

Vision Screener

Operation Manual

Suzhou Microclear Medical Instruments Co., Ltd



Please read carefully before operation



Preface

Thank you for purchasing the Vision Screener produced by Suzhou Microclear Medical Instruments Co., Ltd

For proper and safe operation of the device, please read this manual carefully before your usage.

Usage Range

The Vision Screener is suitable for testing items of diopter, astigmatism and astigmatism axis ,pupil diameter, pupil distance, etc. from children to adults of all ages.

High - speed of information acquisition and accurate detecting.

Contraindication: No

Product Features

- Simple operation and easy for use
- Portable and flexible which satisfied convenient outdoor diagnose for doctors
- Fast detection

Identification and warning

\triangle	Notice: please read precautions and operating instructions in operation manual
Ţ <u>i</u>	Consult Instruction for use
\sim	Date of manufacture.
	Manufacture
†	Type B applied part
X	Please recycle the abandoned batteries
THE SECOND	Keep dry
PROBLE	Fragile
<u>11</u>	Upward
MATERIAL MAT	Handle with care
(+)	Positive pole
\odot	Negative pole

Attentior

Please read the following notes carefully to avoid accidental personal injury, product damage and other possible hazards.



Please do not use this instrument in fire, explosion, dust and high temperature. Please use it indoors and keep the instrument clean and dry.



Please be sure to use Vision Screener according to the instructions in the operation manual.



When use the instrument, please make sure that the lens does not touch the patient's eyes or nose to avoid injury to patients.



Please avoid vibration and knocking on the instrument. When it is off, please disconnect the power plug and put it in a safe place.



Please be sure to check and make sure all parts are not damaged or defected before operating the instrument. If the appearance of the instrument is damaged or there is any surface defects, please contact Suzhou Microclear Medical Instruments Co., Ltd.



Only the battery pattern of 3.7V&34000mAh, which is provided or designated by Suzhou Microclear, is permitted to use in this instrument.



Plesse avoid strong light in order to protect your eyes



When in lighting or photographing, please do not overexpose.Do not use the instrument to do testing too often, otherwise it will cause damage to the eyes.just in order to protect your eyes.



Please do not use alcohol to wipe the lens to avoid blurring the camera and affect the shooting function



If you have qualified technicians to repair the accessories inside of the product, and need the circuit diagram, components list, figures and detailed rules, please contact the manufacturer.



Environment protection: the replacement circuit board, control board and other components should be collected and processed by the manufacturer to reduce environment pollution. At the termination of the camera, the manufacturer should keep tracking of the product and recycle it when the fundus camera is abandoned according to local regulations.

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Operation instruction

1.Product purpose

This product is used for testing items of diopter, astigmatism, astigmatism axis, pupil diameter and pupil distance.

2.Product accessory

Product composition: lens, lithium battery, body shell, TFT LCD, CMOS image sensor, USB charging data cable, LED infrared lamp.

- Switch on/off
- ② LCD screen
- 3 Shooting trigger
- 4 LED infrared
- (5) Focus wheel
- 6 Battery cover



Fig1 Product composition

3. Product overview

3.1 Product model

(This operation manual is available for the following three model) · VS. VS-Pro. VS-Plus

3.2 Power supply condition

- Supply voltage: DC3.6V
- · Available lithium battery model 18650

3.3 Operation environment

- Temperature: 0°C~35°C
- Relative humidity: 10%~80%
- · Air pressure: 760hPa~1060hPa

3.4 Storage environment

- Temperature : -10°C~40°C
- Relative humidity: ≤80%
- Notes: If the device is stored more than 2 weeks, please take battery out.

3.5 Product characteristics

- · Electric shock protection types: Type II
- · Harmful liquid protection levels: IPXO, ordinary equipment
- In mixture of air with flammable gas type: N/A
- Operational mode type: continuous operation
- Voltage rating: DC 3.7V
- Input power : < 6VADefibrillation charges : N/A
- Signal input/output: Yes
- Permanent or non-permanent installed equipment type: non-permanent and portable equipment
- Power type: internal power supply

3.6 Product Life cycle: 7 years

3.7Production date: Please refer to product label

3.8Connection requirements

- 1.The device is not equipped with adapter; If you want to use the adapter, you should comply with GB9706.1-2007 power adapter.
- This device is equipped with a USB data cable; Instructions for use of USB data cable:
- 1) One end of the USB data cable (the raised side is inserted into the USB slot upward) is connected to the device, and the other end is connected to the USB port of the computer for charging; The lightning icon on the upper right side of the display indicates charging.
- 2) Connect the device to the computer with USB data cable, then exchange data (pictures) with the computer.





Fig2

Fig3

4. Operation instruction

4.1 Battery installation

Please open the battery cover by rotating the bottom cover counterclockwise in Fig 4, insert battery ,make sure the mark '+' on battery corresponding to '+' in the slot. then tight it clockwise.





Fig4

Fig6

4.2 Photo operation

Operation steps as follows:

Step 1: open and press switch on, the device will automatically enter into the operation system;

Step 2: click"+"on the upper right, enter into "Patient Record Create", input your Name,ID,Age which are necessary; Click "Saving" on the upper right corner, the "Patient Management" will automatically increase a new patient data record after you well saved.

Step 3: open one patient data record 'click" camera" which is on the upper right corner to start shooting interface.

Step 4: keep around one meter distance between the patients and device. Keep patients' eyes open as much as they can ,stay calm and focused to stare at the LED spot until your eyes are detected by the device , you will see the icon on the upper left corner turns from red to green.

Step 5: keep patients' eyes at the same horizontal level with the device, move forward or back of the device to adjust the distance slightly in order to create a good condition for the device to detect (your pupils on the device screen getting focused and quite bright). After the detection accomplished, it will change to the data result recording interface (this is not available for VS)

4.3 Report browsing

- Detecting accomplished, it will automatically change to the report result interface.
- Browsing a list of Patient recording by click the back button at the bottom (Patient information Management), drag up and down on the left side of the interface to view multiple detection reports.
- The equivalent vision acuity data as follows: (not available for model VS, VS-pro, VS-plus)

Decimal recording	Five-point system	recording	
0.1	4.0	650	
0.12	4.1	550-600	4
0.15	4.2	500	
0.2	4.3	450	
0.25	4.4	400	
0.3	4.5	300-350	
0.4	4.6	250	
0.5	4.7	200	۱
0.6	4.8	150	
0.8	4.9	100	
1.0	5.0		
0.4 0.5 0.6 0.8	4.6 4.7 4.8 4.9	250 200 150	



4.4 Daily cleaning and maintenance of the instrument

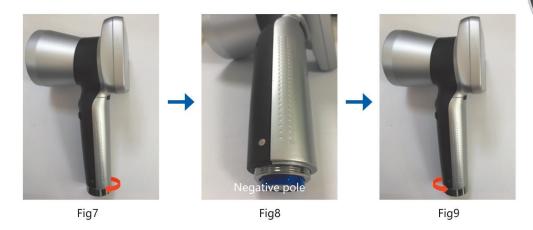
4.4.1Battery safety use and maintenance

- 1) Please do not charge or use different types of batteries, otherwise they may burst or cause serious consequences.
- 2) The lithium-ion battery has no memory function, so you can charge it before fully releasing without reducing its capacity.
- 3) The lithium-ion battery is not allowed to be used over discharging. After the battery discharge protection appeared, please do not use the battery again. The battery should be charged immediately.
- 4) Normal lithium-ion battery is not allowed to overcharge. But this instrument has the function of overcharging protection for battery. Please do not worry about the battery being overcharged.
- 5) Please notice maximum charging and discharging time. Please do not charge and discharge this battery frequently.
- 6) Please do not charge the battery under 0°C or over 40°C
- 7) If the instrument will not be used for a long period time, please take out the battery.
- 8) If the battery is damaged and need to be replaced, please select the same pattern of the battery.

- 9) Please do not put the battery along with keys, rings or other metal materials in your pocket; otherwise it will cause battery damage or even fire
- 10) Please do not use damaged batteries or batteries with peeling shells. The 18650 rechargeable battery is not allowed to be recharged in case of liquid leakage, expansion or abnormal heating. It should be discarded in accordance with national requirements to prevent environmental hazards.
- 11) Never make the battery in short-circuit state, or disassemble it and discard it in the fire.
- 12) If the battery needs to charge in a charger, please confirm that the charger is in accordance with GB9706.1
- 13) When the battery charging completed, please take it out of the charger in time to avoid any danger from overcharging.
- 14) The battery can be charged for more than 300 times, and the frequency of charging depends on the remnant power each time, the lower the power while the time you are going to charge, the longer the battery life span will be.
- 15) After completed charging or will not use the charger for a while, please separate the charger from the power supply and take out the battery.
- 16) It is forbidden to cover the charger while charging to avoid fire.

4.4.3 Battery replace

- Unscrew the battery cover by turning counterclockwise as shown in fig 7.
- Take out the used battery and replace with new battery(18650 lithium batteries), make sure that the positive and negative electrode direction of the battery (see fig 8) should be consistent with the positive and negative electrode mark on the instrument.
- Turn the battery cover clockwise (Fig. 9) until it is tightened



4.4.4 Maintenance

Vision screener is a precise optical instrument, please handle and maintain it carefully. Please pay attention to the following instructions:

- Regular inspection of the instrument and accessory
- · Before cleaning, please do make sure the power is off
- We recommend to use a professional and soft optical lens cloth or paper to clean the surface of the lens
- When wiping the lens surface, please be careful not to damage it.
- Please do not disassemble the lens tube and the main body. If you want to have an internal cleaning, please contact the agent/dealer.





5. Technical specification

5.1 Technical parameters

ltems	parameters
Spherical accuracy	-7.0D~+5.0D±0.5D
Cylindrical accuracy	0.00D~+3.00D±1.0D
Pupil diameter range	3.5mm~9.0mm±0.5mm
Pupil distance range	50mm~80mm±1.0mm

6.Liability clause

Under the following conditions, Suzhou Microclear Medical Instruments Co., Ltd. will take responsibility for the safety, reliability and performance of this product:

- All assembles, extends, adjusts, modifies or repairs of the product are completed by the authorized person.
- · Electrical installation meets the requirements
- The instrument is operated under the instructions

7. Warranty

- We provide one year warranty for the parts. Warranty for battery is six months.
- · The warranty starts at delivery date.
- Natural disasters, man-made damage, lack of reasonable care, disassembly, upgrade, warranty sticker torn off, or any phase-out parts are not included in the warranty.

8. Packing list

Item	Composed parts	Qty	Remarks
1	Vision screener (overall device)	1	1
2	USB cable	1	1
3	18650 battery	2	2
4	Operation manual	1	1
5	Packing list	1	1

Common questions

9.1 Device trouble shooting

Problem	No.	Problem analysis	Solutions	Remarks	
Abnormal crash	1	crash caused by improper operation	restart		
Sudden shutdown	2	battery is insufficient to support working	charge the device		
Camera button	3	improper operation (too fast operation, etc.)	pause to operate and then restart		
100	4	Key malfunction	restart the device		
fails to work	5	Composed parts damaged	contact your manufacturer or agents		
	6	Stain on the lens glass	Please use cleaning lens cloth to clean it		
D.fl. ti	. 7	7 Duration	Dust in CMOS	NOC Harriston to bloom (fight day)	Operate and handle carefully in
Reflective spots	1	Dust in CiviOs	Use an air bag to blow off the dust	case of mis-contacting CMOS	
on the image	0	Unclear focus method	Adjust the focus wheel before you shoot , be sure the focusing lens is clear enough,		
	8	Unclear focus method	and there is no reflective point in the screen		

9.1 Device trouble shooting

Problem	No.	Problem analysis	Solutions	Remarks
	9	Lens loosed	1.re-install the lens, make sure the lens are in well place with the device	
No infrared and	9	Lens loosed	2.contact with manufacturer or agents if you can not deal with it]
flashing light	10	Poor contact between	1. Check whether the connector is well connected	1
	10	lens and the device	2. contact with manufacturer or agents if you can not deal with it	
	11	Low battery	Charge the battery or change full-charged battery	
	12	Internal cable loose	contact with manufacturer or agents if you can not deal with it	
	13	Too much noisy	contact with manufacturer or agents if you can not deal with it	
The battery indicator is		The battery has been used for	.battery belongs to consumed part with a limited lifespan,	High frequent usage means
green, but the camera	14	a long time,	if used with high frequency over than 3 months, we suggested to change a new battery	non-stop working
shuts down automatically				for more than 5 hours
System crashed	15	Highly frequent operation	restart	
Automatic being	16	Battery insufficient	Change with another battery	
into idle state and unable to restart	17	The device is in sleeping mode after a while being from idle state, all function closed ,and when restart , you need to wait for 30 to 60 seconds	Awake your computer by press home key or shooting button, wait for 10 seconds to restart by press it again	
Time and date in the device automatically reset to factory setting	18	The battery in the internal main board is shortage of power supply, there are serious problems with battery consumption	1.In the state of power failure for a long time will result in power failure of the batteries; Please charge the device or replace it with a new battery 2.contact with manufacturer or agents if you can not deal with it	
Unable to	19	Malfunction for keys or parts	Contact with your manufacturer or agents to repair	
switch on/off	20	Wrong operation	Please press the shutdown button for more than 3 seconds to ensure that the button is pressed in place	

10.EMC Information

Guidance and Manufacturer's Declaration

Below cables information are provided for EMC reference.

Cable	Max. cable length, Shielded/unshielded		Number	Cable classification
DC Power Line (USB Cable)	150 + - 5mm	Unshielded	1 Set	DC Power and data

Important information regarding Electro Magnetic Compatibility (EMC)

This electrical medical equipment needs special precautions regarding EMC and put into service according to the EMC information provided in the user manual; The equipment conforms to this IEC 60601-1-2:2014 standard for both immunity and emissions. Nevertheless, special precautions need to be observed:

- The equipment with no ESSENTIAL PERFORMANCE is intended used in Professional healthcare facility environment except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.
- ➤ WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be beserved to verify that they are operating normally".

- The use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the HAND-HELD FUNDUS CAMERA (HFC), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."
- When the AC input voltage is interrupted, the HAND-HELD FUNDUS CAMERA will stop battery charging and if the power supply restored, it should be recovered automatically, this degradation could be accepted because it will not lead to unacceptable risks and it will not result in the loss of basic safety or essential performance.
- Following degradation caused by Electrostatic Discharge or Electrical fast transients/burst could be accepted because it will not lead to unacceptable risks and it will not result in the loss of basic safety or essential performance:

Vertical bars appear on the screen, it can recover to previous condition by operator manually by restart the power switch.

Data transmission stopped, the transmission could be restarted by operator manually by restart the power switch or re-insert the data cable.



EMI Compliance Table (Table 1)

Table 1 - Emission

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class B	Professional healthcare facility environment
Harmonic distortion	IEC 61000-3-2 Class A	Professional healthcare facility environment
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	Professional healthcare facility environment

MS Compliance Table (Table 2-4)

Table 2 - Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels Professional healthcare facility environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	3V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

Table 3 – Proximity fields from RF wireless communications equipment

Test frequency	Band	Immunity test levels	
(MHz)	(MHz)	Professional healthcare facility environment	
385	380-390	Pulse modulation 18Hz, 27V/m	
450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m	
710			
745	704-787	Pulse modulation 217Hz, 9V/m	
780			
810			
870	800-960	Pulse modulation 18Hz, 28V/m	
930			
1720			
1845	1700-1990	Pulse modulation 217Hz, 28V/m	
1970			
2450	2400-2570	Pulse modulation 217Hz, 28V/m	
5240			
5500	5100-5800	Pulse modulation 217Hz, 9V/m	
5785			

Table 4 – Input a.c. power Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrical fast transients/burst	IEC 61000-4-4	±2 kV 100kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	±0.5 kV, ±1 kV
Surges Line-to-ground	IEC 61000-4-5	±0.5 kV, ±1 kV, ±2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0.15MHz-80MHz 6V in ISM bands between 0.15MHz and 80MHz 80%AM at 1kHz
Voltage dips	IEC 61000-4-11	0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0% UT; 250/300 cycles