Automatic Fundus Camera

USER MANUAL

Model: FC162

Shanghai MediWorks Precision Instruments Co., Ltd.

Contents

Preface

Thank you for purchasing the automatic fundus camera made by Shanghai MediWorks Precision Instruments Co., Ltd. Here are some basic facts and performance parameters for the automatic fundus camera you purchased.

Overview

- This user manual is part of the automatic fundus camera. Instructions for use and technical descriptions are given in this manual.
- The user manual includes the device manual and technical manual. The equipment classification for the fundus camera in accordance with the requirements of IEC 60601-1 is also given in this manual.
- The markings specified in the IEC 60601-1 standard have been permanently attached to the device and been explained in the manual.
- This device is suitable for observing, photographing and obtaining retinal images without mydriasis optometry.
- This device has the functions of taking photos, saving photos, and viewing images in real time.
- Light weight and portable. It can meet the carrying requirements of doctors for out-of-patient diagnosis.

Product Composition

The automatic fundus camera consists of the host machine, lianr, eye patch, lithium battery, support frame and power adapter.

Intended Use

- Intended Purpose

  The automatic fundus camera is intended to enable automatically capturing the images of human fundus, without dilating patient's pupils.

- Indications for Use

  The automatic fundus camera is intended for use in eye inspection of the fundus, for example, retina related disease examination. The captured colorful fundus images can provide the evidence to the ophthalmologist for diagnosis purpose.

- Intended Population

  The device can be applied to inspect the adults and the children.

- Intended Users

  The device is intended to use by the well trained technicians.

- Contraindication

It is not clear that if the device will cause serious light radiation to the patient. But it is suggested to adjust the illumination level to the lowest level which suits the patient. The risk to infant, aphasic patient will increase. Please don't test the patient repeatedly during 24 hours with this device.

Caution

The automatic fundus camera must be operated exclusively with the guidance described in this manual. Any other use of the device is considered Off Label use. Failure to observe these instructions may result in an accident, personal injury, damage to the device and accessories. Proper and intended use includes compliance with all inspection and maintenance instructions, along with the observance of all instructions in the manual.

Performance Parameters

Size:	32cm×21.5cm×12.5cm
Weight:	2.7kg
Minimum Pupil Diameter:	3mm
Focusing Mode:	Automatic
Camera Pixel:	15 Mega Pixels
Flash Mode:	Natural white LED
Display:	5” full touch LCD
Picture Format:	JPEG, DICOM
Internal Storage:	16G
Data Connectivity:	WIFI
White LED Spectrum Range:	400nm～750nm
Service Life:	5 years

Operating Environment	Temperature	+5℃～+40℃
	Relative Humidity	≤90%, no condensation
	Atmospheric Pressure	860hPa～1060hPa
Storage	Temperature	－40℃～＋55℃

Environment	Relative Humidity	≤90%, no condensation
	Atmospheric Pressure	860hPa～1060hPa
Transportation Environment	Temperature	－40℃～＋55℃
	Relative Humidity	≤90%, no condensation
	Atmospheric Pressure	860hPa～1060hPa

Field of View:	50 degrees
Diopter Adjustment Range:	-20D～+20D
Power Supply：	Rechargeable lithium battery DC14.4V 47.52Wh
Charger：	~100-240V, 50-60Hz, 1.2A-0.5A
The Color Temperature of the Camera Flash:	4500K≤TC≤6700K
Resolution Center of View:	≥60lp/mm
Resolution at the Middle of the Field of View:	≥40lp/mm
Resolution at the edge of the field of view:	≥25lp/mm

Cautions

🗁 The device needs to be operated by trained and qualified personnel.

🗁 This is a medical device produced in accordance with the requirements of Chinese law.

🗁 Please read carefully the warnings and cautions prior to using the device.

🗁 To avoid damaging the device, please operate the device according to this user manual.

🗁 To avoid electric shock, do not insert metal objects into the holes or slots of the device. Do not disassemble and repair the device by yourself. If you have any questions, please contact Shanghai MediWorks or its authorized distributors. The authorized distributors will provide the necessary information to assist repairing.

🗁 Please use the charger specified by Shanghai MediWorks to prevent electric shock and damage to the device.

🗁 If the device breaks down: Smoke or emit a burning smell, please cut off the power and take out the battery to avoid fire accident.

🗁 The device is not water proof. To prevent fire, electric shock, short circuit and other hazards, please don't put the device close to water. If the device is wet, don't use bake, microwave, or high pressure to dry the device.

🗁 To avoid looseness caused by vibration of the device, please place the device in the box when the device is not in use.

🗁 The device should be put in a clean environment which must be away from fire sources.

🗁 Please check if the device has been damaged prior to usage. If you notice signs of damage or defect, please contact Shanghai MediWorks or its authorized distributors.

🗁 The battery on device shall refer to the recommendation or provided by Shanghai MediWorks. The battery specification is 14.4V, 3300mAh. If the user uses other batteries, Shanghai MediWorks won't be responsible for any loss caused by this.

🗁 If the device is not used for a long time, please remove the battery.

🗁 Do not use the device while it is charging to avoid danger.

🗁 The mask is an integral part of the product, and the patient should wear the mask before being tested.

🗁 The mask is a disposable consumable, please purchase it from Shanghai MediWorks or its authorized distributors.

Graphic, Symbol and Warning Signs

No.	Mark	Description
1		Date of manufacture
2		Manufacturer information
3		WEEE, please dispose of the waste generated by the machine in accordance with relevant laws and regulations
4		CE Mark
5		Power switch

6		TYPE B applied part

Product Main safety features

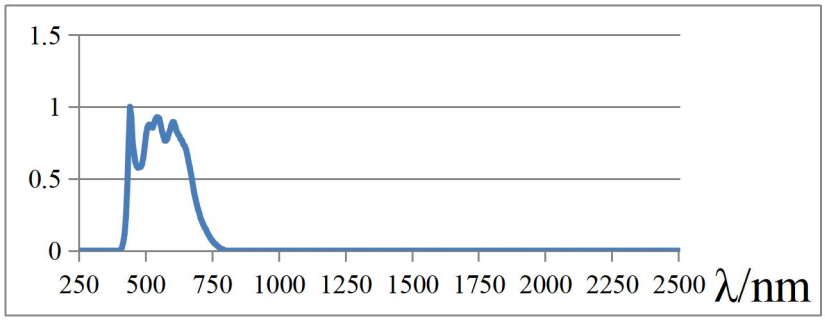
a) Classification on the degree of protection against electric shock: Type B.

b) According to the degree of protection against liquid: IPX0.

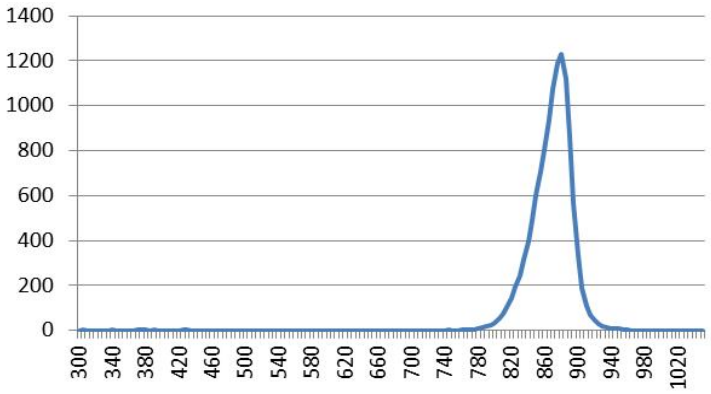
c) Classification according to the degree of safety when using flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrogen oxide: not applicable, not used in the environment.

d) Classification by operating mode: continuous operation.

e) The spectrometer of the device is as follows:



Shooting Spectrum



Near-infrared Spectrum

EMC (Electromagnetic Compatibility)

FC162 automatic fundus camera (hereinafter referred to as FC162) complies with

the International Electro technical Commission standards (IEC 60601-1-2) for electromagnetic compatibility as listed in the tables below. Follow the guidance in the tables for use of the FC162 in an electromagnetic environment.

Guidance and manufacturer's declaration – electromagnetic emissions		
The FC162 is intended for use in the electromagnetic environment specified below. The customer or the user of the FC162 should assure that it is used in such an environment.		
Emissions test	Compliance level	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The FC162 uses RF energy only for its internal function. Therefore, the RF emissions are extremely low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The FC162 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	

Guidance and manufacturer's declaration electromagnetic immunity			
The FC162 is intended for use in the electromagnetic environment specified below. The customer or the user of the FC162 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floor should be wood,concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.

Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage, dips, short interruptions and voltage variationson power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the FC162 requires continued operation during power mains interruptions, it is recommended that the FC162 be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location inatypical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration electromagnetic immunity			
The FC162 is intended for use in the electromagnetic environment specified below. The customer or the user of the FC162 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80	3 Vrms (V1=3)	Portable and mobile RF communications equipment should be used no closer to any part of the FC162, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the

	MHz		transmitter. Recommended separation distance $d=1.2\sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m (E1=3)	$d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the FC162 is used exceeds the applicable RF compliance level above, the FC162 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating theFC162. b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the FC162
The FC162 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the FC162 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FC162 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter/m		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 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 transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Warning

In addition to transducers and cables sold by the manufacturer of the equipment or system as spare parts for internal components, the use of accessories, transducers and cables other than those specified can result in increased emission or reduced immunity of the equipment or system.

The following type cable must be used to ensure compliance with interference radiation and immunity standards:

Cable	Length（m）
Power Supply	1.5

Warning

The equipment or system shall not be used in close proximity to or stacked with other equipment. If it must be approached or stacked, observe and verify that it can work

under the configuration it is using.

Warning

Active medical device subject to special EMC precautions, therefore, must be installed and used in accordance with these guidelines.

Warning

Portable and mobile communication RF equipment may affect the use of medical electrical equipment.

Basic property description

Before, during and after the test, the equipment works normally, the imaging is clear, and there is no flicker or black screen.

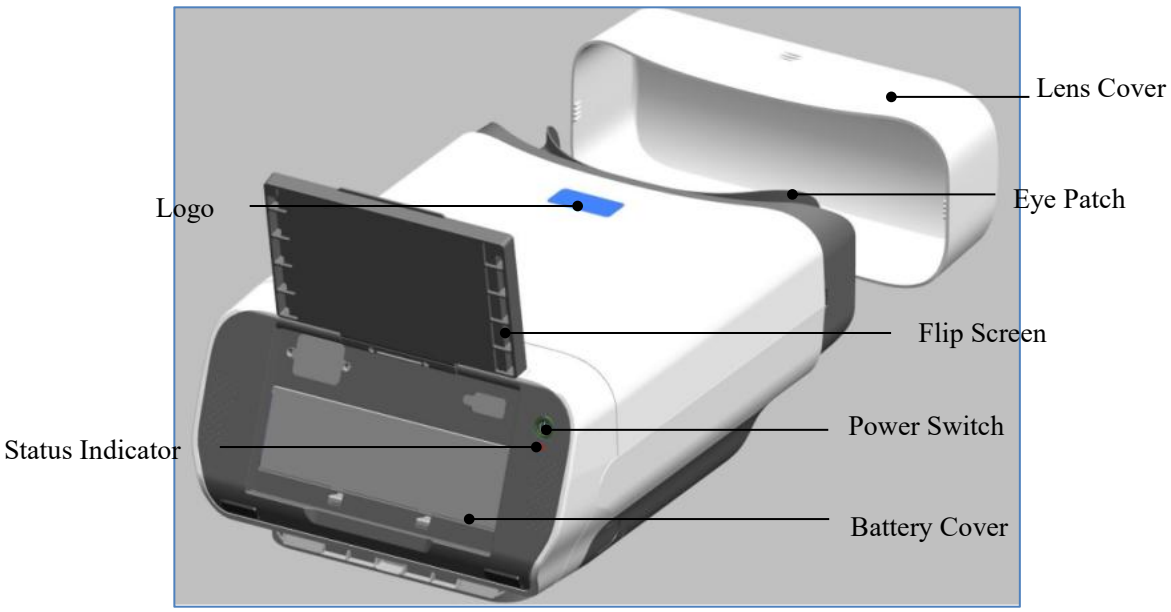
1 Installation

1.1 Product List

Prior to usage, check that all of the following items are included in the product packaging. If there is any missing, please contact Shanghai MediWorks or its authorized distributors.

No.	Part Name	Quantity
1	FC162 Fundus Camera	1
2	Power Adaptor	1
3	Shipping Locking Screw	2

1.2 Product Composition

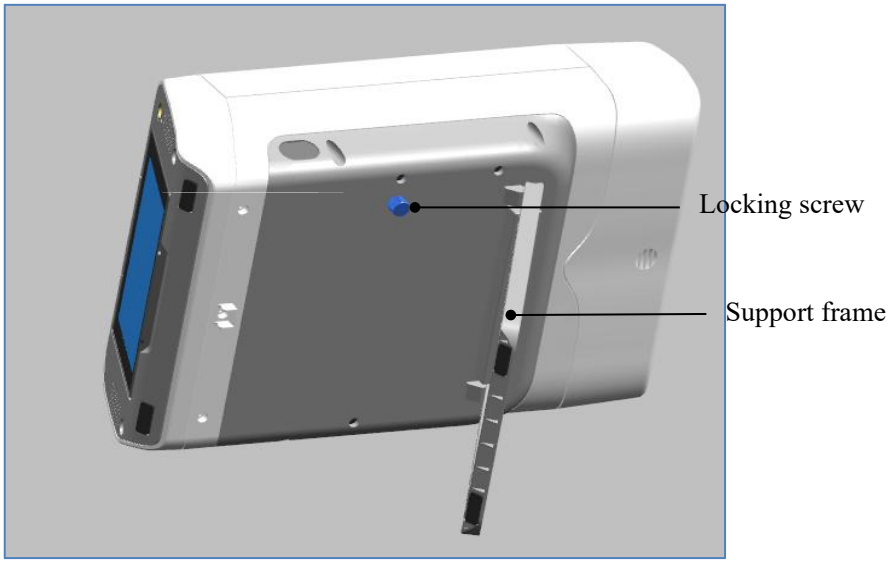


1.3 Remove the Transport Lock

The lower part of the device is equipped with a locking screw, which is used to lock the internal mechanism during transportation, as shown in the figure below.

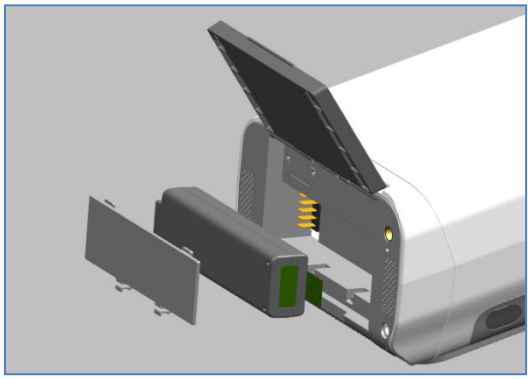
Before using the device, remove the locking screw (open the support frame and unscrew the screw), and place the screw in the packing box to prevent loss.

When the device needs to be transported, be sure to tighten the locking screw, and then put the device in the mobile carrying case. Otherwise, there may be a risk of damage to the device.



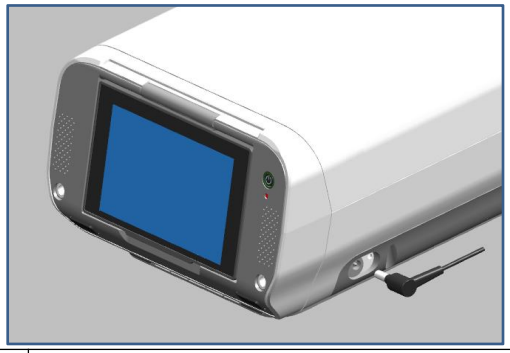
1.4 Installation of Battery

Flip up the screen as presented in the figure below， open the battery cover and insert the battery. Note that the battery notch should be loaded left-side inward, as shown in the figure below. If the direction is reversed, the battery assembly cannot be inserted (the battery cannot be inserted into the slot). Excessive force may cause damage.
After installing the battery, close the battery cover and lock it.



1.5 How to Charge

Plug the power adapter into the power port at the side of the device, and plug the adapter into the power socket, and the fundus camera will automatically be charged.



Power indication	Status
The green light is always on.	In the charging states, the battery is at full capacity, or simply use the network power (no battery)
The blue light is always on.	Device is charging.
No light	The device works only with battery or it is off.

1.6 Operation Procedures

Step 1: Open the support frame and place the device on the table steadily.
Step 2: Turn on the device, ask the tester move close to the eye patch and ensure the

face contact the patch.

Step 3: Keep the eyes look straight forward at the lens and then follow the device's instruction, as shown in the figure below.

Photographing diagram

Note: The device comes with a disposable mask. Before the test, the subject will take a mask and wear it on the eye, and then take the picture as shown in the photographing diagram to avoid direct contact with the machine on the face.

2 Operation Interface

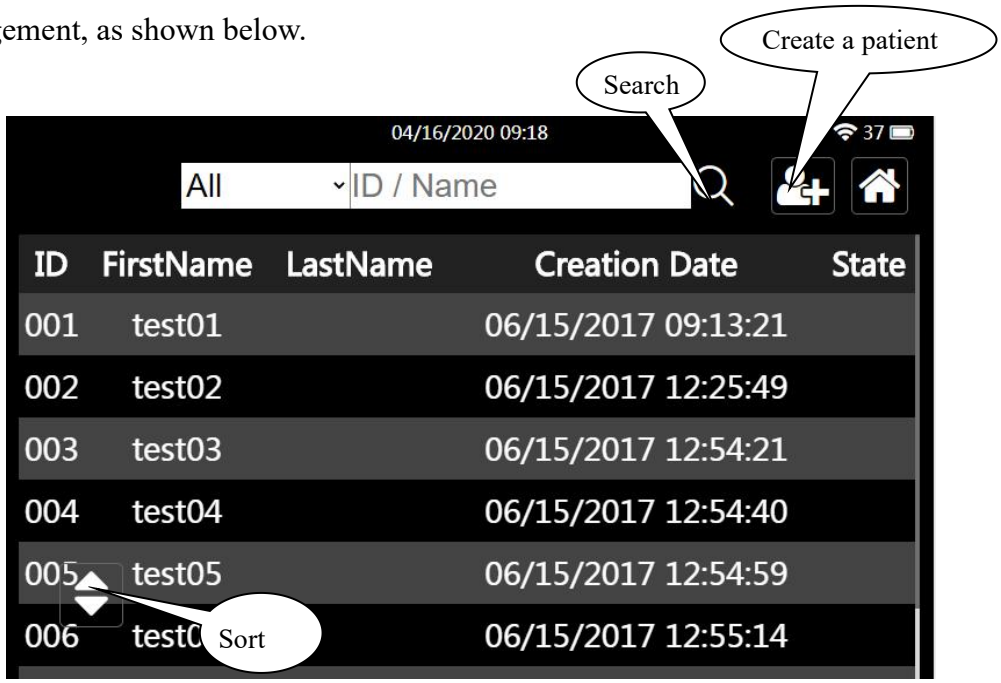
2.1 Main Interface

Start the device and enter the main interface, as shown in the figure below.

Main interface includes Patient, Capture, Album, and Settings.

2.2 Patient

Click the [Patient] button on the main interface to enter the patient information management, as shown below.



1. Click button to create a patient.

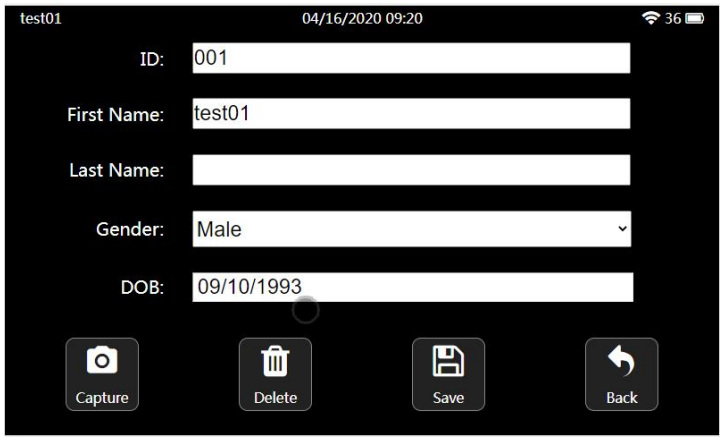
2. Click the button to return to the main interface.

3. Click the [Sort] button to sort the patient list according to ID, creation date or birth date.

4. Enter search criteria to search for patient.

➢ Patient details

Click on any item in the patient list to view the details.

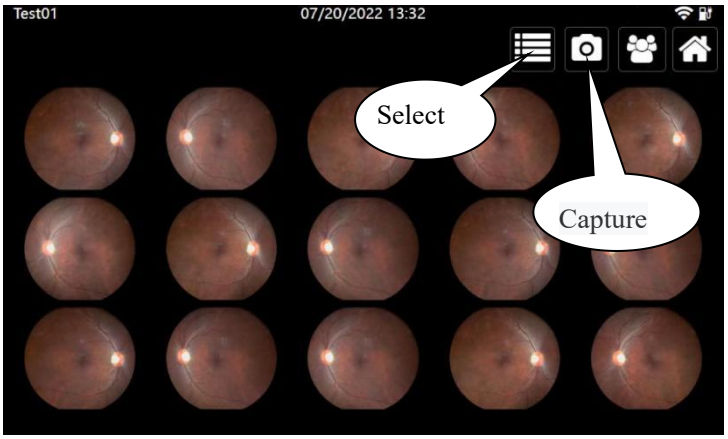


2.3 Capture

Click the [Capture] button on the main interface or any interface to start capture. Follow the vocal guidance provided by the device along with the capturing process till it is completed.

2.4 Album

Click the [Album] button on the main interface or the patient details interface to enter the album, as shown in the figure below.



1. Image deletion: Click the [Selet] button, tick the image to be deleted, and click the [Delete] button to delete it.

2. Capture: Click the [Capture] button to enter the capture state.

3. Click on the picture to enter the single preview mode, as shown in the figure below:

2.5 Settings

2.5.1Language Setting

Click the [Language] button on the setting interface to enter the language setting interface. The language includes both Chinese and English languages.

2.5.2Date Format Setting

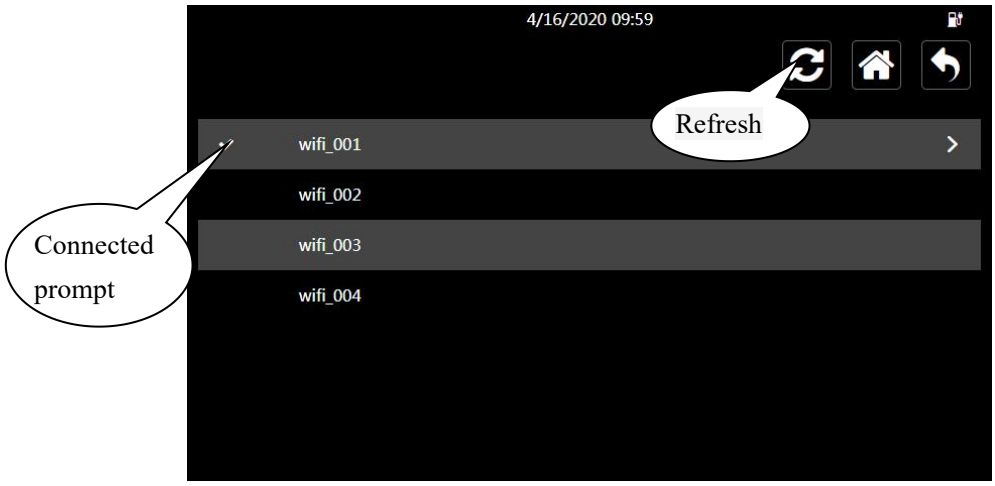
Click the [format] button on the setting interface to enter the date format setting interface, and slide the scroll bar to select the date format.

2.5.3Date Time Setting

Click the [Date Time] button on the setting interface to enter the system time setting interface, slide up and down in the selection box to select the time to change.

2.5.4Network Setting

Click the [Network] button on the setting interface to enter the network setting interface. The WIFI list displays all the WIFI servers that have been searched, as shown in the figure below.



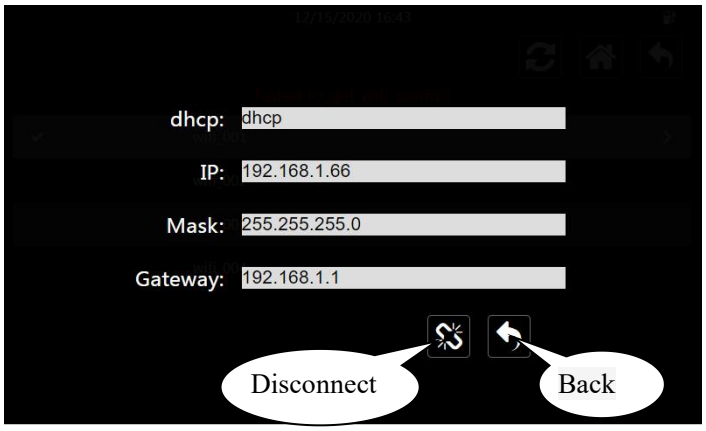
2.5.4.1 WIFI connection

Click the preferred WIFI server in the list and enter the password via input interface, as shown in the figure below.

Click the password input box to enter the password, click for confirmation, and wait for the connection. Click to abandon this connection.

2.5.4.2 WIFI configuration

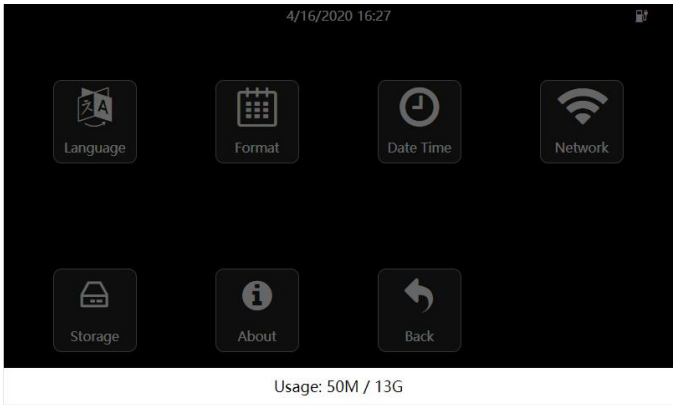
It is used to present the configuration of connected WIFI. Click the connected WIFI in the WIFI list to enter the interface, as shown in the figure below.



This interface presents the information such as the IP address of the connected WIFI.

Note: The information in the figure is only an example and has nothing to do with the actual WIFI information.

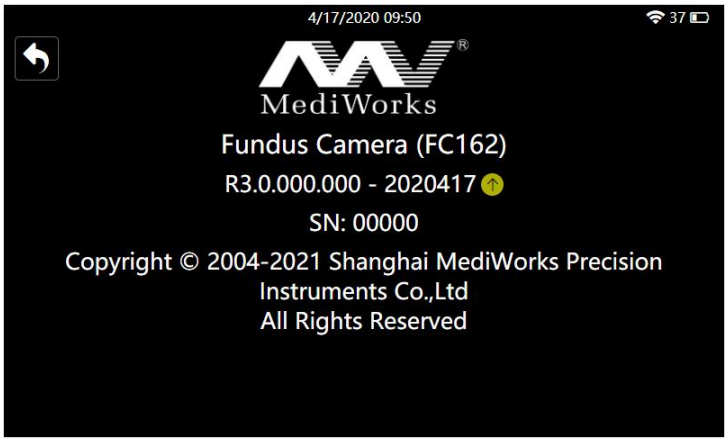
2.5.5 Storage



Click the [Storage] button on the setting interface to check the storage usage of the

system.

2.5.6 About



Click the [About] button in the setting interface to check the system version information.

3 Cleaning, Maintenance and Protection

Cleaning, maintenance and protection in a correct and regular way can ensure the normal operation status of device. Maintenance shall be carried out every 2 months according to the method prescribed in Section 3.2-3.4.

FC162 is a sophisticated optical device, so be sure to handle it with care.

3.1 Cleaning

1. Cleaning the outer surface of the lens: If the outer surface of the lens is exposed to the air or in a non-clean environment for a long time, and the surface of the lens is dusty. Gently wipe it with soft cotton moistened with anhydrous alcohol, or use a special lens cleaner and cleaning cloth.

Note: When the device is not in use, please cover the lens cap to avoid dust on the lens surface.

2. Clean the screen: If dust sticks to the screen, gently wipe it with soft cotton moistened with anhydrous alcohol, or use a special screen cleaner and cleaning cloth.

Note: Do not wipe with hard objects.

3. Clean plastic parts: To clean plastic parts such as the device surface, use a soft cloth dipped in soluble detergent or water to clean the dirt, and then wipe it with medical alcohol.

Note: Do not use any abrasive cleaning agents, as it may damage the surface.

4. Clean the eye patch: The eye patch is a component that comes in frequent contact

with the patient. Cleaning and disinfection should be performed before each patient is examined. Clean the dirt with a soft cloth dampened with a soluble cleaner or water, then wipe with medical alcohol.

Note: Since the eye patch is made of silicone, please do not wipe it with any corrosive cleaning agents, so as not to damage it.

3.2 Maintenance

The automatic fundus camera should be used in a relatively clean environment. The main parts that need to be cleaned are described in Chapter 3.1. In order to ensure the normal use of the fundus camera, it is recommended to perform cleaning operations every 2 months. After cleaning, wait until the device is dry before using it.

Because the surface of the lens is coated with an antireflection coating and a reflective film, although the coating is strong enough, frequent wiping tends to cause damage to the film, which affects the optical effect of observation. This cycle is only a suggestion. If the lens has a particularly large amount of dust that has affected the quality of observation, it is recommended to clean it immediately according to the prescribed method.

3.3 Protection

After use, place the device in the mobile carrying case to avoid bumps.

3.4 Battery Care

1. After the battery is fully charged, unplug the power cord to avoid overcharging or danger.
2. When the device is not used for a long time, the battery should be removed and placed in the corresponding position in the portable packing box.
3. When the device is not used for a long time, the battery should be charged every 3 months.

3.5 Product Life Cycle

The life cycle of the automatic fundus camera is 5 years.

Troubleshooting

If a fault occurs, please check it according to the following table for guidance. If the fault is still not rectified, please contact Shanghai MediWorks Precision Instruments Co., Ltd or its authorized distributors.

Fault	Possible Cause	Solution
It will be dark after booting	The battery is exhausted.	Fully charge the battery before use
Does not boot	Battery is placed reversely.	Install the battery correctly according to the instructions

Exceptions

1. Shanghai MediWorks Precision Instruments Co., Ltd. is not responsible for damage caused by fire, earthquake, third party behavior, other accidents, and carelessness of the user, misuse, or use under abnormal conditions.

2. Shanghai MediWorks Precision Instruments Co., Ltd. is not responsible for the deficit, bankrupt, and any loss due to unable to use this device.

3. Shanghai MediWorks Precision Instruments Co., Ltd. is not liable for any damage to the operation not described in the instruction.

4. Diagnosis is the responsibility of the doctors, and Shanghai MediWorks Precision Instruments Co., Ltd. is not responsible for the results of those diagnoses.

Model: FC162

Serial Number: See it on the product nameplate.

Date of purchase: Please tell us the date you purchased the device.

Fault: Please tell us as much as possible about the fault.

Production date：see label

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