Kestrel 3100m
Fundus Camera
Technical and Operation Manual

Shanghai Topview Industry Co. Ltd.

Introduction

Thank you for choosing our products, and we hereby express our sincere gratitude. In order to use this equipment properly, please read this manual carefully before use.

In case of any doubts or questions on any content or term of this manual, or any technical problems during the use, please contact our company or the authorized dealers.

⚠️Warning

Read the operation manual before use;

Do not use it in a flammable and explosive environment;

Indoor use only;

Please do not splash liquid or other sundries into the equipment;

Please do not place the parts of the equipment on the ground;

Do not plunge the plug in the process of equipment operation;

The AC power and equipment must be disconnected when cleaning up the equipment;

The fuse used must be in accordance with the rated current specified in the instruction;

No one shall be allowed to crack open the shell of equipment without our company's permission, otherwise, the user shall undertake the consequences at its own risk.

In case of any fault that cannot be handled independently, please contact our company or the authorized dealers.

In the state of handling, installation and operation, the instrument cannot be reversed or moved strenuously for fear of the damage against the instrument.

Contents

1 Product Introduction

1.1 Product name

For short: Basic version

Full Name: Fundus Camera

1.2 Product model

Kestrel 3100m

1.3 Applicable scope

Kestrel 3100m Fundus Camera can, by taking advantage of fundus imaging technology with light going through pupils, directly photography patients' retina and capture fundus images. It can be used by medical personnel of clinical units, optometrists or health care providers who master this operation.

Applicable place: Department of Ophthalmology at hospitals, eye center and optometrists' office.

1.4 Intended purposes

Fundus camera can be used for fundus imaging.

1.5 Contraindications

1) It should be used with caution in patients with keratopathy (such as corneal edema and corneal scar);

2) It should be forbidden for patients with severe keratopathy (such as evident cornea thinning, corneal inflammation);

3) It should be used with caution in patients with infectious corneal lesion.

1.6 Working principles

Kestrel 3100m , based on near-infrared light imaging technology, can capture the required visible light images of fundus exposed to visible light within milliseconds (no enough time for pupils to shrink).

Kestrel 3100m can photography the retina, i.e. neurosensory tissues of eyes, and then convert the captured optical image into electronic pulses that can be understood by the brain. Pupils serve as both the inlet and outlet of light for illumination and imaging of Kestrel 3100m, thus monitoring

the fundus. Patients shall put the chin on the chin rest and lean the forehead on the forehead rest. The operator shall operate it manually to focalize and align to the fundus, and capture the fundus images upon clicking, with such images directly shown on the touch screen. Ophthalmologists will trace the progression of eye diseases on the basis of such retinographs, which will serve as the basis of diagnosis and treatment.

1.7 Technical parameters

(1) Acquisition mode: Color

(2) Control mode: alignment mode of eyes: manual/auto; focusing mode: manual/Auto focusing; exposure mode; full auto mode/manual mode .

(3) One-click operation, automatically imaging for left and right eyes continuously, and no need for separate selecting eye position.

(4) View angle: Field angle is 50°;

(5) Compensation range for ametropia: ±20D

(6) Image resolution: 3264×2488 pixel

(7) Acquisition pixel: 8 million

(8) Light source for observation: Color rendering index: Ra≥85%

(9) Light source for shooting: Xenon lamp

(10) Operating distance: 35mm

(11) Minimum filmique pupil diameter: ≥3.3mm

(12) Inner fixation lamp: 9-orientation fixation + adjustable fixation points

(13) Outer fixation lamp: LED

(14) Motion range of the 3D platform: 30mm in the up-down direction, 90mm in the right-left direction, 40mm in the front-rear direction

(15) Motion range of the chin rest: 60mm in the up-down direction

(16) Human-machine interface: Equipped with double-screen (major and minor screen), which can be used for teaching and other operations, and simultaneous display of infrared real-time monitoring data of fundus and relevant parameter settings.

(17) Compatible DICOM: Equipped with control software and compatible DICOM net interfaces,

which is accessible to hospitals' PACS and HIS system and supports the available ports to connect with the ophthalmic remote PACS system for data sharing.

1.8 Normal working conditions

[Temperature]: +10℃ - +40℃, [Relative humidity]: 40%-80%;

[Atmospheric pressure]: 760-1,060hPa.

[Power supply conditions]: Voltage: a.c.220V; Frequency: 50Hz.

1.9 Electrical safety characteristics

1) Classification by the type of electric shock protection: Class I.

2) Classification by the degree of electric shock protection: Type B, applied part.

3) Classification by the degree of liquid inlet protection stated in GB/T 4208: Conventional.

4) Classification by the degree of safety when applied together with flammable anesthetizing gas mixed with air or with nitrous oxide: Do not use it together with the flammable anesthetizing gas mixed with air or nitrous oxide.

5) Classification by operating mode: Continuous operation.

6) Rated voltage and frequency: 220V, 50 Hz.

7) Input power of medical electrical equipment: 200VA.

8) With/without the applied part that can shield the defibrillation discharge effects: None.

9) Whether the device has a signal output or input part: It has a signal output part.

10) Permanently/non-permanently installed equipment: Non-permanently installed equipment.

1.10 Instructions on network safety

Operation environment

Demand name	Details
Hardware conditions	CPU: 1.6GHz RAM: 4GB Hard disk: 120GB Display: 10 inches
Operating system	Windows 8.1 (64 bits);

Security software:

Self-contained firewall system of Windows 8.1 (64 bits) operation system

Data and equipment interface

1) Transmission protocol: The software can carry out two-way data transmission between different equipment via USB 2.0 data interface, with the transmission protocol being USB2.0 communication protocol.

2) Data will be saved in the disk of equipment permanently, with image files in bmp format and user-defined header files in binary format.

Software environment

Windows 8.1 (64 bits) serves as the system software, without the need for additional support software or application software.

1.11 Device installation

Remove the packing according to the following pictures, and keep the packing materials properly for future use.

1) Place the packing box on the flat ground;

2) Remove the upper box;

3) Remove the foam surrounding the product;

4) Two workers work together to lift up the base of equipment from the front and back end respectively, and put it on the flat ground smoothly.
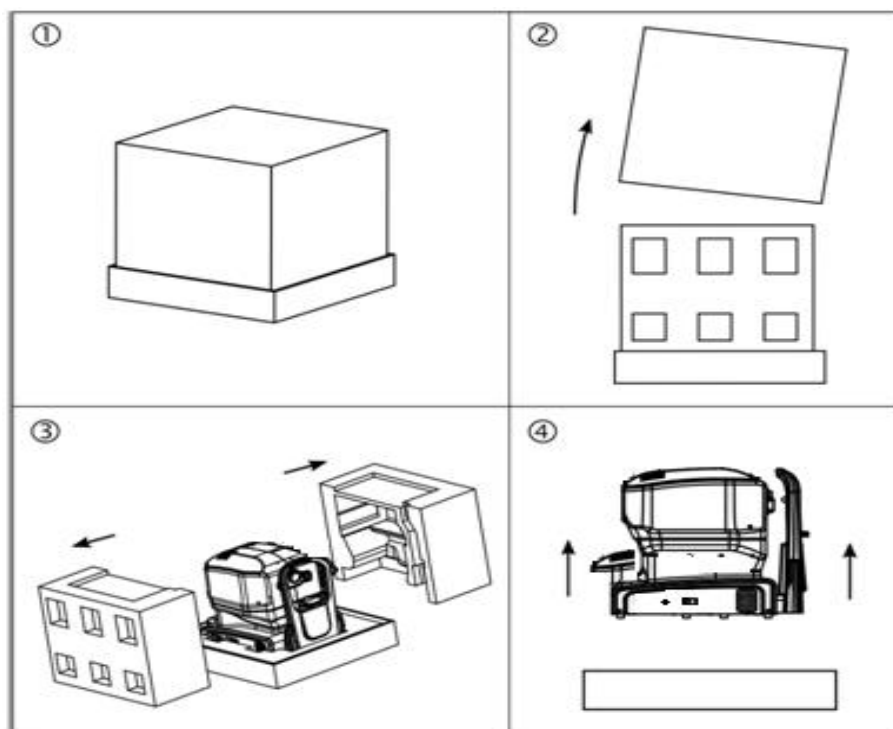
☞ Notes:

In order to prevent any damage to equipment or personnel, two workers shall be

required to move the equipment with equivalent force from both sides, and they shall also pay attention to protecting their waist from any sprain on exertion.

Considering the specialized knowledge involved in the installation, the equipment shall only be installed by service representatives authorized by our company. Our company will negotiate with the buyer to make an appointment on the installation, and will install it free of charge upon delivery. It will take about one working day to install the system and perform the initial calibration. Installation requirements:

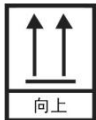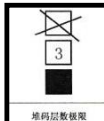➢ In order to ensure the convenient installation and comfortable utilization by patients, this equipment shall at least be installed at the place with an area being 6 inches*8 inches (about 1.8m*2.4m).

➢ In order to prevent heat build-up effect that could damage equipment, it shall be installed in the well-ventilated room, with the equipment's ventilation cover for heat dissipation unblocked.

➢ Only the trained personnel can perform the installation and calibration. Equipment shall be handled and transported with great caution, since the equipment consists of fragile optical modules that shall be calibrated in a highly accurate way.

1.12 Symbols and labels

⚠	Important! Refer to the random files	☞	Notes
⏻	Computer switch	⎓	Fuse
❙	Connect (main power)	🚶	Type B, applied part
◯	Switch off the general power supply.	⏚	Protective grounding (earth)
☂ 怕雨	Keep the package away from rain	↑↑ 向上	The package should be moved upright when transported
易碎物品	Since the transport package contains fragile pieces, please handle with great care.	3 堆码层数极限	Indicates that the maximum number of layers for stacking the same packages is 3

1.13 Service life

The service life of this product is 5 years. Upon the expiry, the manufacturer shall carry out regular maintenance and calibration every year to ensure the normal operation of the product.

1.14 Designation and address of supplier

Supplier designation: Chongqing Bio NewVision Medical Equipment Ltd.

Supplier address: #1-10, Floor 9th of building #4, Group 2N of 2nd Project, Fulicheng Zhihuiguoji, Shapingba District, 401331 Chongqing, CHINA.

2 Product structure

2.1 Structural composition of the product

Performance structure and composition of the product: This product consists of RetiCam3100 host (including optical parts, motion platform, and electronic control parts), computer system (computer host, display, keyboard, mouse) and RetiCam3100 software.

2.2 Product structure diagram
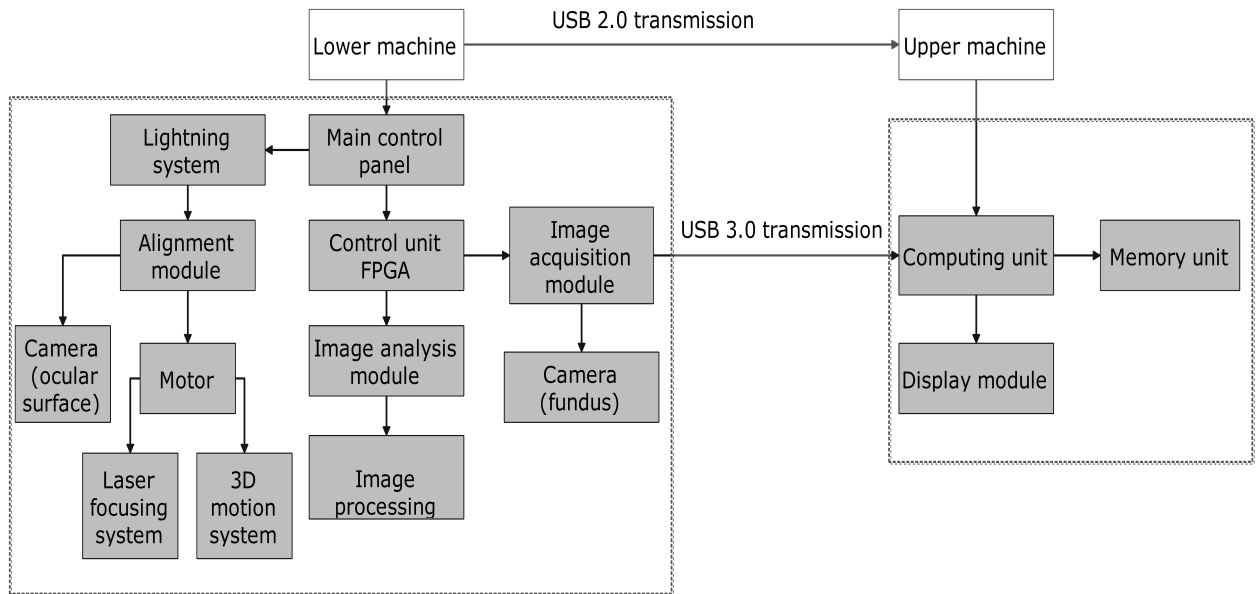
2.3 Division of function modules

```
                    ┌─────────────────────────────┐
                    │  Information input module   │
                    └─────────────────────────────┘

                              ┌──────────────────┐
                              │ Patient management│
                              └──────────────────┘
                                       │
                                       ▼
        ┌──────────────┐      ┌──────────────────┐      ┌──────────────────┐
        │     Data     │──────│     Patient      │      │ History records  │
        │ maintenance  │      │   information    │      └──────────────────┘
        └──────────────┘      └──────────────────┘
           │        │                  │
           ▼        ▼                  ▼
  ┌──────────────┐ ┌────────┐  ┌──────────────────┐
  │Export data and│ │ Remove │  │  New folder of   │
  │    images     │ └────────┘  │ the next patient │
  └──────────────┘             └──────────────────┘
                                       │
                                       ▼
                              ┌──────────────────┐
                              │  Resetting of    │
                              │    anonymous     │
                              │     patient      │
                              └──────────────────┘
                                       │
                                       ▼
                              ┌──────────────────┐
                              │       Save       │
                              └──────────────────┘
                                  │        │
                                  ▼        ▼
                        ┌──────────────┐ ┌──────────────────┐
                        │  View image  │ │  Start checking  │
                        └──────────────┘ └──────────────────┘
```
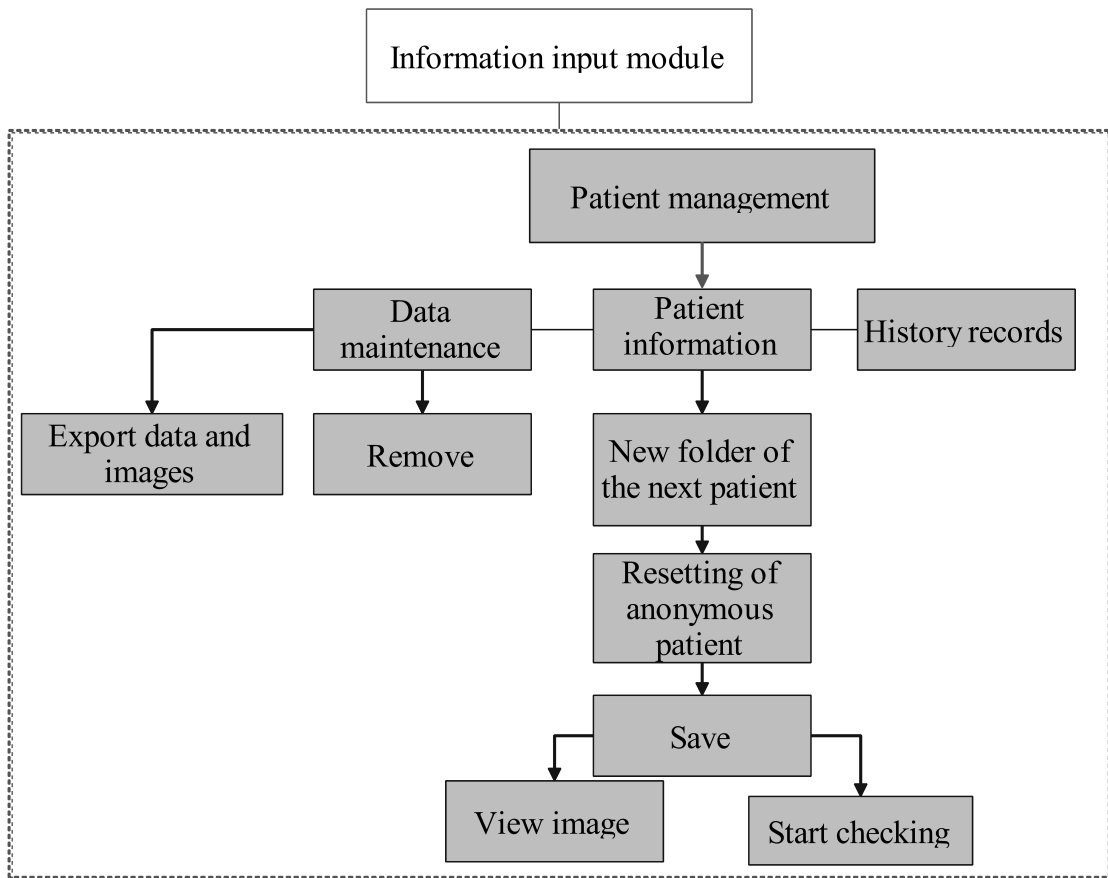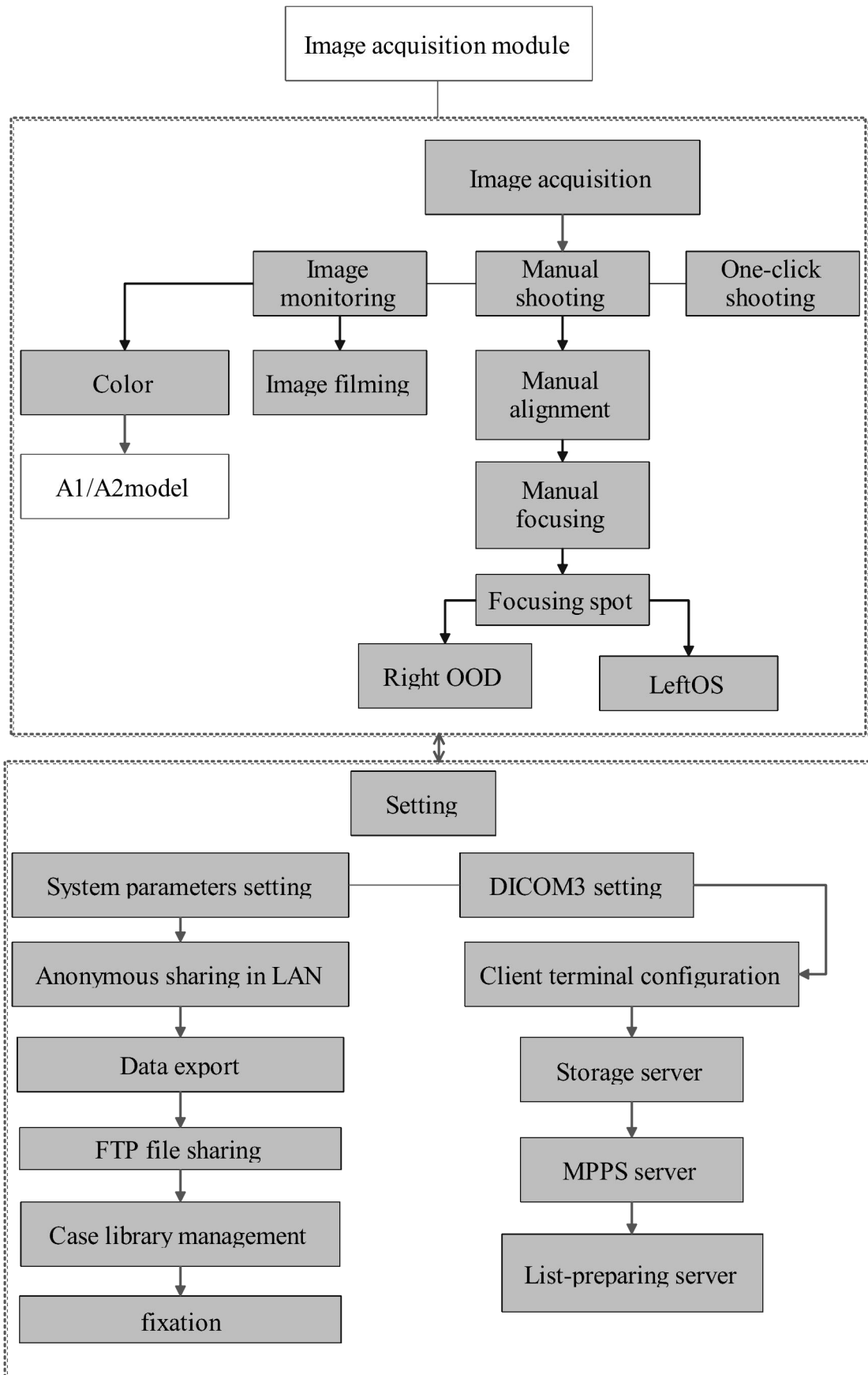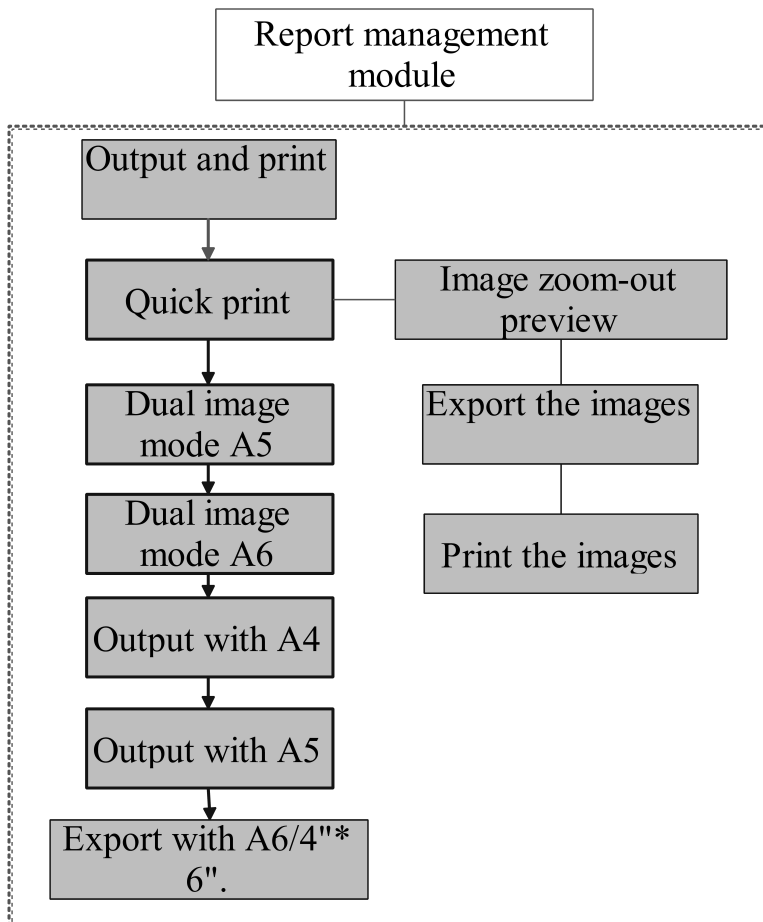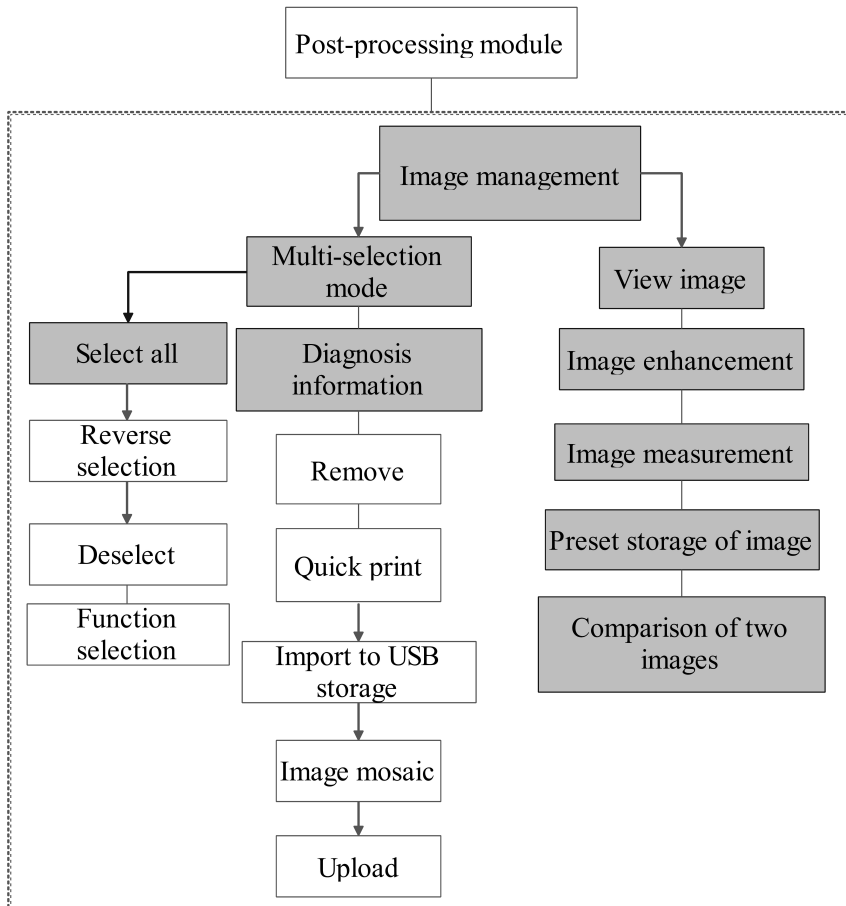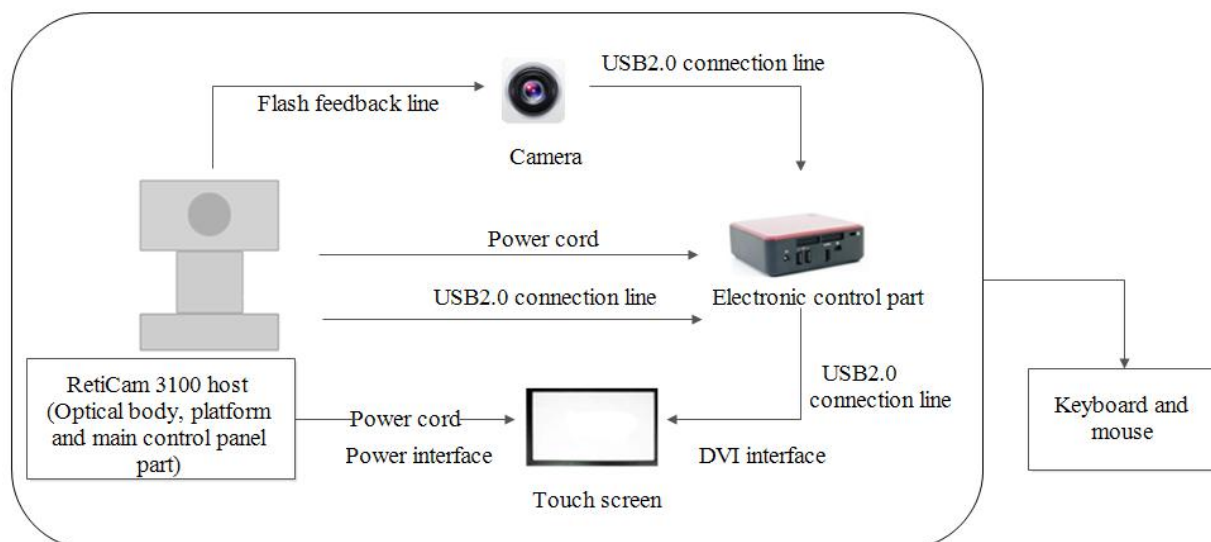
```
                    ┌─────────────────────────────┐
                    │  Image acquisition module   │
                    └─────────────────────────────┘
                                   │
    ┌──────────────────────────────┼──────────────────────────────┐
    ╎                              │                               ╎
    ╎                    ┌───────────────────┐                     ╎
    ╎                    │  Image acquisition │                    ╎
    ╎                    └───────────────────┘                     ╎
    ╎                              │                               ╎
    ╎        ┌──────────────┐  ┌───────────────┐  ┌──────────────┐ ╎
    ╎        │    Image     │──│    Manual     │──│  One-click   │ ╎
    ╎        │  monitoring  │  │   shooting    │  │   shooting   │ ╎
    ╎        └──────────────┘  └───────────────┘  └──────────────┘ ╎
    ╎    ┌──────────┐  ┌──────────────┐  ┌──────────────┐          ╎
    ╎    │  Color   │  │ Image filming │  │    Manual    │          ╎
    ╎    └──────────┘  └──────────────┘  │  alignment   │          ╎
    ╎         │                          └──────────────┘          ╎
    ╎   ┌──────────┐                     ┌──────────────┐          ╎
    ╎   │ A1/A2model │                   │    Manual    │          ╎
    ╎   └──────────┘                     │   focusing   │          ╎
    ╎                                    └──────────────┘          ╎
    ╎                                    ┌──────────────┐          ╎
    ╎                                    │ Focusing spot │          ╎
    ╎                                    └──────────────┘          ╎
    ╎                        ┌──────────────┐  ┌──────────────┐    ╎
    ╎                        │  Right OOD   │  │    LeftOS    │    ╎
    ╎                        └──────────────┘  └──────────────┘    ╎
    └──────────────────────────────────────────────────────────────┘
```

(Image acquisition module flow chart)

- Image acquisition module
  - Image acquisition
    - Image monitoring — Manual shooting — One-click shooting
    - Color
      - A1/A2model
    - Image filming
    - Manual alignment
      - Manual focusing
        - Focusing spot
          - Right OOD
          - LeftOS

- Setting
  - System parameters setting — DICOM3 setting
    - Anonymous sharing in LAN
      - Data export
        - FTP file sharing
          - Case library management
            - fixation
    - Client terminal configuration
      - Storage server
        - MPPS server
          - List-preparing server

```
                    ┌─────────────────────────┐
                    │  Post-processing module │
                    └─────────────────────────┘

┌┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┐
┊                    ┌───────────────────┐               ┊
┊                    │ Image management  │               ┊
┊                    └───────────────────┘               ┊
┊                                                        ┊
┊        ┌───────────────────┐      ┌──────────────┐     ┊
┊        │  Multi-selection  │      │  View image  │     ┊
┊        │       mode        │      └──────────────┘     ┊
┊        └───────────────────┘                           ┊
┊    ┌───────────┐  ┌──────────────┐  ┌────────────────┐ ┊
┊    │ Select all│  │  Diagnosis   │  │     Image      │ ┊
┊    └───────────┘  │ information  │  │  enhancement   │ ┊
┊                   └──────────────┘  └────────────────┘ ┊
┊    ┌───────────┐  ┌──────────────┐  ┌────────────────┐ ┊
┊    │  Reverse  │  │    Remove    │  │     Image      │ ┊
┊    │ selection │  └──────────────┘  │  measurement   │ ┊
┊    └───────────┘                    └────────────────┘ ┊
┊    ┌───────────┐  ┌──────────────┐  ┌────────────────┐ ┊
┊    │ Deselect  │  │ Quick print  │  │ Preset storage │ ┊
┊    └───────────┘  └──────────────┘  │   of image     │ ┊
┊    ┌───────────┐                    └────────────────┘ ┊
┊    │ Function  │  ┌──────────────┐  ┌────────────────┐ ┊
┊    │ selection │  │ Import to USB│  │ Comparison of  │ ┊
┊    └───────────┘  │   storage    │  │   two images   │ ┊
┊                   └──────────────┘  └────────────────┘ ┊
┊                   ┌──────────────┐                     ┊
┊                   │ Image mosaic │                     ┊
┊                   └──────────────┘                     ┊
┊                   ┌──────────────┐                     ┊
┊                   │    Upload    │                     ┊
┊                   └──────────────┘                     ┊
└┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┘

                    ┌─────────────────────────┐
                    │    Report management    │
                    │         module          │
                    └─────────────────────────┘

┌┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┐
┊   ┌─────────────────────┐                            ┊
┊   │  Output and print   │                            ┊
┊   └─────────────────────┘                            ┊
┊   ┌─────────────────┐   ┌───────────────────────┐    ┊
┊   │   Quick print   │───│   Image zoom-out      │    ┊
┊   └─────────────────┘   │      preview          │    ┊
┊                         └───────────────────────┘    ┊
┊   ┌─────────────────┐   ┌───────────────────────┐    ┊
┊   │  Dual image     │   │  Export the images    │    ┊
┊   │   mode A5       │   └───────────────────────┘    ┊
┊   └─────────────────┘                                ┊
┊   ┌─────────────────┐   ┌───────────────────────┐    ┊
┊   │  Dual image     │   │  Print the images     │    ┊
┊   │   mode A6       │   └───────────────────────┘    ┊
┊   └─────────────────┘                                ┊
┊   ┌─────────────────┐                                ┊
┊   │ Output with A4  │                                ┊
┊   └─────────────────┘                                ┊
┊   ┌─────────────────┐                                ┊
┊   │ Output with A5  │                                ┊
┊   └─────────────────┘                                ┊
┊   ┌─────────────────┐                                ┊
┊   │ Export with     │                                ┊
┊   │ A6/4"*6".       │                                ┊
┊   └─────────────────┘                                ┊
└┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┄┘
```

2.4 Topology of hardware equipment

Topology Diagram of Network Connection Types Supported by Hardware Equipment

Peripheral interface

　　Peripheral interface refers to the interface connecting with external equipment, consisting of three kinds: USB interface, DVI interface and net interface.

USB interface: USB 2.0 interface or above, which is mainly used to update software, save data and print reports; In case of any fault in the touch screen, data shall still be input via connecting USB2.0 supportive keyboard and mouse.

DVI interface: DVI-D format interface, which is mainly used for data output by connecting to the external display in case of any fault of LCD touch screen.

Network interface: Disabled currently (reserved interface for software upgrade in the future), RJ-45 Ethernet interface, following IEEE802.3 Standards.

Power cord interface

　　Power cord interface is the port for external power cords.

2.5 Names of the product parts

1	Objective lens		
2	Forehead rest (forehead cushion)		
3	Chin rest		
4	Base (foundation)		
5	Touch screen		
6	Power button		
7	Computer switch		
8	USB		

Front View 1
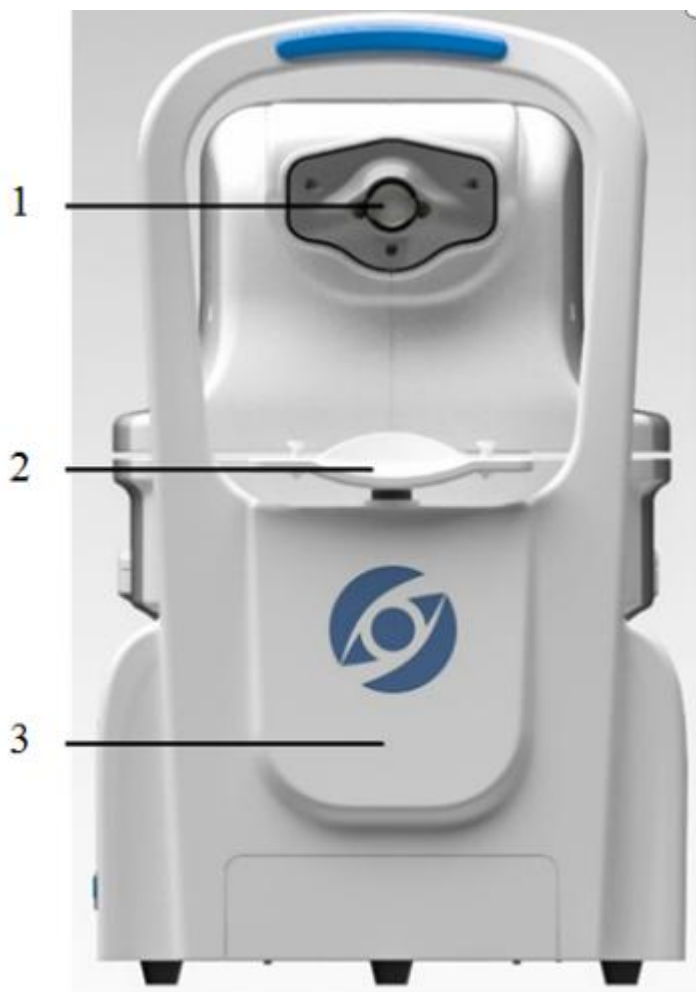
Side View 2
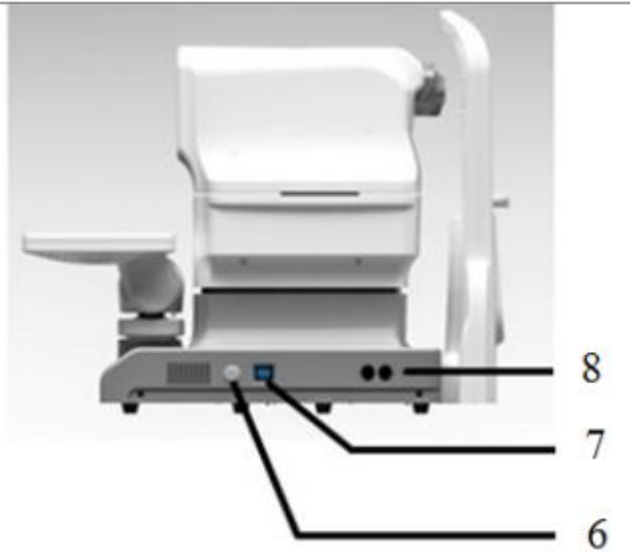
Side View 3

2.6 Description of product parts

➢ Chin rest
➢ Before the data acquisition, please make sure that patients have their chins closely attached to the bottom and front end of chin rest.
➢ Forehead rest
➢ During the data acquisition, please make sure that patients have their foreheads closely attached to the forehead rest.
➢ Connect the external device
➢ Print and output data.
➢ Head
➢ Head consists of main working parts of the equipment.
➢ Touch screen
➢ Touch screen serves as the interactive interface, and makes it possible for users to collect data, manage medical records and print reports via touching the screen.
➢ Computer switch
➢ Operators can start up or shut down the computer built in the equipment by pressing down the computer switch. Pressing the computer switch will not cut off the main power of the

equipment, and if the equipment is idle for a long run, it's better to turn off the power switch.

➢ Power switch

➢ Power switch is used to connect and disconnect the equipment's power supply, with " | " meaning "connected" and "○" meaning "disconnected". Power cord interface is the port for external power cords. Power cord interface is set next to the protective tube.

➢ Base

➢ The base is mainly used to support the head and control the three-dimensional movement of head.

➢ Peripheral interface

➢ Peripheral interface refers to the interface connecting with external equipment, consisting of three kinds: USB interface, DVI interface and net interface.

➢ USB interface: USB 2.0 interface or above, which is mainly used to update software, save data and print reports; In case of any fault in the touch screen, data shall still be input via connecting USB2.0 supportive keyboard and mouse.

➢ DVI interface: DVI-D format interface, which is mainly used for data output by connecting to the external display in case of any fault of LCD touch screen.

➢ Network interface: Disabled currently (reserved interface for software upgrade in the future), RJ-45 Ethernet interface, following IEEE802.3 Standards.

➢ The power cord interface is located at the bottom right part of head base. Power cord interface is the port for external power cords.

3　Basic operation

This chapter is intended to introduce the basic operation procedures when operating

RetiCam3100 for data acquisition.

3.1 Equipment startup

1) Connect the power cords, turn on the power switch, and press the computer switch to start it up.

2) Have patient's head firmly rested on the chin rest and forehead rest of fundus camera. Align and focus the camera on the fundus of the patient. Making sure the comfort of every patient can be beneficial to achieve the stability needed for capturing clear fundus images.

3.2 Information input module

(1) Input patient information

Fill in the patient information in "Patient Information" list (ID number will be generated automatically upon clicking). Then click [Save]. In case of re-write completely, the operator shall click "New Folder" or "Anonymous Patient", and then click "Save" after filling out the information.

(2) Work list query

Place the cursor at "Patient Information" list, select [Work List] to enter the work list interface, and then click [Query] to get the work list, and click [Load] to load the data of the selected work list into the Patient Information interface.

(3) Patient query

Click "History" to look through the patient's recorded data. For patients with established medical records, the operator can search it via history window. Click "Latest Record" at the upper part of the interface, click [Search] via inputting the patient's first name/last name or ID or creation date and other conditions. After confirming the patient, click "Load" to select [Load] and carry out the next step.

(4) Data deletion

Click "Data Maintenance" to remove the patient's data. Select the pull-down list, confirm the specific month, click "Remove" to remove data of all patients during these months. Export data and images at specific month or data.
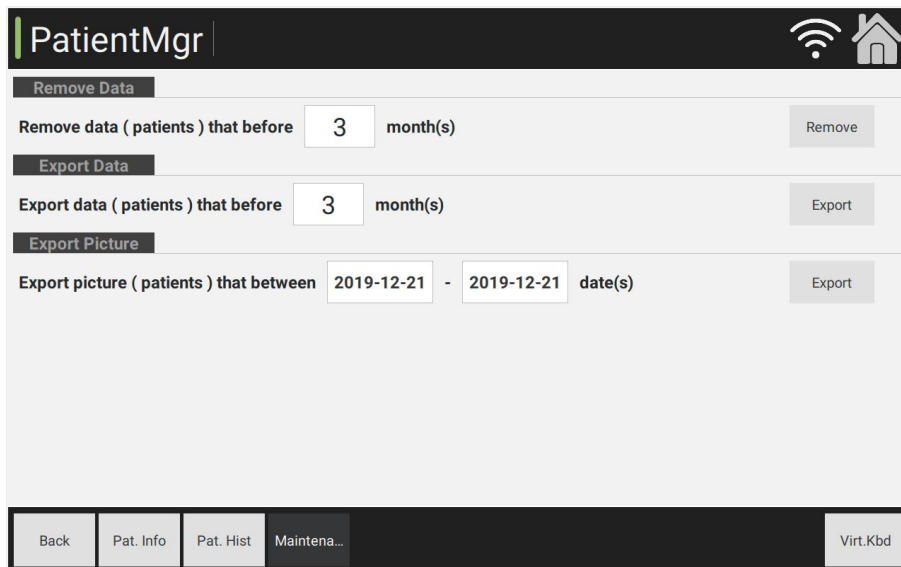
(5) Data export

Export data under "Data Maintenance" interface. Connect the external USB storage, select specified month and date, and then click "Export". Export patient data based on the specified date, and do well in the data compilation and backup; export data based on the specified month, and export images based on the specified date.
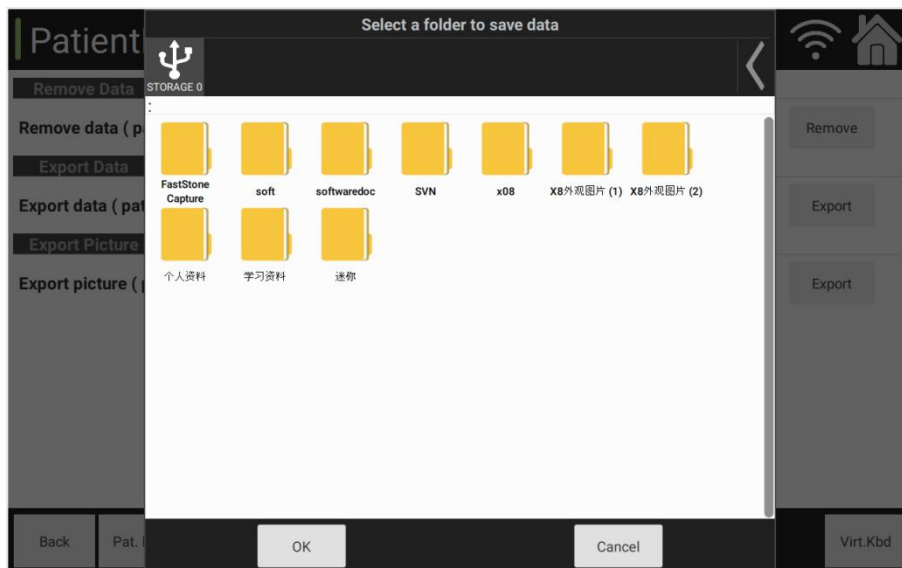
3.3 Image acquisition module

(1) Image monitoring
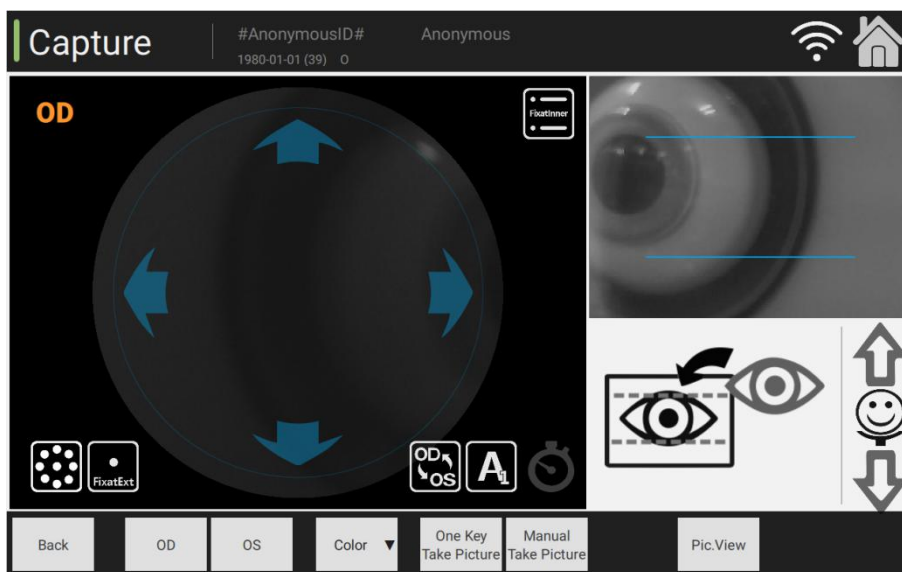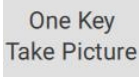
(2) Fundus alignment: Manual and auto
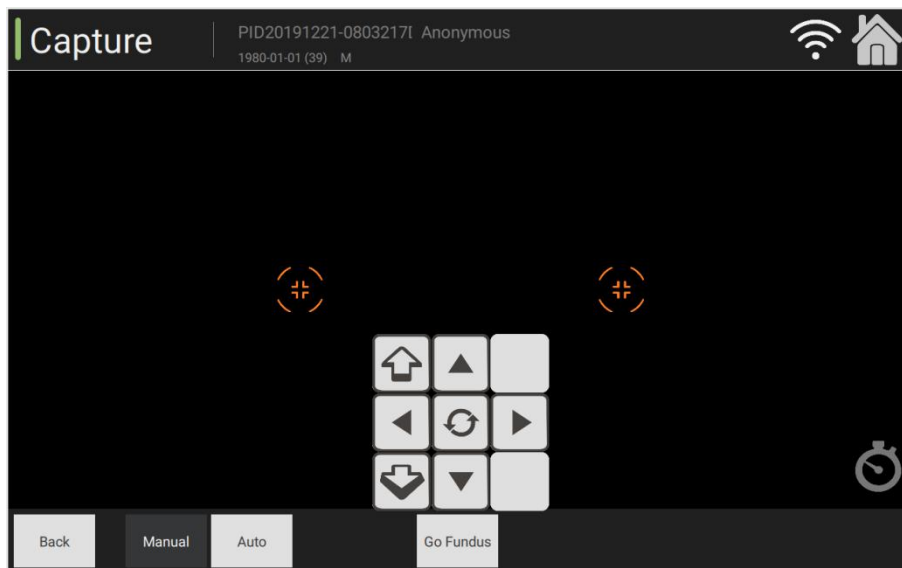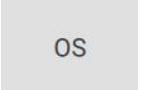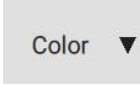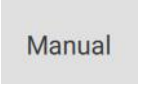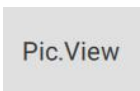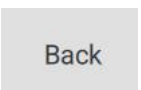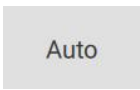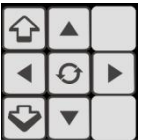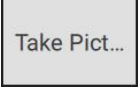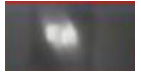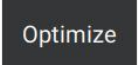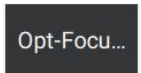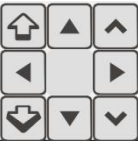
(3) Fundus images
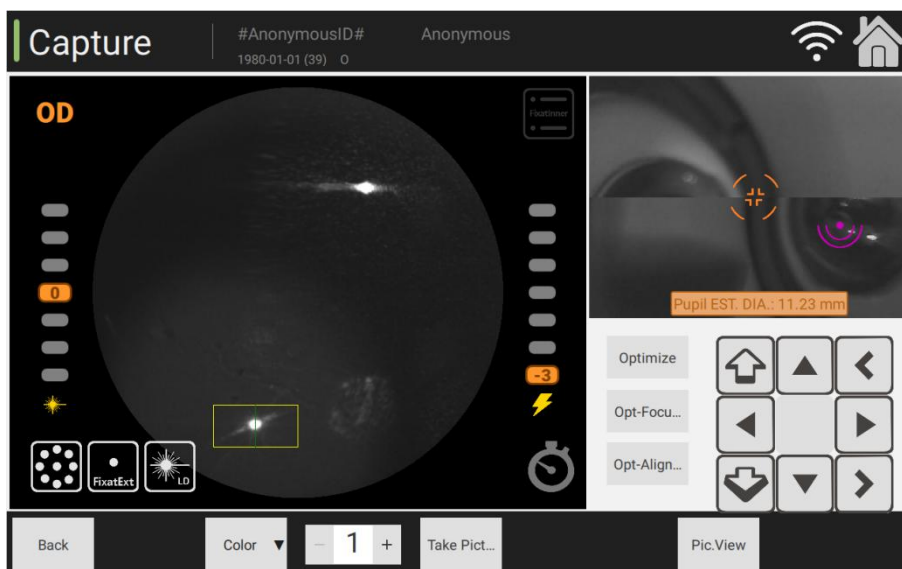
(4) Introduction to icons on the acquisition function interface

Manual Take Picture	Select manual mode to take pictures	⬆	Up (3D movement system)
One Key Take Picture	One-click shooting	⬇	Down (3D movement system)
OD	Eye position: Right	⬅	Left (3D movement system)
OS	Eye position: Left	➡	Right (3D movement system)

	Display the switch between focusing spot and infrared light		Focusing spot: Display the focusing spot
OD	Switch eye position: Right	OS	Switch eye position: Left
Color ▼	Color mode	Manual	Alignment mode (Auto)
	Turn on/off the timer	▶❙❙ 00:00:00.000 ❙❙▶ 00:00:05.478	Start/suspend the film recording
A1	A1: Auto mode, adjust the chin rest manually	A2	A2: Full auto mode, including adjusting the chin rest automatically
OD↘OS	Auto binocular filming mode: Automatically film one eye and then the other one		Turn on/off the outer fixation lamp
FixatExt	Inner fixation lamp:		Prompt that pupils shall be between two lines.
Pic.View	Photo viewer: Enter the image management interface		Adjust the height of chin rest: Click the up/down arrow
	Lift the chin rest up (3D movement system)		Lower the chin rest (3D movement system)
	Return to the main interface	Back	Return to the main interface
Auto	Alignment mode (Manual)		Adjust the alignment point manually - up/down/left/right/reset /front/back/direction

	Central point of focusing pupils	Go Fundus	Switch to the fundus image manually
-3	Indicator of lighting intensity: Adjust the infrared-light brightness	-3	Indicator of filming intensity: Adjust the flash intensity
− 1 +	Adjust the number of captured images based on the needs	Take Pict...	Take pictures, and directly capture the images shown on the current screen.
	Focusing indicator	Optimize	Optimization of alignment
Opt-Focu...	Optimization of focusing		Adjust the position of head manually - up/down/left/right/front /back/direction, and adjust the focal length manually

(5) Image acquisition process

Preparation work for image acquisition: Swab the patient's contact part with cotton balls immersed in medical alcohol, or use disposable chin rest paper. Have the patient sit down, and adjust the height of the chair or worktable to have patient's chin and forehead closely leaned on the chin rest and forehead rest.

1) Manual mode: Switch eye position, adjust the up-down height of chin rest and front/back/left/right/up/down , , , , , , click [Manual Picturing] , make sure that patient's eyes are aligned to the central part of yellow circle with clear images, then select [Manual] alignment, click [Camera] to complete the manual picturing, and repeat the foregoing steps after switching OS/OD and complete the image acquisition of both eyes.

2) Auto mode: Adjust the up-down height of chin rest , to make sure that patient's eyes are aligned to the central part of yellow circle , then click [One-click Shooting]

[One Key Take Picture] to complete the auto acquisition, and then switch eye position and click [One-click Shooting] [One Key Take Picture] again to complete the image acquisition of both eyes.

(6) Parameter setting

1) **System setting:** Modify all the parameters of the system.

2) DICOM3 setting: Configurations relating to client side, storage server, MPPS and work list server.

3) **Set the LAN anonymous sharing (Windows):** Configurations of anonymous address sharing of local area network (LAN).
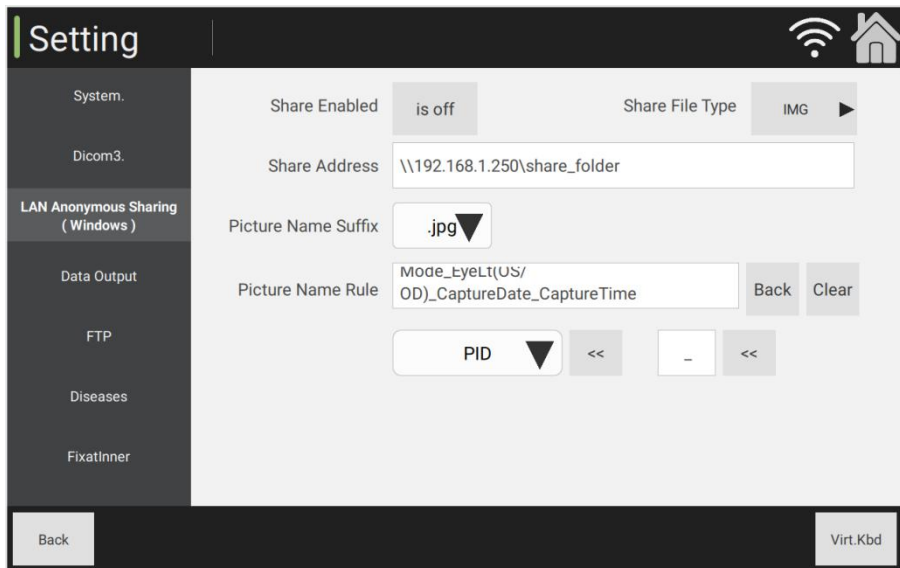
4) **Data output:** Modify the options on the connected printer, and select the corresponding printer.
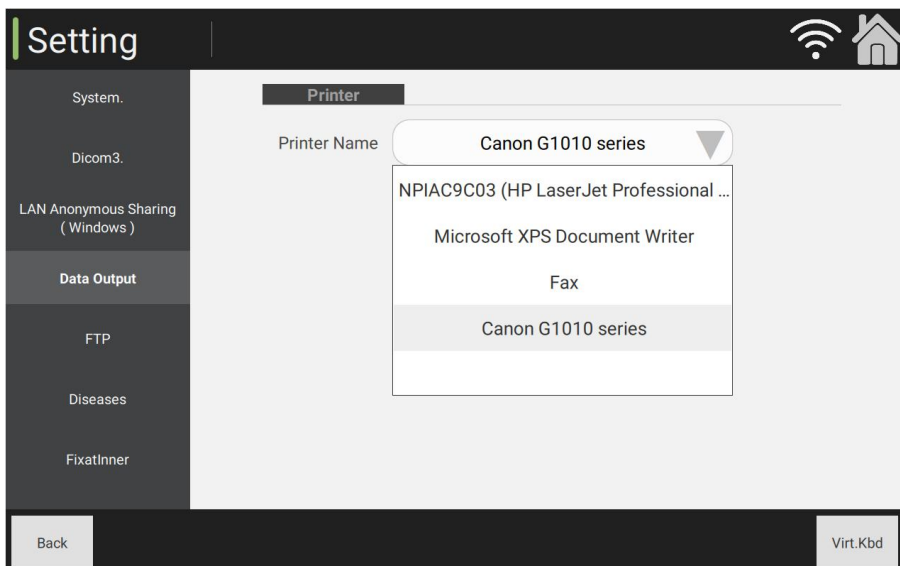
5) **FTP:** Transmit images to the shared folders simultaneously via LAN, and complete the real-time analysis by the third party.
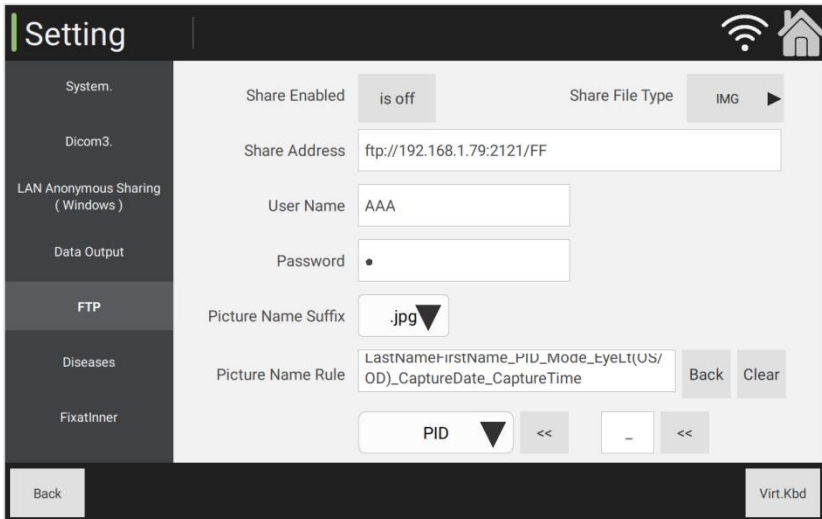
6) **Case:** Establish the case database, and achieve the management on viewing, adding, replacing or removing cases.

7) Inner fixation parameters setting.
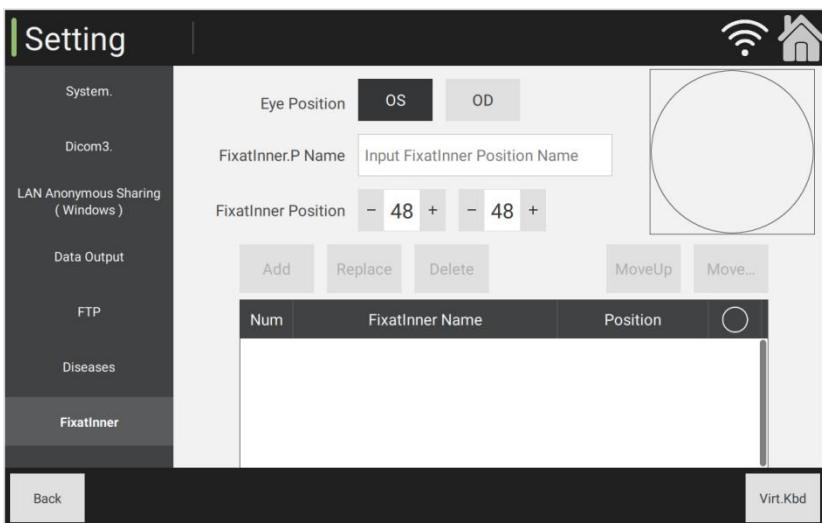
3.4 Post-processing module
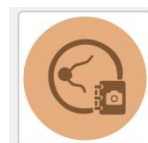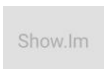
1. Image management: After completing image acquisition, click Picture Management icon at the homepage to enter the image management interface to manage the acquired images.
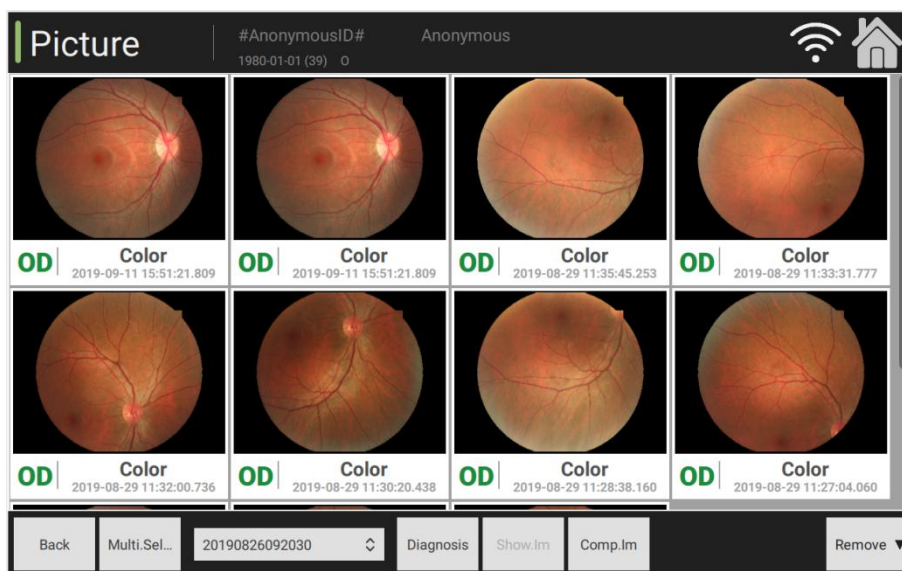
Instructions:

(1) View image After double clicking the image or single clicking the targeted image, click the image viewer [Show.lm] button to view images by rolling the mouse wheel or touch screen gestures to zoom in/out.

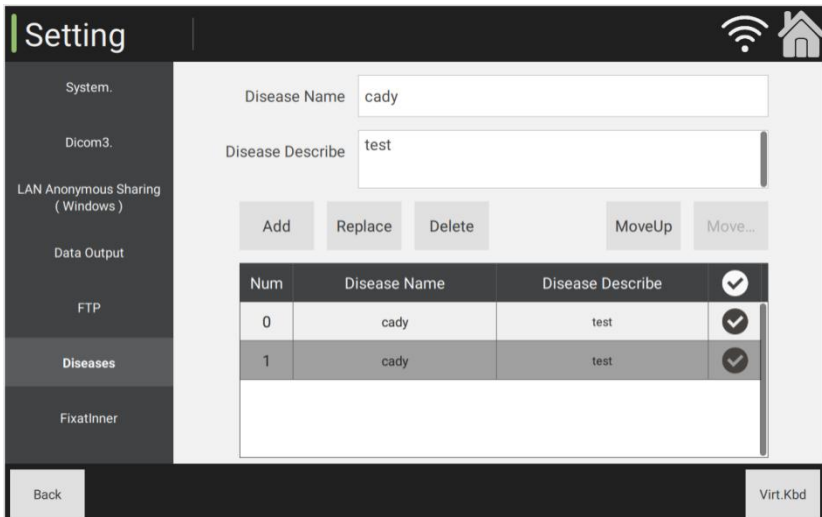(2) Multi-selection mode: Under the multi-selection mode, total three modes are available for selecting and ticking the targeted images, namely, Select All, Reverse Selection and Deselect All.

(3) Acquiring date: Select the corresponding acquiring date as needed and check the patient's fundus images.
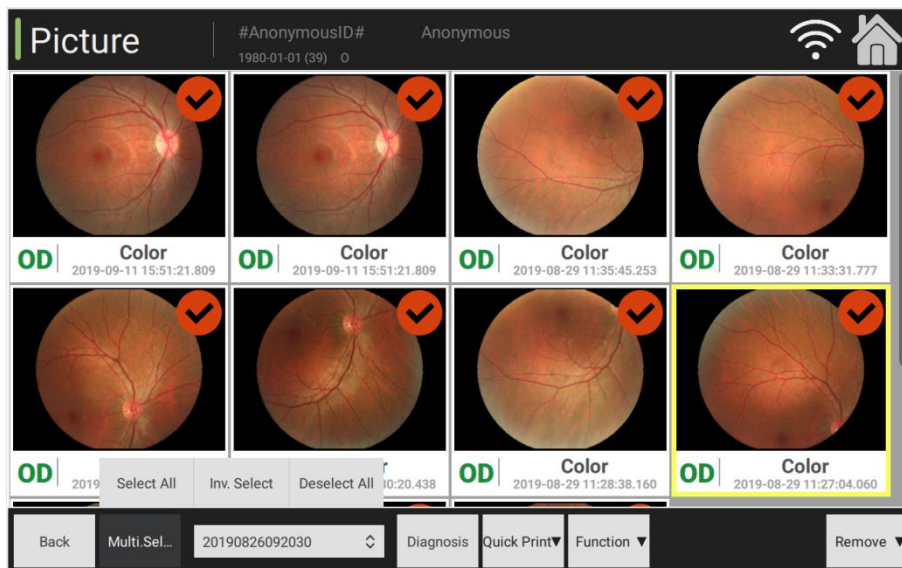
(4) Delete and check: Delete all the images in the current folder.

(5) Delete an image: Under the multi-selection mode, tick one image, click "Delete" to remove the ticked image.
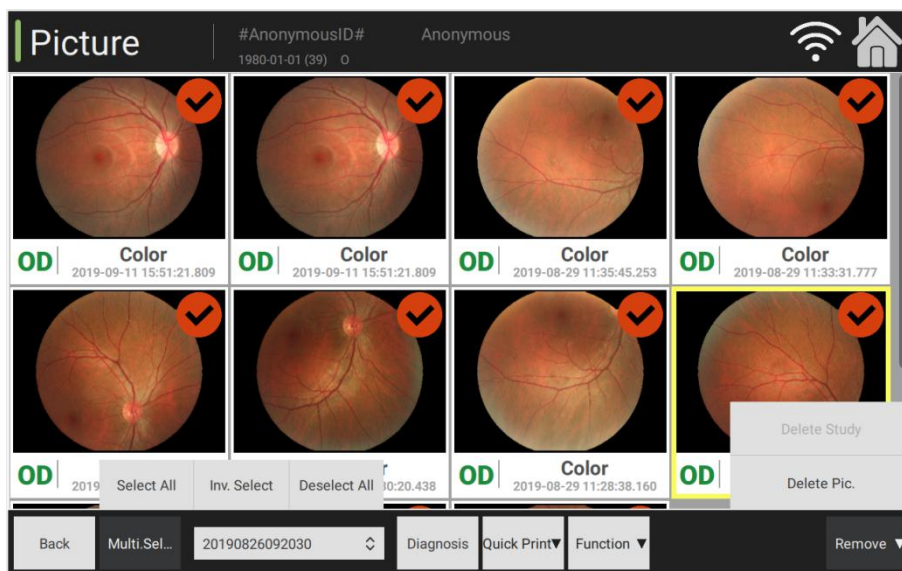
(6) Diagnosis information: Select　Diagnosis　, click　DiagnosisList　to select the record list, double click the content in the list, fill in the diagnosis information and click　OK　to confirm. Otherwise, click　Cancel　to cancel. Click　Clear　button to clear all content and double lick

again to fill in the diagnosis information. Click virtual keyboard [VirtlKbd] to initiate and then input diagnosis information manually.
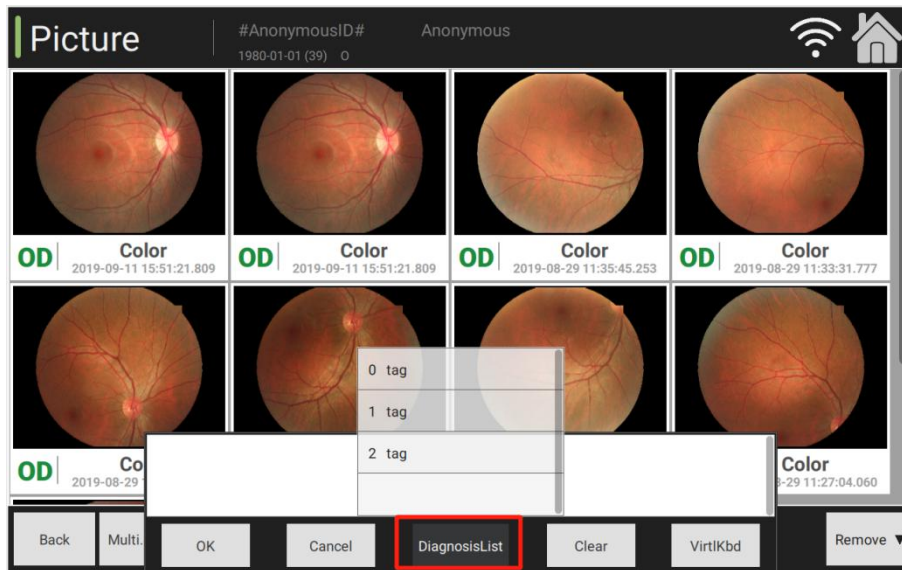
(7) Function selection: Upload DICOM3, export to USB storage and image mosaic
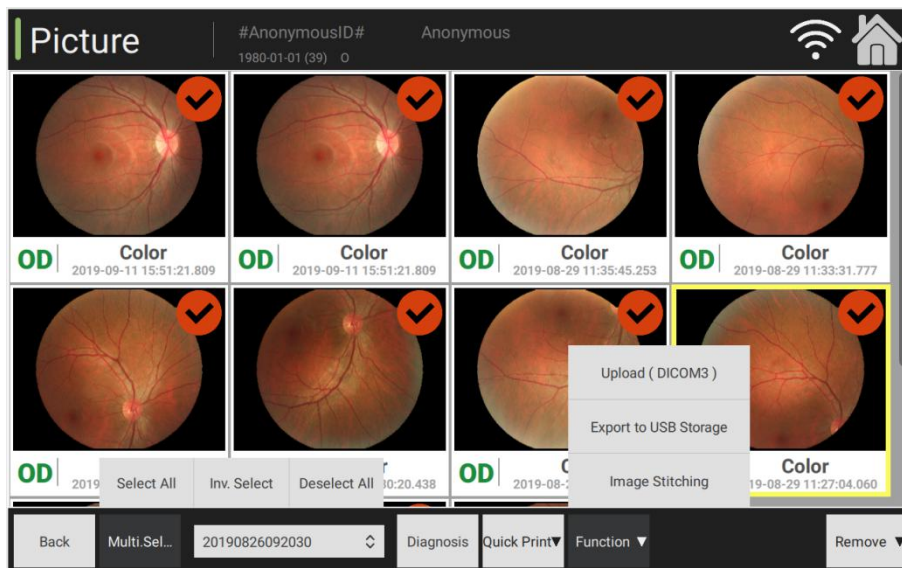
2.   Comparison of two images

(1) It is at the image management interface. Select the function of comparison of two images and enter the interface

(2) Comparison of two images: Select any image, click [Comparison of Two Images]   button to

enter the interface, and then [Double Click to Select] two fundus images of the same part for comparing and observing the locations of lesions. Select and click to the lock icon ![lock icon] to zoom in and out the two images to the same scale by rolling the mouse wheel. Select and click the unlock icon ![unlock icon] to disconnect the two images. Select [Quick Print].
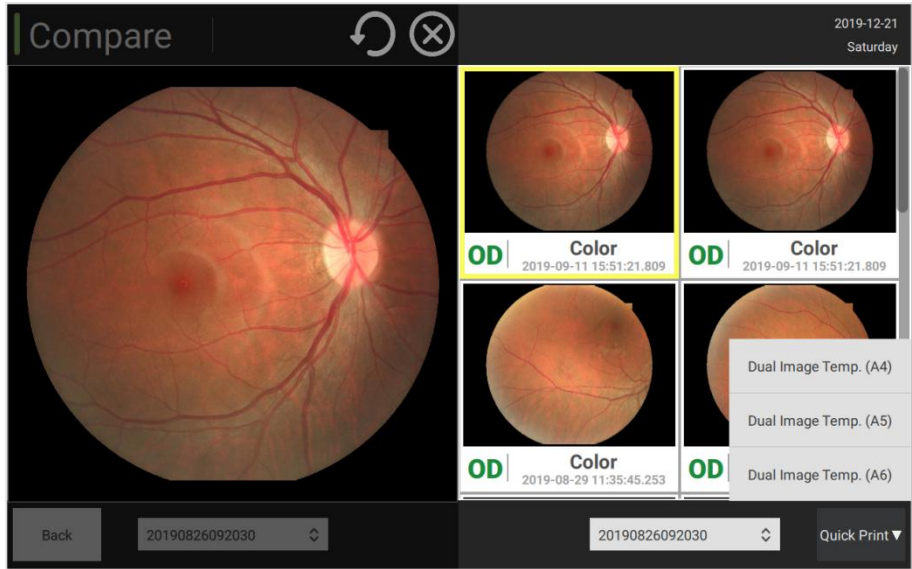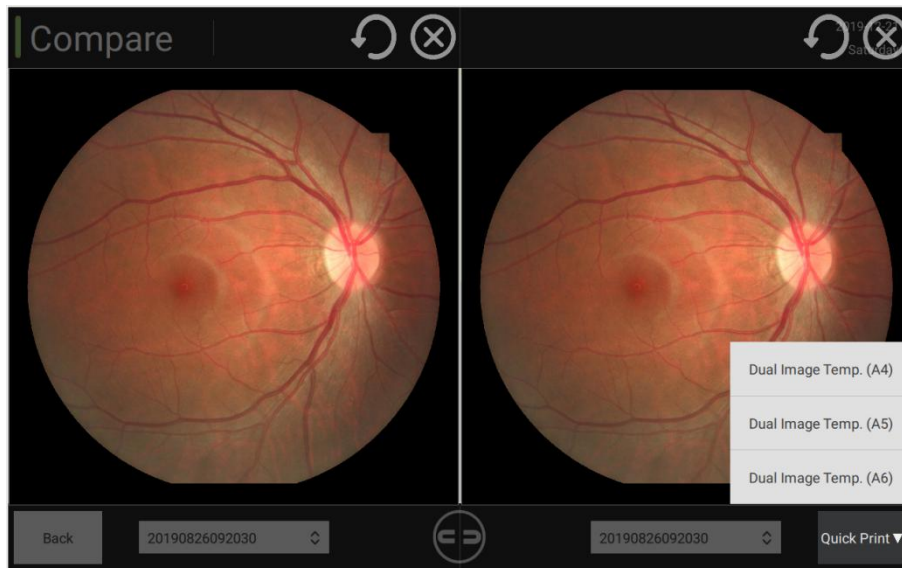
➢ Image mosaic

(1) Enter into the image management interface, click [Multi-selection Mode] button at the bottom to check the image mosaic among the function options.

(2) Click [Function] button to carry out image mosaic as needed.
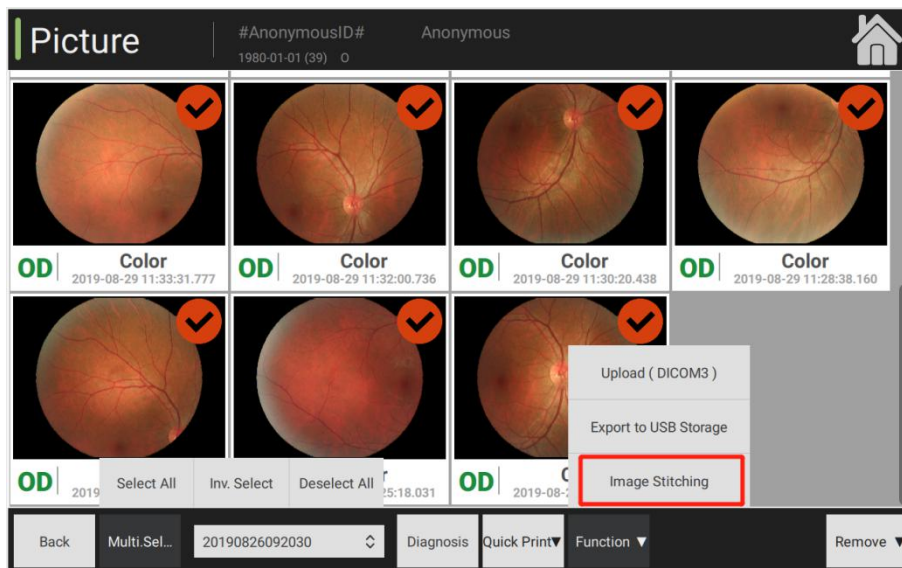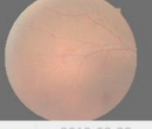
- Select fundus images of the patient's one eye at different part for image mosaic.
- Image mosaic: Combine several small images into one big image, on the preconditions that these small images are images of the same patient's one eye.
- Different positions: Adjust the position of inner fixation lamp, and require patient's eyes to focus on different directions to acquire fundus images of different eye positions.
- Number of image mosaic: Maximum 9 images for each time.
- Select images as needed and then start the image mosaic.
- Positioning: Click [Positioning] button to automatically align fundus images.
- Image mosaic: After successful alignment, click [Image Mosaic] button.
- Check the effect of image mosaic: If the image mosaic succeeds, return to the image management interface, and the first image in the image list is the composite fundus image by default after the image mosaic.
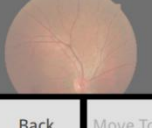
ImStitching
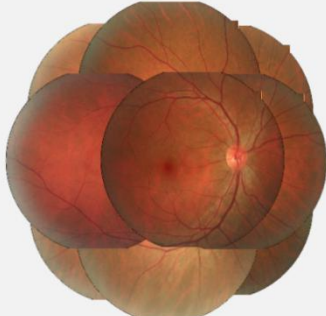
OD 2019-08-29 03:35:45.253

OD 2019-08-29 03:33:31.777
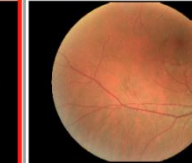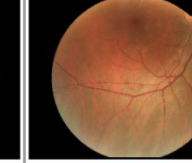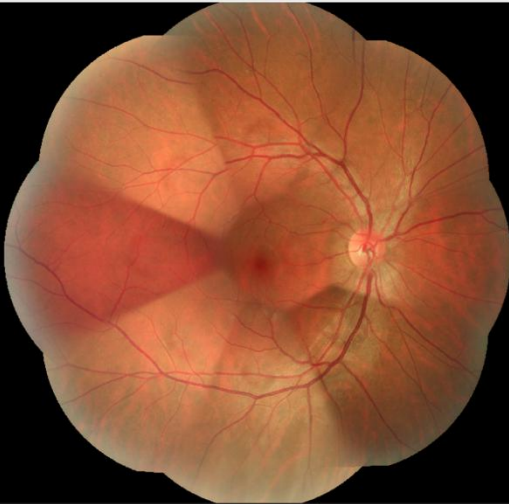
Back | Move To Workspace | Position | Fusion

Picture

#AnonymousID#   Anonymous
1980-01-01 (39)   **

OD | Color 2019-11-13 16:03:58.927
OD | Color 2019-11-13 16:03:05.097
OD | Color 2019-11-13 16:00:46.251
OD | Color 2019-08-29 11:35:45.253

OD | Color 2019-08-29 11:33:31.777
OD | Color 2019-08-29 11:32:00.736
OD | Color 2019-08-29 11:30:20.438
OD | Color 2019-08-29 11:28:38.160

Back | Multi.Sel··· | 20190826092030 | Diagnosis | Show.Im | Comp.Im | Remove ▼

Back | Save

3.　　Image processing

After entering the composite image preview interface, process the image as needed.

1、Image adjusting tool

➢ Image intensification effect: Click ![icon] button to adjust the image effect as needed

Gamma adjustment ![gamma icon] , brightness adjustment ![brightness icon] , contrast adjustment ![contrast icon] , RGB gain

adjustment ![RGB icon] . After the image effect intensification and adjustment is completed, click [Save]

to generate new images.
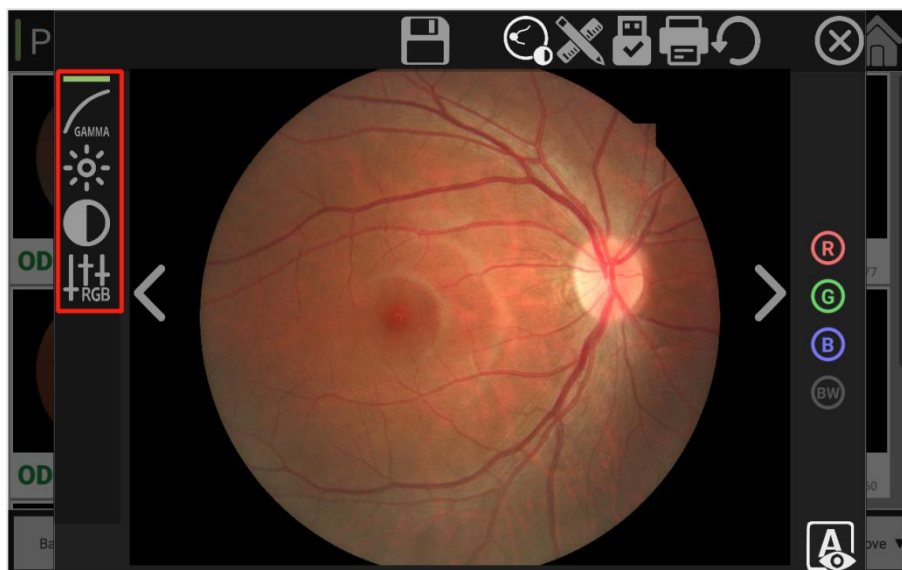
2、Image annotation tools
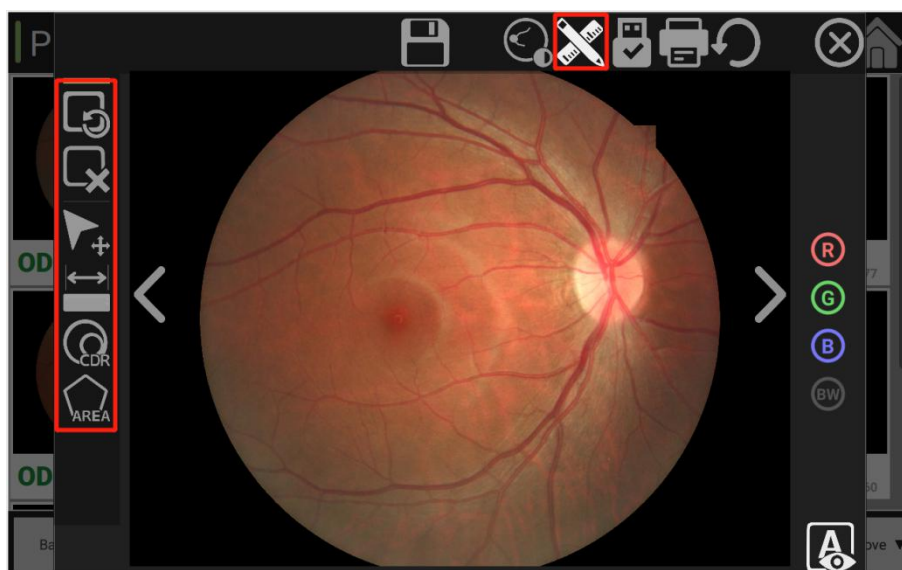
➢ Annotation and measurement: Click ![ruler icon] button to annotate images as needed, and use
annotation tools (distance tool, CDR tool and polygon area calculation tool) to label and

measure the length, area and cup-disc ratio of the image, and then click "Save" to generate new images.
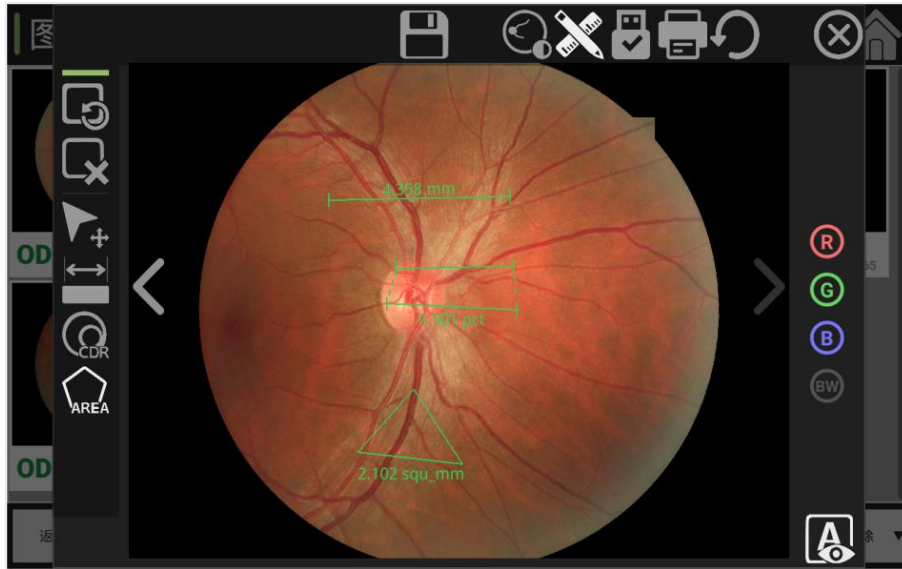
	Clear data		Remove		Select and move		Annotation tool
	Distance tool		CDR tool		Polygon area calculation tool		Adjustment tool
	Display the calculation result		Refresh, restore the default size of images		Hide the calculation result		Print the images
	Save and generate new images		Close the window		Export the images		

3、Image export tool
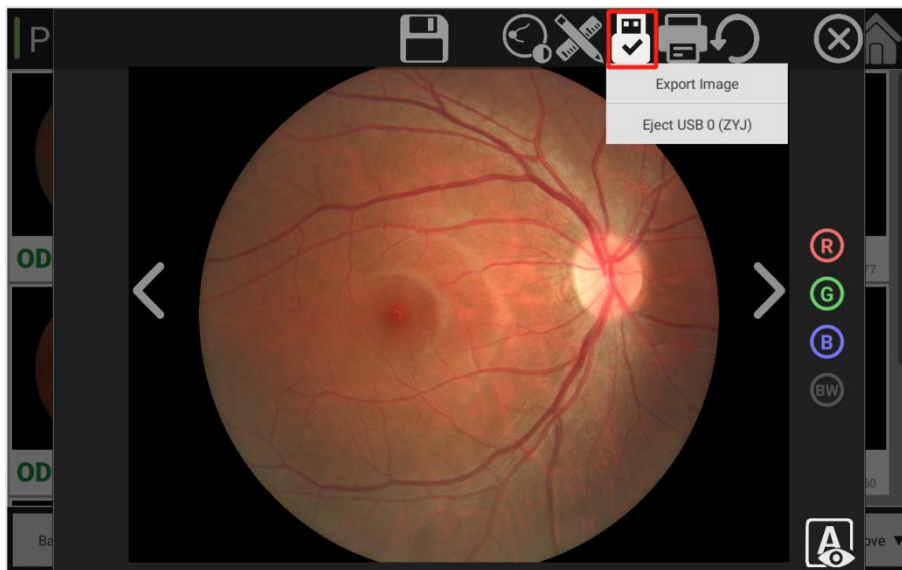
3.5 Printout module:
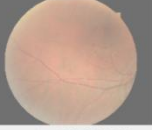
Enter the image management interface, click [Multi-selection Mode] button at the bottom to check the print function among the function options.

➢ Quick print: Click [Quick Print] button to print reports as needed.

Dual image template (A5): Use A5 paper to print 2 images.

Print with A4: Print and export the report on A4 paper.

Print with A5: Print and export the report on A5 paper.

Print with A6/4"*6": Print and export the report on A6 paper.
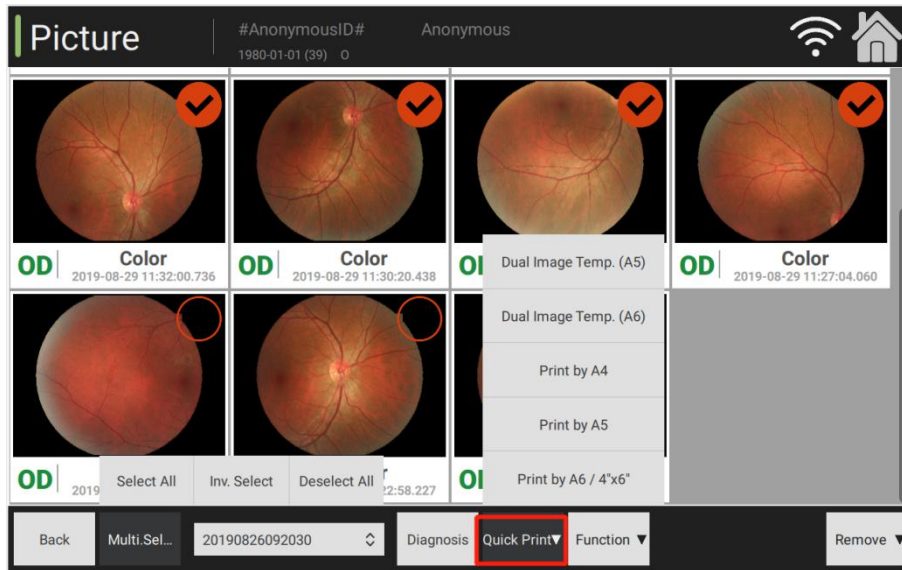
➢ Image printing tool: Two options: Export and write diagnosis information with A6/4"*6". Connect to printers, and then directly print images.
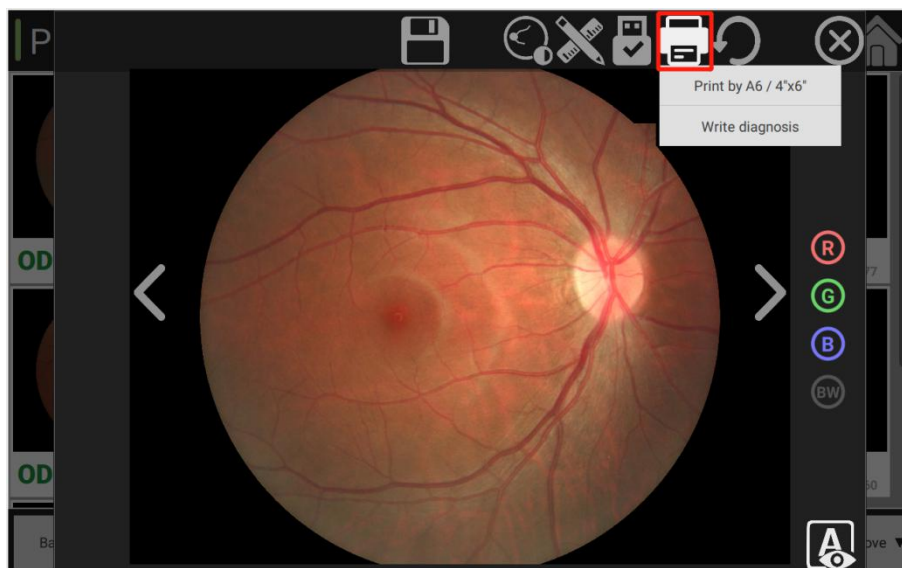
3.6 Information of software version

Main interface: Enter the main interface of the system, click [About] button at the right bottom to check the information about software version.
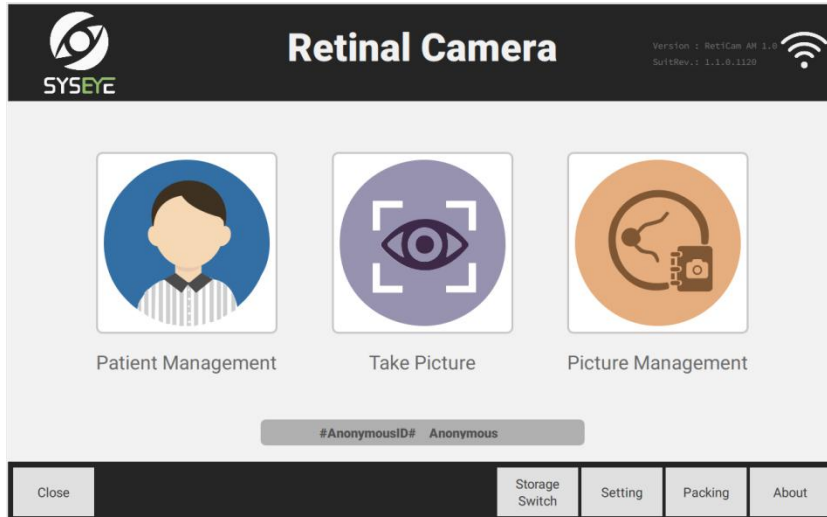
About the version: Detailed information of the product is as below.
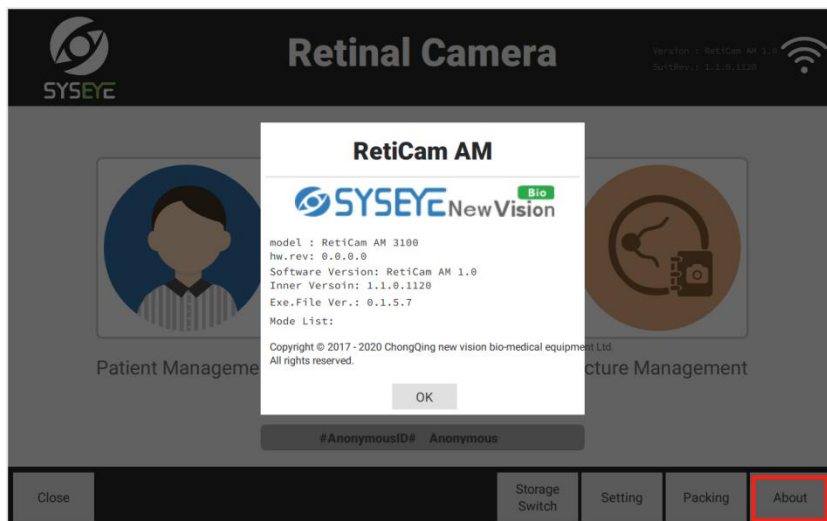
Storage switch: Click [Storage Switch] button at the right bottom to switch among local storage and external USB storage. Local storage by default
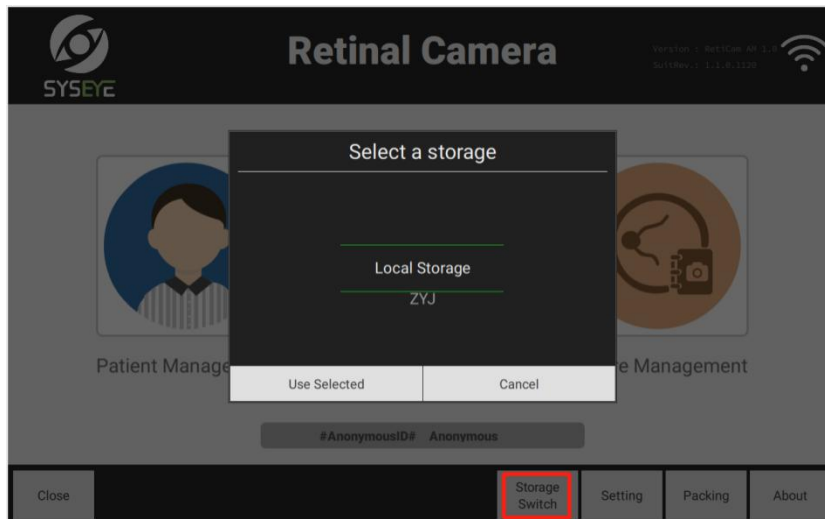
3.7 Shutdown

1. Before the shutdown, carry out the equipment packing operation. Packing: Click [Packing] button at the right bottom to pack at the minimized form automatically.
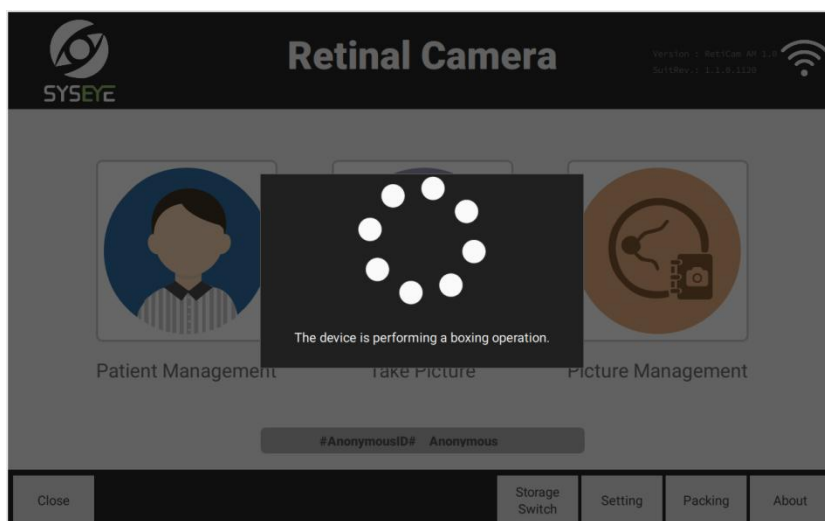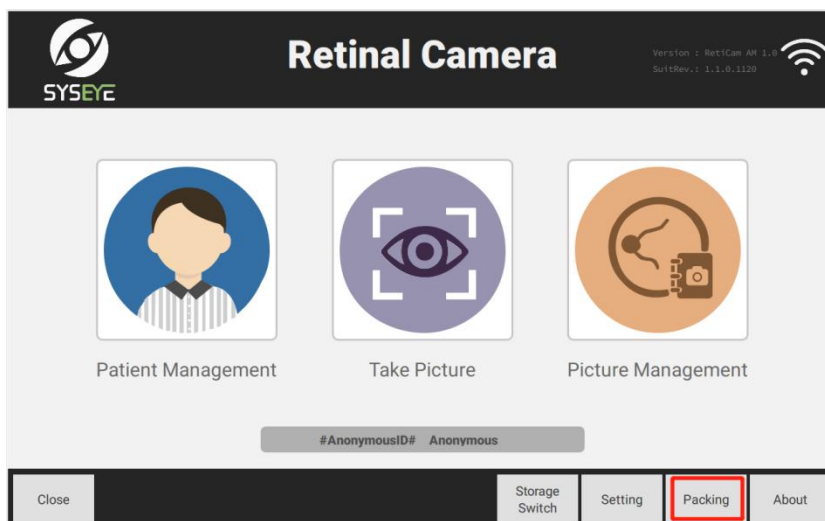
2. After entering the homepage of the system operation interface, click [Close] button at the bottom left, and then select different modes as needed.

Close: Select corresponding modes as needed. Click "Close" button on the main interface, and the equipment will exit from the program and shut down the computer.
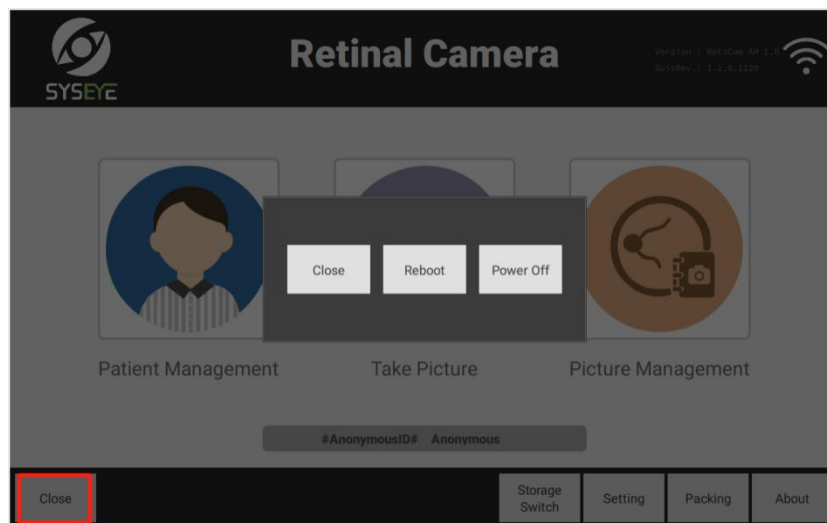
3.8 Backup and update of software

① Data backup: During the data management, select data according to the targeted date range and export data to USB storage file.

② US-disk upgrade

Software upgrade package (fcm-updatedir-0-8-5-1.zip), validation file (fcm-updatedir-0-8-5-1.key).

Preparations before upgrade: Place software upgrade package and validation file under the catalogue of USB specified folder.

➢ Conditions when the software is not started: When the software is not started, the first step: Insert U-disk first.

Step 2: Turn on the power switch and start the equipment; Step 3: Run software detection function and identify U-disk, with software upgrade package window popping out. Step 4: Select the software version to be upgraded and corresponding software upgrade package to upgrade the software.

Step 5: After the software upgrade is completed, the U-disk will be rejected.

➢ Conditions when the software is started: When the software is started, the first step: Insert U-disk first. Step 2: Restart the software.

Step 3: After software resets, it will identify the software upgrade package in the U-disk.

Step 4: Select the software upgrade package corresponding to the software version, and upgrade the software.

Step 5: After the software upgrade is completed, the U-disk will be rejected.
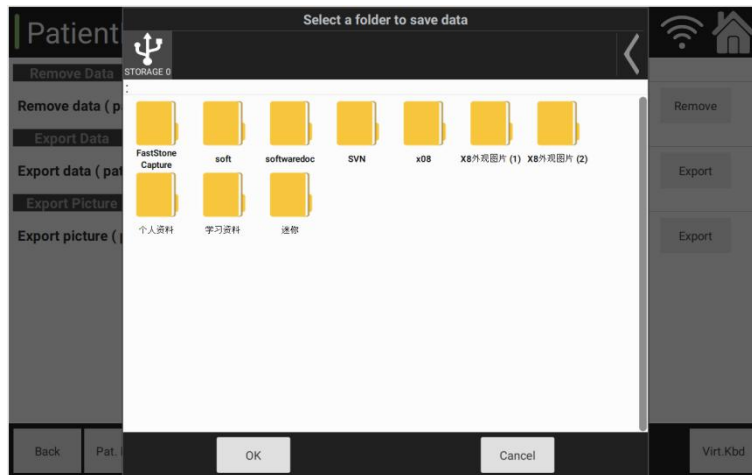
Figure-1 Data Backup
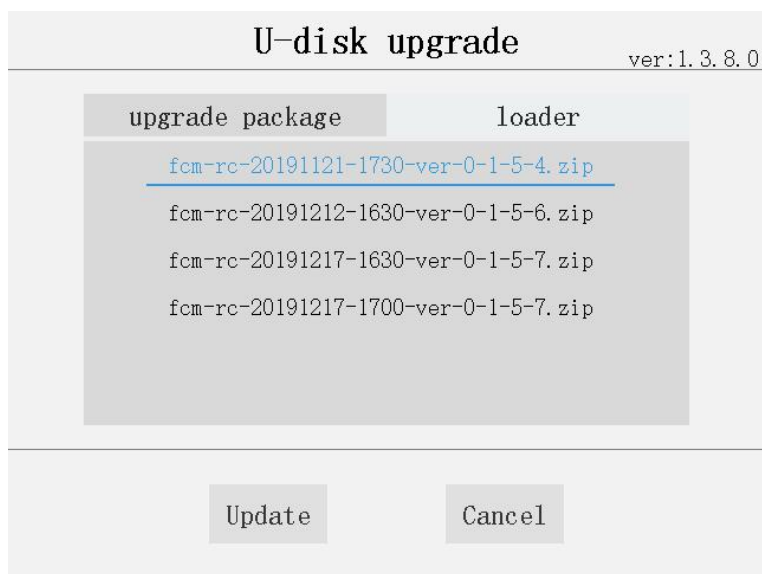
Figure-2 U-disk Upgrade

4 Cleaning and maintenance

Considering that RetiCam3100 is an integrated auto diagnostic equipment for ophthalmology department, it does not require much daily maintenance, and its daily maintenance is only about cleaning the parts exposed to the human body. Before cleaning and maintenance, please disconnect the power supply of the equipment.

4.1 Cleaning and maintenance

➢ Chin rest and forehead rest

Swab them with 75% medical alcohol to clean and sterilize every day before use. Before use, put the disposable chin rest paper for each patient.

➢ Optical device

Any pollution at the positioning window may result in failure to recognize or align the center between eyes, which may lead to measurement error or even failure to measure; please dip neutral detergent with the clean cotton swab to clean the external surface of positioning window. Monitoring window

➢ Touch screen

Clean the display with soft lint-free cloth. In case of any stain that cannot be removed completely, please dip some water to wet the soft cloth.

➢ Other external surface

Other external surface of equipment can be cleaned with soft lint-free cloth wetted with little water.

➢ Cleaning cycle

It is suggested to clean the whole equipment every two months. Clean the optical devices only when they are dirty.

☞ Notes:

Since optical devices are easily damageable, they cannot be wiped frequently, and the operators shall try to avoid contacting the optical surface directly with objects during use. Patience and technical skills are required for cleaning optical devices, and please contact after-sales service person or professional person in case of any doubt about cleaning.

Protect the equipment from water during the cleaning. Lint-free cloth can be wetted but free from any drops. Prevent any fluids flowing into the equipment.

4.2 Replacement and maintenance

1) Turn off the power switch, and pull out the power cord.

2) Take off the base of protective tube with tools.

3) After replacing the protective tube, install the base back.

4) Notes: Please select the new fuse tubes of the same models, specifications and rated values (T2AL250V).

5　Content, cycle and methods for preventive inspection

1）Cosmetic inspection

　　Check if there is any looseness or dislocation of the equipment switch and connector socket, if there is any oxidation, rust or bad contact of plugs and sockets, and if there is any aging of power cords. If any, please replace it in time.

2) Cleaning and maintenance

➢ Chin rest and forehead rest

Swab them with 75% medical alcohol to clean and sterilize every day before use. Before use, put the disposable chin rest paper for each patient.

➢ Optical device

Any pollution at the positioning window may result in failure to recognize or align the center between eyes, which may lead to measurement error, or even failure to measure; please dip neutral detergent with the clean cotton swab to clean the external surface of positioning window.

➢ Touch screen

Clean the display with soft lint-free cloth. In case of any stain that cannot be removed completely, please dip some water to wet the soft cloth.

➢ Other external surface

Other external surface of equipment can be cleaned with soft lint-free cloth wetted with little water.

➢ Cleaning cycle

It is suggested to clean the whole equipment every two months. Clean the optical devices only when they are dirty.

☞ Notes:

　　Since optical devices are easily damageable, they cannot be wiped frequently, and the operators shall try to avoid contacting the optical surface directly with objects during use. Patience and technical skills are required for cleaning optical devices, and please contact after-sales service person or professional person in case of any doubt about cleaning.

　　Protect the equipment from water during the cleaning. Lint-free cloth can be wetted but free from any drops. Prevent any fluids flowing into the equipment.

3) Safety inspection

　　Check if the chin rest is installed firmly, and if the 3D movement system works well; check if there is any looseness, fall-off or rupture of connecting pieces. If any, please contact our company or authorized dealers.

4) Functional inspection

Check if the power switches and buttons work well; check if all the indicators light up normally after start-up; if any, please replace it in time. Enter the software to check if all the basic functions work well. In case of any software anomalies, please contact our company or authorized dealers to get the latest version for software upgrade.

5) Performance test and calibration

The quality of medical equipment shall rely not only on the qualified acceptance procedures, but also on the effective measurement monitoring during the use. Since the equipment will depreciate during the use, whose performance indicators and technical parameters will vary along with frequency of use and working conditions, operators shall check it regularly with measurement techniques for the change of performance, and carry out the calibration and maintenance of unqualified equipment timely.

This equipment shall be checked according to JJG 1143-2017 code, and can be used only after passing the inspection.

Verification cycle, in general, shall be no longer than 1 year.

If it is confirmed to be unqualified, please contact our company or authorized dealers.

6　　Precautions

1) Never use this equipment in the flammable, explosive, hot and dusty environment. It shall be used indoors.
2) Keep the floor clean and dry.
3) Before use, please check if all the cords are connected correctly and solidly, and make sure that the equipment is well grounded.
4) Please use the fuse tubes of models and rated values meeting the specifications of this product. The specification of the configured fuse tube is T2AL250V. Before replacing the fuse tube, please cut off the power supply.
5) Adopt the power cords specialized for this equipment.
6) Never touch the surface of optical elements with hands or hard objects.
7) Never put fingers, hair or other body parts at the moveable parts of equipment, or otherwise, you may be injured.
8) The equipment shall be installed on the flat ground, which can prevent the equipment from falling down.
9) When the equipment is idle, it's necessary to disconnect the power supply and cover it with dust guard.
10) Other medical devices and equipment that are required to install in the same environment for use shall follow the same electromagnetic compatibility principles. Those failing to follow electromagnetic compatibility principles or with poor electromagnetic compatibility shall be located at the place at least 3m away from this equipment and powered by different power cords.
11) In case of any fault, please contact our company or the authorized dealers.

7   Common faults and causes

In case of any fault, please check according to the following list, and try to find out the reason. If the following solutions cannot solve faults or warming, please cut off the power supply and contact our after-sales service personnel. Please provide details of faults and displayed information when contacting.

List of solutions to erroneous operations		
Problem	Possible cause	Solution
Failure to start up	Failure to connect the power cord to the power socket correctly	Check whether the connection is loose.
	Put power switch at "○" position	Turn the switch to " ｜ " position
	Fuse burn-out	Replace a new fuse of the same specification and model.
Failure to observe the targeted eyes	1) Stain on the positioning window 2) Intervention from external lights on the positioning system	1) Clean the window 2) Isolate the external lights (for illumination or infrared ray)
Failure to read data	1) Patient's position is dislocated. 2) Patient's eyes are too far away from the measurement window. 3) Patient fails to align with the visual target 4) Patient has extremely dry eyes.	1) Require the patient to stay still 2) Require the patient to put the chin on the chin rest, and lean the head on the forehead rest. 3) Require the patient to focus on the fixation lamp 4) Require the patient to blink a few times before continuing to measure
No image shown after opening the software	Computer system failure, computer poisoning, or loose wiring.	Reinstall the system, eliminate antivirus, check the wiring, and re-plug the cable.
Failure of the printer	1) Lack of printing papers 2) Printing papers are put in the wrong direction 3) Failure to use the printing papers produced by our company	1) Place printing paper 2) Reverse the direction of printing papers 3) Place printing papers produced by our company
Failure to acquire the idealized images	1) Pupils are shielded by eyelids or eyelashes 2) The patient wears contact lenses.	1) Require the patient to open the eyes 2) Require the patient to take off the contact lenses
Failure to see the work distance point clearly	1) The intensity of observation lights is too high 2) Eyes fail to align with the camera	1) Lower the light intensity 2) Adjust the camera to achieve correct alignment manually
Light spots appear in the images	4. Orange spots appear around the images 5. Light spots on the left sides of images	1) The distance between the patient's eyes and equipment is too close. Move the objective lens to get away from the patient's eyes

6.	Light spots on the right sides of images	2) Move the objective lens in the left-right direction 3) Move the objective lens in the left-right direction

8   Transport and storage

➢   During the transportation, proper measures shall be taken to protect this equipment from moisture, upside down and violent vibration.

➢   This equipment shall be stored at the well-ventilated room with the relative moisture no higher than 93%, ambient temperature being -40℃ - +55℃ and free of corrosive gases.

➢   Please require workers to lift up the equipment and then move it in case of short-distance movement. In case of long-distance movement, please repack it in the original box and then move it.

9   Environmental protection

During the normal use and maintenance of the equipment, the replaced components or other wastes should be properly disposed according to local laws and regulations and should not be discarded arbitrarily. The equipment should be recycled in accordance with the requirements of local laws and regulations at the end of the service life, to avoid causing environmental pollution.

10   Electro-magnetic compatibility

The design of RetiCam 3100 meets the specifications of EMC standards on the medical electronic equipment -- IEC 60601-1-2 (EN 60601-1-2) Standards, and the equipment shall be installed and used according to the following EMC declaration.

• All parameters set can display normally as expected, all functional keys can work well, and there is no wrong order during operation.

• The chin rest and machine can work well, free from any unexpected movement.

Turning on/off the power supply of this equipment may intervene other equipment. In case of this condition, please adopt the following solutions:

• Re-locate the direction or re-arrange the receiving devices.

• Enlarge the distance between equipment.

• Connect this equipment to the socket of other circuits.

In case where the fault cannot be solved by taking the foregoing measures, please stop using it and consult our after-sales service personnel.

Precautions for EMC

1. Special attention shall be paid to EMC when using medical electronic equipment and such equipment shall be installed and used according to the EMC information provided in this manual.

2. Portable and mobile radio frequency communication equipment may influence the running of medical electronic equipment.

3. Cables that can intervene EMC are as below:

In order to maintain the best EMC performance, please adopt the specialized cables.

Name	Type	Length	Remarks
AC power cord	Non-shielded	Fixed length of 3.0m	Parenthesis
USB cable	Shielded	3.0m at most	Not attached
HDMI cable	Shielded	2.7m at most	Not attached

4. Failure to adopt the specified accessories, energy converters and cables may result in the increase in the electromagnetic radiation quantity or the decline in anti-interference performance of Kestrel 3100m.

5. Never place Kestrel 3100m on the accessories of other equipment or other equipment. If it is mandatory, please check if Kestrel 3100m can work well.

Guidance for Electromagnetic Emission and Manufacturer's Declaration

Kestrel 3100m is especially designed to work in the following specified electromagnetic environment.

Customers or users shall ensure that Kestrel 3100m is used in the following environment.

1) Electromagnetic emission

Emission test	Conformity	Electromagnetic environment - guidance
RF emission GB 4824	1 set	Kestrel 3100m can exert the radio frequency energy when running its internal functions. Therefore, its radio frequency radiation level is quite low, and there is a small chance to

			intervene adjacent electromagnetic equipment.
RF emission GB 4824	Class A		Fundus Camera Kestrel 3100m is intended for use in all facilities/hospital-specific low-voltage power grids that are not directly connected to the public and residential public low-voltage networks.
Harmonic emission GB 17625.1	Not applicable		
Voltage fluctuation/flicker emission GB 17625.2	Not applicable		

2) Electromagnetic immunity

Immunity test	IEC 60601 test level	Conforming level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) GB/T 17626.2	±6kV contact discharge ±8kV air discharge	±6kV contact discharge ±8kV air discharge	The ground shall be paved with wood, concrete or tiles. In case of composite materials used to pave the ground, its relative moisture shall be no lower than 30%.
Electrical fast transient (EFT)/burst pluses GB/T 17626.4	±2kV supply line	±2kV supply line	The network power supply shall be of typical quality applicable to commercial or hospital environment.
Surge (impact) GB/T 17626.5	±1kV line to ground ±2kV line to ground	±1kV line to ground ±2kV line to ground	The network power supply shall be of typical quality applicable to commercial or hospital environment.
Voltage dips, short interruption and voltage variations GB/T 17626.11	$< 5\%U^T$, lasting for 0.5 cycle (Above U_T, > 95% dip) 40% U_T, lasting for 5 cycles (Above U_T, 60% dip) 70% U_T, lasting for 25 cycles (Above U_T, 30% dip) <5%U_T, lasting for 5s (Above U_T, > 95% dip)	$< 5\%U^T$, lasting for 0.5 cycle (Above U_T, > 95% dip) 40% U_T, lasting for 5 cycles (Above U_T, 60% dip) 70% U_T, lasting for 25 cycles (Above U_T, 30% dip) <5%U_T, lasting for 5s (Above U_T, > 95% dip)	The network power supply shall be of typical quality applicable to commercial or hospital environment. If the user wants to run RetiCam 3100 during the power outrage period, it's recommended to adopt uninterruptible power supply (UPS) for powering on Kestrel 3100m.
Power frequency magnetic field (50Hz) magnetic field GB/T 17626.8	3 A/m	3 A/m	Power frequency magnetic fields shall be featured with the power frequency magnetic field level characteristics for typical places in typical commercial or hospital environment.

3) Guidance for Electromagnetic Immunity and Manufacturer's Declaration

Immunity test	IEC 60601 test level	Conforming level	Electromagnetic environment - guidance
			When using portable communication equipment and mobile radio frequency communication equipment, their distance towards any part of Kestrel 3100m (including cables) shall be larger than the recommended distance calculated according to the transmitter's frequency equation. Recommended spacing $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz~800 MHz $d=2.3\sqrt{P}$ 800 MHz~2.5 GHz
RF conduction GB/T 17626.2	3 Vrms 150 kHz~80 MHz	3 Vrms	Wherein, "P" refers to the maximum rated output of transmitter specified by the transmitter's manufacturer, with the unit as watt (W); "d" refers to the recommended distance, with the unit as meter (m).
RF radiation GB/T 17626.3	3 V/m 80 MHz~2.5 GHz	3 V/m	The magnetic field intensity of the fixed radio frequency transmitter shall be same as that determined in the electromagnetic field survey a, and it shall be lower than the standard b at each frequency range. There will be interference when approaching equipment labeled with following symbols:

Comment 1: When the frequency is 80MHz and 800MHz, a higher frequency range shall be applicable.

Comment 2: This guidance may not be applicable to all the conditions. Electromagnetic communication is influenced by the absorption and reflection of buildings, objects, and human bodies.

Recommended Distance between Portable/mobile Radio Frequency Communication Equipment and Kestrel 3100m

Kestrel 3100m is designed especially for using at the controlled electromagnetic environment with radio frequency interference.

Customers and users can maintain one of following recommended minimum distances between portable /mobile radio frequency communication equipment (transmitter) and Kestrel 3100m based on the maximum output of communication equipment, and thus avoid the electromagnetic interference.

Maximum rated output of the transmitter (W) depends on the frequency distance of transmitters (m)	150 kHz~80 MHz $d=1.2\sqrt{P}$	80 MHz~800 MHz $d=1.2\sqrt{P}$	800 MHz~2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For the maximum rated output of transmitter not listed in the foregoing list, it's recommended to adopt isolation distance (d), with the unit of meter (m), which can be determined by the formula concerned with the frequency of corresponding transmitters, wherein, "P" refers to the maximum rated output of transmitter provided by the transmitter manufacturer, with the unit as watt (W).

Comment 1: When the frequency is between 80MHz and 800MHz, a higher frequency range shall be applicable.

Comment 2: This guidance may not be applicable to all the conditions, since the electromagnetic propagation is under the influence of buildings, objects and absorption and reflection of human bodies.

11　Manufacturer's liability

    If any maintenance materials are needed when using this product, including circuit diagrams, component list, legends, calibration rules, please contact our company or the authorized dealers.

    All the parts of this equipment to be replaced, including computer system, air injection device and chin rest can only be provided by our company. If the user adopts the parts that are not provided by the company, it will reduce the degree of minimum security. The users should take the full responsibility for any adverse consequences therefrom.

    This equipment is equipped with built-in computer system, and its internal button battery (CR2032) usually can work for 5 years. In case of any fault during the use, please handle it with the following methods:

    1. When removing button batteries, it's necessary to remove the shell of the equipment (please contact our company or authorized dealers).

    2. Determine if the power of button batteries is run out.

    Measure it with the voltage function of the multimeter, and when the power is lower than 2V, the equipment will fail to work.

    3. Confirm the cathode and anode of button batteries, and then replace them.

    The cathode of button batteries is marked with "+". Replace the button batteries (CR2032) of the same specification and model.

Never use the disposable batteries as rechargeable batteries.

Warranty Statement

Commitment: the factory may provide the necessary data of serviceable equipment parts to be specified by the manufacturer.

1. Our company will provide life-time maintenance and free consultation.

2. If used according to the operation manual, this equipment is offered free warranty for one year from the date of purchase.

3. Maintenance under the following conditions will be charged during the warranty period:

- Damage caused by use, maintenance or storage failing to conform to the operation manual;
- Equipment damage caused by the unauthorized demolition/modification by the operator unauthorized by the company;
- Equipment damage due to accident, misuse, or force majeure.