

Portable Fundus Camera

Instruction Manual

Please read the instruction manual before using the product

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Portable Fundus Camera

In order to better use this instrument, please read the instruction manual carefully before use.

General safety requirements

Please read the following precautions carefully to prevent product damage and possible dangers.

Equipment classification

According to the classification standard of medical electrical equipment according to GB9706.1-2007 standard,

1) Classification according to the type of protection against electric shock: Class II internal power

supply equipment 2) Classification according to the degree of protection

against electric shock: Type B 3) Classification according to the degree of protection against

liquid intrusion: ordinary equipment 4) Classification according to flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide

Classification of safety level during use: non-AP or A PG equipment 5) Classification by

operating mode: continuous operation

Precautions

1. Do not use this instrument in flammable, explosive, high-heat and dusty environments; it should be used indoors. And pay attention to keep the product clean and dry.

















Usage environment: Temperature: 10 °C~40°C; Relative humidity: ≤90%; Air pressure: 500hPa ~1060hPa

2. Please note the ratings of all electrical connection ports.
3. The special power cord provided with this instrument should be used.
4. Do not touch the surface of optical parts with hands or hard objects
5. When the instrument is not in use, it should be shut down and covered with a dust cover.
6. If a malfunction occurs, please contact our company's authorized dealer or our company's maintenance department.
7. Other medical instruments and equipment that must be installed with the same use must comply with the same electromagnetic compatibility in principle.
8. Before using this product, you need to wear gloves that comply with "GB/T 10213-2019 Disposable Medical Rubber Examination Gloves".

Graphics, symbols and warning signs on the product

According to the GB 9706.1-2007 standard, the following graphics are used on the product. Symbols and signs, their specific

See the table below for meaning explanation:

Serial number	graphics/symbols/marks	Schematic description
1		Classification according to the type of protection against electric shock is Class II electrical equipment
2		Classified as type B equipment according to the degree of protection against electric shock
3		alternating current
4		direct current
5		USB interface
6		Information storage card interface
7		photo button
8		Off button
9		Diopter compensation positive and negative adjustment indication
10		Battery positive identification
11		Battery negative pole identification
12		Note, consult the accompanying documentation
13		Identifiers for electrical and electronic equipment according to Directive 2002/96/EC Number. Equipment, accessories and packaging must be properly disposed of after use reason. Please refer to relevant local laws.
14		up
15		Fragile items
16		Afraid of rain

1. Scope of application

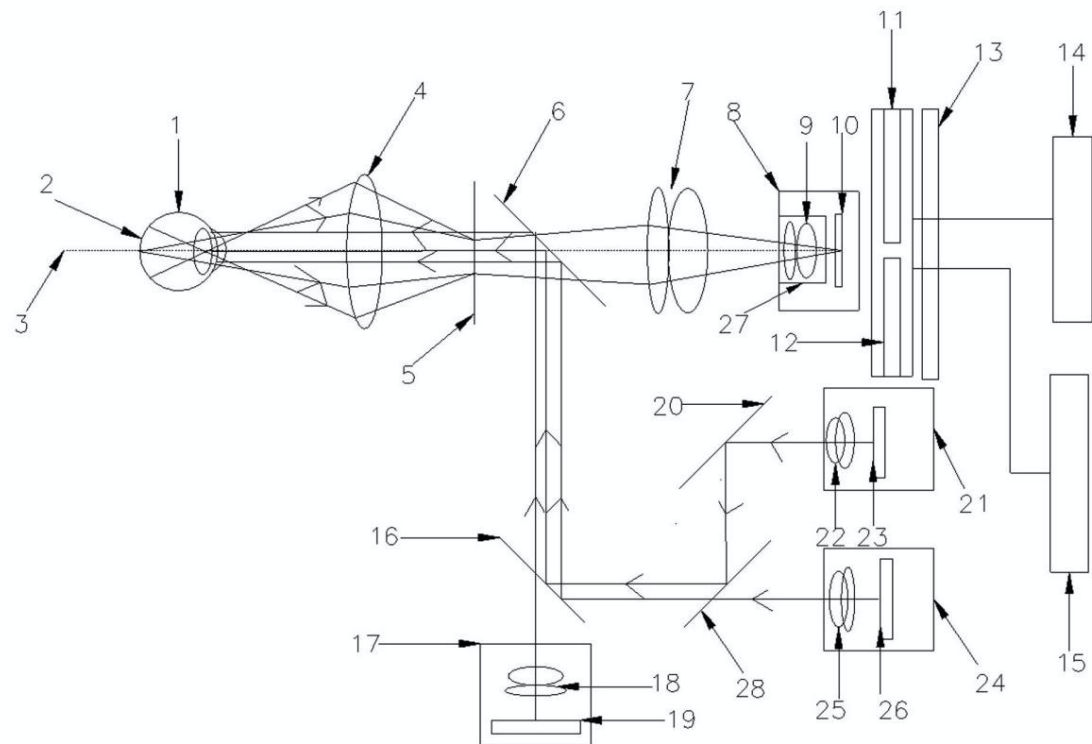
The portable fundus camera is suitable for observing and photographing the patient's fundus to obtain retinal images without the need for pupil dilation.

2. Structural composition

The portable fundus camera consists of a host (including lighting system, imaging system, electronic control processing system, and display system), base, eyepiece, and charging accessories.

3. Working principle

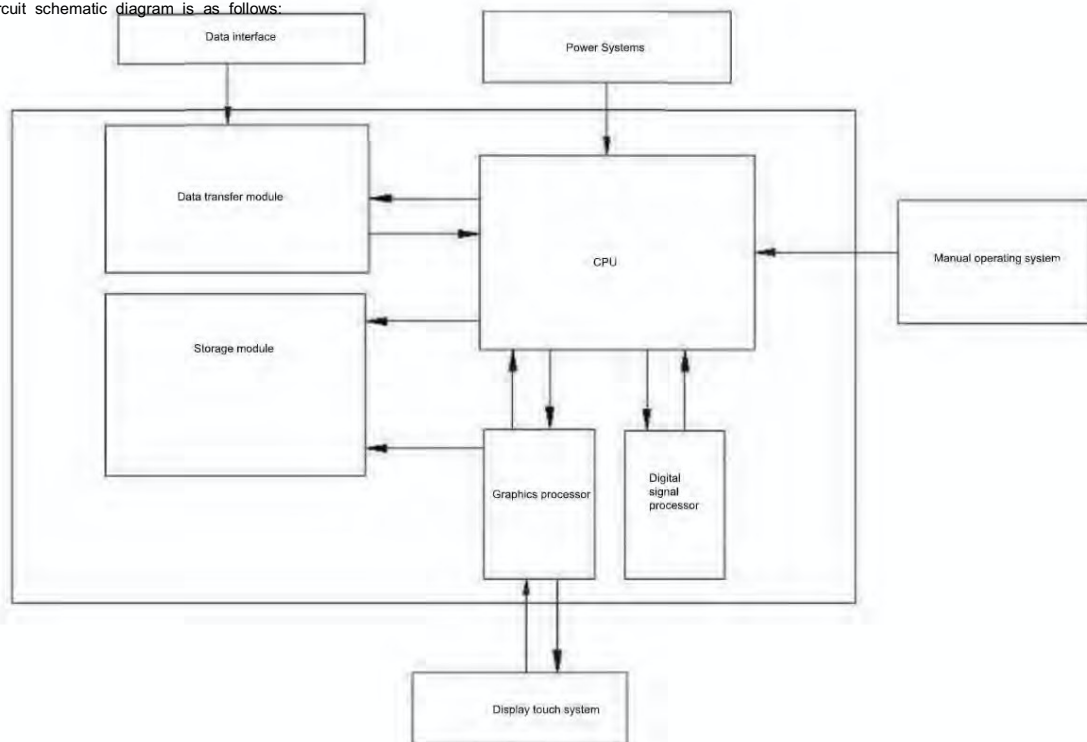
The fundus camera is based on the principle of the Goldmann non-reflective indirect ophthalmoscope. The exit pupil of the lighting system coincides with the entrance pupil of the camera system, so that the reflected light from the cornea and lens does not enter the camera system, thereby obtaining clear fundus images.



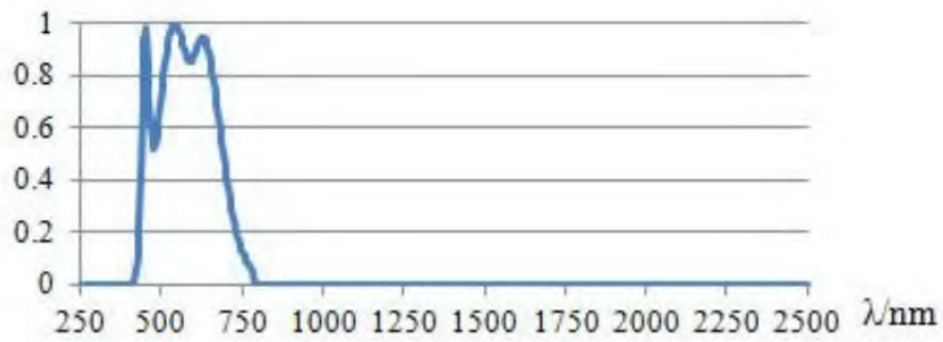
- 1: Observed eye
- 2: Fundus
- 3: Optical axis of main imaging optical system
- 4: Eyepiece objective lens
- 5: Focal plane 1
- 6: Beam splitter 1
- 7: Rear lens group
- 8: Manual and automatic focusing components
- 9: Focusing lens group

- 10: Photosensitive element
- 11: AI artificial intelligence hardware processing platform
- 12: Data transmission system
- 13: Display touch system
- 14: Manual control system
- 15: Power system
- 16: Beam splitter 2
- 17: Flash assembly
- 18: Flash lens group
- 19: Flash board
- 20: Beam splitter 3
- 21: Fixation light assembly
- 22: Fixation light lens set
- 23: Fixed light panel
- 24: Infrared light assembly
- 25: Infrared light lens group
- 26: Infrared light board
- 27: Focus motor

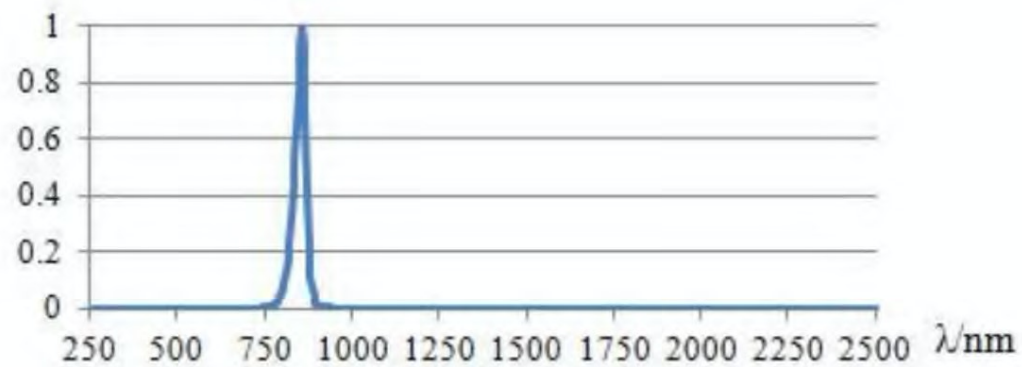
The circuit schematic diagram is as follows:



Relative spectral output diagram of light source:




Relative spectral output graph (flash)




Relative spectral output chart (infrared light)

4. Specifications

Technical Parameters

parameter name	CFC-X
field of view	45°
working distance	24mm
resolution	Center of field of view ≥ 60 lp/mm
	At the middle of the field of view (r/2) ≥ 40 lp/mm
	Edge of field of view (r) ≥ 25 lp/mm
Field of view tolerance	$\pm 7\%$
Refractive compensation range	$\geq \pm 15D$
Photographic flash correlated color temperature	$4500K \leq T_c \leq 6700K$
Equipment input power	0.4A
Charging power supply voltage	100-240V 
Charging power frequency	50-60Hz

Internal supply voltage	3.6V 
Dimensions	210X130X210(mm)
Host weight	<500g

5.Electromagnetic compatibility information

With this equipment, special precautions are taken regarding electromagnetic compatibility (EMC) and must be installed and used according to the electromagnetic compatibility information specified in this manual.

Portable and mobile radio frequency communications equipment may affect this device.

Except for cables (transducers) sold as spare parts for internal components, use of accessories and cables other than those specified Cables (transducers) may cause increased emissions or reduced immunity of the device or system.

Equipment or systems should not be used close to or stacked with other equipment. If they must be used close to or stacked, they should be observed and verified to function normally in the configuration in which they are used.


Guidance and Manufacturer's Statement - Electromagnetic Emission		
equipment is intended for use in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment:		
Emission Test	Conformity	Electromagnetic Environment - Guidance
Radio Frequency Emission GB 4824	Group 1	The device uses RF energy only for its internal functions and, therefore, its RF emissions are low and have a minimal potential to cause interference in nearby electronic equipment
RF emissions GB 4824	Category B	
Harmonic radiation GB 17625.1	Class A	
Voltage fluctuation/flicker emission GB 17625.2	conform to	The equipment is suitable for use in all establishments, both domestic and directly connected to the residential public low-voltage supply network for domestic use.

Guidance and Manufacturer's Statement - Electromagnetic Immunity			
The equipment 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 level		Compliance with Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) GB/T 17626.2	±6kV contact discharge ±8kV air discharge	±6kV in contact with ±8kV air	Floors should be wood, concrete or ceramic tiles and if floors are covered with synthetic materials the relative humidity should be at least 30%

Electrical fast transient pulse group GB/T 17626.4	±2kV to power lines ±1kV to input/output lines	±2kV not applicable to power lines	Mains power should be of a quality typically used in a commercial or hospital environment.
Surge GB/T 17626.5	±1kV line to line ±2kV line to ground	±1kV line-to-line not applicable	Mains power should be of a quality typically used in a commercial or hospital environment.
Voltage sag, short interruption and voltage change on power input line GB/T 17626.11	< 5 % U _T for 0.5 period (> 95% dip in U _T) 40% U _T for 5 cycles (60% dip in U _T) 70% U _T for 25 cycles (30% dip in U _T) < 5 % U _T for 5 s (on U _T , > 95% dip)	< 5 % U _T for 0.5 period (> 95% dip in U _T) 40% U _T for 5 cycles (60% dip in U _T) 70% U _T for 25 cycles (30% temporary drop) < 5 % U _T , lasting 5 s (95% dip on U _T , > 95% dip on U _T)	Mains power should be of a quality typically used in a commercial or hospital environment. If the user of the device requires continuous operation during a power outage, it is recommended that the device be powered by an uninterruptible power supply or battery
Power frequency magnetic field 50/60Hz GB/T 17626.8	3 A/m	3 A/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.

Note: U_T refers to the AC network voltage before the test voltage is applied.

Guidance and Manufacturer's Statement - Electromagnetic Immunity			
The equipment 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 test level	compliance level		Electromagnetic Environment -
RF conduction GB/T 17626.6	3 V (rms) 150kHz - 80MHz	3 V (rms)	<p>Guidance Portable and mobile radio frequency communications equipment should not be used closer than the recommended isolation distance to any part of the equipment, including cables. The distance is calculated by the formula corresponding to the transmitter frequency</p> <p>Recommended isolation distance</p> $d = 1.2 \sqrt{P} \quad 150\text{kHz}-80\text{MHz}$

radiofrequency radiation GB/T 17262.3	3 V /m 80MHz - 2.5GHz	3 V /m	$d = 1.2\sqrt{(P)}$ 80MHz-800MHz $d = 2.3\sqrt{(P)}$ 800MHz-2.5GHz In the formula: P - According to the transmitter manufacturer Maximum rated transmitter output power provided Power, measured in watts (W); d—is the recommended isolation distance, in meters (m). Field strength from fixed RF transmitters Confirm through electromagnetic field surveys is determined and should be compared in each frequency range Match level or below. Equipment marked with the following symbols is attached Interference may occur nearby. 
Note 1 : At 80MHz and 800MHz frequencies, the formula for the higher frequency band is used. Note 2 : These guidelines may not be suitable for all situations. Electromagnetic propagation is absorbed by buildings, objects and the human body and reflection effects.			
aFixed transmitters such as: base stations for wireless (cellular/cordless) telephones and land mobile radios stations, amateur radio, AM and FM radio broadcasts, and television broadcasts, etc., their field strengths are theoretically It cannot be predicted accurately. To assess the electromagnetic environment of fixed RF transmitters, a survey of the electromagnetic field should be considered. If the measured field strength in a location where the equipment is located is greater than the applicable RF compliance level above, the equipment should be observed to Verify that it is functioning properly. If a normal performance is observed, supplementary measures may be necessary, such as Reorient or relocate the device. bIn the entire frequency range of 150kHz-80MHz, the field strength should be lower than 3 V/M.			

Recommended isolation distances between portable and mobile radio frequency communications equipment and equipment			
The equipment is intended for use in an electromagnetic environment where radio frequency radiation disturbance is controlled. According to the maximum rating of communication equipment			
Output power, the purchaser or user can maintain portable and mobile radio frequency communication equipment through the following recommended			
Minimum distance between equipment (transmitter) and equipment to prevent electromagnetic interference			
Transmitter maximum rating Output Power IN	Isolation distance corresponding to different frequencies of transmitter/m		
	150kHz - 80MHz	80MHz - 800MHz	800MHz - 2.5GHz
	$d = 1.2\sqrt{(P)}$	$d = 1.2\sqrt{(P)}$	$d = 2.3\sqrt{(P)}$
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 maximum rated output power of transmitters not listed in the above table, the recommended isolation distance d is in meters (m)

The unit can be determined by the formula in the corresponding transmitter frequency column, where P is provided by the transmitter manufacturer.

The maximum rated output power of the supplied transmitter. Measured in watts (W).

Note 1: At the 80MHz and 800MHz frequency points, the formula for the higher frequency band is used.

Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption of buildings, objects and human bodies, absorption and reflection effects.

1. The power adapter and accessories provided with this device must be used. The cable information is as follows

Cable name	Model	Length
Charging cable	MIA-11CA	1.0 meters

2. Basic performance

Name	specific description
working mode charging	After powering on, the screen displays the software interface normally, and you can take pictures by pressing the camera button.
mode	The charging indicator light is always on. After powering on, the screen displays the software interface normally. Press the camera button to take pictures.

6. Detailed description of instrument components

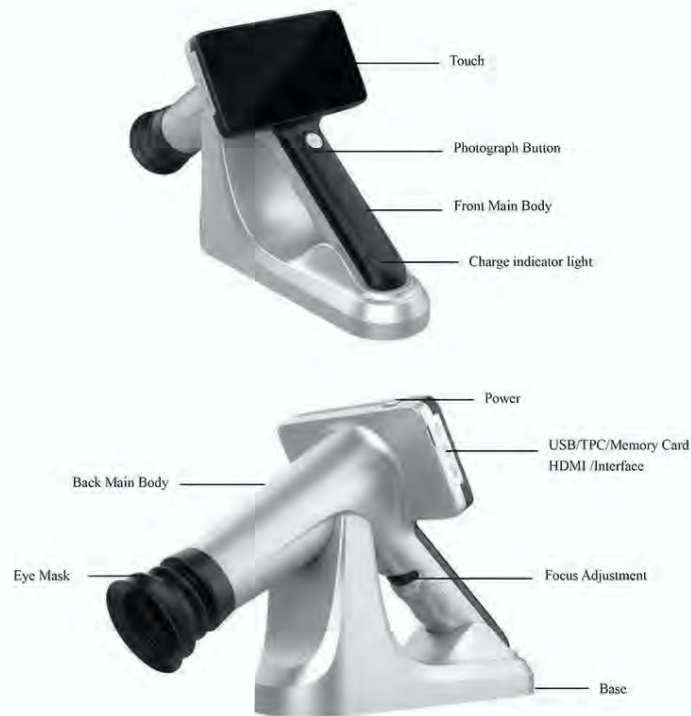


Figure 1 Names of various parts of the equipment

7. Installation method

1. Take out the device host from the packaging box and remove the lens dust cover.



Figure 3 Remove the dust cover

2. Install an eyecup on the lens.



Figure 4 Installing the eyecup

3. Install the battery.





Figure 5 Installing the battery

4. Device charging

- 1) Plug one end of the charging adapter equipped with the device into the indoor power supply and the other end into the port of the device to charge.
- 2) The indicator light will light up after the charging cable is connected, it will be blue during charging and green when fully charged.



3) Indicator light status color

- (1) Power off charging status: blue
- (2) Shut down and fully charged status: green
- (3) Power on (power on) status: green
- (4) Power-on charging status: green + blue
- (5) Fully charged status when turned on: green

Special note: The device cannot be used while charging. If you want to use it, please unplug the charging cable before proceeding.

8. How to use the operation method

1. Power on: Long press the power button to enter the shooting preview interface;
2. Create a new case: click the new case icon and enter the case name, case ID, Date of birth, etc. to create a new case;
3. Photo mode selection: the modes include video mode, color photo mode, and monochrome photo mode;
4. Turn the fixation light: According to the shooting needs, select the fixation light in the required direction and click B right;

5. Select the left and right eyes: click on the left and right eye icons, and click **Correct**; 6.

focus: Hold the fundus camera handle with your right hand, support the front end of the lens barrel with your left hand, and focus on the distant scene.

Adjust the focus to make the preview clear;

7. Take pictures: Ask the patient to cover the untested eye with his hand, and the eye to be tested looks at the fixation light in the lens tube; support the front of the lens with the tiger's mouth of his left hand, and put the four fingers of his left hand together to gently support it on the patient's forehead, adjust the lens tube perpendicular to the eye being detected. Adjust the position of the lens barrel forward, backward, left, and right so that the entire field of view is filled with bright infrared fundus images. At the same time, use your index finger to slightly adjust the focus left and right to make the previewed infrared fundus image clear, and quickly press the camera button with your thumb to capture the fundus image.

9. Instrument maintenance

1. The instrument should be kept away from dust, moisture and environments containing acidic and alkaline vapors.

2. If the surface of the lens or prism is dirty, use clean degreasing gauze dipped in a little mixture of ether and absolute alcohol to wipe it gently.

3. When the instrument is not in use, the goggles should be removed and the dust covers should be put on.

4. If the optical lens of the instrument is damaged and cannot produce images, please contact the manufacturer to return it for repair.

5. Cleaning/disinfection

1) Eyepiece: If it is contaminated with dust, use lens paper dipped in absolute alcohol to gently wipe it off for cleaning and disinfection. 2) Goggles: equipment host, dust cover, and base: they can be wiped, cleaned and disinfected with absolute alcohol. 3) Cleaning/disinfection cycle: It is recommended that the entire machine be cleaned and disinfected once a month. 7. Declaration of designated parts and materials 1) When using the equipment, be sure to use accessories provided by the manufacturer;

using other parts may cause the equipment to malfunction or be damaged; it may also cause allergic reactions and other adverse reactions in patients.

2) The accessories specified by the manufacturer are as follows

1	Power adapter	MIA-11CA
2	Battery	NCR18650GA
3	Eye mask	Rubber/matrix-produced
4	Dust Cover	Rubber/matrix-produced
5	Cleaning paper	Special lens paper for lens

If the above accessories No. 1-4 need to be replaced, please be sure to contact the manufacturer for replacement; for No. 5 accessories, please use special lens paper. 8. Battery

replacement 1) Batteries are

consumables and have a general lifespan of 3 to 5 years based on normal frequency of use. When the battery power cannot support normal use of the device, the battery specified by the manufacturer needs to be replaced.

2) The battery replacement steps are as follows

Note: When replacing the battery, the operator should not touch the battery and the patient at the same time.

9. Safe use and maintenance of batteries

1) Precautions for safe use

- (1) To ensure the safe use of the battery, battery charging is only allowed through the designated power supply equipped with the device.

Charging with the device; and only allowed to be installed inside the device for charging, and charging through other chargers is strictly prohibited.

Charge.

- (2) Do not mix lithium-ion batteries.
- (3) Do not connect the battery core to the socket.
- (4) Do not short-circuit, overcharge or over-discharge the battery core.
- (5) Do not reverse the positive and negative poles of the battery.
- (6) Do not expose the battery core to extreme heat or sparks.
- (7) Do not solder the battery core directly.
- (8) Do not place the battery core in a place exposed to direct sunlight.
- (9) Do not place batteries and metal objects such as necklaces, coins or hairpins together.
- (10) Do not hit, squeeze, throw, needle, or trample on the battery cells.
- (11) Do not disassemble or modify the battery core.
- (12) Do not immerse the battery core in water or allow it to absorb moisture.

2) Battery maintenance

- (1) Batteries should be stored in a clean, ventilated room with a relative humidity of no more than 75%, and should be kept away from corrosion.

If in contact with corrosive substances, keep away from fire and heat sources.

- (2) Complete a charging cycle for the battery at least every month, that is, a cycle of charging and discharging.

10. For replacement of other parts, please contact our after-sales department.

11. Troubleshooting Guide

If a fault occurs, please check according to the table for guidance. If the fault is still not eliminated, please contact the company for repair.

Contact our department or authorized dealer.

Fault	Possible Causes	Solution
Infrared light not bright	Battery is low	Charge or replace the battery
	The conversion ejector pin is loose and has poor contact.	Please contact after-sales service
	The connector is loose and the contact is poor.	Please contact after-sales service
	Cable damaged	Please contact after-sales service
	Infrared light damaged	Please contact after-sales service
flash not bright	Battery is low	Charge or replace the battery
	The conversion ejector pin is loose and has poor contact.	Please contact after-sales service
	The connector is loose and the contact is poor.	Please contact after-sales service
	Cable damaged	Please contact after-sales service
	Flash damaged	Please contact after-sales service
fixation light not bright	Battery is low	Charge or replace the battery
	The conversion ejector pin is loose and has poor contact.	Please contact after-sales service

	The connector is loose and the contact is poor.	Please contact after-sales service
	Cable damaged	Please contact after-sales service
	Flash damaged	Please contact after-sales service

10. Software description

10.1 Software name

Portable fundus camera control software

10.2 Software model specifications

The specification model is CFC-X.

10.3 Software releases

This software releases version 1.0

10.4 Version Naming Rules

The naming rules for the complete version of this software are as follows:

X.Y.Z.B

Among them:

Y——Indicates a slight enhancement software update, the first release is 0, and each subsequent update accumulates 1; when X is released

When an update occurs, Y is reset to 0, and updated again to accumulate 1;

Z——Indicates corrective software updates, the first release is 0, and each subsequent update accumulates 1; when X is updated

When new, Z is reset to 0 and updated again to accumulate 1;

B——Indicates the number of software compilations, automatically generated by the software.

10.5. Software functions

10.5.1 New case

Click the new case icon to pop up the new file dialog box. Enter your name, ID, gender, and date of birth.

After that, click the save icon in the upper right corner to complete the case creation. Click the return icon in the lower right corner to enter

The main page review interface of the current case.

10.5.2 Case management

Click the case management icon to enter the file list interface.

At the top of the file list is a search box. Enter your name or ID information to quickly search the case list.

Quickly filter to find the cases you need.

In this interface, click on the case that needs to be tested to enter the current case test results interface. In this world

You can check the test results of current cases here. Click the camera icon in the upper right corner to recheck the measurement.

10.5.3 Image mode

Click the image mode conversion icon. The color icon is color image mode, and the gray icon is monochrome image mode.

10.5.4 Acquisition

mode Click the acquisition mode conversion icon. The camera icon is in still image acquisition mode, and the video recording icon is in video acquisition mode.

10.5.5 Fixation light

Click the 5-point fixation light icon to pop up the fixation light control panel. Click the fixation light image in the corresponding direction to light up, click again to turn it off.

10.5.6 Left and right eye selection

There are left and right eye selection icons in the lower left and right corners of the main interface. According to the current shooting eye selection, the image is captured. Afterwards, there will be left and right eye markers on the image.

10.5.7 Device

Click the device settings icon to enter the settings interface. This interface mainly consists of hospital settings, system settings, version information, etc.

10.5.7.1 Hospital Settings

Click Hospital Settings to enter the hospital setting interface. Enter the hospital name and doctor's name to create hospital information.

10.5.7.2 System settings

You can set the system language in the system settings interface.

10.5.7.3 Version Information

The current interface displays software version information and product information.

11. Transportation and storage

When transporting this instrument, it should be protected from moisture, stored upside down, and violent vibrations should be avoided.

Transportation environment:

Temperature: $-40^{\circ}\text{C} \sim +55^{\circ}\text{C}$

Relative humidity: $\leq 90\%$

Air pressure: 860hPa ~ 1060hPa

Storage environment:

Temperature: $-40^{\circ}\text{C} \sim +55^{\circ}\text{C}$

Relative humidity: $\leq 90\%$

Air pressure: 860hPa ~ 1060hPa

12. Complete set of instruments

Fundus camera host: 1 unit;

Base: 1 pc

Eye mask: 1pc

Dust cover: 1 pc

Charging cable: 1 set

Product manual: 1 copy

13. Instrument service life and environmental protection

Instrument life: 5 years

After the service life of the instrument expires, the user can dispose of the instrument in accordance with the "Medical Waste Management Regulations"

reason. 14. Contraindications

None.

15.Warning

The light emitted by this instrument is potentially dangerous. The longer the exposure time, the greater the risk of eye damage. ,

16.Instructions related to network security

1.Basic information

1.1 Type

1) Health data: patient fundus images, involving patient private information;

1.2 Function

One-way exchange of electronic data is performed, and the patient's fundus pictures are imported into other viewing devices.

1.3 Purpose

Purpose: clinical application, storing fundus images captured by the camera in TF card

1.4 Data exchange method

Exchange method: The product exchanges data through TF card.

Transmission protocol: transmitted data format, capacity, etc. For example: the data format is JPG, external storage device

The backup capacity is not less than 4 G.

1.5 Security software

The product supports common security software (such as 360 Security Guard, 360 Antivirus, QQ Computer Manager, Kingsoft

Anti-virus, etc.), security software should be a new effective version that can ensure the security of the computer system. Product operating environment such as

Down:

Software name	specification model	version	supplier	Operating environment requirements
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360 Security Guard			Beijing Qihu Technology Co., Ltd.	Android 6.0
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2.Risk management

For the medical device network security risk analysis report, see the "Risk Analysis Report".

3. Verification and confirmation

The network security requirements of medical device products (such as confidentiality, integrity, availability and other characteristics) have been met to satisfy

4. Maintenance plan

Flow Description:

Update confirmation:

Users need to modify the generated data for various reasons and submit maintenance applications. maintain

Scope includes error data correction only.

If necessary, backup the system. (The specific operation is determined by the plan)

If necessary, conduct simulation verification of maintenance operations. (The specific operation is determined by the plan)

User notification:

The maintenance engineer (generally refers to the person who proposes the plan) makes modifications according to the plan. .

The maintenance application requires users to provide feedback and evaluation on the maintenance results.

The product exchanges data through the TFC card and does not require Internet access. The TFC card can be run on a ordinary computer.

Import data through the computer's own hardware interface.

Special Note

Commitment: The factory can provide the necessary information for the repairable equipment parts specified by the factory.

1. Our company will provide equipment maintenance and free consultation for life.

2. This checker has a free one-year warranty from the date of purchase, provided that this instruction manual is followed.

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

- Damage caused by failure to follow the instructions for use, maintenance, and storage.

- Personnel without authorization from Hangzhou Aishijie Medical Devices Co., Ltd. dismantles/modifies the equipment without permission, causing damage to the equipment.

- Equipment damage caused by accidents, misuse, or irresistible natural factors.

Design or specifications are subject to change without prior notice!