Optical Biometer
OB12

User Manual

Introduction

Thank you for choosing to use our products, and I would like to express my gratitude. In order to be able to use this equipment rationally, please read the manual carefully before using it.

If you have any doubts or objections to any content or terms of this manual, or encounter technical problems during use, please contact the company or an authorized distributor.

Warning

Please read the instruction manual carefully before use;

When cleaning up the equipment, the AC power supply must be disconnected;

Don’t turn on the device without permission;

In order to avoid the risk of electric shock, this equipment must be connected to a power supply network with a protected grounding;

Indoor use only.

Contents

1 Product introduction

1.1 Product name

Optical Biometer

1.2 Model

OB12

1.3 Range of application/Intended use

It is used to measure the diopter of the cornea, the axial direction of astigmatism, the length of the ocular axis, the central thickness of the cornea, the depth of the anterior chamber, the white-to-white distance, the diameter of the pupil, and calculate the degree of the intraocular lens.

1.4 Contraindications

None.

1.5 Working principle

Optical Biometer is based on the principle of optical low-coherence reflection (OLCR), using a beam of light emitted by a super-bright diode, divided into two beams of light, one beam of light passes through the irradiated eye to obtain backscattered optical signals of different depths of tissue, and the other beam of light passes through the reference arm and is reflected into the optical receptors at the same time. When the two beams of light meet, if the difference in the distance between the two beams of light path is less than the interference length, the optical receptors can measure the interference signal, and the distance measured according to the position of the mirror in the interferometer is equivalent to the optical path from the cornea to the retina.

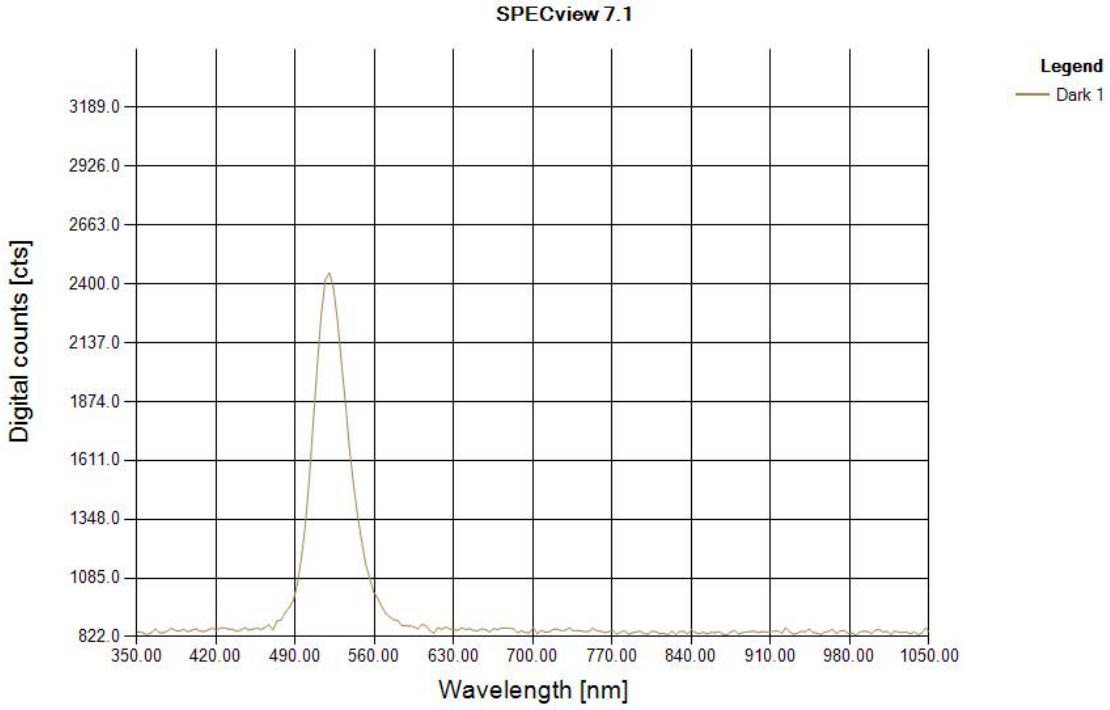
1.6 Technical parameters

1.6.1Performance parameters

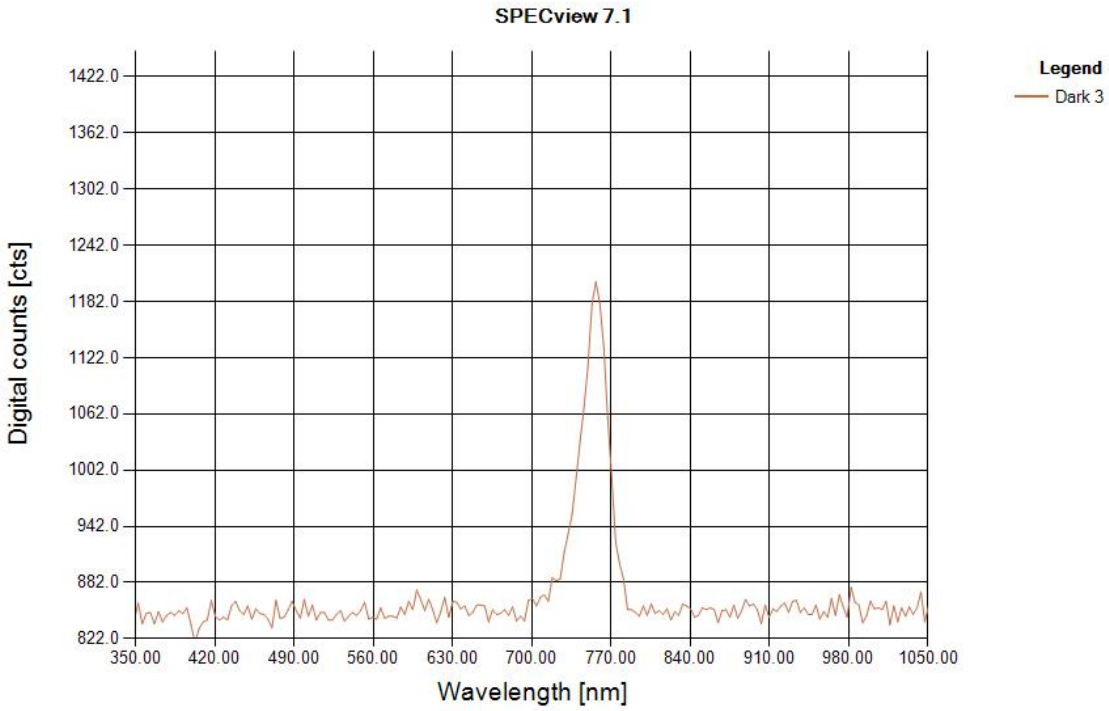
No.	Measurement items	Measuring range	Measurement error	Repeatability
1	Corneal diopter (K)	36.21D～50.60 D	±0.25 D	≤0.13 D
2	Axial astigmatism (AST)	0°～180°	±4°	≤2°
3	Eye axis length (AL)	14 mm～33mm	±0.1 mm	≤0.025 mm
4	Central corneal	200μm～1200 μm	±15 μm	≤10μm

	thickness (CCT)			
5	Front room depth (ACD)	0.7 mm～11 mm	±0.3 mm	≤0.02 mm
6	White to white distance (WTW)	7 mm～16 mm	±0.5 mm	≤0.3 mm
7	Pupil diameter (PD)	2 mm～13 mm	±0.5 mm	≤0.3 mm

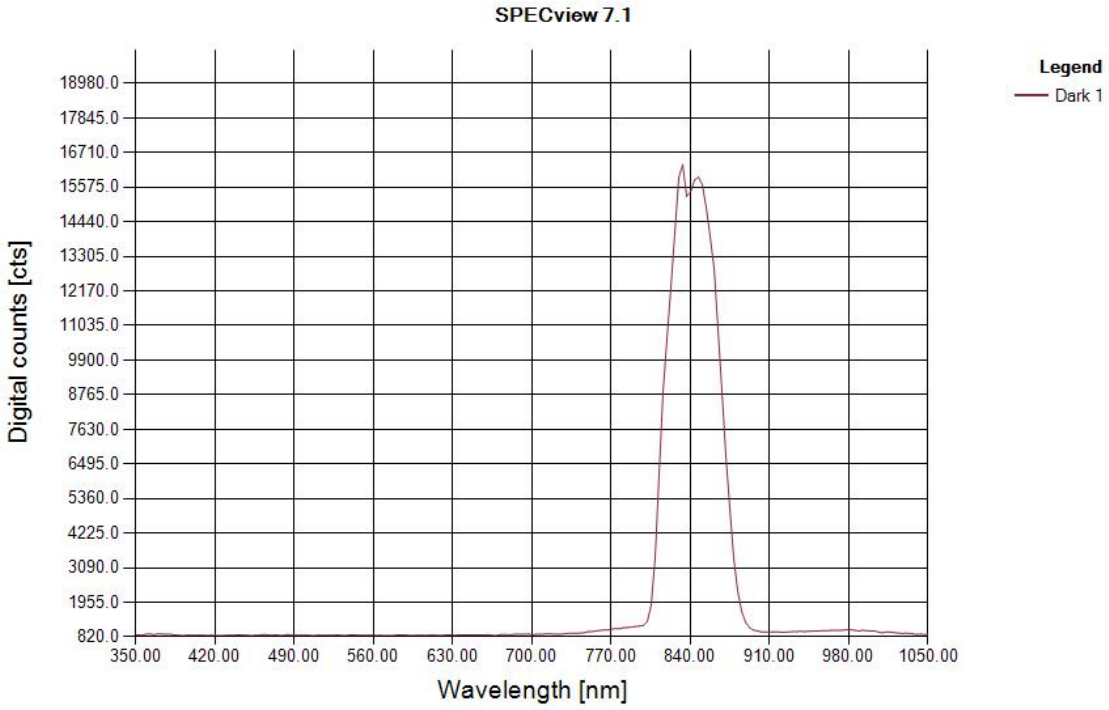
1.6.2 When the device is in the state of maximum light intensity and maximum aperture, the relative spectrum output between the spectral wavelength of 305 nm and 1100 nm is shown in the figure below.



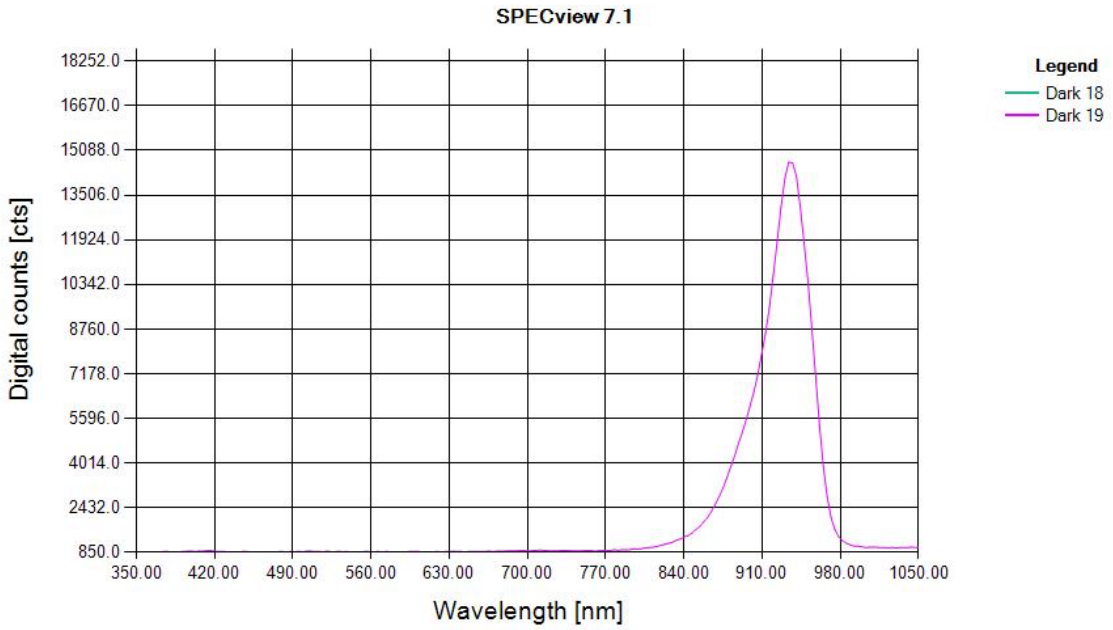
White-to-white measuring light source (525nm)



Curvature measurement light source (765nm)



Ocular axis length measurement and central fixed vision light source (845nm)



IInfrared lighting source (940nm)

1.7 Normal working environment

1) Environmental temperature: +5℃～+40℃

2) Relative humidity:40％～80％

3) Atmospheric pressure: 620 hPa～1060 hPa

4) Power conditions:　220 V～, 50 Hz

5) Typical software operating environment: a) Hardware configuration: CPU is not less than 1.6GHz; memory is not less than 4 GB; hard disk is not less than 120 GB; display resolution is not less than 1280×800.　b) External software environment: Windows 10 operating system and above compatible versions.　c) Network conditions: Network architecture: CS; network type: local area network; bandwidth: more than 100Mbps.

6) Security software: Microsoft Defender 4.18.1909.6 and above compatible versions.

7) External software environment and security software updates: Users cannot update the external software environment and security software by themselves. After verification and confirmation by our company, our staff will update it.

1.8 Product electrical safety features

1) Classify by type of protection against electric shock: class I equipment.

2) Classify by degree of protection against electric shock: type B applied part.

3) Classify according to the degree of protection against liquid ingress: IPX0.

4) Classification by sterilization method: no sterilization requirements.

5) Classification according to suitable for use in oxygen-rich environments: use in non-oxygen-rich environments.

6) Classification by operating mode: continuous operation.

7) The rated voltage and frequency of the equipment: 220 V～, 50 Hz.

8) The input power of the device: 200 VA.

9) Altitude: ≤4000m.

10) Pollution level: 2.

11) Whether it has a signal input/output part: There is a signal input/output part.

12) Application part: chin rest and forehead rest.

13) Basic performance: None.

14) Expected use environment: it is used in medical institutions, such as hospitals, large clinics, and optometry centers, and cannot be used in home care and emergency environments.

1.9 Symbols and labels

	operation instruction		Type B, applied part
	Computer switch		Alternating current
	Connect (main power)		Switch off main power supply.
	network interface		USB interface
	Protect the ground (earth)		fuse
 当心夹手	warning! Beware of clamps	+ -	The built-in computer system battery is loaded into the position, the battery model is: CR2032, where“ "+" is the positive electrode of the battery, “-” is the negative electrode of the battery

	Keep the package away from rain		The package should be moved upright when transported
	Since the transport package contains fragile pieces, please handle with		Indicates that the maximum number of layers for stacking the same

1.10 Cyber security

1.10.1 Interface

1) The software uses a U disk as the storage medium for two-way data transmission with the computer, and the storage format is.dat.

2) The software performs two-way data transmission with the computer through the USB interface, and the transmission protocol is USB2.0.

3) The software performs two-way data transmission with the local area network PACS server through the network interface, and the transmission protocol is DICOM3.0.

1.10.2Access control

The software has a user access control mechanism, and the user name and password are used to log in for authentication and permission restrictions.User types include administrator users, maintenance personnel users, and doctor users.The usage rights corresponding to each user type are shown in the table below.

User type	Usage rights
Administrator	You can create other users, collect data, analyze data, and export data functions.
Repair	Have all permissions and can operate all functions.
User（doctor）	Functions of collecting data, analyzing data, and exporting data.

1.10.3 Expected access to IT-network and precautions

1.10.3.1A valid description of the IT-network confirmed by the PEMS manufacturer

1) The purpose of PEMS connecting to the IT-network: local area network PACS service.

2) The characteristics required by the IT-network connected to PEMS: limited coverage, high transmission rate, low bit error rate and high security.

3) The configuration required for the IT-network connected to PEMS: see 3.6.1 for details.

4) Technical specifications for PEMS network connection: support 10/100M rate, full-duplex and half-duplex adaptive; data security specifications: operating system firewall, local area network access control list and local area network encryption technology.

1.10.3.2 Precautions

1) The equipment is used for risk control through user authorization and password verification. This product does not need to be connected to the IT-network during use, nor does it need to be upgraded.

2) Users should not connect to the IT-network by themselves to prevent it from affecting the normal use of the software.If you need to connect to the IT-network for data transmission, users need to identify, analyze, evaluate and control the risks that the network has not identified in the past.

3) You must use a virus-free and secure USB flash drive for data copying.

4) Users cannot modify the IT-network connection without authorization, which may introduce new risks.

5) IT-network changes include:

●IT-network configuration changes

●New items for connecting to IT-network

●Items whose connection to the IT-network is interrupted

●Update of equipment connected to the IT-network

●Upgrade of equipment connected to IT-network

To set up an IT-network connection, please contact the device administrator.

1.11 Device installation

1.11.1 Hardware installation

In order to ensure the safe and stable operation of the equipment, please ensure a good installation environment:

1) This equipment must be installed in a clean, quiet and dry environment, on a flat table without a slope.

2) This equipment needs to install a dedicated ground wire.

3) Open the packaging box, remove the foam inside, and the two work together to lift the

equipment out.

1.11.2 Software installation

Software name: Biometer software

Software model:

Software release version: V 1.2

1.11.2.1Software installation, configuration, maintenance

This software is free of installation of the green version, unzip the file to the D disk and you can use it.The software does not need to be configured and basically does not require maintenance.When there is new software that needs to be upgraded, just reinstall the new software; viruses, serious misoperation, or hardware system failures may damage the software system of the device.If the software system is severely damaged, please unzip the software again.

1.11.2.2 Software backup

After the software check is completed, the data file will be.The dat format is stored in the software installation folder, and the contents of the entire installation folder can be backed up.The default directory of the system software is “D:\albio\dbfs ”.

1.11.2.3 Software uninstall

Open“D:\albio "Delete this folder after the directory, and the uninstall is complete.

1.12 Service life

Calculated based on 10 hours of continuous work per day, 365 days a year, or 100 patients per day, the use period of this product is 10 years.

1.13 The name and address of the supplier

2 Product structure

2.1 Structure composition

Ophthalmic optical biometer consists of a console, a power cord and external control software.

2.2Part diagram

D

2.3 Part Description

- Computer switch

The computer switch controls the start and shutdown of the internal computer of the device.The computer switch will not cut off the total power supply of the equipment. If the equipment is not in use for a long time, it is recommended to turn off the power switch.

- Power switch

The power switch controls the connection and disconnection of the power supply of the equipment, "|" is the connection, and "○" is the disconnection.The power cord interface is the connection port of the external power cord.Next to the power cord interface is the fuse.

- Display

The display screen provides an interactive interface for device operation. Users can preview inspection results, manage medical record data, etc. through the display screen.

- External interface

Network interface: RJ-45 Ethernet interface, following the IEEE 802.3 standard.

USB interface: a total of 4 interfaces, using the USB 2.0 standard, supporting devices with USB 2.0 or above protocols, and can be connected to an external keyboard, mouse or printer.

- Chin bracket

The mandibular support device automatically adapts to the body shape and face shape of different patients by adjusting up and down.The tensile safety factor of the support device is 6 (minimum fracture load 30 kg, safe working load 5 kg, chin support safety factor: minimum fracture load/safe working load=30kg/5kg=6).

- HDMI interface

Used to extend the connection of the display.

Note: When used with external equipment, the external equipment should meet the requirements of IEC 60601 series, IEC 60601-1-2 and IEC 62368-1.All external equipment cannot cause the basic performance and basic safety of this product to be reduced.

3 Basic operation

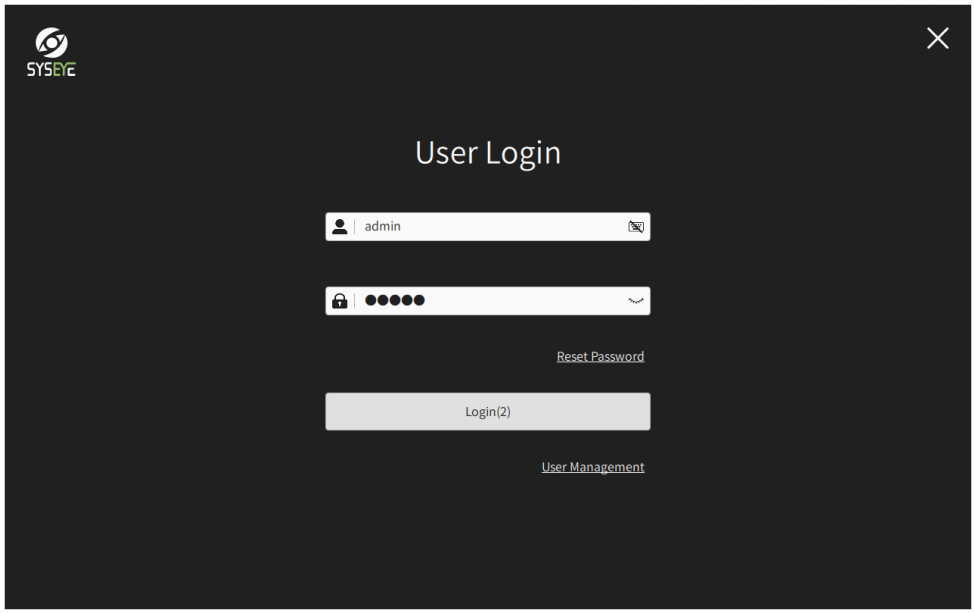
This chapter introduces the basic operation process of the inspection procedure of the ophthalmological optical biological biometer (note: the operation of this product should be operated by professionally trained, qualified and authorized personnel).

Measurement accuracy:

1.Optical Biometer are only used for sitting posture/sitting position;
2.Incomplete cornea, the measurement data obtained may be inaccurate;
3.Make sure you don't bring contact lenses before measuring;
4.Cannot measure patients who cannot fix their eyes normally;
5.Severe lens turbidity, vitreous bleeding, and stellate vitreous lesions may make the length of the ocular axis impossible to measure;
6.The central cornea is opaque and may not be able to measure the thickness of the cornea, the depth of the anterior chamber, and the length of the ocular axis;
7.The curvature measurement of the cornea of the eye that has undergone refractive surgery may be wrong;
8.The white-to-white distance only provides a rough indication of the actual internal horizontal size of the first section;
9.This product has not been verified on special eyes (false crystal eyes with different IOLS, non-crystal eyes, silicone oil filled eyes), and there may be a risk of inaccurate measurement when measuring these special eyes.

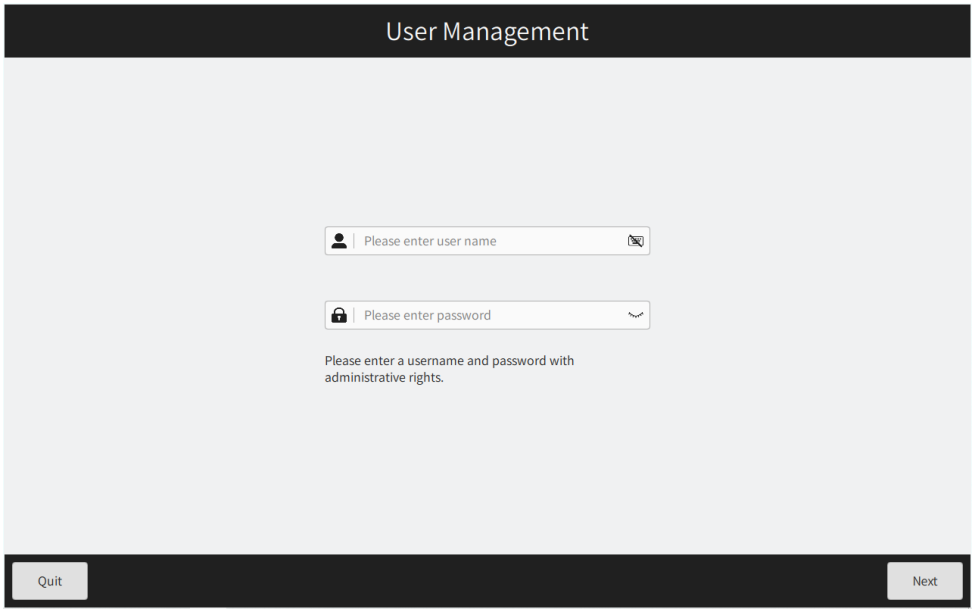
3.1 User login

User login, enter username and password, click “Login”.



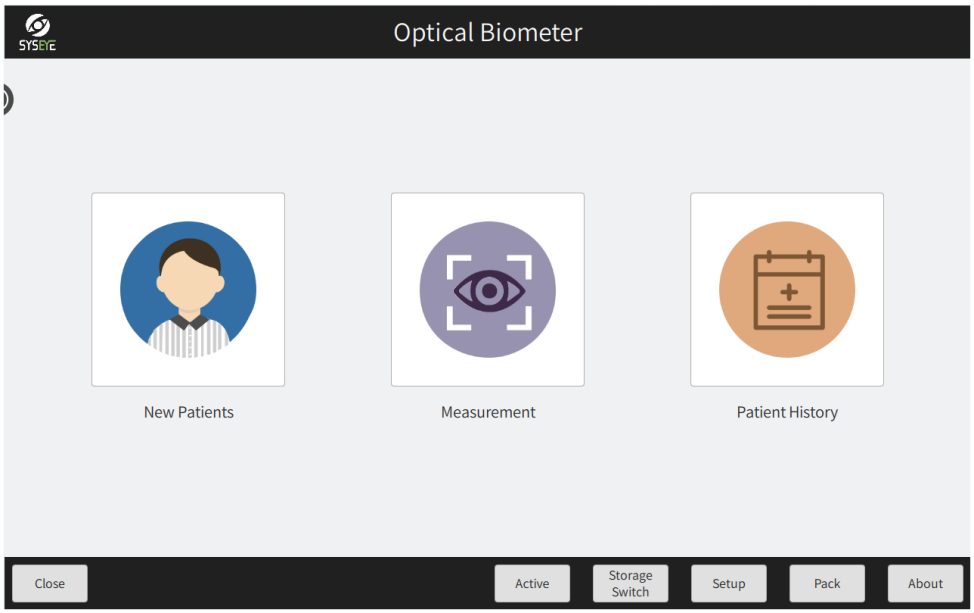
In this interface, you can create, delete, or browse user information.To create a new user,

delete, or browse all user information, you need to log in with an administrator account.Default administrator: admin, password: admin.



The software should have an account number and password to identify the user's identity, user type and permissions. The user types include Administrator (administrator), Repair (maintenance personnel), and User (doctor). The user rights are administrator rights, maintenance personnel rights, and doctor rights.Administrator (Administrator): You can create other users, collect data, analyze data, and export data functions; Repair (maintenance personnel): Have all permissions and can operate all functions; User (doctor): Collect data, analyze data, and export data functions.

After successfully logging in, enter the homepage of the user interface.

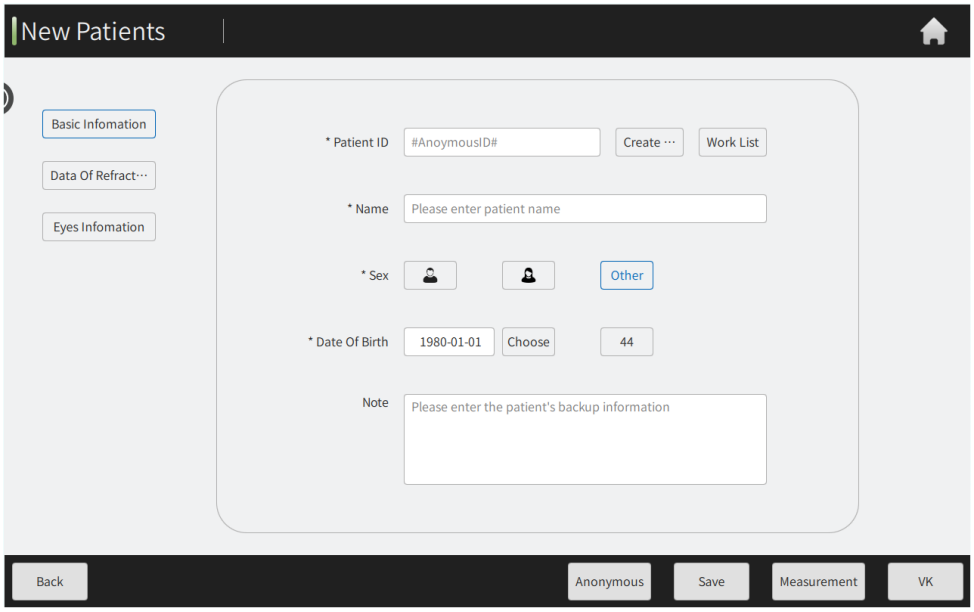


- Active: used for factory settings, according to the customer's purchase needs, the software for configuring lite equipment is only carried out by our staff;
- Storage Switch: Select the default storage location of the measurement data (local/U DISK);
- Pack: Restore the hardware to its original position for easy packaging and packing.

3.2 Information entry

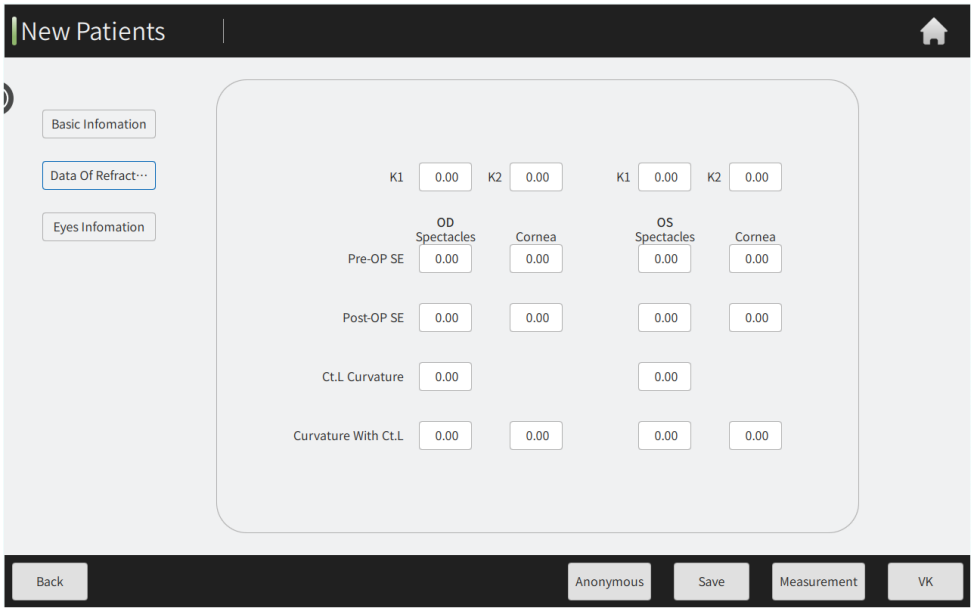
3.2.1 New Patients

Click the “New Patients” icon to enter the New patient interface, enter the relevant information and click “Save”.



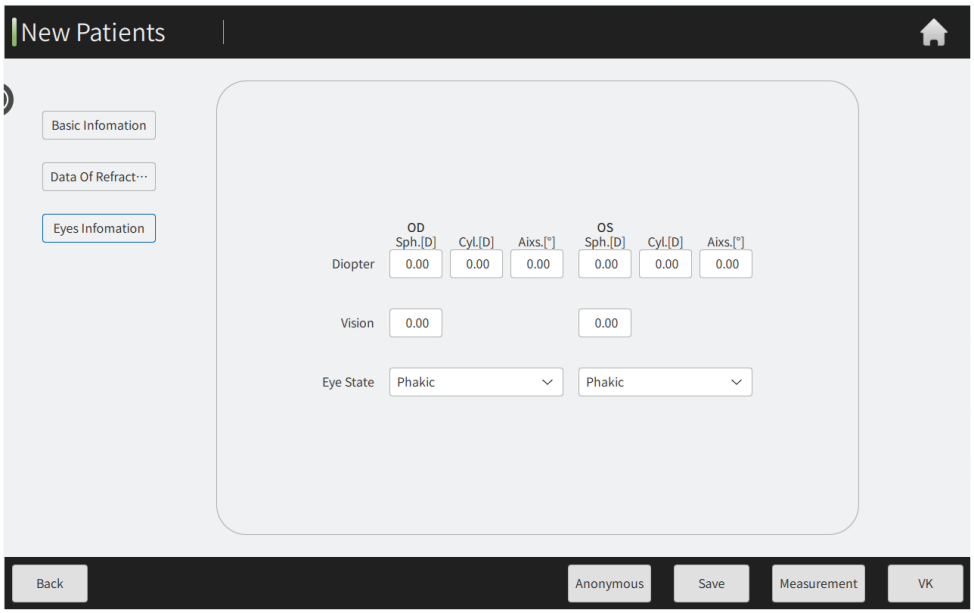
Description of the meaning of the icon：			
Generate PID	No need to enter patient information, randomly generate ID	Worklist	Transfer patient information from the information system of the medical institution (if any)
Scan code	Scan the QR code from the scanning equipment of the medical institution (if any) to obtain patient information.		

Enter the “New Patients” interface and click “Data Of Refractive Surgery Eye”. According to the actual situation of the patient, the doctor enters K1 (corneal diopter-flat corneal curvature), K2 (corneal diopter-steep corneal curvature), preoperative refractive, postoperative refractive, contact lens curvature, and curvature after wearing contact lens.



Description of the meaning of the icon：			
OD	Right eye	K1	Corneal diopter-flat corneal curvature
OS	Left eye	K2	Corneal diopter-steep corneal curvature

Click “Eyes Information”, the doctor enters the diopter, vision, and eye status of both eyes (with lens/without lens) according to the actual situation of the patient, and clicks “Save”.

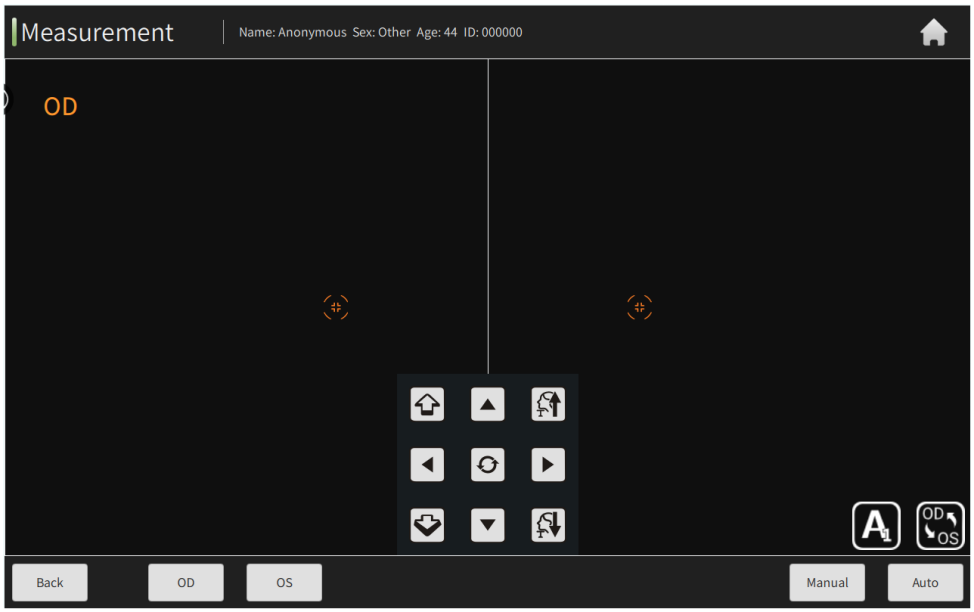


Description of the meaning of the icon：			
Sph.	Ball mirror	CyL.	Column mirror
Aixs.	Axial	OD/OS	Right eye/left eye

3.3 Data measurement

3.3.1 Preparation before measurement

Click  icon to enter the start measurement interface to collect data.



Description of the meaning of the icon：			
	Back to main menu		reset
	Upper (three-dimensional motion system)		Rise (chin support)
	Next (three-dimensional motion system)		Drop (chin support)
	Left (three-dimensional motion system)		Front (three-dimensional motion system)
	Right (three-dimensional motion system)		Rear (three-dimensional motion system)

3.3.2 Patient position adjustment

1) The patient's jaw is placed on the chin rest, his forehead is close to the forehead rest, and his eyes are fixed on the front.

2) Eye selection: right eye/left eye.

3) Chin support adjustment: Click   , align the patient's eyes parallel to the eye position line of the chin support.

3.3.3 Manual alignment

1) Click  , adjust the alignment, and basically move the patient's eyes to the center of the screen, so that the two alignment orange signs are placed in the middle of the pupil.

2) Adjust  the front/rear arrows to align the alignment point with the pupil.

Description of the meaning of the icon：			
OD	Show right eye	OS	Show left eye
	Upper (three-dimensional motion system)		On the cheek pads
	Next (three-dimensional motion system)		Under the gills
	Left (three-dimensional motion system)		The head of the machine rises
	Right (three-dimensional motion system)		The head of the machine down

3.3.4 Start measuring

Click “Manual” to enter the measurement interface.

Description of the meaning of the icon：			
K1	Corneal diopter-flat corneal curvature	K2	Corneal diopter-steep corneal curvature
AST	Axial astigmatism	AL	Eye axis length
CCT	Central thickness of the cornea	ACD	Front room depth
WTW	White to white distance/corneal diameter	PD	Pupil diameter

LT	Crystal thickness	VT	Vitreous thickness
lx/ly	Eccentricity of the center of the visual axis relative to the center of the cornea	Px/Py	Eccentricity of the center of the visual axis relative to the center of the pupil
CWC	Eccentric distance	/	/

Note: LT, VT, lx, ly, Px, Py, CWC measurements do not display values, this function is reserved.

When the center of the pupil of the subject eye is fixed in the center of the ring, focus on the center focus; click the “Measure” button.

If you need to take another eye, click “Left eye”/“Right eye” (the other side of the eye position where the eye position starts by default), please repeat the above steps.

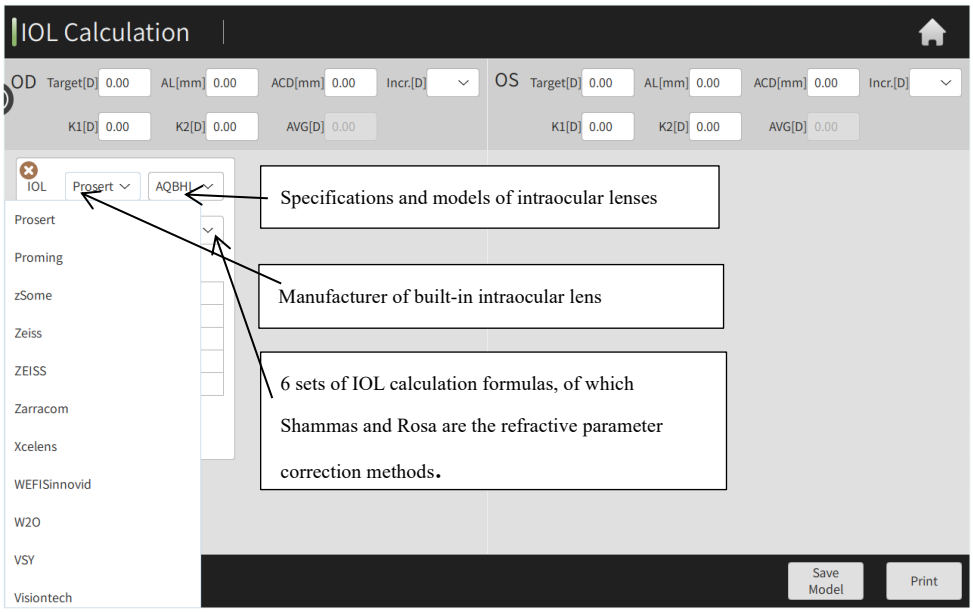
3.3.5 Fully automatic alignment

Click “Auto”, the device will automatically complete the alignment, focus, and automatically complete the binocular data measurement.

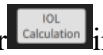
3.3.6 Calculate the degree of intraocular lens

3.3.6.1 IOL calculation

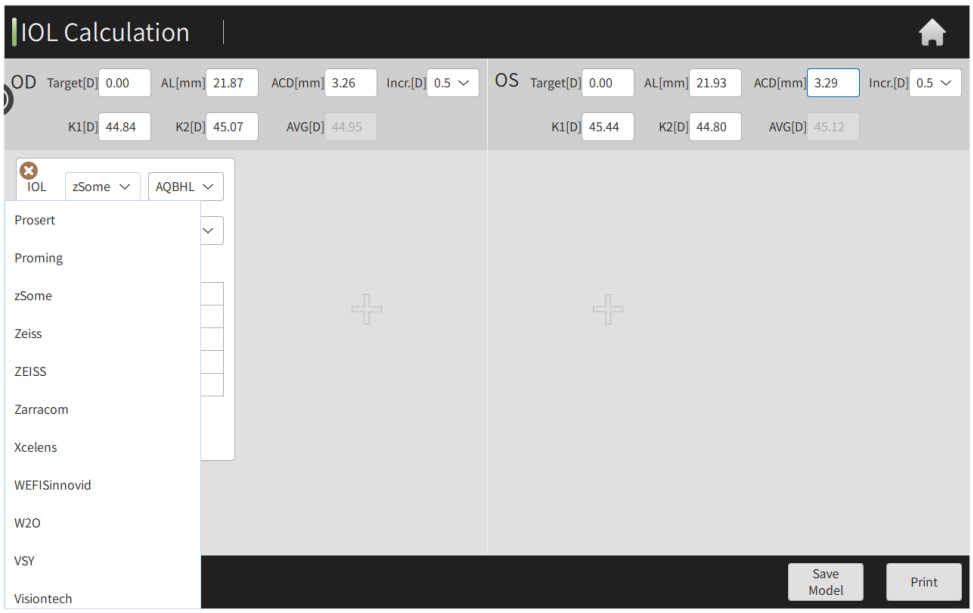
Enter  interface, if all measured values have been measured (including AL, ACD, K1, K2 and AVG), according to the different needs of the patient after surgery or surgery, fill in the target diopter and increment values, and perform various intraocular lens degree calculation operations, click  icon, enter the IOL calculation interface.



3.3.6.2 IOL parameter setting

Enter 

interface, click  , and enter the list parameters, target diopter, ocular axis length, anterior chamber, cornea, and eyeball; select the corresponding crystal type and formula according to your needs, and calculate.The degree of the corresponding implanted intraocular lens is automatically calculated and a list of IOL calculation results is displayed.

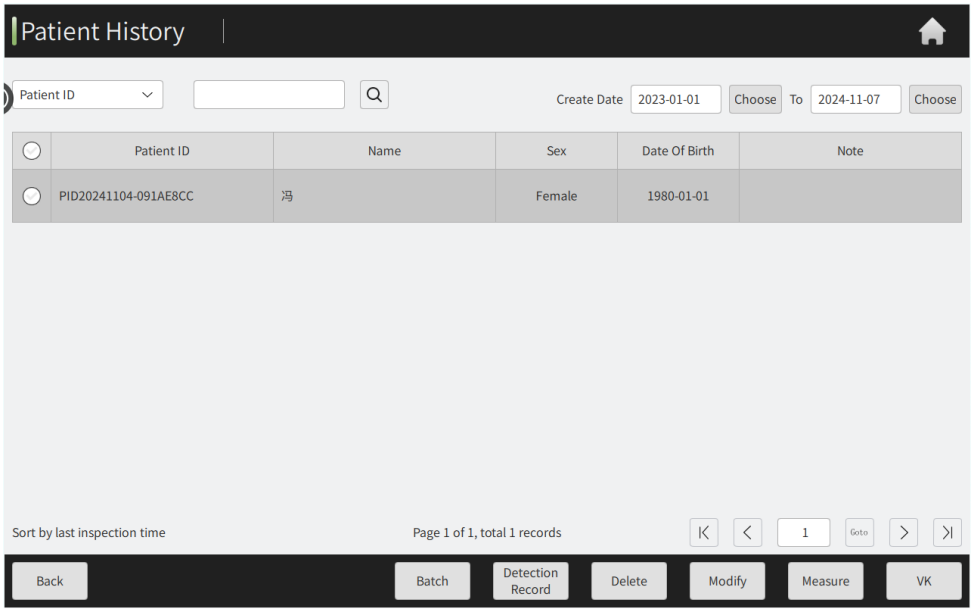


3.4 Data management

3.4.1 Inspection records

Click  icon, enter the information management interface, enter the query information and click  , select the patient in the results, and then select the “Detection Record” button at the bottom right to view the patient's medical records.You can also choose other retrieval methods

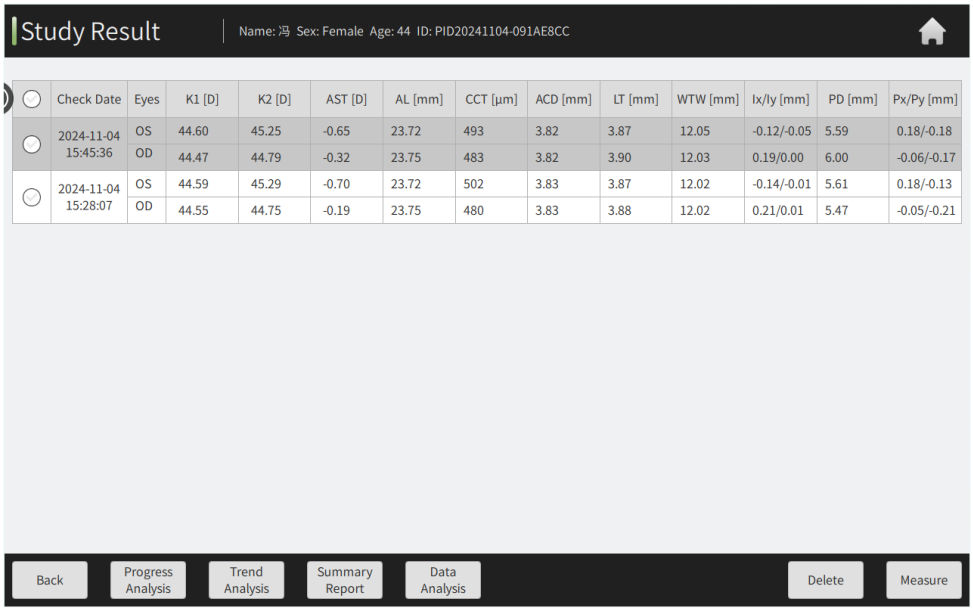
as needed: such as recent inspections.



- Batch: select multiple patients (or patient records for a certain period of time) for data export and deletion.
- Detection Record: After selecting the patient, click “Detection Record” to enter the data analysis interface.
- Delete: After selecting the patient, click “Delete” to delete all the data of the selected patient.
- Modify: After selecting the patient, click “Modify” to modify the basic patient information.
- Measure: After selecting the patient, click "Measure” to quickly enter the measurement interface for review.
- VK: click to display/close the keyboard in the interface.

3.4.2 Detection results

Enter and selecte patient, click “Detection Record”, and enter the examination results page.The system provides a variety of indicators to help the inspector evaluate the reliability of the test results of the subject's eye measurement.Indicators include: K1 (corneal diopter-flat corneal curvature), K2 (corneal diopter-steep corneal curvature), AST (astigmatism axial direction), AL (ocular axis length), CCT (corneal central thickness), ACD (anterior chamber depth), WTW (white to white distance), PD (pupil diameter).

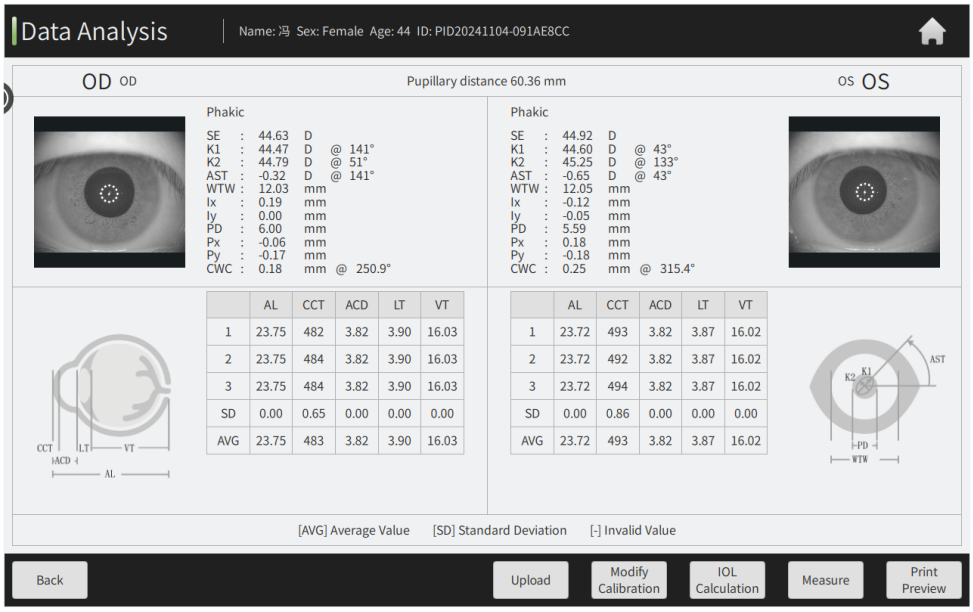


- Progress Analysis: Select a number of examination data of patients in different time periods, and click “Progress Analysis” to view the trend of examination data in each time period.
- Trend analysis: This button is gray, and this function is reserved.
- Summary Report: Select a number of examination data of the patient on different dates, and click “Summary Report” to display the selected examination data on a report page for easier viewing. □
- Data Analysis: see the description of 3.4.3 for details. □
- Delete: Click this button to delete the selected check result.
- Measure: Click this button to jump to the measurement interface to review this patient.

Note: The trend analysis function is gray, and this function is reserved.

3.4.3 Data analysis

Enter the inspection record page and click “Data Analysis” to view and analyze data, upload data, print and preview reports, etc.

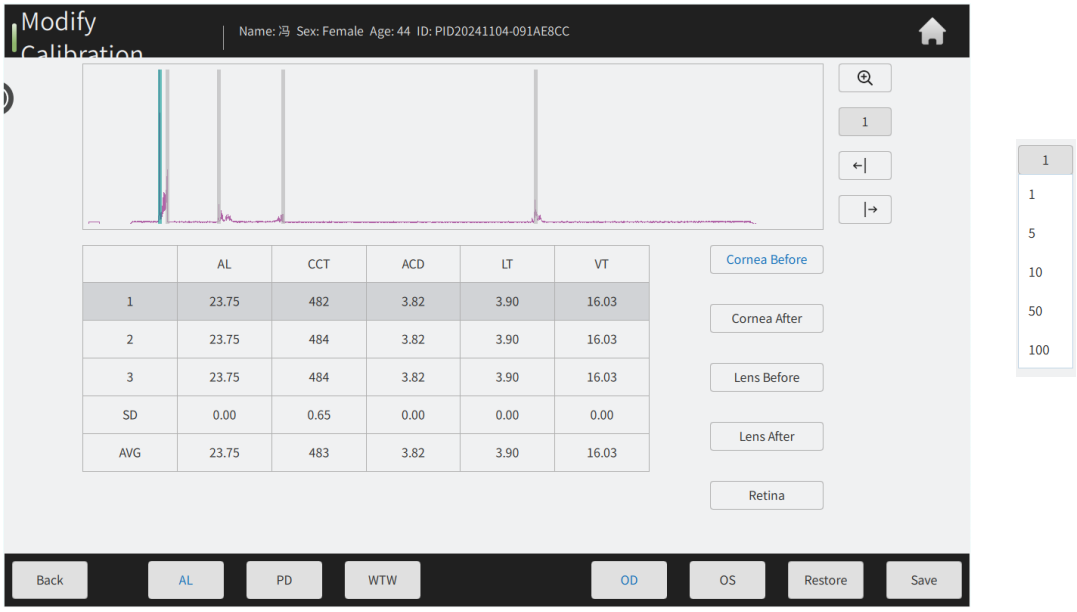


- Upload: Upload the check record to the designated DICOM server.
- Modify Calibration: You can choose the type of calibration you want to modify: eye axis length, pupil diameter, white-to-white distance.
- IOL Calculation: Click this button to enter the IOL calculation interface;
- Measure: Click this button to enter the measurement interface;
- Print Preview: Click this button to enter the print preview interface.

Click “Modify Calibration” to enter the modify calibration interface.

1) Eye axis length calibration modification:

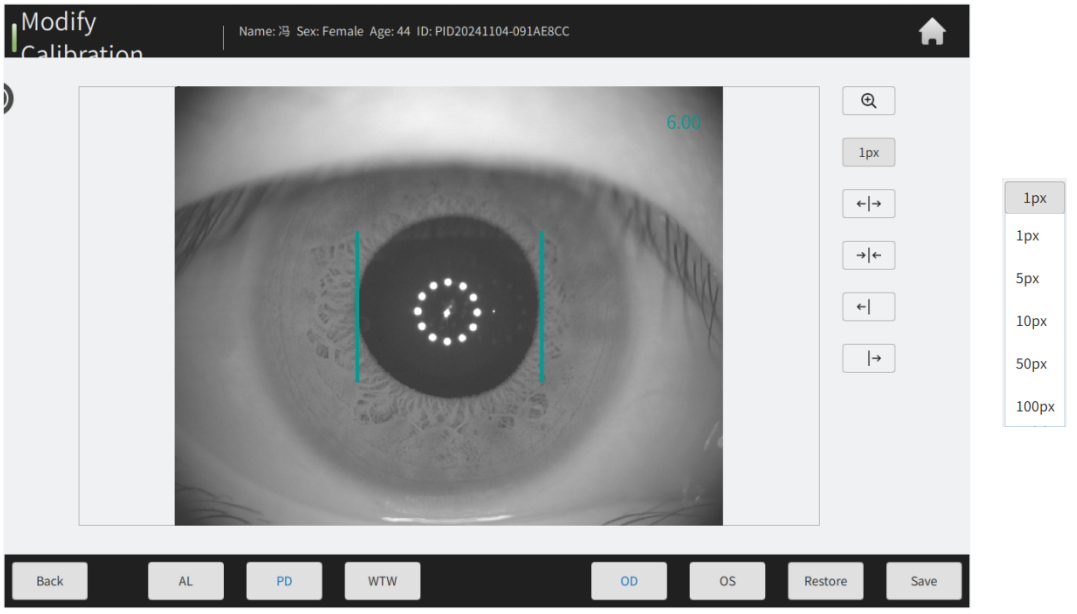
Click “AL” to enter the ocular axis length calibration modification interface. The first set of measurement data is selected by default. You can choose to modify the calibration position of the anterior corneal/posterior corneal/anterior crystal/posterior crystal/retina, click to enlarge the waveform, select the step size and click the tool button to move the position of the calibration line so that it coincides with the peak of the wave.Click the save button to save the revised result, and the AL\CCT\ACD value will be recalculated.Click restore to discard the corrected result.



Description of the meaning of the tool button:			
1	Step size selection button, you can select the step size of the calibration line movement: 1 pixel/time, 5 pixels/time, 10 pixels/time, 50 pixels/time, 100 pixels/time.		
←|	The calibration line moves to the left	|→	The calibration line moves to the right

2) Pupil diameter calibration modification:

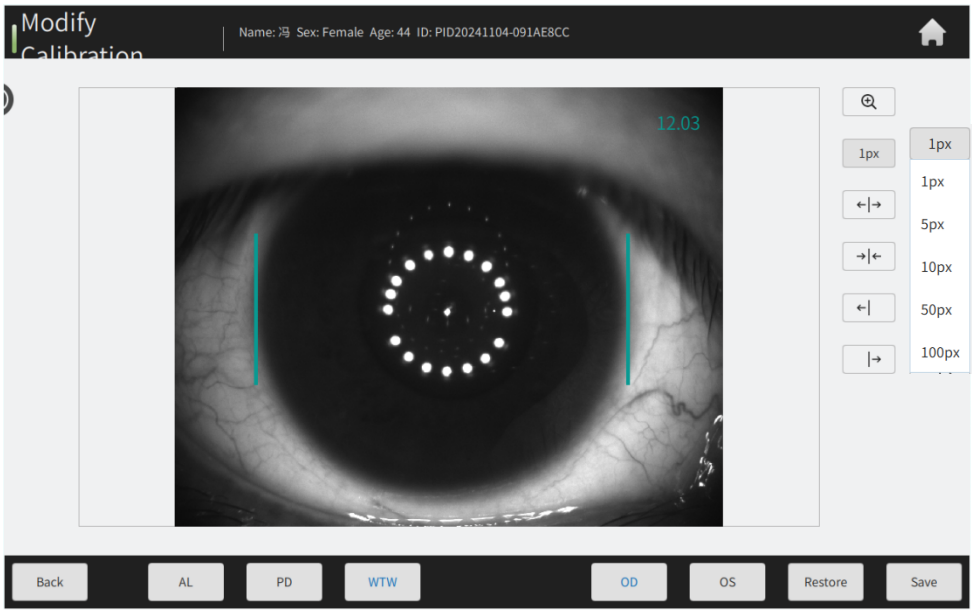
Click “PD” to enter the pupil diameter calibration modification interface, and click to enlarge the image.Select the step size (1 pixel/time, 5 pixels/time, 10 pixels/time, 50 pixels/time, 100 pixels/time;), click the tool button, you can correct the pupil diameter result.Click the save button to save the revised result, click Restore to discard the revised result.



Description of the meaning of the tool button:			
←|→	Increase the spacing between the two calibration lines.	←|	The two calibration lines move to the left synchronously.
→|←	Reduce the spacing between the two calibration lines.	|→	The two calibration lines move to the right synchronously.

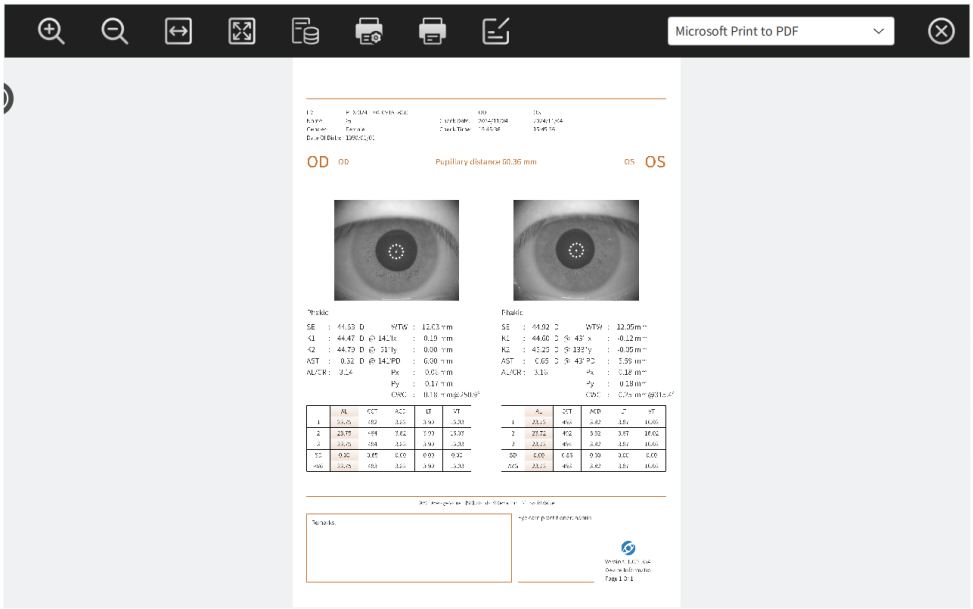
3) White-to-white distance calibration modification:

Click “WTW” to enter the white-to-white distance calibration and modification interface. The method is the same as the pupil diameter calibration and modification method.



3.5 Print output

Click Print Preview, you can browse the report form of the inspection results, click on the print preview interface to choose to print the report form.



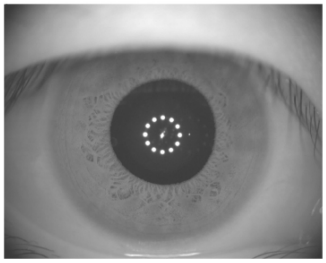
(Eye clear format)

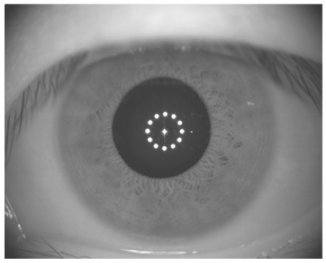
Description of the meaning of the icon:			
	Page zoom in		Widescreen display
	Page zoom out		Show the full page of the report
	Report upload		Print settings
	Direct printing		Close preview

ID: PID20241104-091AE8CC

		OD	OS
名字:	冯	检查日期: 2024/11/04	2024/11/04
性别:	女性	检查时间: 15:45:36	15:45:36
出生日期:	1980/01/01		

OD 右眼 Pupillary distance 60.36 mm 左眼 OS





有晶状体

SE : 44.63 D
K1 : 44.47 D @ 141°
K2 : 44.79 D @ 51°
AST : -0.32 D @ 141°
AL/CR : 3.14

WTW : 12.03mm
Ix : 0.19 mm
Iy : 0.00 mm
PD : 6.00 mm
Px : -0.06 mm
Py : -0.17 mm
CWC : 0.18 mm@250.9°

	AL	CCT	ACD	LT	VT
1	23.75	482	3.82	3.90	16.03
2	23.75	484	3.82	3.90	16.03
3	23.75	484	3.82	3.90	16.03
SD	0.00	0.65	0.00	0.00	0.00
AVG	23.75	483	3.82	3.90	16.03

有晶状体

SE : 44.92 D
K1 : 44.60 D @ 43°
K2 : 45.25 D @ 133°
AST : -0.65 D @ 43°
AL/CR : 3.16

WTW : 12.05mm
Ix : -0.12 mm
Iy : -0.05 mm
PD : 5.59 mm
Px : 0.18 mm
Py : -0.18 mm
CWC : 0.25 mm@315.4°

	AL	CCT	ACD	LT	VT
1	23.72	493	3.82	3.87	16.02
2	23.72	492	3.82	3.87	16.02
3	23.72	494	3.82	3.87	16.02
SD	0.00	0.86	0.00	0.00	0.00
AVG	23.72	493	3.82	3.87	16.02

[AVG] 平均值 [SD] 标准偏差 [-] 无效数值

注释:

操作者签名: admin

型号: 1.0.2.354
设备信息: Study
第1页，共1页

(Mode format)

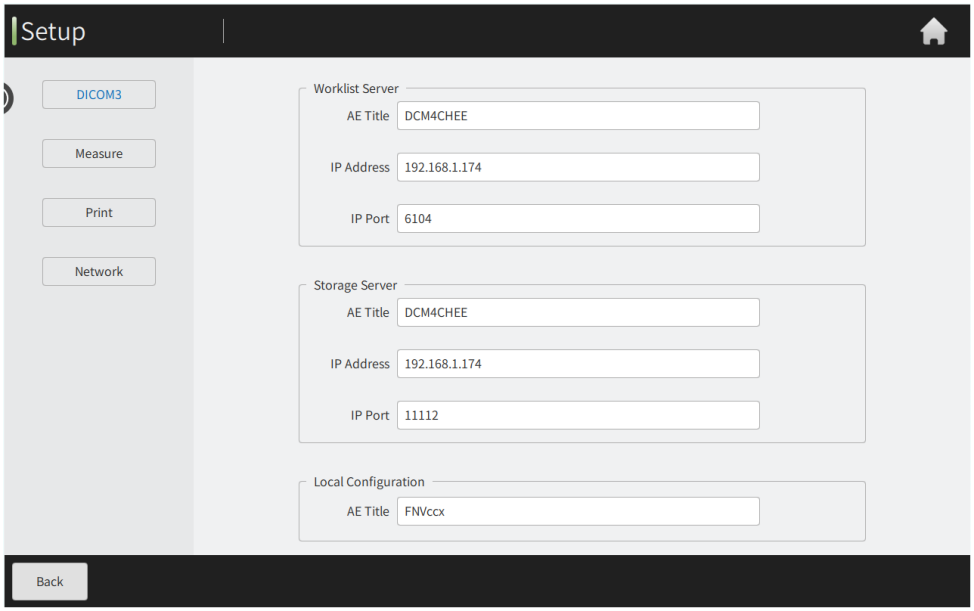
3.6 Parameter setting

Enter the main login interface, select 

settings, and the system can modify the parameters of the settings.

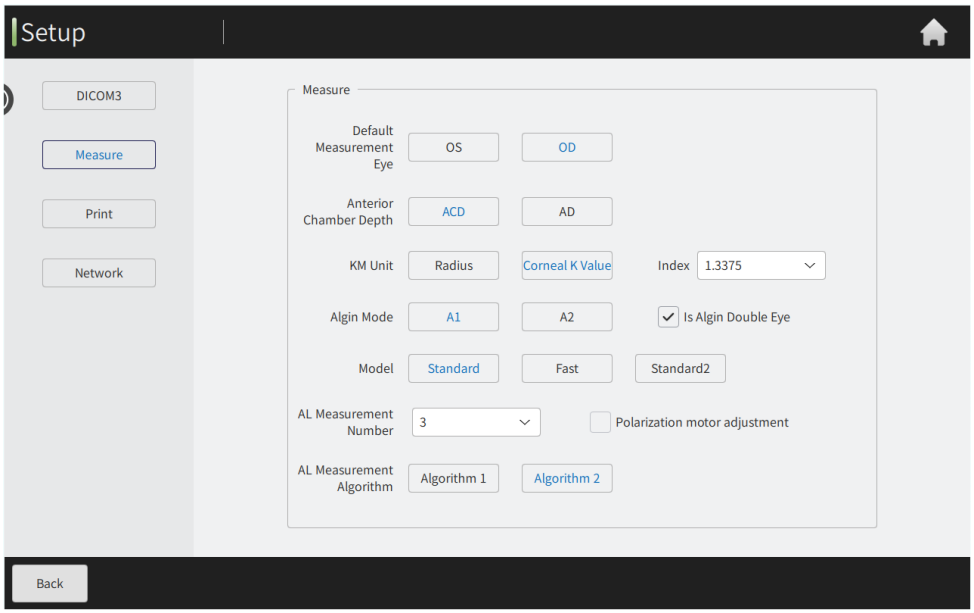
3.6.1 DICOM3 setting

Various parameters such as server IP address can be set.



3.6.2 Setting of measurement parameters

Parameters such as eye position at the beginning of the inspection and the number of measurements of eye axis length can be set.



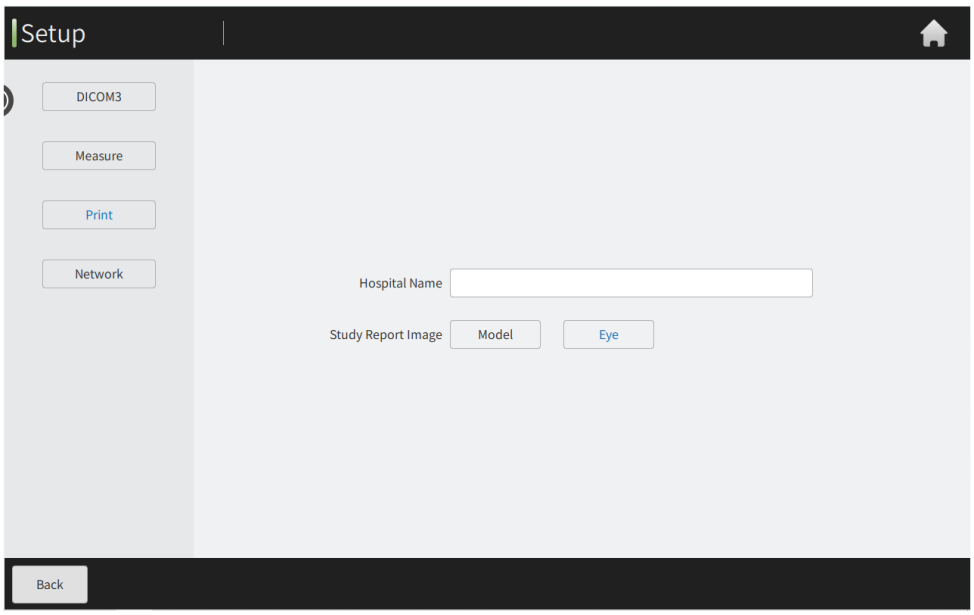
- Anterior Chamber Depth: ACD contains CCT, AD does not contain CCT.
- KM Unit: the radius of curvature unit is "mm“, the corneal diopter value unit is ”D", and the

refractive index is 1.3375.

- Algin Model: A1 mode, the lens moves back and forth to recognize the pupil position; A2 mode, the cheek rest automatically adjusts up and down to recognize the pupil; the alignment mode can be switched according to the size of the patient's face in the measurement interface.You can choose whether to align your eyes.
- Model: standard (default measurement speed), fast (fast measurement speed), standard 2 (slower speed than standard).
- Polarization motor adjustment: only operated by professionals, used in cases where calibration is required.
- AL Measurement Algorithm: 1, 2, 3, 4, and 5 are optional.

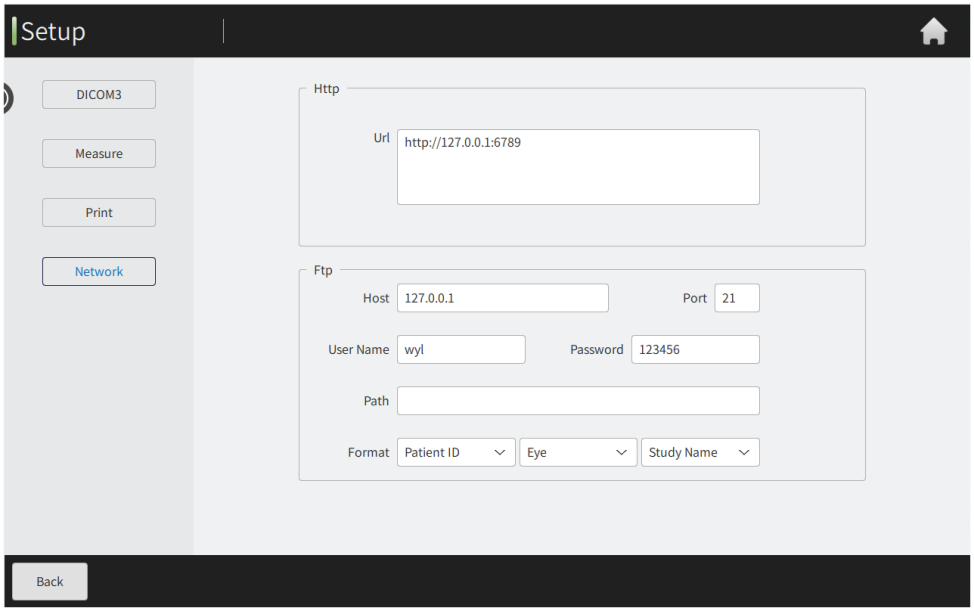
3.6.3 Print setting

You can set the hospital name and print the report display format.



3.6.4 Network setting

Various parameters such as network connection address can be set.



3.7 Shut down

Click the “Back” button on the main interface and select “Turn off the computer”. The device will exit the program and turn off the computer, turning off the power switch.

Measures to safely disconnect the equipment from the power supply network: turn off the power switch, remove the power connector, and unplug the power plug.

Warning: Do not place the device in a position where it is difficult to operate the disconnection device. If the plug of the power supply cannot be disconnected immediately in an emergency, please make sure that the wall socket connected to the power supply of the device can be reached by hand at any time.

4 Cleaning, maintenance and preventive inspection

4.1Cleaning and Disinfection

1) Chin support, forehead support

The patient's contact area is equipped with a disposable gills support paper; please replace it for next use after the examination is completed.Replacement method: The user first removes the buckles at both ends of the fixed cheek pads, installs the disposable cheek pads, and then installs the buckles.

Note: The material of the patient's contact part: the chin rest is plastic and the forehead rest is rubber.

2) Display screen

The user first wet the soft cloth with a little water, and then dry the surface with a soft flannel-

free cloth.

3) Other external surfaces

Users can use a soft flannel-free cloth dipped in a small amount of water for cleaning.

4) Treatment of reuse

Disinfection of chin rest and forehead rest: The user will dip the cotton pad with 75% medical disinfection alcohol and wipe it for disinfection.The action time is not less than 3 minutes.Number of reuses: Disinfect before and after each use.

5) Cleaning and disinfection cycle

Some users who come into direct contact with patients should be cleaned and disinfected before use; it is recommended to clean the whole machine once a month.

Note: Users should pay attention to waterproofing when cleaning. The flannel-free cloth can be moistened but not dripping water to prevent any liquid from entering the equipment.

4.2 Replacement and repair

4.2.1 Fuse

1) Turn off the power switch and unplug the power cord.

2) Remove the fuse holder with a phillips screwdriver.

3) After replacing the new fuse, install the fuse holder.

4) Please choose a fuse tube (T2AL250V) of the same model, specification and rating.

4.2.2 Button battery

1) The positive electrode of the button battery is marked with "+" and the negative electrode is marked with “-”.

2) Replace the button battery (CR2032) of the same specification and model.

Note: Replacement and maintenance need to be completed by professionally qualified personnel.

4.3 Preventive inspection

1) Basic safety inspection

Check the chin rest, forehead rest, whether the assembled parts are firm and the operation is normal; whether the power cord is loose, falling off or the line is damaged, etc.If so, please contact our company or an authorized distributor.It is recommended to do it once a month.

2) Function check

Whether the power switch and buttons are normal; check whether the indicator lights are normal after turning on; if so, please replace them in time.Enter the software to check whether the basic functions are normal.If the software is abnormal, please contact the company or an

authorized distributor to obtain the latest version of the software upgrade.It is recommended to do it once a month.

5 Precautions

1) Do not use this equipment in flammable, explosive, high temperature and dusty environments. The equipment should be used indoors.

2) Keep the equipment clean and dry.

3) Before use, please check whether all wires are connected correctly and firmly, and make sure that the equipment is well grounded.

4) Please use a fuse tube that meets the specified type and rating of this equipment.The configured fuse tube is T2AL250V.When replacing the fuse tube, the power supply should be cut off first.

5) Please use the dedicated power cord configured by this device.

6) Do not place body parts such as fingers, hair, etc. on the moving parts of the equipment, otherwise there will be a risk of injury.

7) The equipment should be installed on a flat plane to avoid dumping of the equipment.

8) When the equipment is not in use, the power supply should be cut off first, and then a dust cover should be put on.

9) If a failure occurs, please contact the company or an authorized dealer.

10) When used by patients, it is forbidden to maintain the equipment.

 Warning: Recommendations to avoid or reduce interference---Other medical equipment and equipment that must be installed and used in the same environment must comply with the same electromagnetic compatibility principles.Equipment that cannot be installed or has poor electromagnetic compatibility must be installed at least 3 meters away from the equipment and must be powered by a different power cord.

6 Common faults and causes

If a problem occurs, please check the table below to try to resolve the cause of the problem.If the problem is still unresolved, please contact our company or an authorized distributor.

Problem	Possible reasons	Solution
Unable to start normally	The power cord is not connected correctly	Check the connections to see if they are loose
	The power switch is in the "○" position	Place the switch in the "|" position
	The fuse is blown	Replace the fuse of the same specification and model
The display does not display	The cable is loose and the display screen is broken	Tighten the loose connection and replace the display screen
Open the software, Image not showing	Computer system failure, computer poisoning, loose wiring	Reinstall the operating system, anti-virus, check the wiring, and unplug the cable again

7 Transportation and storage

- All equipment should be moisture-proof, anti-inverted storage, and avoid severe vibration during transportation.
- This equipment should be stored in an ambient temperature range of -40℃～55℃, relative humidity range≤85%, atmospheric pressure range: 620hPa～1060hPa, non-corrosive gas and well-ventilated indoor.
- If the equipment needs to be moved for a short distance, please carry it carefully by hand; if the equipment needs to be transported for a long distance, it should be reloaded into the original packaging before being transported.
- There are random accessories, please check after receiving the goods.

No.	Product name	Quantity	Unit	Note
1	Console	1	unit	
2	Power cord	1	piece	
3	Fuse	2	pc	
4	Manual	1	serving	
5	Certificate of conformity	1	sheet	
6	Warranty card	1	sheet	

8 Environmental protection

During the normal use and maintenance of this equipment, the replaced components or other waste should be properly disposed of in accordance with the requirements of local laws and regulations, and cannot be discarded at will.At the end of the life of the equipment, it should be recycled in accordance with the requirements of local laws and regulations.So as not to cause pollution to the environment.

The materials used in this equipment are ABS resin, metal, 2A12 alloy, 304 stainless steel, optical glass lenses, etc.During its expected service life, corrosion, aging, mechanical wear or degradation of biological materials caused by bacteria, plants, animals, etc. will not reduce the mechanical properties of the equipment.

9 Electromagnetic compatibility

1. Equipment group classification

According to the national standard CISPR 11, it belongs to a group of class A equipment.

2. The function of evaluating the immunity test results

Under the test conditions specified in IEC 60601-1-2, the following requirements should be met:

1) The parameters can be displayed normally as expected, and the normal functions of each button should not fail.

3. Electromagnetic emission

Guidance and Manufacturer's Statement - Electromagnetic Emissions		
Optical Biometer is expected to be used in the electromagnetic environment specified below. The purchaser or user should ensure that it is used in this electromagnetic environment:		
Emission test	Conformity	Electromagnetic environment – guidance
RF emission CISPR 11	Group 1	Optical Biometer uses radiofrequency energy only for its internal functions. Therefore, its RF emissions are very low and have a low potential to cause interference in nearby electronic equipment.
RF emission CISPR 11	Class A	Optical Biometer is suitable for use in non-domestic and residential public low-voltage power supply networks that are not directly connected to the optical Biometer.
Harmonic emission IEC 61000-3-2	N/A	
Voltage fluctuation/flicker emission IEC 61000-3-3	N/A	

4. Electromagnetic immunity

Guidance and Manufacturer's Statement - Electromagnetic Immunity			
Optical Biometer is expected to be used in the electromagnetic environment specified below. The purchaser or user should ensure that it is used in this electromagnetic environment.			
Immunity test	IEC 60601test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact discharge	±6 kV contact discharge	Floors should be wood, concrete or ceramic tiles, and

	±8 kV air discharge	±8 kV air discharge	if they are covered with synthetic materials, the relative humidity should be at least 30%.
Electrical fast transient (EFT)/burst pluses IEC 61000-4-4	±2 kV power cord	±2 kV power cord	Mains power should be of a quality typically used in a commercial or hospital environment
Surge (impact) IEC 61000-4-5	±1 kV line to line ±2 kV line to ground	±1 kV line to line ±2 kV line to ground	Mains power should be of a quality typically used in a commercial or hospital environment.
Voltage dips, short interruption and voltage variations IEC 61000-4-11	<5%U_T, lasting 0.5 cycles (On U_T, >95% dip) 40% U_T for 5 cycles (On U_T, 60% dip) 70% U_T for 25 cycles (On U_T, 30% dip) <5% U_T for 5 s (On U_T, >95% dip) Note: U_T is the AC network voltage of 220 V before the test voltage is applied.	<5%U_T for 0.5 weeks (On U_T, >95% dip) 40% U_T for 5 weeks (On U_T, 60% dip) 70% U_T for 25 weeks (On U_T, 30% dip) <5% U_T for 5 s (On U_T, >95% dip) Note: U_T is the AC network voltage of 220 V before the test voltage is applied.	Mains power should be of a quality typically used in a commercial or hospital environment. If the user of the optical Biometer requires continuous operation during a power outage, it is recommended that the optical Biometer be powered by an uninterruptible power supply.
Power frequency magnetic field (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should have power frequency magnetic field level characteristics typical

			of a typical location in a typical commercial or hospital environment.

5. Electromagnetic immunity - for non-life support equipment and systems

Guidance and Manufacturer's Statement - Electromagnetic Immunity			
The optical Biometer is expected to be used in the electromagnetic environment specified below. The purchaser or user should ensure that it is used in this electromagnetic environment.			
Immunity test	IEC 60601test level	Compliance level	Electromagnetic environment – guidance
RF conduction IEC 61000-4-2 RF radiation IEC 61000-4-3	3 V (Valid values) 150kHz～80MHz 3V/m 80MHz～2.5GHz	3 V (Valid values) 3V/m	Portable and mobile RF communications equipment should not be used closer to any part of the optical Biometer, including cables, than the recommended isolation distance. This distance should be calculated by the formula corresponding to the frequency of the transmitter. Recommended isolation distance: $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz～800MHz $d=2.3\sqrt{P}$ 800MHz～2.5GHz in formula: P—Maximum transmitter output power rating in watts according to transmitter manufacturer(W); d—Recommended isolation distance in meters (m); The field strength of fixed RF transmitters is determined by a survey of the electromagnetic field and should be lower than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol.

Note 1: At 80MHz and 800MHz frequencies, the formula for the higher frequency band is used. Note 2: These guidelines may not be suitable in all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and human bodies.
A: The field strengths of fixed transmitters such as base stations for wireless (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts, and television broadcasts cannot be predicted with theoretical accuracy. To assess the electromagnetic environment of fixed RF transmitters, a survey of the electromagnetic field should be considered. If the measured field strength of the location where the optical Biometer is located is higher than the above radio frequency compliance level, the optical Biometer should be observed to verify its normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the optical Biometer. B: In the entire frequency range of 150kHz-80MHz, the field strength should be less than 3V/m.

6. Recommended isolation distance between portable and mobile radio frequency communication equipment and optical Biometer - For non-life support equipment and systems

Recommended isolation distance between portable and mobile radio frequency communication equipment and the optical Biometer			
The optical Biometer is intended for use in an electromagnetic environment with controlled radiofrequency radiation disturbance. Based on the maximum output power of the communication equipment, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between portable and mobile radio frequency communication equipment (transmitter) and the optical Biometer as recommended below.			
Maximum rated output power of the transmitter W	Isolation distance corresponding to different frequencies of transmitter/m		
	150kHz～80MHz $d=1.2\sqrt{P}$	80MHz～800MHz $d=1.2\sqrt{P}$	800MHz～2.5GHz $d=2.3\sqrt{P}$
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 with maximum rated output power not listed in the above table, the recommended isolation distance d, in meters (m), can be determined using the formula in the corresponding			

transmitter frequency column, where P is provided by the transmitter manufacturer Transmitter maximum output power rating in Watts (W).
Note 1: At frequencies 80 MHz and 800 MHz, the formula for the higher frequency range is used.
Note 2: These guidelines may not be suitable in all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and human bodies.

7. Installation environment

The optical Biometer is used in non-domestic and residential public low-voltage power supply networks that are not directly connected to the optical Biometer. The power socket should have reliable protective grounding measures, and use the supplied power cords, components and accessories. Floors should be wood, concrete or ceramic tiles, and if they are covered with synthetic materials, the relative humidity should be at least 30%. Other equipment used simultaneously near this equipment should comply with electromagnetic compatibility requirements.

For the possible effects of portable and mobile radio frequency communication equipment on the optical Biometer, see “6 Recommended isolation distance between portable and mobile radio frequency communication equipment and the optical Biometer” for details.

The optical Biometer is limited to the use of accessories randomly matched by the manufacturer (see the list of accessories) and components.When using these accessories (list of accessories) and components, they meet the requirements of IEC 60601-1-2.

Equipment operation in a specific environment may cause radio frequency interference.

⚠Warning: Except for accessories and cables sold by the manufacturer of the device as spare parts for internal components, the use of accessories and cables other than those specified may result in increased emissions or reduced immunity of the device.

⚠Warning: Use of unspecified accessories or cables with the device may result in increased emissions or reduced immunity of the device.

⚠Warning: The equipment should not be used close to or stacked with other equipment. If it must be used close to or stacked, it should be observed to verify that it can operate normally under the configuration it is used in.

⚠Warning: Use of equipment in the vicinity of marked  equipment may cause interference

and/or performance degradation related to basic performance and safety.

⚠Warning: This device is not used in a residential environment and cannot provide sufficient protection for radio reception in this environment.

8. List of accessories

No.	Name	Model	Parameter
1	power cable	D1-3	10 A, 250 V～0.75 mm² Cable length 2.0 m unshielded

10 Manufacturer's Responsibilities

1) The company is only responsible for the impact on the safety of the equipment in the following cases:

—Assembly, addition, commissioning, modification or maintenance are all carried out by approved personnel.

—The electrical facilities in the relevant room meet the relevant requirements.

—The correct operation of the instrument is used in accordance with the requirements of the instruction manual.

2) When using this product, users need relevant maintenance information, such as circuit diagrams, component lists, drawing notes, correction rules, etc., please contact the company or an authorized distributor.

All parts that need to be replaced by this equipment, such as computer systems, display screens, etc., can only be provided by our company.If the user adopts components that are not provided by the company, the minimum safety level will be reduced and the adverse consequences will be caused. The user shall bear the responsibility.

⚠Warning: Modification of this equipment is not allowed.

⚠Warning: Do not modify this equipment without the authorization of the manufacturer.

⚠Warning: If you modify this equipment, you must conduct appropriate inspections and tests to ensure that the equipment can continue to be used safely.

Warranty statement

Commitment: The company can provide the information necessary for the designated repairable equipment parts.

1.The company provides equipment maintenance and free consultation for life.

2.From the date of purchase, the equipment shall be guaranteed for one year free of charge under the premise of complying with the instruction manual of this book.

3.During the warranty period, repairs will be charged for the following conditions:

●Damage caused by failure to use, maintain, or keep in accordance with the instruction manual.

● Damage to equipment caused by unauthorized disassembly/modification by personnel authorized by the company.

● Damage to equipment caused by accidents, incorrect use, or irresistible natural factors.