to earth | Mains power quality should be that of a typical professional healthcare environment. |
| Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | Voltage dips: 0 % UT; 0,5 cycle 0 % UT; 1 cycle 70 % UT; 25/30 cycles Voltage interruptions: 0 % UT; 250/300 cycle | Voltage dips: 0 % UT; 0,5 cycle 0 % UT; 1 cycle 70 % UT; 25 cycles Voltage interruptions: 0 % UT; 250 cycles | Mains power quality should be that of a typical professional healthcare environment. If the user of the <u>Optomed Halo</u> requires continued operation during power mains interruptions, it is recommended that the <u>Optomed Halo</u> be powered from an uninterruptible power supply or a battery. |
| Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8 | 30 A/m 50 Hz or 60 Hz | 30 A/m 50 Hz | The <u>Optomed Halo</u> power frequency magnetic fields should be at levels characteristic of a typical location in a typical professional healthcare environment. |

NOTE UT is the a.c. mains voltage prior to application of the test level.

| Manufacturer's declaration-electromagnetic immunity | | | |
|--|--|--|---|
| <p>The <u>Optomed Halo</u> is intended for use in the electromagnetic environment (for professional healthcare) specified below.</p> <p>The customer or the user of the <u>Optomed Halo</u> should assure that it is used in such and environment.</p> | | | |
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment-guidance (for professional healthcare environment) |
| <p>Conducted RF</p> <p>IEC 61000-4-6</p> | <p>3 Vrms:</p> <p>0,15 MHz – 80 MHz</p> <p>6 Vrms:</p> <p>in ISM bands between 0,15 MHz and 80 MHz</p> <p>80 % AM at 1 kHz</p> | <p>3 Vrms:</p> <p>0,15 MHz – 80 MHz</p> <p>6 Vrms:</p> <p>in ISM bands between 0,15 MHz and 80 MHz</p> <p>80 % AM at 1 kHz</p> | <p>Portable and mobile RF communications equipment should be used no closer to any part of the <u>Optomed Halo</u> including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> <p>$d = 1,2 \sqrt{P}$</p> <p>$d = 1,2 \sqrt{P}$ 80MHz to 800 MHz</p> <p>$d = 2,3 \sqrt{P}$ 800MHz to 2,7 GHz</p> <p>Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m).</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div>  </div> |
| <p>Radiated RF</p> <p>IEC 61000-4-3</p> | <p>3 V/m</p> <p>80 MHz – 2,7 GHz</p> <p>80 % AM at 1 kHz</p> | <p>3 V/m</p> <p>80 MHz – 2,7 GHz</p> <p>80 % AM at 1 kHz</p> | |
| <p>NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> | | | |

Recommended separation distance between portable and mobile RF communications equipment and the Optomed Halo

The Optomed Halo is intended for use in an electromagnetic environment (for professional healthcare) in which radiated RF disturbances are controlled. The customer or the user of the Optomed Halo can help prevent electromagnetic interference by maintaining a minimum **and wall** portable and mobile RF communications equipment (transmitters) and the Optomed Halo as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power of transmitter W | Separation distance according to frequency of transmitter m | | |
|---|--|--|---|
| | 150 kHz to 80 MHz $d = 1,2\sqrt{P}$ | 80 MHz to 800 MHz $d = 1,2\sqrt{P}$ | 800 MHz to 2,7 GHz $d = 2,3\sqrt{P}$ |
| 0,01 | 0,12 | 0,12 | 0,23 |
| 0,1 | 0,38 | 0,38 | 0,73 |
| 1 | 1,2 | 1,2 | 2,3 |
| 10 | 3,8 | 3,8 | 7,3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

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

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The Optomed Halo is intended for use in the electromagnetic environment (for professional healthcare) specified below.

The customer or the user of the Optomed Halo should assure that it is used in such an environment.

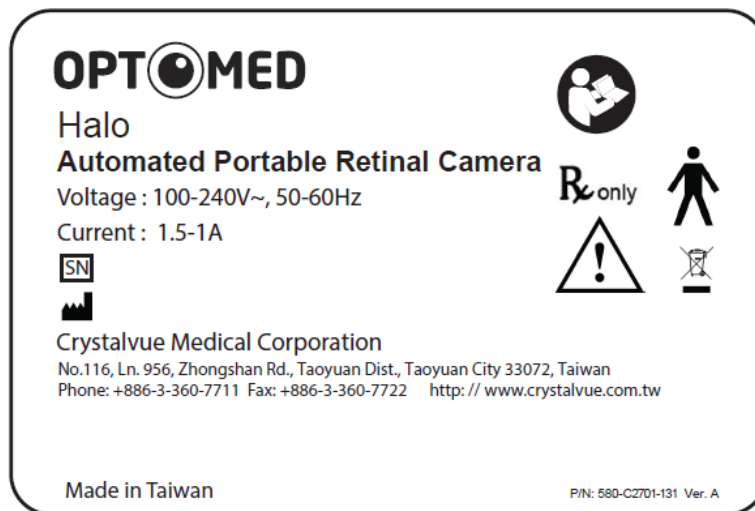
| Test frequency (MHz) | Band ^{a)} (MHz) | Service ^{a)} | Modulation ^{b)} | Maximum power (W) | Distance (m) | IMMUNITY TEST LEVEL (V/m) | Compliance LEVEL (V/m) (for professional healthcare) |
|----------------------|--------------------------|---|-----------------------------------|-------------------|--------------|---------------------------|--|
| 385 | 380 – 390 | TETRA 400 | Pulse modulation b) 18 Hz | 1,8 | 0,3 | 27 | 27 |
| 450 | 430 – 470 | GMRS 460, FRS 460 | FM c) ±5 kHz deviation 1 kHz sine | 2 | 0,3 | 28 | 28 |
| 710 | 704 – 787 | LTE Band 13, 17 | Pulse modulation b) 217 Hz | 0,2 | 0,3 | 9 | 9 |
| 745 | | | | | | | |
| 780 | | | | | | | |
| 810 | 800 – 960 | GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5 | Pulse modulation b) 18 Hz | 2 | 0,3 | 28 | 28 |
| 870 | | | | | | | |
| 930 | | | | | | | |
| 1 720 | 1 700 – 1 990 | GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS | Pulse modulation b) 217 Hz | 2 | 0,3 | 28 | 28 |
| 1 845 | | | | | | | |
| 1 970 | | | | | | | |
| 2 450 | 2 400 – 2 570 | Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulation b) 217 Hz | 2 | 0,3 | 28 | 28 |
| 5 240 | 5 100 – 5 800 | WLAN 802.11 a/n | Pulse modulation b) 217 Hz | 0,2 | 0,3 | 9 | 9 |
| 5 500 | | | | | | | |
| 5 785 | | | | | | | |

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

- a) For some services, only the uplink frequencies are included.
- b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
- c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

2.4 Product labels

Optomed Halo system labels (samples only):



2.5 Service life

The service life of Optomed Halo is five years if specified inspections and maintenance are done.

2.6 Cybersecurity information

2.6.1 Objective

The purpose of this section is to summarize the cybersecurity controls of the Optomed Halo system.

2.6.2 System overview

The Optomed Halo system has the following interface that are critical for cybersecurity:

- USB ports of the laptop or PC for connecting to various USB devices.

2.6.3 General principles

- Cybersecurity risk management is a shared responsibility among stakeholders including the medical device manufacturer, the user, and the health care facility. Failure to

maintain cybersecurity can result in compromised device functionality, loss of data availability or integrity, or expose other connected devices or networks to security threats.

- The laptop or PC is limited to install Windows 10 operation system and is dedicated for Optomed Halo, for the risk of viruses and other malwares, users must install and enable window defender or anti-virus software and follow the suggestion of third- party software (including virus updates) to update it.

2.7 Cybersecurity functions

2.7.1 Authentication of users

Optomed Halo system uses Microsoft Windows 10 as the main operating system. The operating system itself allows the end user to establish and configure “User Accounts” (example: standard users, power users, administrators) and “User Passwords” so that authentication is performed by password.

2.7.2 Auto-logout

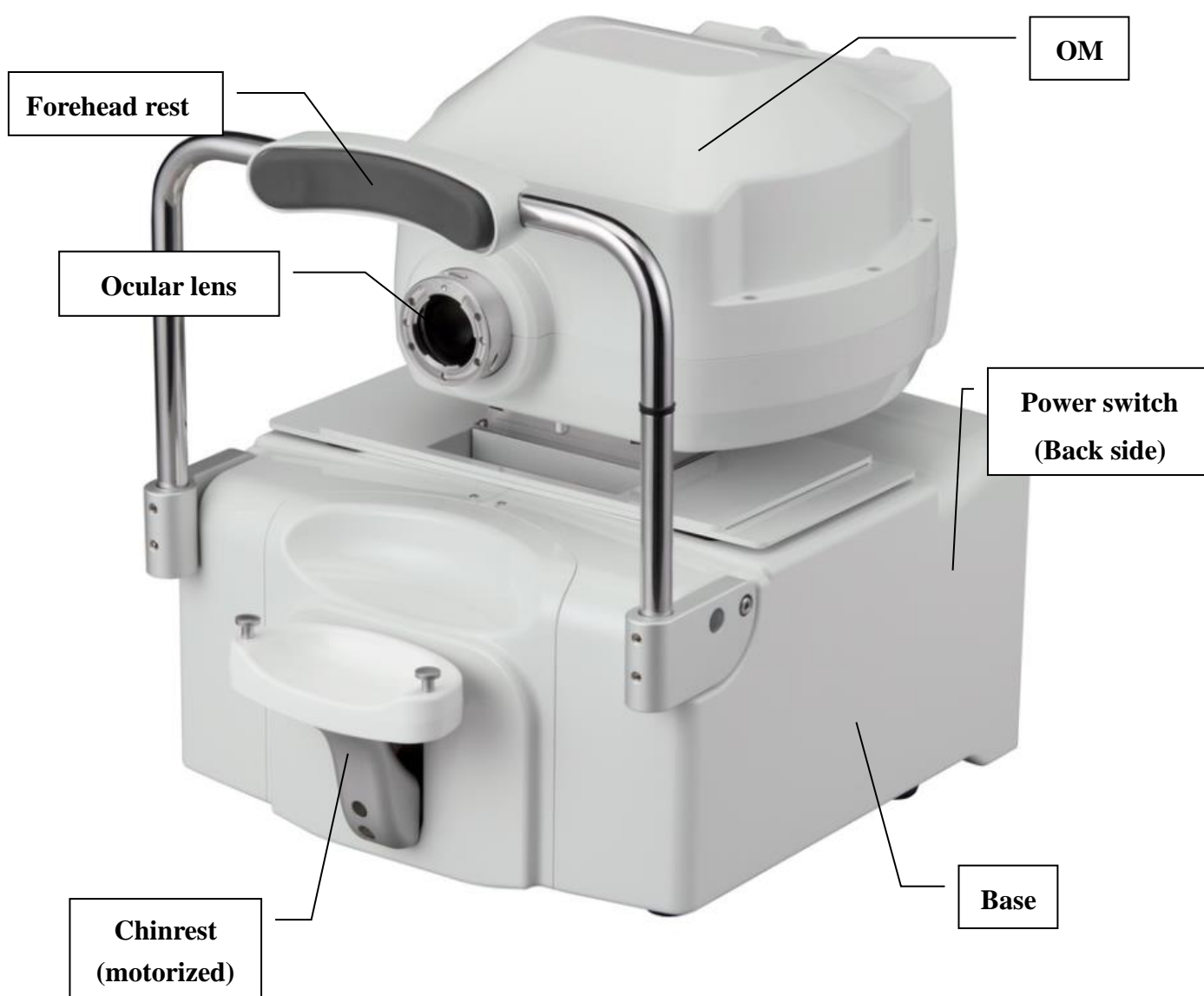
- The operating system has the ability to prevent access and misuse by unauthorized users if the device is left idle for a period of time.
- The length of inactivity time before auto-logout/screen lock is user/administrator configurable.
- The auto-logout/screen lock should be always enabled.
- Local supervisor should avoid unauthorized users access the delicate Laptop or PC in order to preserve system and data confidentiality, integrity and availability. •
- Local supervisor must set the expiration time of screen saver to reduce casual viewing data.

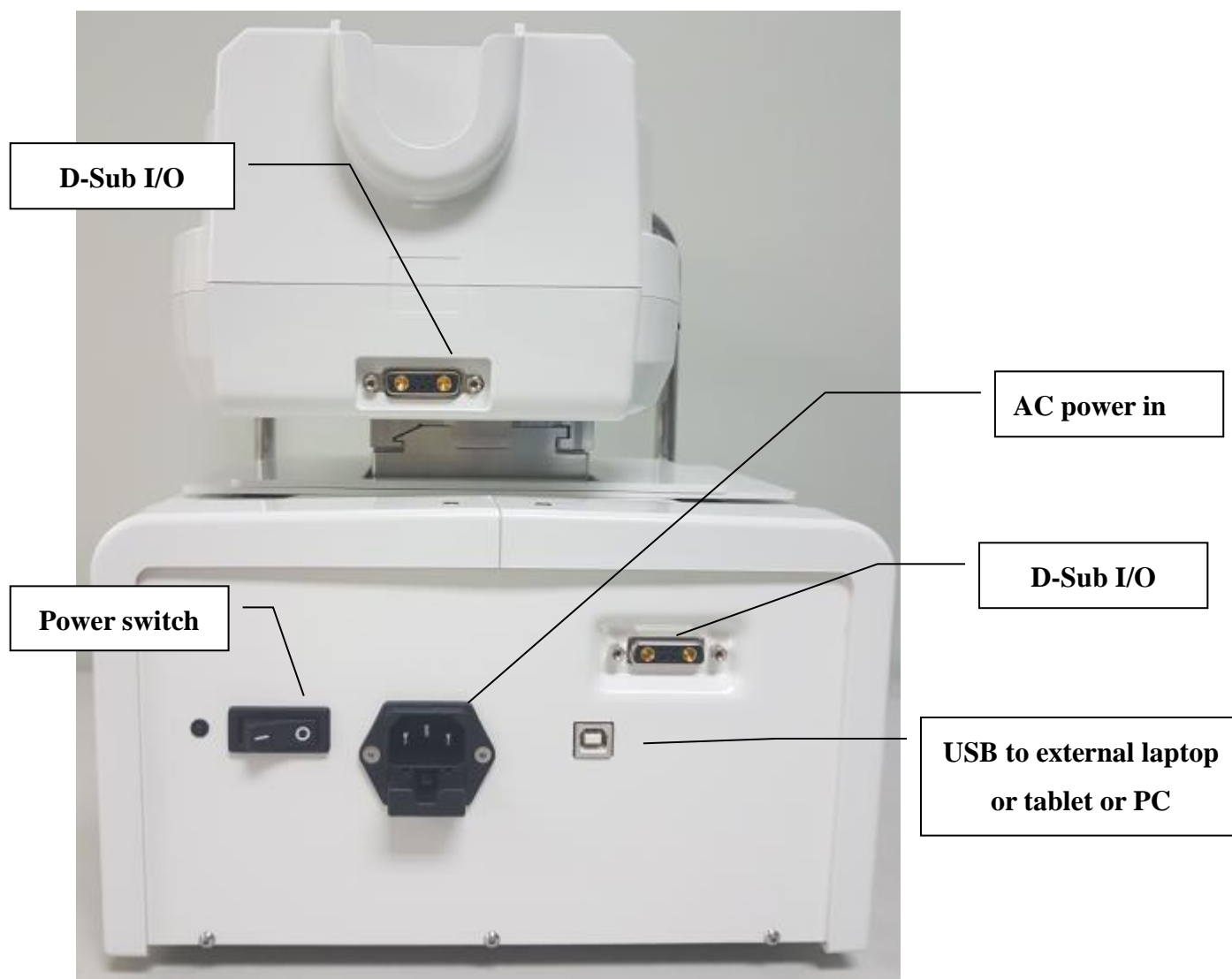
2.8 Data back up

- To avoid the loss of patient data due to damage to the storage device of the user's PC, it is recommended that the user should regularly back up the data.
- It is recommended to store the data in multiple different and independent storage media to disperse the risk of data loss or damage to the storage device.

3 Instrument description

3.1 Introduction



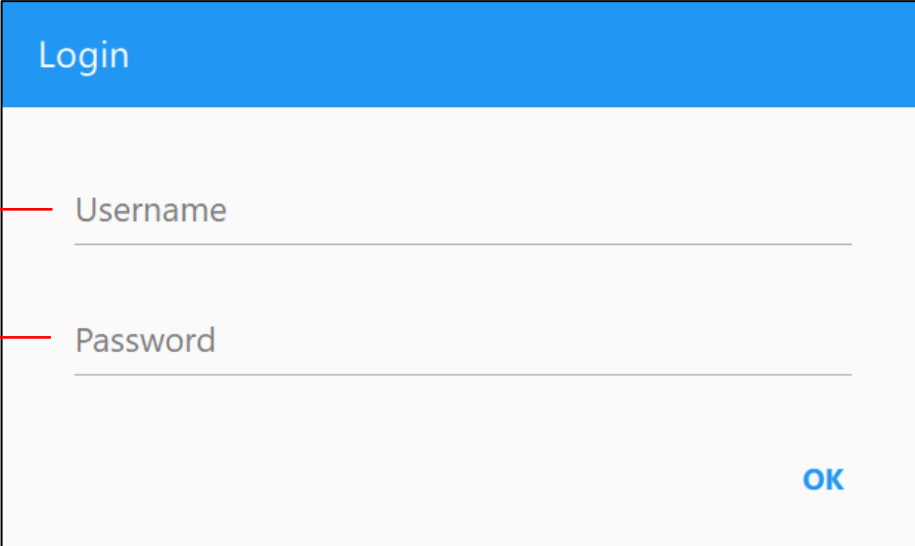


3.2 Standard accessories

| Item | Description | Q'ty |
|------|---------------|-------|
| 1 | User manual | 1 pc. |
| 2 | USB cable | 1 pc. |
| 3 | AC power cord | 1 pc. |
| 4 | D-Sub cable | 1 pc. |
| 5 | Dust cover | 1 pc. |
| 6 | Lens cover | 1 pc. |

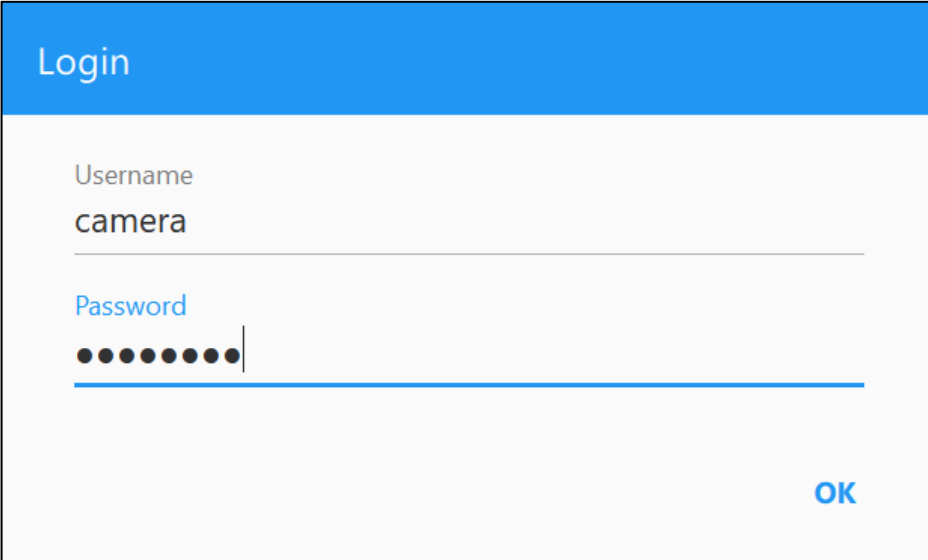
4 Log in and introduction of user interface

■ Log in



The screenshot shows a 'Login' dialog box with a blue header. Below the header are two input fields. A red line points from the label 'Username' to the first input field, which contains the placeholder text 'Username'. Another red line points from the label 'Password' to the second input field, which contains the placeholder text 'Password'. A blue 'OK' button is located in the bottom right corner of the dialog box.

- Username: Input the user name.
- Password: Input the password.



The screenshot shows the same 'Login' dialog box. The 'Username' field is now filled with the text 'camera'. The 'Password' field is filled with eight black dots, with a blue cursor line at the end. The blue 'OK' button remains in the bottom right corner.

■ Default account:

- Username: camera
- Password: 00000000

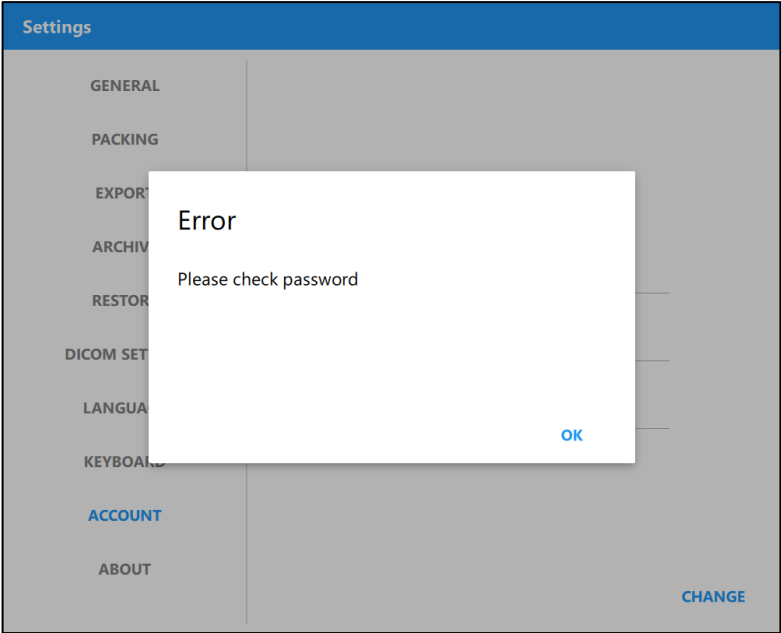
■ Modify account

After logging in, go to the settings page to modify the username and password.

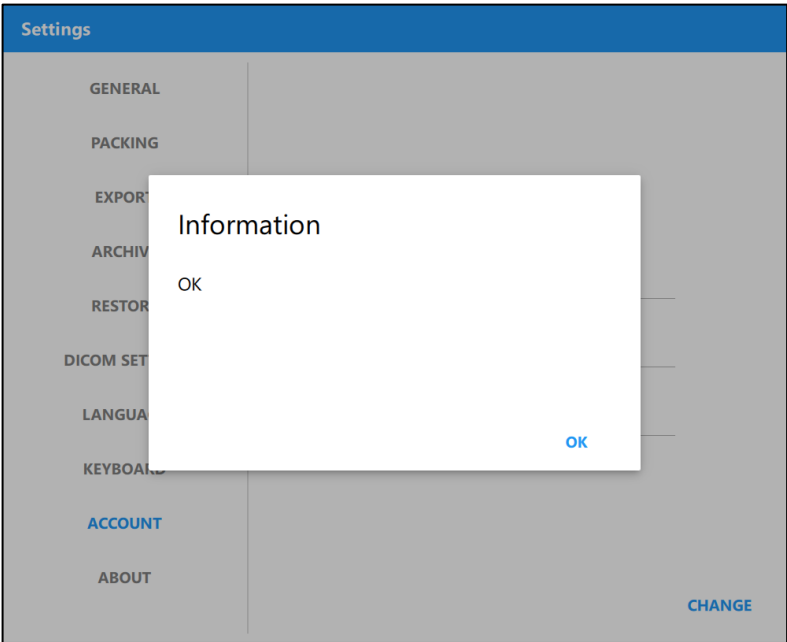
The screenshot shows the 'Settings' page of the Optomed HALO application. On the left is a sidebar menu with options: GENERAL, PACKING, EXPORT, ARCHIVE, RESTORE, LANGUAGE, KEYBOARD, ACCOUNT (highlighted with a red box and labeled 'Account'), and ABOUT. The main content area has a blue header 'Settings'. Below it, there are three input fields: 'Username' (containing 'camera'), 'Password' (with a red note 'At least 6 characters and 1 numeric'), and 'Confirm'. Red lines connect these fields to labels on the right: 'Username', 'Password', and 'Confirm Password'. A blue 'CHANGE' button is at the bottom right of the settings area.

- Username: Change username when needed.
- Password: Change password when needed.
- Confirm password: Confirm the password.

If the password inputs are not same, please check them again.



If the password inputs are same, below dialog is displayed.



■ Change password every six months

Password is requested to be changed every six months.

Need to change password

Old password

New password

At least 6 characters and 1 numeric

Confirm new password

CHANGE

- Old password: Input the old password.
- New password: Input the new password.
- Confirm new password: Input the password again.

Below graph shows error occurs.

Need to change password

Old password

●●●●●●

Wrong password

New password

●●●●●●

At least 6 characters and 1 numeric

Confirm new password

●●●●●●

Wrong password

CHANGE

Click Change button if no error occurs.

Need to change password

Old password

●●●●●●

New password

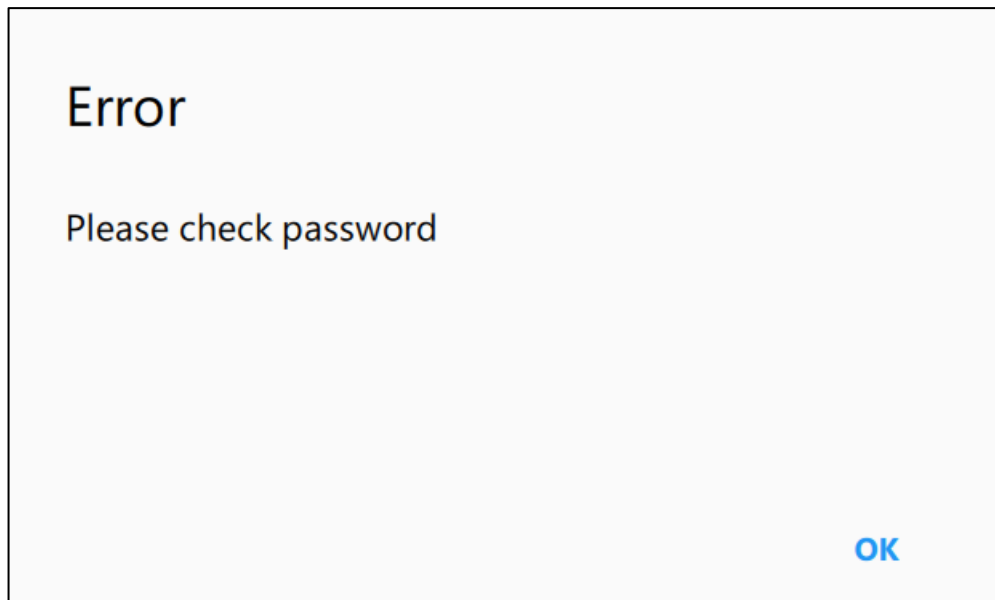
●●●●●●

Confirm new password

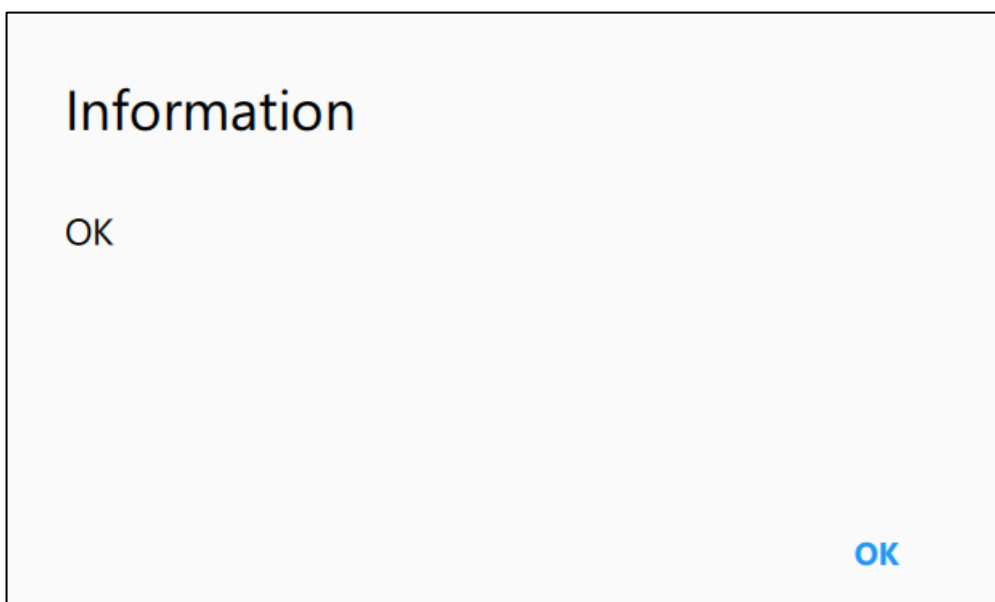
●●●●●●

CHANGE

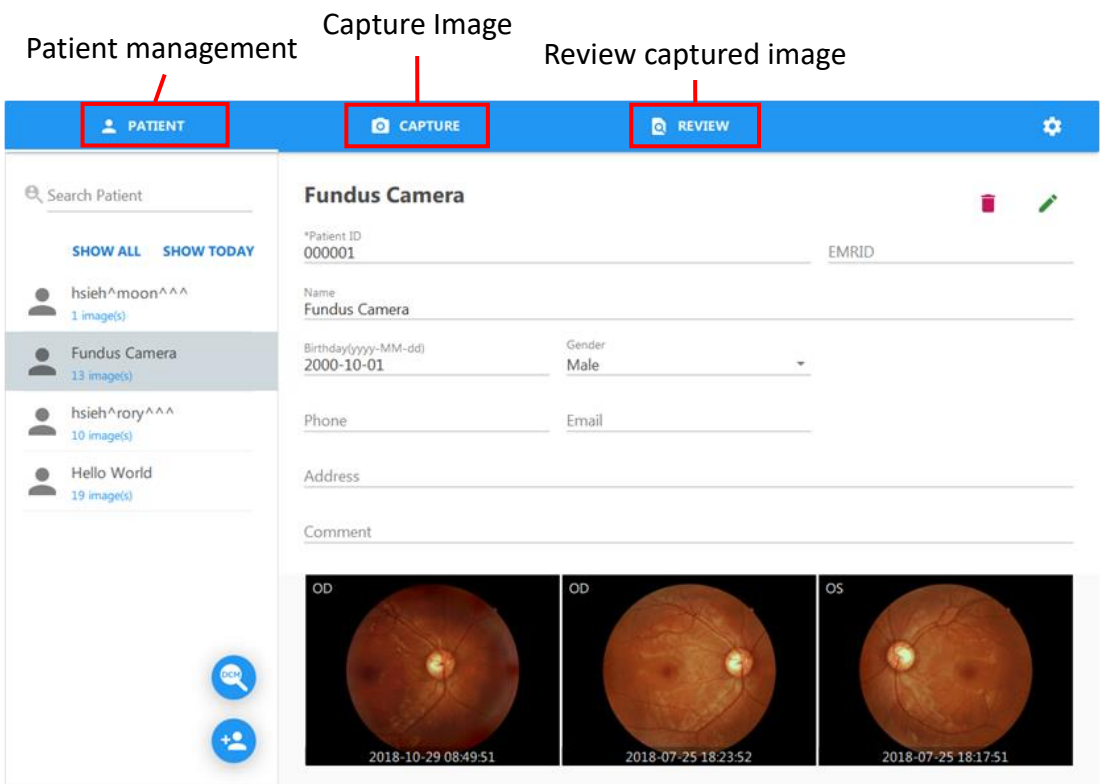
Below error message means input password is incorrect.



Below graph shows new password is changed successfully.

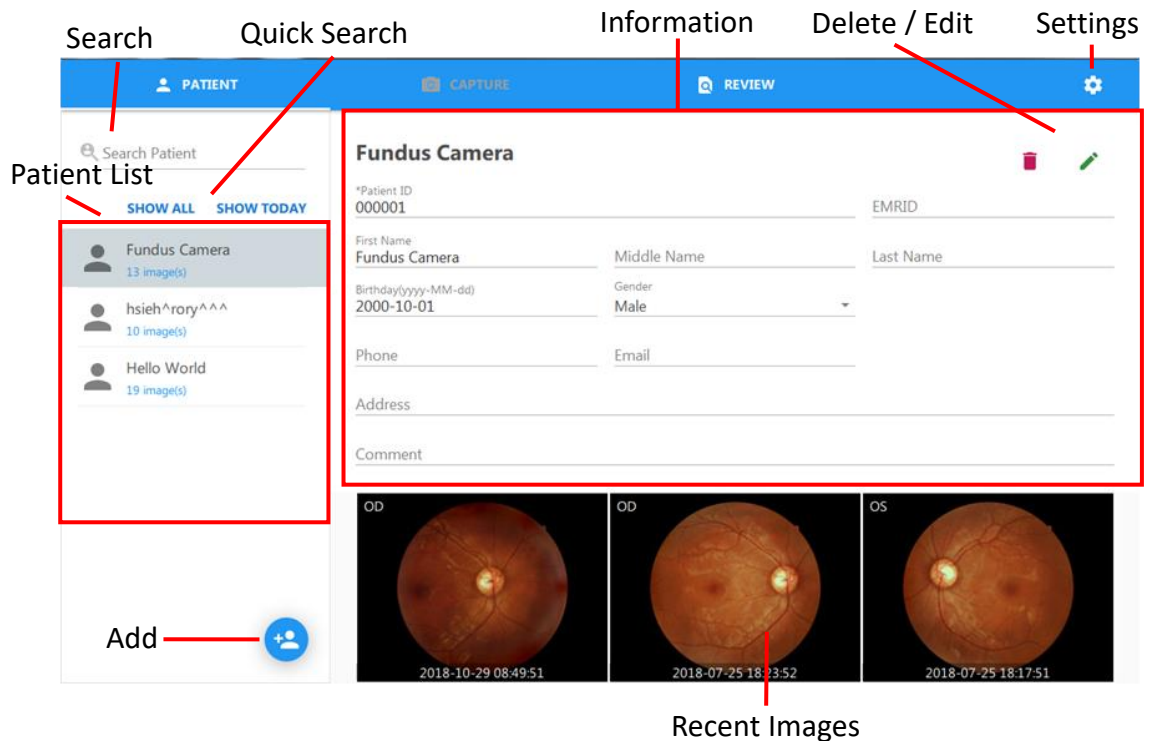


Three tabs are displayed on screen after logging in and describe in below sections.



4.1 Patient management

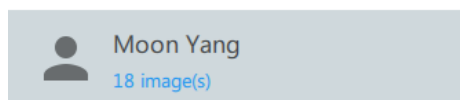
Select patient, add patient and modify patient information



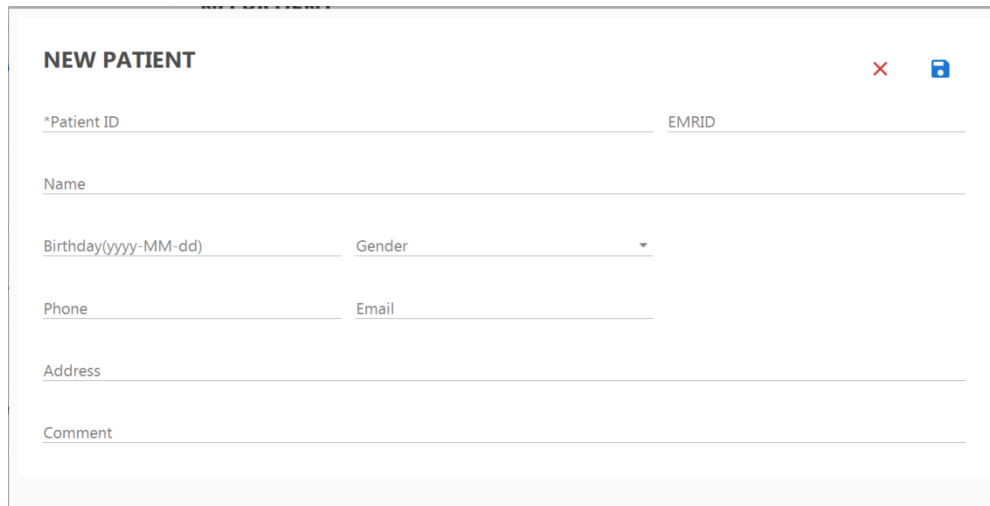
- Patient list: Displays all the patients associated with the search result.





Search Patient

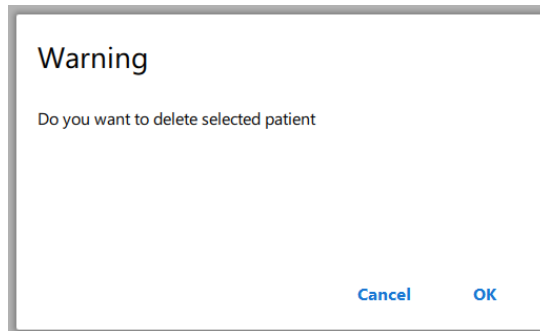
SHOW ALL **SHOW TODAY**




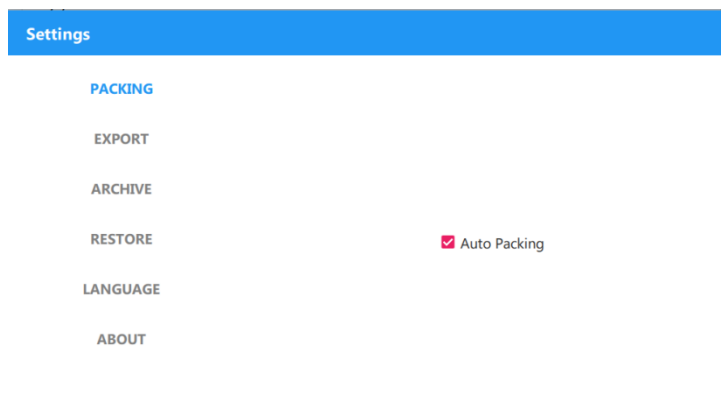
- Search: Provide patient search function by entering keywords.
 - Search by all fields: Fill in keyword such as “Moon”
- Add patient : Click to add new patient profile and information.



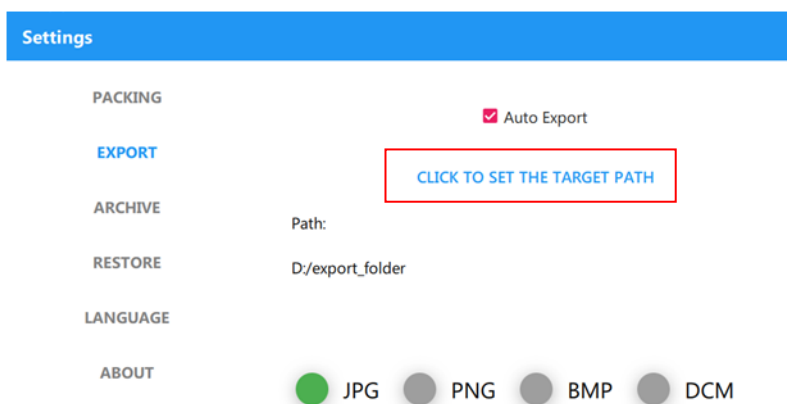
- The columns with * mark are mandatory before adding new patient to database.
 - By clicking , the new patient information is saved to the database. The main screen will then return to the main Patient Information window and the newly added patient is listed under the patient list window. Select the new patient added and patient detail will be displayed accordingly.
 - By clicking , it will return to main patient window without saving.
- Patient information
- Displaying selected patient information
- Edit patient information  : Click for patient information editing and comment editing saving. The operations are just like Add Patient.
 - Delete patient  : Click for delete patient information and images. When the “Delete” dialog appears, click “OK” to delete patient information or click “Cancel” to quit.



- Settings  : Click to show settings of Optomed Halo program
- Packing: Enabling auto packing, the camera head moves to packing position before Optomed Halo shutting down.



- Export: Enabling auto export, the captured image will be copied to specific path automatically where the user set



- Archive: Creates a backup file of Optomed Halo database.

Step1. Choose the target folder for backup file

The screenshot shows the 'Settings' page with a blue header. On the left is a sidebar menu with options: PACKING, EXPORT, ARCHIVE (highlighted in blue), RESTORE, LANGUAGE, and ABOUT. On the right, there is a button labeled 'CLICK TO SET THE TARGET PATH' enclosed in a red rectangle. Below this, there is a horizontal line and a grey button labeled 'ARCHIVE'.

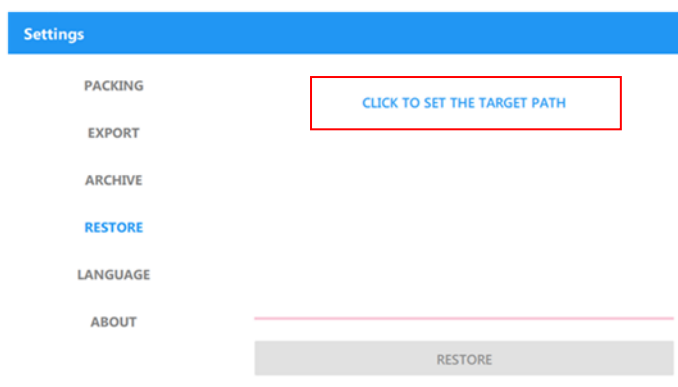
Step2. Click “ARCHIVE” button to create backup file

This screenshot shows the 'Settings' page after clicking the 'ARCHIVE' button. The 'ARCHIVE' option in the sidebar is still highlighted. The 'CLICK TO SET THE TARGET PATH' button is now a text input field containing 'D:/backup', with the label 'Archive Path:' above it. This input field is enclosed in a red rectangle. Below it, the text 'The target folder for backup file' is displayed. Further down, the text 'Process progress' is shown above a progress bar, which is also enclosed in a red rectangle. At the bottom, the 'ARCHIVE' button is visible.

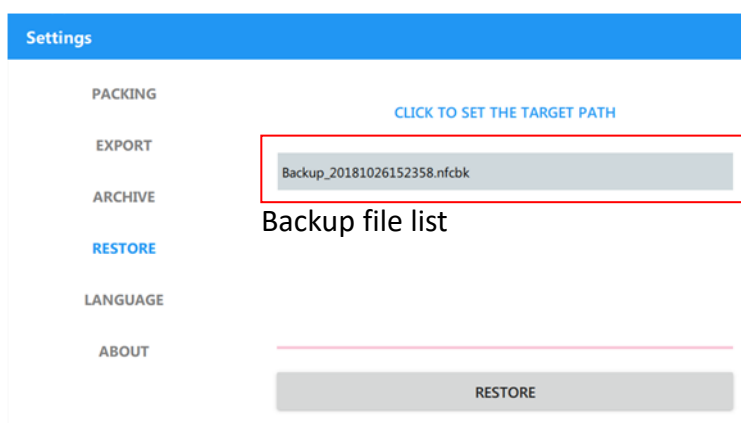
NOTE: The file system of target drive should be NTFS

- Restore: Restore the database of Optomed Halo by backup file

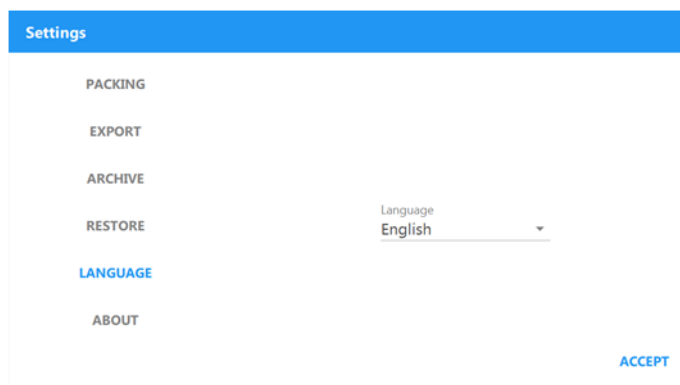
Step1. Choose the target folder where the backup file is saved



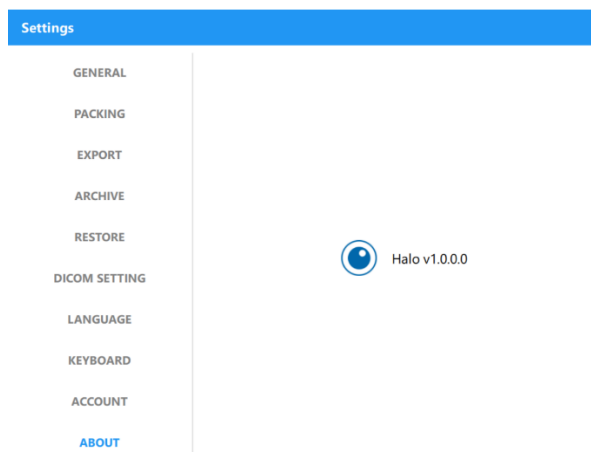
Step2. Choose the backup file from the list and click the “RESTORE” button to restore the database of Optomed Halo



- Language: Multi-language selection

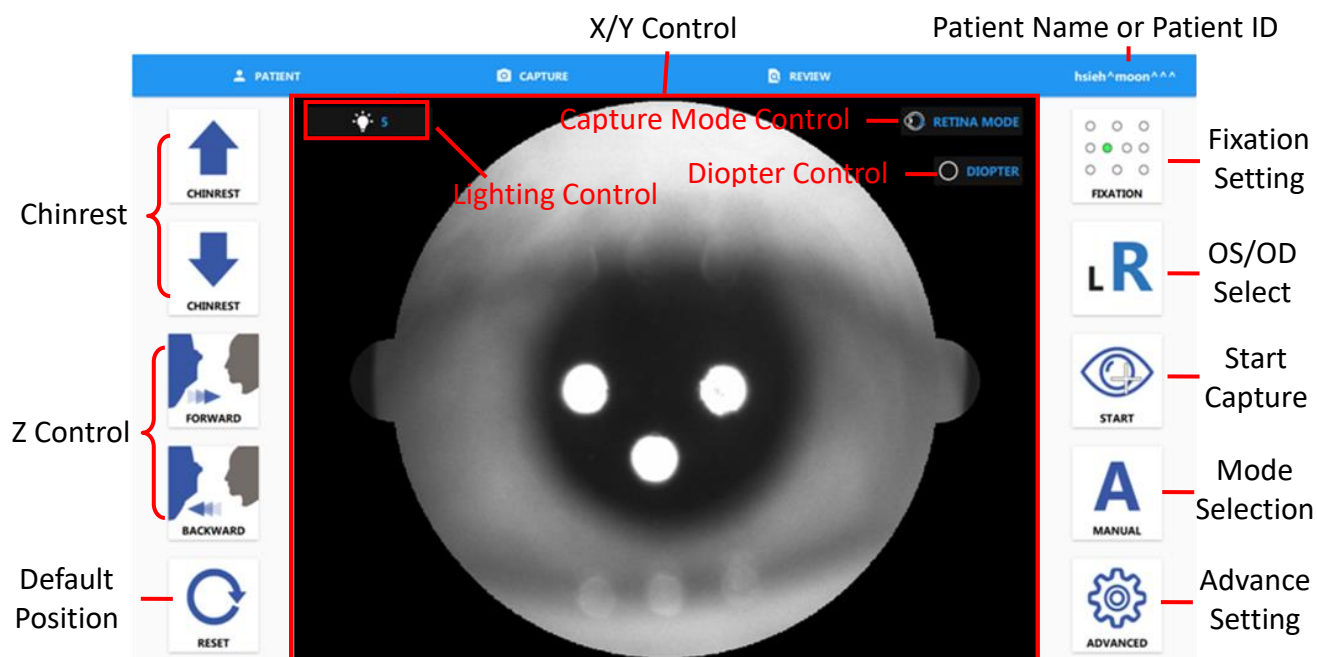


- About: Display software version of Optomed Halo



4.2 Capture image

Main window for image capture



Control buttons on the screen

- Chinrest: Control chinrest up and down
- Z Control: Move camera forward or backward
- X/Y Control: Click center of pupil on screen to alignment

- Reset: Reset camera to default position
- Fixation setting: Selection of the fixation position
- OS/OD select: Choose OD or OS for image capture
- Start: Click for automatic eye alignment and image capture
- Mode selection: Auto alignment mode or manual alignment mode
- Advanced: Display settings of Optomed Halo program
 - Semi auto mode: User needs to switch eye manually.
 - Full auto mode: The Optomed Halo will switch to another eye automatically.
 - Enable manual mode helper: It can help to find suitable working distance and do capture processes automatically if enable it.

Settings

Mode

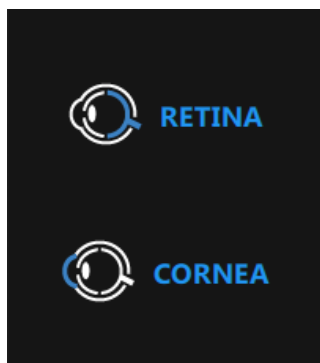
☒ Semi Auto

☐ Full Auto

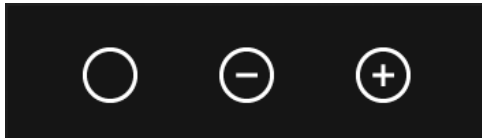
Manual Mode

☒ Enable manual mode helper

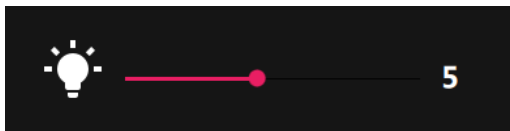
- Capture mode control: Display capture mode setting panel and provide retina (default) and cornea mode.



- Diopter control: Display diopter setting panel and provide empty lens (default), - lens and + lens






- Lighting control: Display lighting setting panel and provides viewing and flash LED level



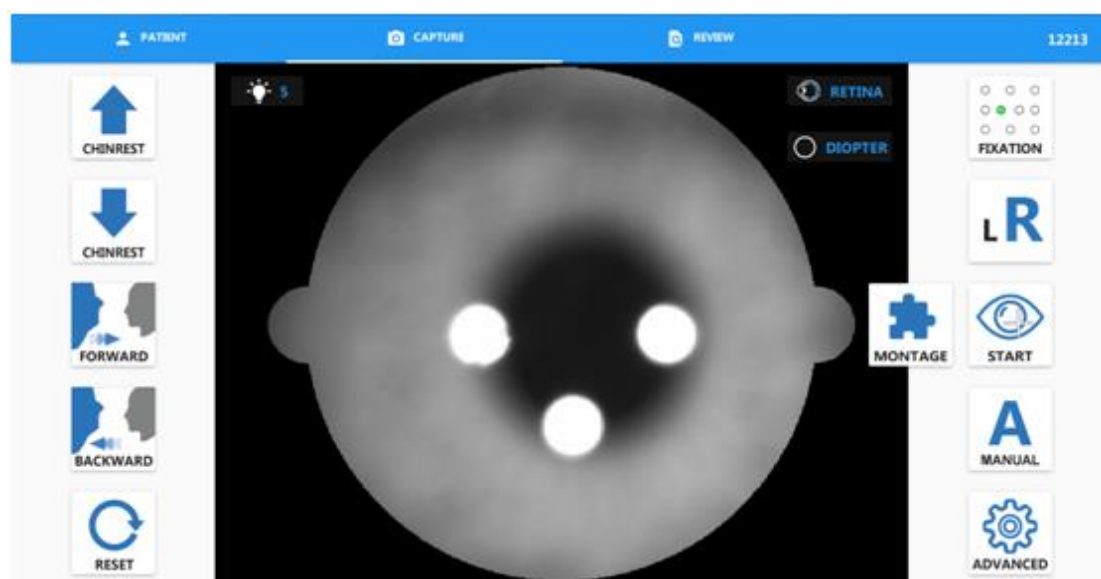
- Dilate selection: The captured image will save with this setting.

4.2.1 Automatic alignment and focus operation

- Adjust chinrest with   and table to suitable position.
- Click pupil position on screen to align the camera.
- Click  to start tracking and capture.

4.2.2 Montage mode

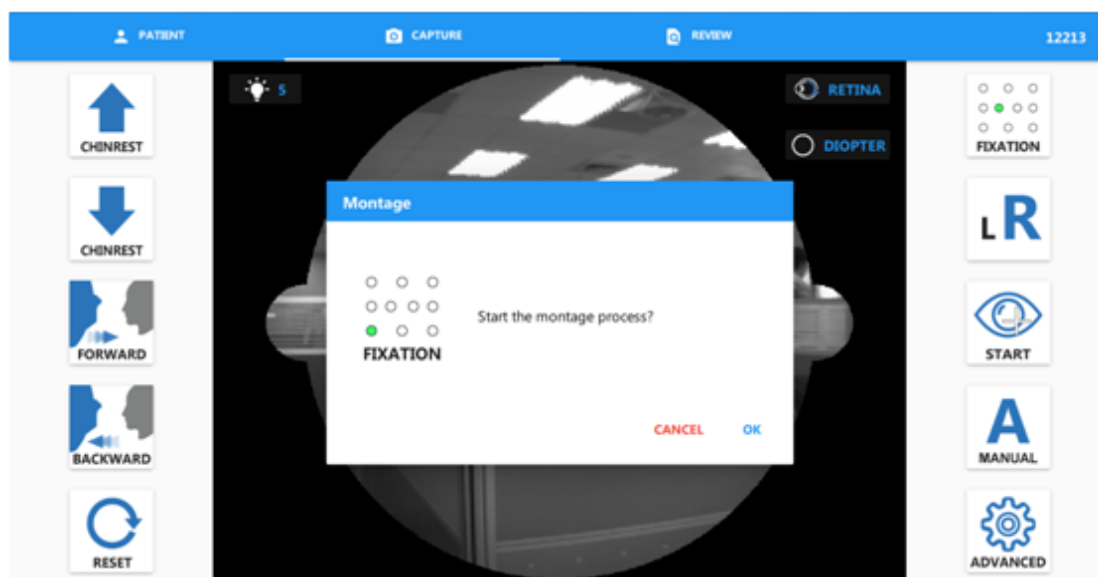
- Press and hold the Start button for 3 seconds, the Montage button will be shown.



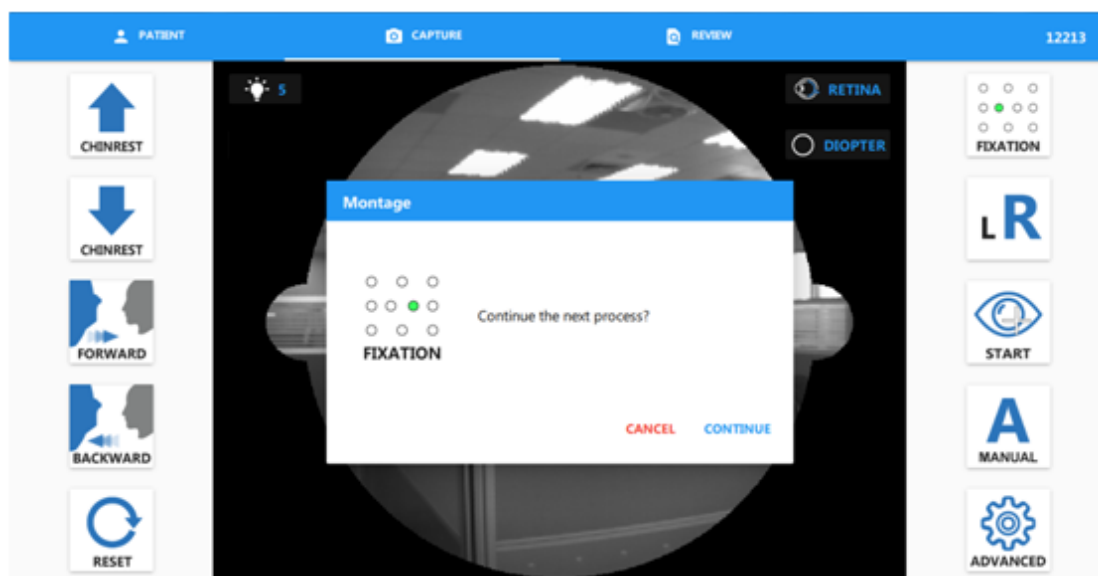
- Click the montage button and select fixation LEDs.



- Click the SET button.
- Click the OK to start montage capture







- Click CONTINUE button for next shot.

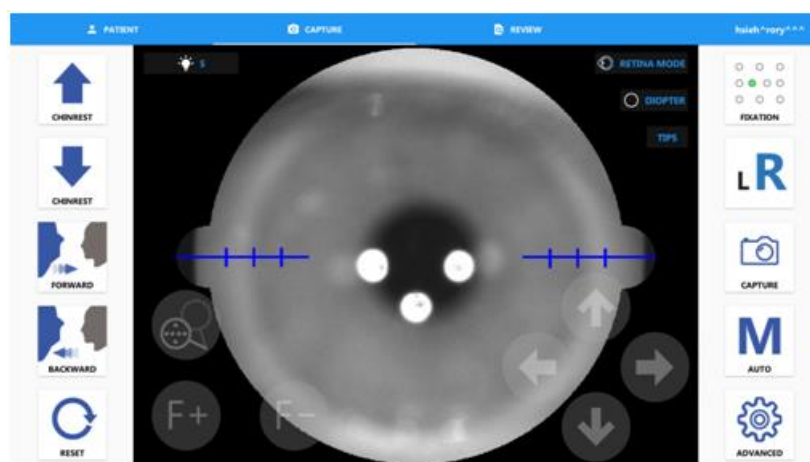


4.2.3 Manual alignment and manual capture

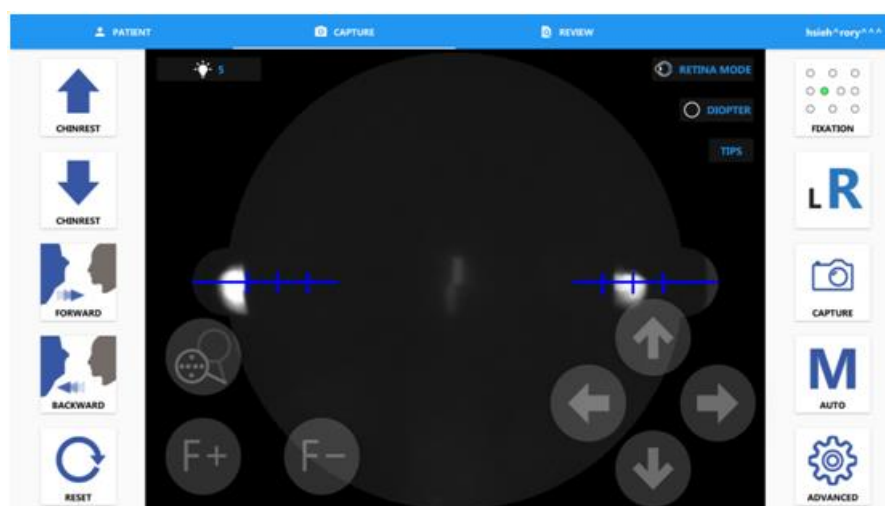
- Click mode selection button to manual mode




- Adjust chinrest by   and table to suitable position.

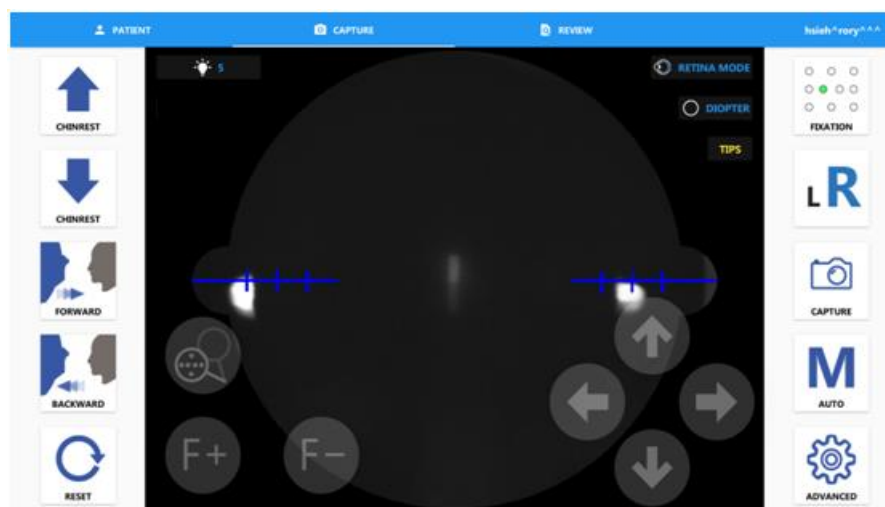
- Click pupil position on screen or press     buttons to align the camera.



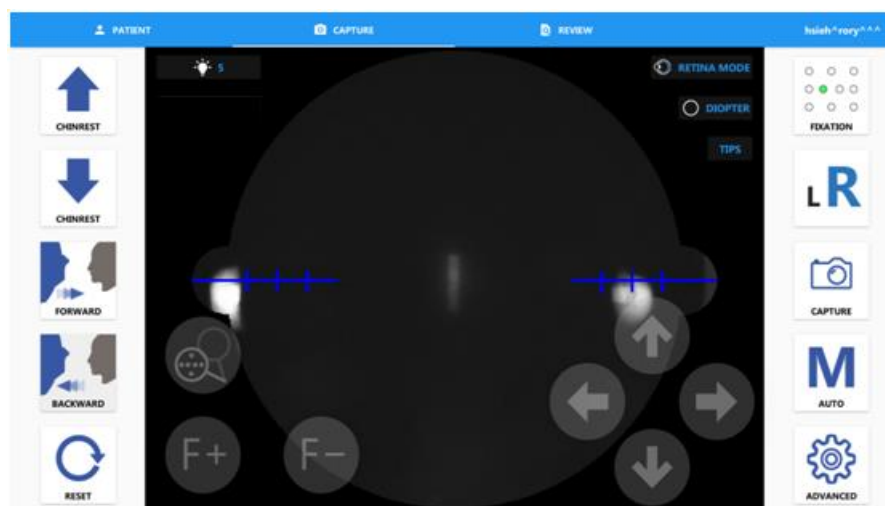
- Approach to the pupil by   buttons until split bar is visible



- Align split bar by   (Click on the  button, the fixation mask plate will be removed. User can see the live retina video.)

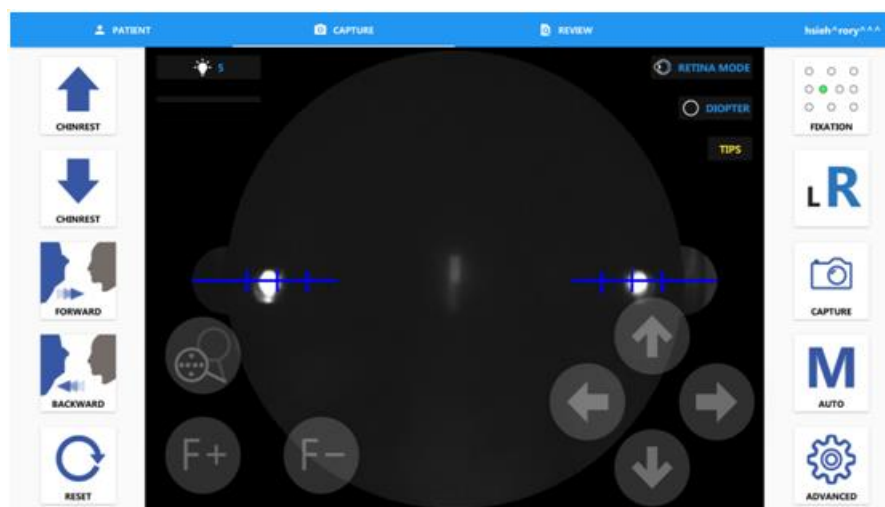


- Enter the pupil by  buttons until two spots are appeared



- Use  buttons to align two spots and

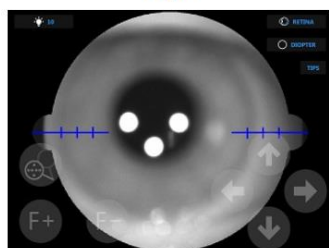
click button  to capture



- Click on the **TIPS** button, the operation tips will be shown.

Manual Mode Tips

Step 1



Align the pupil and move forward



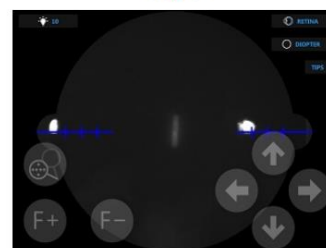
Step 2



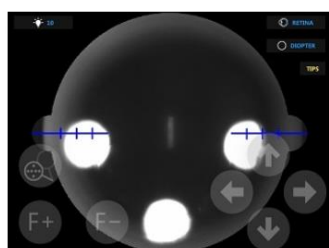
Move forward again



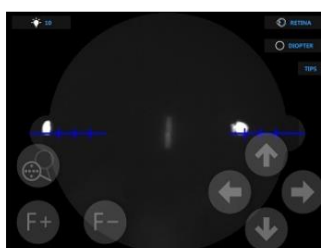
Step 3



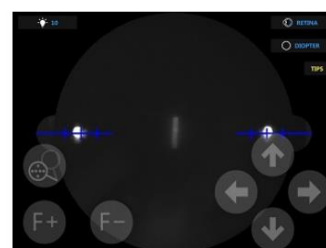
Move WD on the blue lines and symmetrically



Align split bars




Press capture button if WD appears
(with manual mode helper)

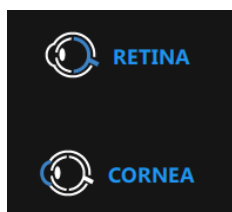




Press capture button
(without manual mode helper)

4.2.4 Cornea capture mode

- Add forehead adaptor to forehead rest (refer to item 7.1 forehead rest installation)

- Click the  button and then select the cornea capture mode.



- Adjust Chinrest with   and table to suitable position.
- Click pupil position on screen or press     buttons to align the camera.



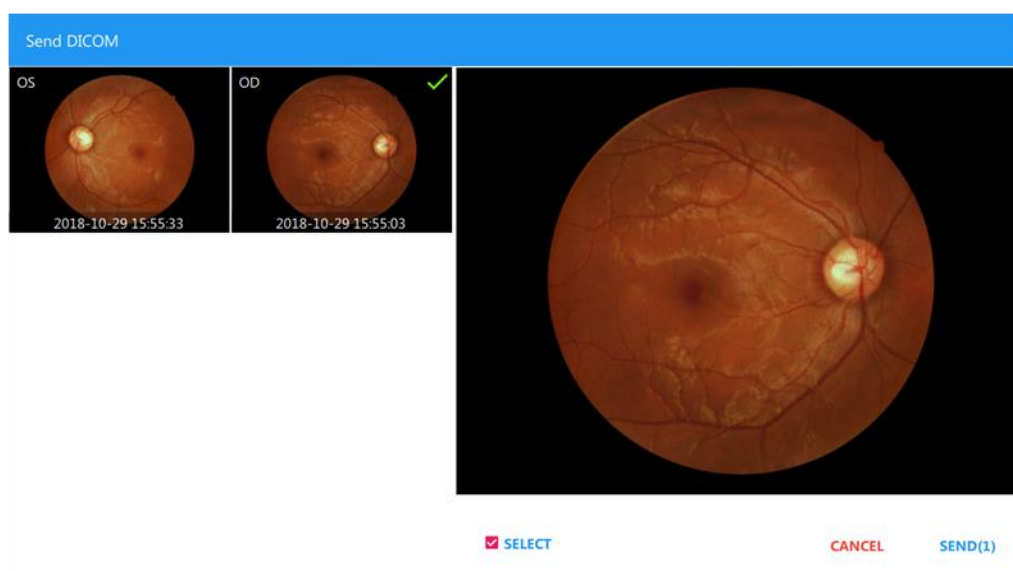
- Use   buttons until the image is clear.



- Click  CAPTURE to capture

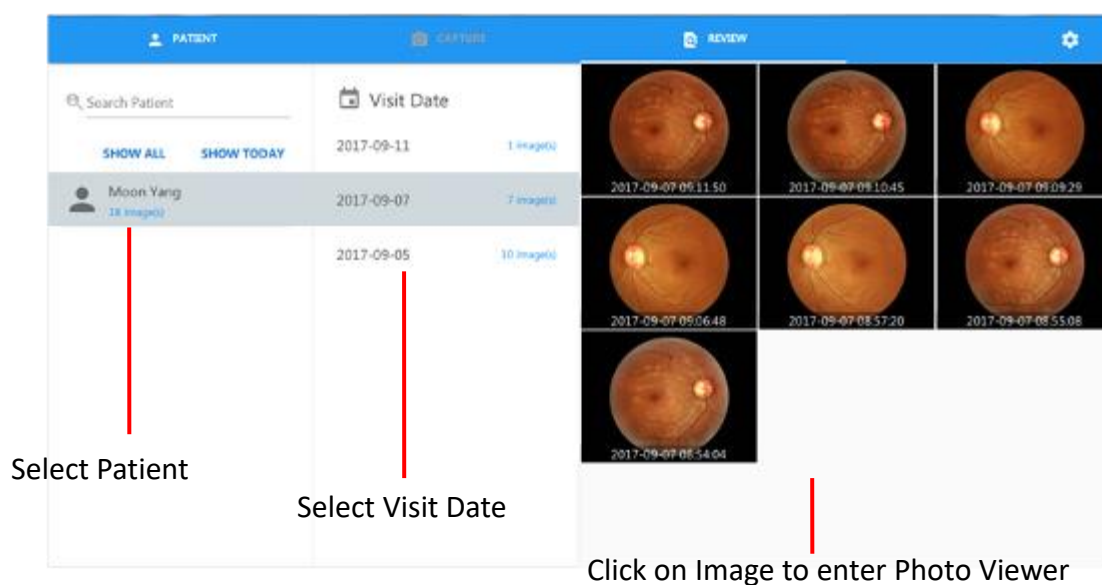
4.2.5 Send DICOM Image

When the selected patient which is found from DICOM server, the DICOM sending window is displayed before user leaves the Capture Image page. User can choose images and send them to DICOM server.



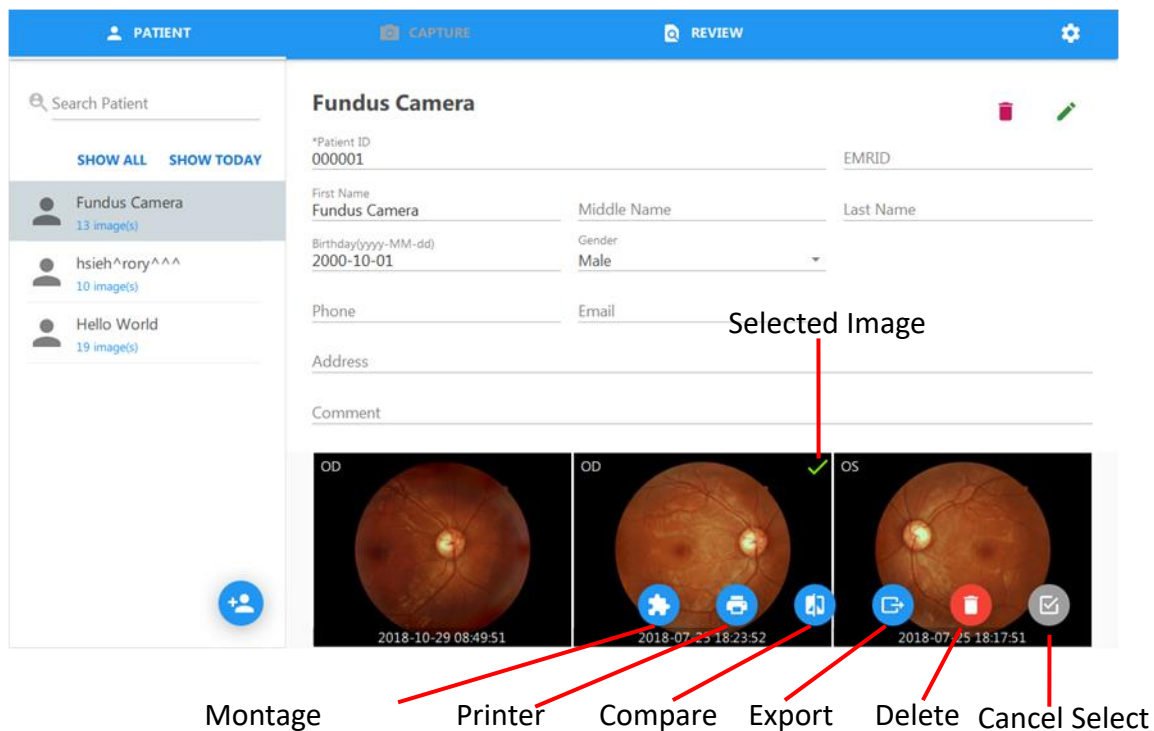
4.2.6 Review captured image

Display the Visit List classified by capture date, and the capture time is also displayed with each image. Operator can review images in this window on a particular date.




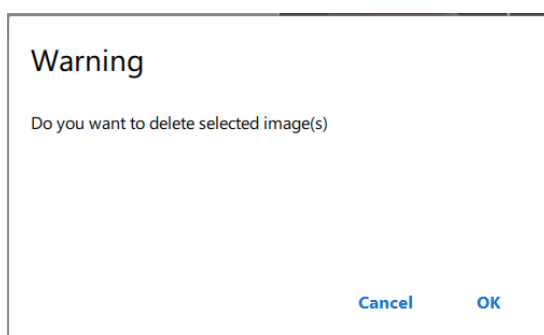
■ Multiple selections

- Press and hold on image thumbnail can enter the multiple selection mode.
- Click image thumbnail to select image for batch delete or export.




■ Image delete

- Click on  button, warning dialog will show. Click yes to delete selected image. Be careful, Deleted image cannot restore!

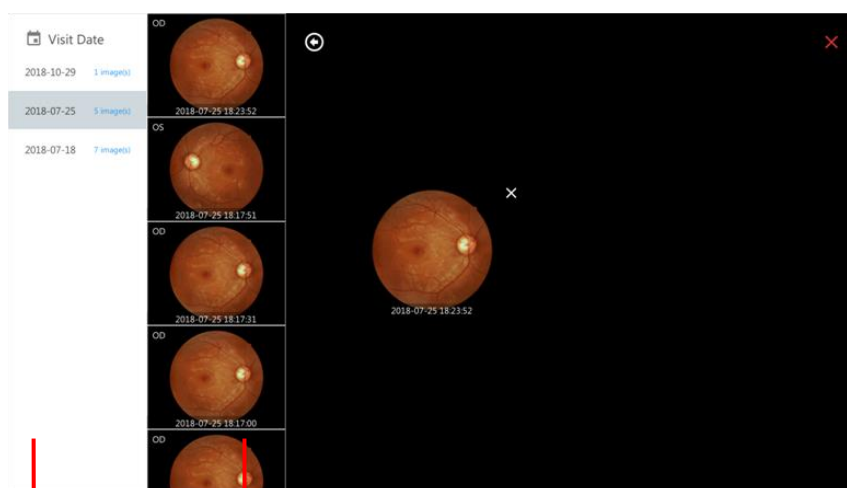


■ Montage

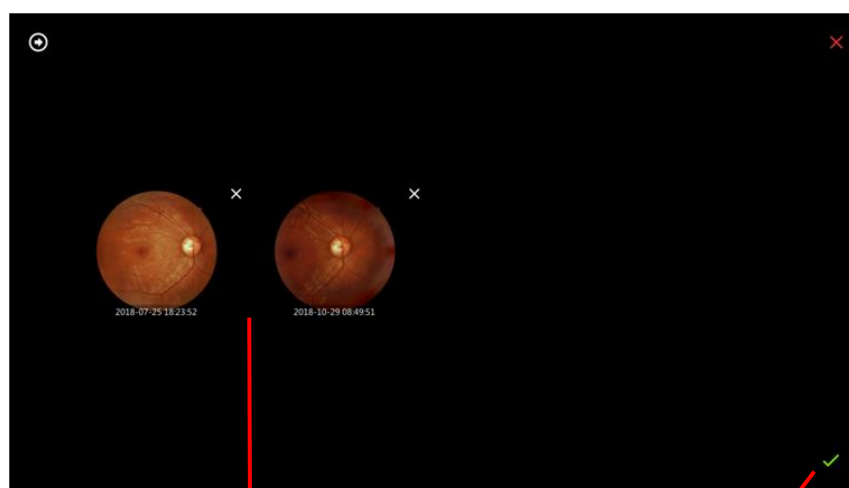
- Click on  button, montage dialog will show.



- Click  button, the visit date list of selected patient will show.




Visit Date List Click on image to assign it to candidate list




Candidate List

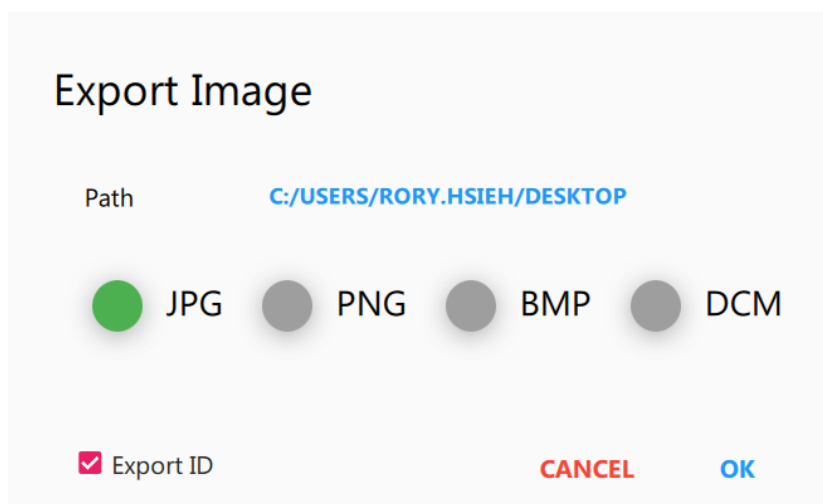
Start Montage


- Click  button and the montage result will be shown.



■ Image export

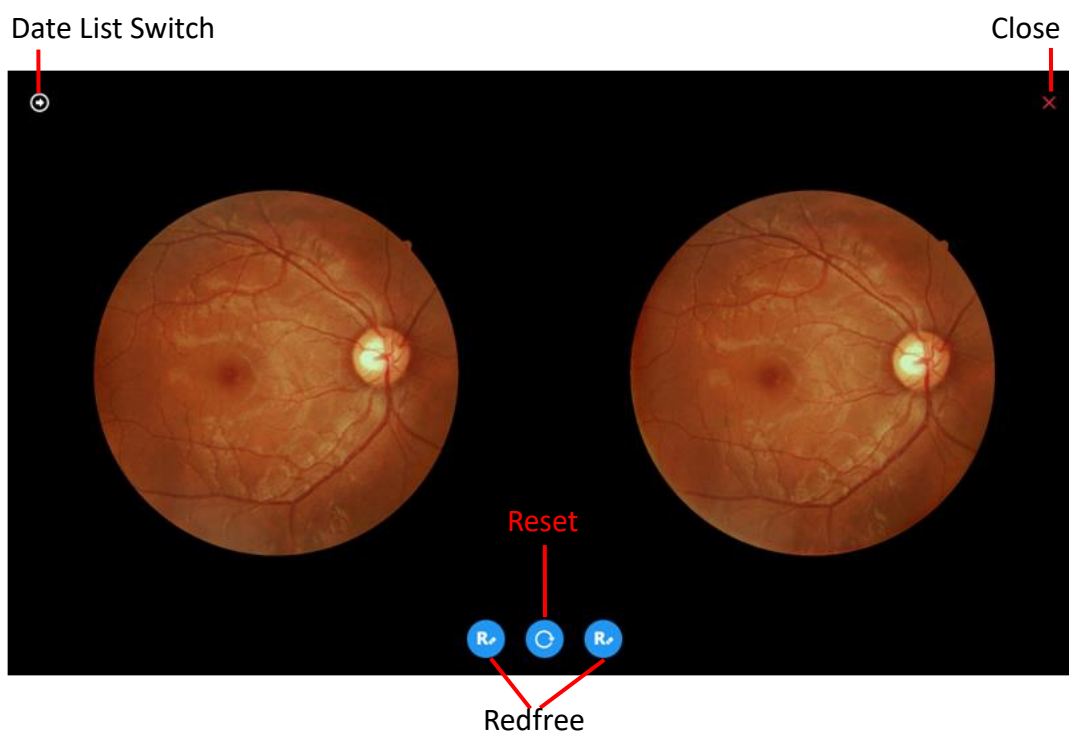
- Click on  button, warning dialog will be shown and then choose the destination folder, image compression format. The Export ID means the file name should be included patient ID.



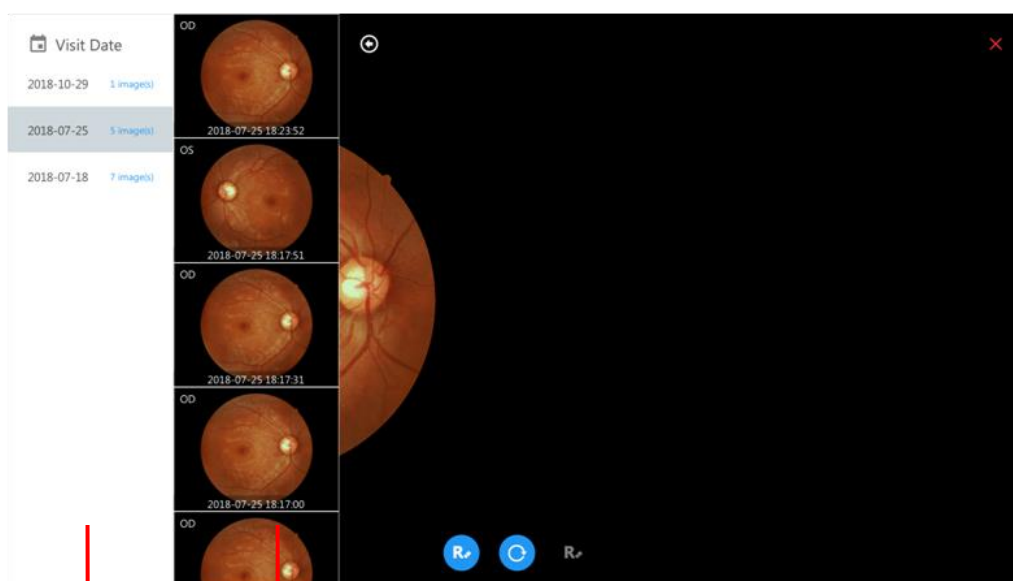
- Press and hold the patient name from patient list, the export button will be appeared. Click the  button and finish export options, the all images of selected patient will be exported.

■ Image comparison

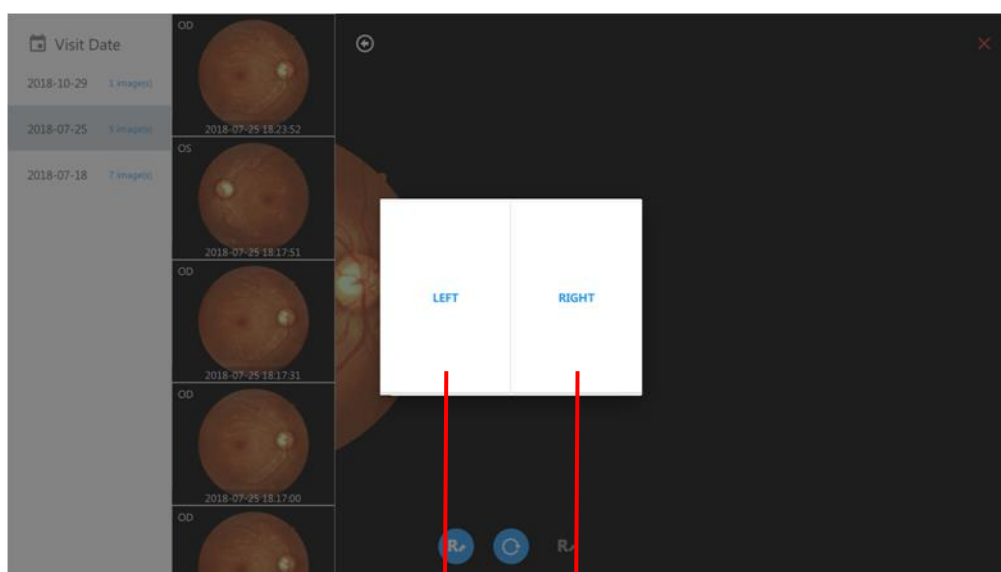
- Click on  button, comparison dialog will be shown






- Date list switch: Click  button, the visit date list of selected patient will be shown.

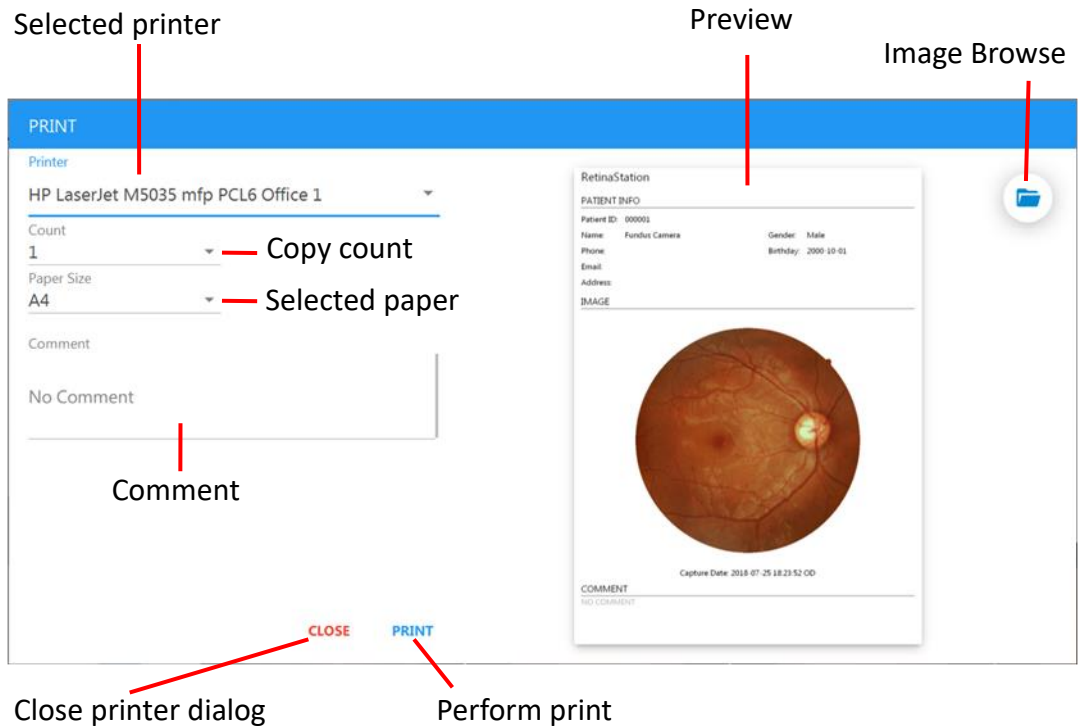



Visit date list Click on image to assign it to left or right frame

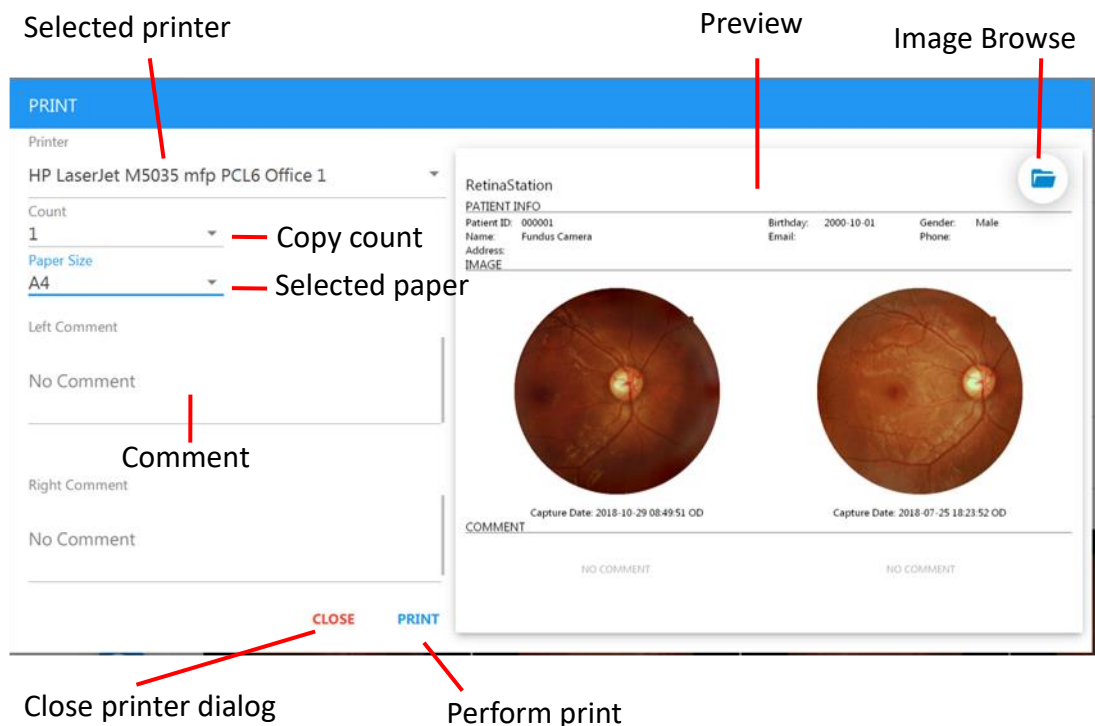


Left frame Right frame

- Reset: Click  button, all image settings are reset to default
- Redfree: Click  button to show the redfree image
- Printer
 - Click on  button, printer dialog will show. Click the PRINT to print selected image.

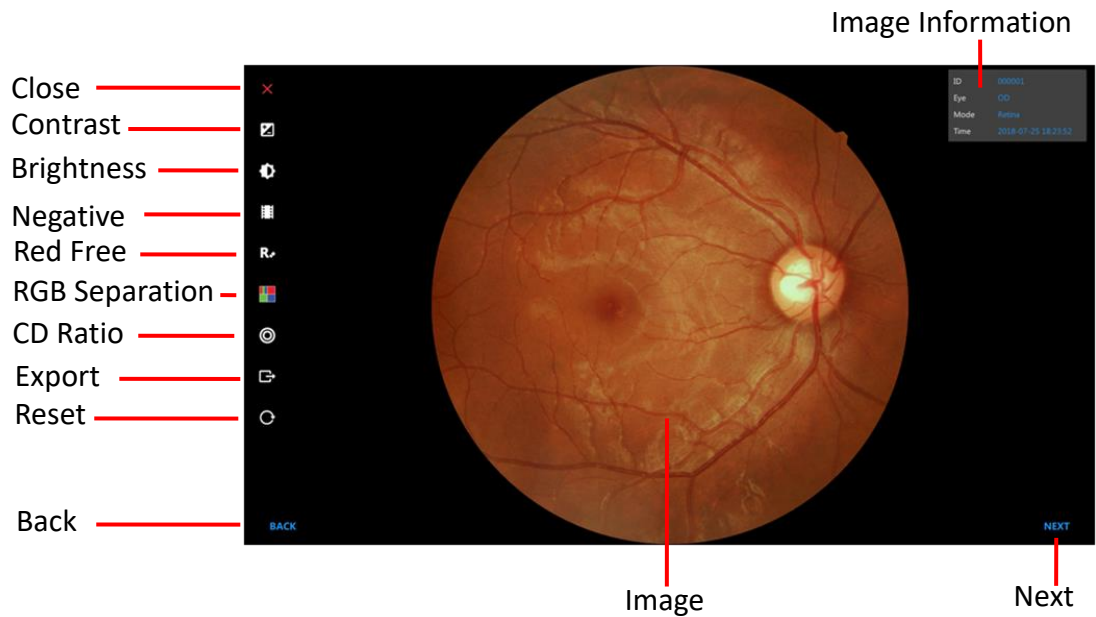




- Select two images and click on  button, printer dialog will show.
Click the PRINT to print selected images.





4.2.7 Photo viewer

- Click image of Image List, the Photo Viewer will show. The Photo Viewer includes below functions.





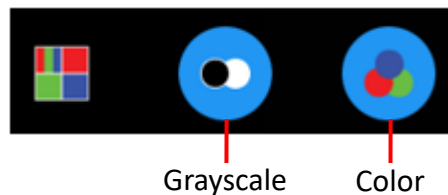
- Image information
 - ID: Patient ID
 - Eye: Captured eye
 - Mode: Capture mode
 - Time: Capture date and time
- Close: Exit the photo viewer
- Contrast: Adjust the selected image. The  button is contrast level up and the  button is contrast level down.




- Brightness: Adjust the selected image. The  button is brightness level up and the  button is brightness level down.



- Negative: To do negative process for selected image
- RedFree: Remove the red channel and convert to grayscale for selected image.
- RGB Separation: To do RGB channels separation and display in color or grayscale mode. The  button is grayscale mode and the  is color mode.



- CD Ratio: To do disc and cup measurement. Below describes how to measure the cup to disc ratio.
Step1. Use the pinch gesture to zoom in/out for region of interest
Step2. Click the CD Ratio button and click the  button.


Step3. Tap the border of disc until the blue line fit it.



Step4. Click the CD ratio button and click the  button.


Step5. Tap the border of cup until the yellow line fit it.



Step6. Click the CD ratio button and click the  button to save the measurement result. The measurement is displayed on the top-right side of Photo Viewer.

Cup to disc horizontal ratio —
Cup to disc vertical ratio —

| | |
|------|---------------------|
| ID | 000001 |
| Eye | OD |
| Mode | Retina |
| Time | 2018-07-25 18:23:52 |
| CD H | 0.7 |
| CD V | 0.6 |

Click the  button is for clear measurement.

- Export: Export the current image

- Reset: Reset all measurement, scaling ratio, image position and processing level etc...

Back/Next: Choose the next or previous image

The estimate CD ratio is obtained manually by operator and it is for reference only.

5 Specifications

5.1 Product specification

| Function | Value/Type | Remark |
|---|-----------------------------|--|
| Fundus image | | Non-mydratic, color image |
| Field of view | 45 degrees | |
| Illumination for retina image (Capture) | White LED | Strobe mode with flashing illumination. |
| Cornea Image (Capture) | White LED | Strobe mode with flashing illumination |
| Illumination during alignment to patient's retina | NIR LED | Central wavelength in the range of 735-850nm |
| Focus Diopter adjustment range | -15D to +10 D | Without compensation lens |
| | -30D to -10D or +5D to +30D | With compensation lens |
| Minimum pupil size | 4 mm | |
| Focus Adjustment | Auto/ Manual | Split-image technique |
| Image sensor | CMOS 12 Megapixel | |
| Working Distance | 25mm from lens to cornea | Accuracy: +/- 0.5mm |
| Fixation | Internal | 10 points |
| Alignment | Fully automatic 3D tracking | |
| Alignment Mode | Full Auto / Auto/ Manual | |
| Chinrest | Motorized | |
| Interface | USB 2.0 port | |
| Input/ Output format | Image format: JPEG, PNG | DICOM : optional |
| Operation Range | Front / Back: 40mm | |

| | | |
|----------------|-------------------|--|
| | Left/ Right: 90mm | |
| | Up/ Down: 30mm | |
| Chinrest Range | Up/ Down: 50mm | |

Note-1:

USB interface is used to connect external laptop or tablet or PC.

Note-2:

Spec of external laptop or PC, the laptop or PC is dedicated for Optomed Halo and for the risk of viruses and other malwares, users must install and enable window defender and anti-virus software and follow the suggestion of third- party software (including Windows defender and virus updates) to update it.

- Operating system: Windows 10 (64bits), OS limit to Windows.
- Memory: ≥ 2 GB;
- Hard disk: ≥ 500 GB;
- USB I/O ports: ≥ 2 USB 2.0 ports

5.2 Environmental conditions

1) Operating conditions:

- Temperature: 10°C to 35°C
- Humidity: 30% to 90%RH
- Atmospheric pressure: 800–1060 hPa

2) Storage conditions:

- Temperature: -10–55°C
- Relative humidity: 10–95%RH
- Atmospheric pressure: 700–1060 hPa

3) Transport conditions:

- Temperature: -40–70°C
- Relative humidity: 10–95%RH
- Vibration, sinusoidal: 10–500Hz, 0.5g
- Shock: 1/2 Sine Wave, 6 msec, 30G peak (packaged)
- Bump: 1/2 Sine Wave, 6 msec, 10G peak (packaged)

5.3 Electric rating

- Source voltage : AC100-240V
- Frequency : 50-60Hz
- Power input : < 65VA

6 Maintenance

6.1 Lens cleaning

It is recommended to regularly clean the ocular lens of the Optomed Halo on weekly basis or when needed.

6.1.1 Material required for ocular lens:

- a) Diluted Acetone or Lens cleaning solution
- b) Lens cleaning paper

6.1.2 Method:

Wet the lens paper with cleaning solution and wipe the ocular lens with one pass in one direction. Discard the used lens paper. Use a new sheet for each repeat cleaning until the ocular lens is clean.

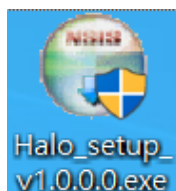
6.2 Chinrest and forehead rest

Soak the cleaning cloth or towel in disinfecting solution or use a wet isopropyl alcohol cleaning paper pad. Wipe the chinrest and forehead rest with the cleaning towels or paper pad before or after use.

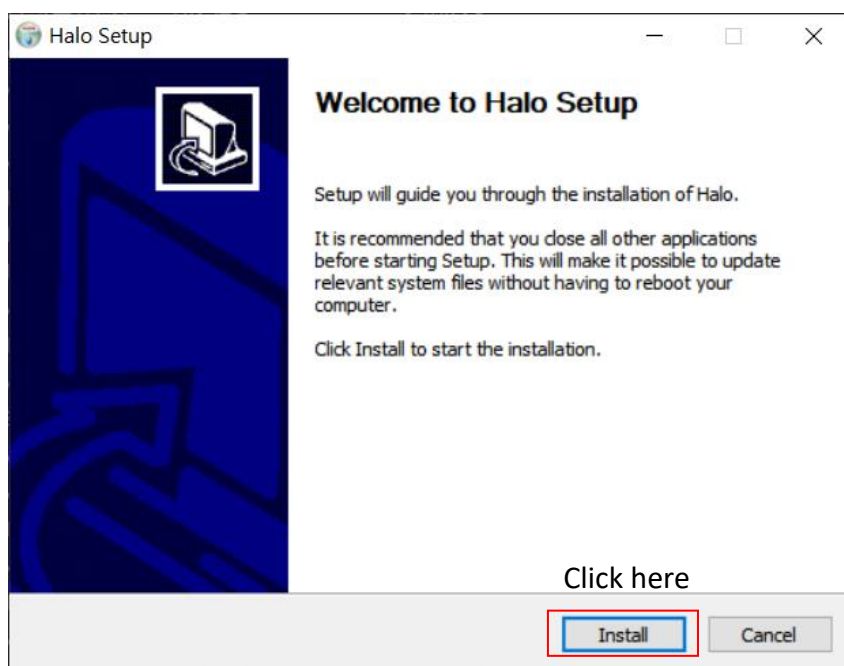
The chinrest paper must be used, remove one piece for each patient. When the chinrest paper has run out, pull off the chinrest pins and replace it with new paper.

7 Software installation

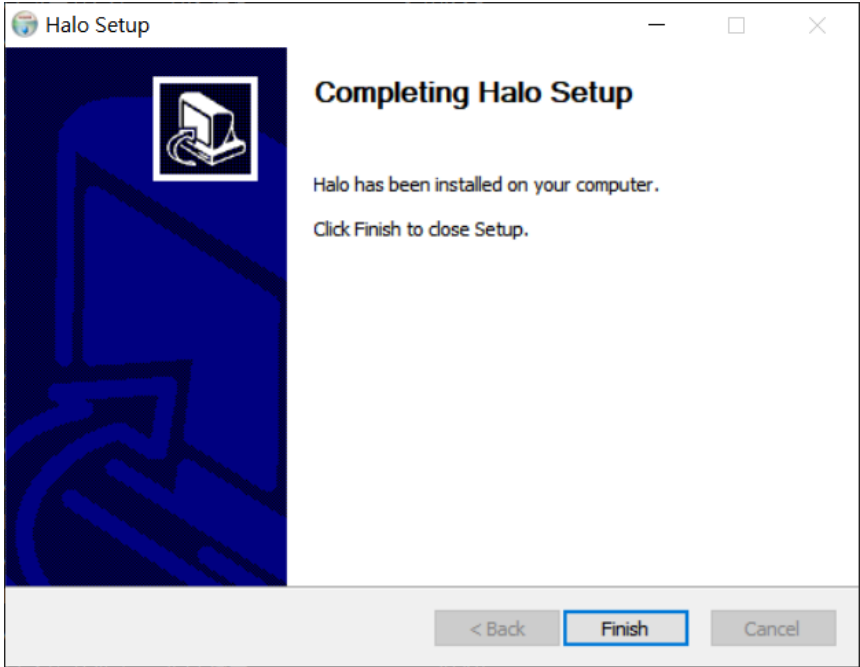
Step 1. Copy the Optomed Halo installation package file to Windows desktop.



Step 2. Perform the Optomed Halo installation package, below installation dialog will be shown.



Step 3. Click the “Install” button and wait for installation

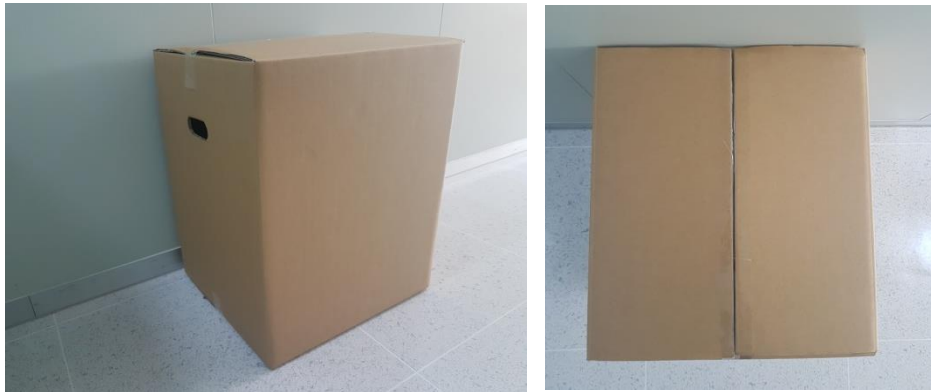


Step 4. Perform the Optomed Halo program.

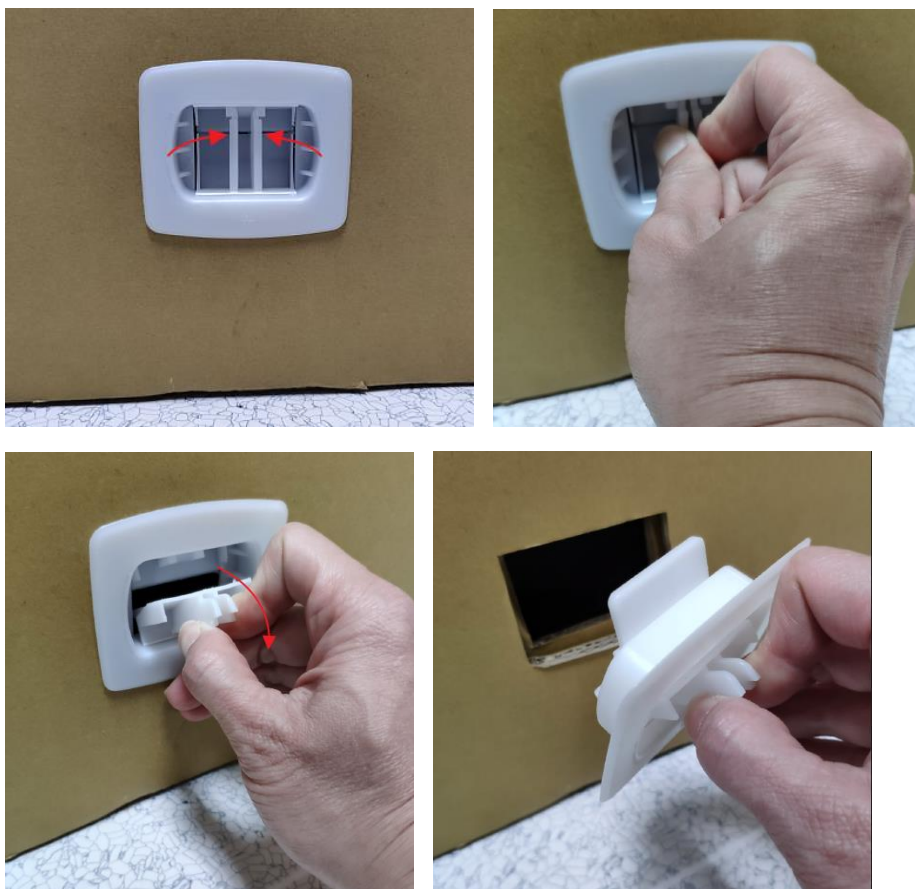


8 Installation and setup with external laptop (Need to be executed by trained person or qualified agency).

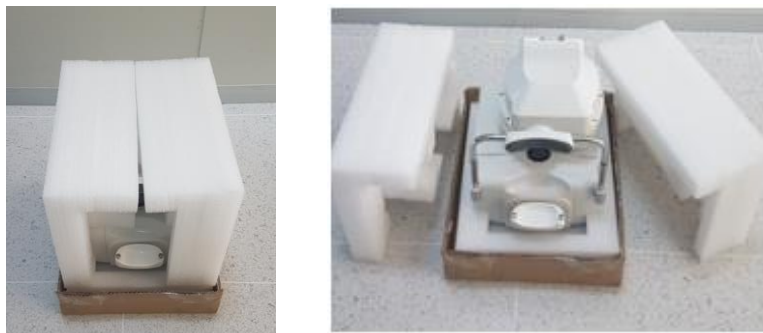
8.1 Place carton box on the floor.



8.2 Remove the buckles



8.3 Take off the Optomed Halo machine



8.4 Setup machine and relative cables



8.5 Connect the external laptop



8.6 Remove lens cover

